Title: The Relationship Between Psychosocial Variables and Treatment Outcome in Chronic Fatigue Syndrome

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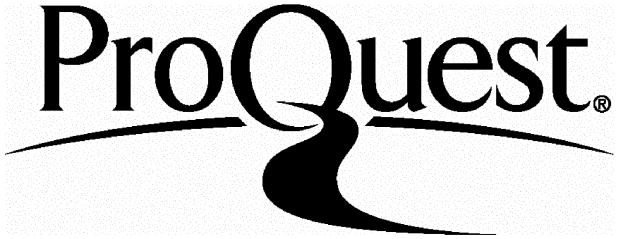
1998



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ABSTRACT

Objective: To evaluate the efficacy of cognitive behaviour therapy (CBT) for treating chronic fatigue syndrome (CFS) and the relationship between treatment outcome and psychosocial variables including stressful life-events, social support, illness attributions and perfectionism. Design: Retrospective, uncontrolled study based on CFS patients' responses to questionnaires filled in before and after CBT treatment, assessing outcome and psychosocial variables. Setting: Specialist tertiary referral outpatient CFS clinic. Subjects: Eighty-six CFS patients assessed between April '94 and May '96, who subsequently completed a course of CBT. Results: Thirty-five per cent and 33 per cent of patients who completed CBT treatment achieved a clinically significant improvement on a measure of functional impairment at 6 month and 1 year follow-ups respectively. There was considerable evidence for a relationship between the number and severity of stressful life-events experienced since the start of treatment and treatment outcome at 1 year follow-up. There was no evidence for a relationship between other psychosocial variables- social support, perfectionism and illness attributions - and treatment outcome. Conclusions: CBT treatment in routine clinical practice does not lead to clinically significant improvements in as many patients as was found in previous CBT clinical trials based on a more selected group of CFS sufferers. Further prospective research is needed, to assess whether stressful life-events, social support, illness attributions and perfectionism are predictive of treatment outcome, using a larger sample size and measures of these psychosocial variables at pre-treatment.

ACKNOWLEDGMENTS

I would like to particularly thank Trudie Chalder and Chris Barker for supervising this project and for providing me with useful guidance and advice. I also wish to thank Marion DeLima for her administrative advice on finding information on CFS patients at the CFS unit. Lastly I would like to thank my friends and family for their support and encouragement throughout.

CHAPTER 1: INTRODUCTION

Over the last decade, the syndrome known variously as chronic fatigue syndrome (CFS), myalgic encephalomyelitis (ME) and post-viral fatigue syndrome (PVFS), has attracted much research attention and controversy. There is little consensus on the nosology, aetiology, symptomatology, management and prognosis of this syndrome. In the present paper the term Chronic Fatigue Syndrome will be used to describe this syndrome as it is purely descriptive, makes no aetiological assumptions, and does not imply a unitary phenomenon.

CFS is a chronic illness characterised by debilitating fatigue and a variety of other complaints such as muscle and joint pain, headache, sore throat, fever, dizziness, concentration difficulties, memory loss and depressive symptoms. The set of symptoms currently best known as CFS are not new however. A variety of fatigue related illnesses with similar symptoms to CFS have been described over the years (Wessely, 1994). The origins of CFS probably lie in the condition known as neurasthenia which enjoyed considerable popularity as a diagnosis in the late 19th and early 20th century. There is a close resemblance between the clinical profile and symptoms of patients diagnosed as having neurasthenia and the profile and symptoms of CFS sufferers (Abbey & Garfinkel, 1991a). There are also similarities between the aetiological theories and treatment of CFS and neurasthenia (Wessely,

1990). As psychiatric nosology became more sophisticated, the diagnosis of neurasthenia was gradually replaced by new psychiatic diagnoses such as various affective and anxiety disorders (Wessely, 1990). However, patients who later on were diagnosed as having various other fatigue related illnesses such as effort syndrome, chronic brucellosis and chronic Epstein-Barr virus infection, had identical symptoms to some patients diagnosed as having neurasthenia at the turn of the century.

The origins of CFS also lie with a number of ill-defined epidemic outbreaks reported between 1930 and 1960 (Aronowitz, 1992). One of the best known epidemics is the one which affected the staff at the Royal Free Hospital in 1955, from which the term 'myalgic encephalomyelitis' originates. The aetiology of these epidemic outbreaks has never been established, and a recent report on CFS by a joint committee of the Royal Colleges of Physicians, Psychiatrists and General Practitioners (1996) has suggested that it is unlikely that any single explanation will be found which unites these different illness phenomena.

There are many differences between the relatively uncommon epidemic cases of CFS and the large number of sporadic cases of CFS, and the relationship between them is uncertain. Whereas many epidemic cases of CFS in the past were of a contagious, paralytic illness with neurologic signs and a good prognosis, current cases of CFS tend to be noncontagious and fatiguing, are not associated with neurologic signs, and have a poor prognosis (Wessely, 1995). It is therefore not possible to draw on any findings from research on

epidemics, to understand more about endemic cases of CFS which are the focus of the present paper.

1.1 Definitions of CFS

Three operational case definitions for CFS currently exist. One definition was proposed by the Centres for Disease Control (CDC) in the United States (Holmes, Kaplan,Grantz, Komaroff, Shonberger et al, 1988) and has been revised twice. Another comes from Australia (Lloyd, Hickie, Boughton, Spencer & Wakefield, 1990) and a third from Oxford in the United Kingdom (Sharpe, Archald, Banatvala, Borysiewicz, Clare et al, 1991). All these definitions require a principal complaint of chronic fatigue for a minimal duration of at least six months, and substantial functional impairment not attributable to any known medical causes.

Unlike the other two definitions however, the original American CDC definition required multiple somatic symptoms and signs such as a sore throat, generalised headaches, painful lymph nodes, and sleep disturbance, and excluded persons with psychiatric disorders. A subsequent revision of this definition widened the exclusion criteria to include persons with affective, anxiety and somatization disorders (Schluederberg, Straus, Peterson et al, 1992).

Since then, several studies have suggested that the requirement of multiple somatic symptoms biases the cases selected towards those with psychiatric disorders, and does not increase the homogeneity of cases (Fukuda,

Straus, Hickie, Sharpe, Dobbins & Komaroff, 1994). In the most recent revised CDC definition (Fukuda et al, 1994) this requirement has been modified, so that only four symptoms from a list of eight are now required rather than eight symptoms from a list of 11. It has also become clear that excluding persons with psychiatric diagnoses such as anxiety disorders and less severe forms of depression made the definition too restrictive. Such psychiatric conditions occur commonly in CFS sufferers, and excluding persons with these conditions would hinder attempts to further investigate the role of psychiatric illnesses in CFS (Fukuda et al, 1994). Therefore, in the most recent revised CDC definition therefore, only people with psychiatric or physical disorders with little relevance to CFS such as dementias, substance abuse, severe eating disorders, and psychotic disorders are excluded. Non-psychotic and non-melancholic depression, anxiety and somatoform disorders are not exclusion criteria.

The Oxford and Australian CFS case definitions, on the other hand, are much broader, and include fewer symptom criteria than the CDC definitions. The Oxford definition does not require any specific symptoms to be present other than mental and physical fatigue. The Australian definition likewise only requires fatigue and cognitive or neuropsychiatric symptoms to be present. Both the Oxford and Australian definitions only exclude individuals with severe psychiatric diagnoses, and do not exclude individuals with major depression. The Australian definition differs from the Oxford definition however, by emphasising immune dysfunction (Salit, 1996).

None of these various definitions of CFS have any particular validity or can be considered definitive, and there is no evidence as yet that CFS even represents an independent and discrete nosological entity. The various case definitions of CFS that have been proposed were devised primarily to act as operational criteria for clinical research. Current definitions of CFS overlap with definitions of fibromyalgia (FM) and major depressive, anxiety, panic and somatoform disorders, and the presence of any of these conditions does not exclude a person from the diagnosis of CFS at present (Salit, 1996).

It is also uncertain whether CFS represents an arbitrarily defined end of a spectrum of fatigue severity. A more common but less severe fatigue-related illness is chronic fatigue (CF). Chronic fatigue has been defined as severe fatigue, present 50 per cent of the time for a duration of at least six months, which is not necessarily accompanied by functional impairment (Joyce, Hotopf & Wessely, 1997). As yet CFS and CF have not been distinguished by any "laboratory, demographic, or psychiatric variable" (Wessely,Chalder, Hirsch, Wallace & Wright, 1996, pp. 1057).

1.2 Epidemiology

A number of epidemiological studies which have obtained data using general practitioners or hospital physicians as key informants have suggested that CFS, unlike CF, is not a common problem. A point prevalence of 0.4 per 1000 patients was recorded in Lloyd et al's (1990) Australian study, in which cases were identified using general practitioners as key informants. The

authors argue that this prevalence figure should be regarded as a minimum estimate of the true prevalence of CFS in the Australian community they sampled however, because they obtained a higher estimate in their pilot study. A prevalence rate of 1.3 per 1000 patients was reported in Ho-Yen & McNamara's (1991) extensive postal survey of general practitioners on 10 local government lists in two Scottish health boards. A prevalence rate of 1.3 per 1000 patients has also been reported in Dunedin, New Zealand (Murdoch, 1987, in Lloyd et al, 1990). A prevalence of 2-7 per 100,000 population, was found in a study by the Centers for Disease Control and Prevention, from a surveillance of selected physicians in four US cities (Gunn, Connell & Randall, 1993).

It has however been suggested that factors such as attribution, recognition and recall will have distorted the accuracy of the prevalence figures in these studies. For example, Wessely, Chalder, Hirsch, Wallace,Wright (1997) have suggested that many of those who fulfill the criteria for CFS would not have labelled themselves or been labelled by their general practitioners as having CFS or ME, and therefore would not have been identified as cases in a key informant survey or a tertiary referral setting. In Pawlikowska, Chalder, Hirsch, Wallace, Wright & Wessely's (1994) study, only 1.4 per cent of the large number of subjects reporting excessive fatigue used a label such as CFS or ME to describe their symptoms.

Much higher prevalence rates have been reported in more systematic and methodologically rigorous studies carried out recently. A point prevalence of CFS of between 0.08 per cent and 0.3 per cent has been reported in a study

based on a Health Maintenance Organisation (HMO) in the USA (Buchwald, Umali, Umali, Kith,Pearlman & Komaroff, 1995). The results of this latter study may be an underestimate of the true prevalence of CFS however, because they are based on the 1988 CDC criteria for CFS, which are now considered overly restrictive. A recent survey of an ambulatory care clinic at a teaching hospital in America similarly found a point prevalence of CFS varying from 0.3 per cent to 1.0 per cent, depending on the criteria for CFS used (Bates, Schmitt, Buchwald, Ware, Lee et al, 1993).

Higher prevalence rates have also emerged from several recent British epidemiological studies. A study of subjects registered with a general practice in Scotland reported a point prevalence of 0.6 per cent using the Oxford criteria, although the study was only based on four cases (Lawrie & Pelosi, 1995). In a recent prospective primary care study of 2,376 patients aged from 18 to 45 years registered at five general practices in South England, a point prevalence of CFS of 2.6 per cent was found using 1994 CDC criteria, falling to 0.5 per cent if comorbid psychological disorders were excluded (Wessely, Chalder, Hirsch, Wallace & Wright, 1997).

A number of epidemiological studies based on tertiary care samples from specialist clinics, where patients have often already received a diagnosis of CFS prior to their referral, have reported an overrepresentation of women, higher social classes and certain professions among CFS sufferers (e.g. Wessely & Powell, 1989). It has been suggested, however, that some of these findings are the result of selection and referral biases rather than intrinsic characteristics of CFS sufferers (e.g. Euba, Chalder, Deale & Wessely, 1996).

In support of this suggestion, some differences have been found between the characteristics of sufferers in primary and tertiary care. For example, Euba et al (1996) found that CFS sufferers from a hospital unit specialising in CFS were more likely to belong to higher socio-economic classes than CFS sufferers seen in primary care. This suggests that the overrepresentation of high socio-economic classes among CFS sufferers in tertiary care may have been due to selection and referral bias. On the other hand, an overrepresentation of females was found in both hospital and primary care groups in this latter study, suggesting that this may be an intrinsic characteristic of CFS sufferers.

1.3 Aetiology

Debates concerning the aetiology of CFS have often until now been based on the outmoded assumption that the mind and body are separate (Ware, 1993). Much research has therefore tried to explain the aetiology of the syndrome in solely physical or psychological terms, assuming the two to be mutually exclusive rather than interdependent.

1.3.1. Psychiatry, psychology and neuropsychiatry

One line of research has tried to establish whether CFS is a psychiatric disorder, and more then 20 studies have been published on the role of psychiatric disorders in CFS. These studies have consistently shown that a relatively high proportion of CFS patients meet diagnostic criteria for a

psychiatric disorder, in both primary and tertiary care (e.g. Wessely, Chalder, Hirsch et al, 1996; Wessely & Powell, 1989). Most studies have found that between two-thirds and three-quarters of patients with CFS have psychiatric disorders, and depression in particular (David, 1991; Katon & Walker, 1993).

These findings do not necessarily suggest that CFS is caused by depression or psychiatric disorder however, and there are various ways of explaining the associations between CFS and psychiatric disorder that have been found (Abbey & Garfinkel, 1991b; Ray, 1991). Emotional disturbance may predispose individuals to illness, or may be a reaction to illness. A third explanation is that there may be considerable overlap in symptomatology between CFS and psychiatric disorder due to some overlap between current definitions of CFS and common psychiatric disorders. Another explanation is that CFS and psychiatric disorder may both result from overlapping neurochemical processes.

Contrary to the explanation that psychiatric disorder in CFS is purely a consequence of physical illness, it has been noted that no symptoms or physical pathology specific to CFS have been clearly established yet (e.g. Hickie, Lloyd, Hadzi-Pavlovic, Parker, Bird, Wakefield, in press, in Fukuda et al, 1994). Also, several studies comparing rates of psychiatric illness in CFS sufferers and physically ill control subjects have found higher rates of psychiatric illness in CFS sufferers. For example, Wessely & Powell (1989), in a consecutive series of patients seen at the National Hospital in London, found that 72 per cent of CFS patients fulfilled criteria for psychiatric disorder, compared to 36 per cent of controls with neuromuscular disorders. Likewise,

Wood, Bentall, Gopfert & Edwards (1991), in a series of patients from a specialist unit in Liverpool, found that 41.2 per cent of CFS patients were psychiatric cases, compared to 12.5 per cent of controls with muscle disease.

A number of studies have found differences between individuals with CFS and depression, which disconfirm any suggestion that CFS can be equated to depression. Powell, Dolan & Wessely (1990) have reported differences between the nature and phenomenology of depressive symptoms in CFS and clinical depression. They found some significant symptomatic differences between depressed CFS patients and clinically depressed controls in relation to self-esteem, guilt and illness attribution. The CFS sufferers in this study tended to attribute their illness to external rather than internal causes, experienced less guilt and had higher self esteem than depressed controls. Robson (1988) has suggested that an outward style of attribution may defend individuals against certain cognitive changes which lead to psychological distress and low self esteem. There is some preliminary evidence from neurobiological research for differences in neuroendocrine function, immune function and cognitive evoked potentials between CFS sufferers and individuals with depression (e.g. Prasher, Smith & Findley, 1990). Also, despite the high rate of psychiatric disorder among CFS suffferers, the majority of studies have found that one-quarter to one-third of CFS sufferers do not meet any criteria for psychiatric disorders.

There is some evidence that CFS sufferers are more likely to have experienced prior psychiatric episodes than non-sufferers, although not all CFS sufferers have a previous psychiatric history (Katon, Buchwald, Simon, Russon & Mease, 1991; Wessely et al, 1996). Wessely et al (1996) have

suggested that the relationship between CFS and previous psychiatric disorder in their study might have been due to the influence of confounding variables, and the close association between CFS and psychiatric disorder. In support of this idea, there was some evidence from their findings that previous psychiatric disorder predicted current psychiatric disorder alone, rather than CFS. Considerable confusion still exists about the role of previous psychiatric illness in CFS therefore, and there is a lack of consensus on whether individuals with a past psychiatric history should be excluded from a CFS diagnosis.

Other research has focused on physical explanations for the illness.

1.3.2. Virology

Many patients who are seeking specialist help at present report that their CFS illness followed an episode of viral infection. A considerable amount of research has focused on the aetiological role of viral agents in CFS. Research has mainly addressed whether abnormal viral persistence causes CFS and/or whether episodes of viral infection precipitate CFS.

The evidence for an association between CFS and viral infection in many studies has been weakened by a number of methodological problems. For example, viral infection is very common in the community, and it is therefore difficult to exclude the possibility that any associations between viral infection and the onset of fatigue which are found are due to chance. Inaccurate and biased recall in studies based on CFS sufferers' self reports is

another potential problem. Gunn (1993) argues that many CFS sufferers who initially report that their illness began after a viral infection will, after further questioning, remember a period of illness which occurred prior to the virus.

Persistent infection with viruses such as Epstein-Barr viruses and herpes and Coxsackie A and B have been suggested in relation to CFS. For example, Bell, McCartney & Riding (1988) compared 290 CFS sufferers to 500 'well' controls and found evidence for recent and persisting infection with Coxsackie B virus in a significantly higher proportion of CFS sufferers than controls. There is no evidence, however, that a single virus occurs in all sufferers and not in the population at large, and not all sufferers have reported an acute viral infection preceding the onset of illness. The specific association between elevated antibodies to Epstein-Barr virus and CFS which was found in some early studies has not been replicated in subsequent studies, and interest in the aetiological role of the Epstein-Barr virus has waned (Ware, 1992). More recently it has been suggested that the human herpes virus six may have an aetiological role in CFS. It is difficult to rule out the possibility that associations that have been found between this human herpes virus six and CFS in serological studies are not due to chance factors, because this herpes virus is so widespread. As with the Epstein Barr virus, it has been suggested that any associations between human herpes virus 6 and CFS are artefactual or due to secondary reactivation (Wessely, 1991).

Most attention in the United Kingdom has been directed at the role of enteroviral persistence in CFS. A number of previous studies which have shown relationships between various enteroviruses and CFS are no longer

considered reliable however, because the tests on which these studies were based are now known to have been inaccurate (Wessely, 1991). For example, the reliability of the serological tests of enteroviral exposure have recently been called into question. Also, some of the associations which have been found between persistence of enteroviruses and CFS have not been replicated in subsequent studies. For example, Gow, Behan, Clements, Woodall, Riding & Behan (1991) identified enteroviral persistence in the muscle biopsies of a significantly higher proportion of CFS sufferers than non-fatigued older controls. More recently, however these researchers have failed to confirm their own findings (Royal College of Physicians, Psychiatrists, and General Practitioners Report on CFS, 1996). At present, there is a lack of any substantial evidence that enteroviruses contribute to the development of CFS.

Although it seems unlikely now that CFS will be linked to any specific viral agent, clinical findings suggest that CFS represents a non-specific response that may be triggered by various different viral, bacterial or protozoal infective and non-infective agents (Wessely, 1995).

The strongest evidence for the claim that CFS may be precipitated by certain infective agents comes from recent epidemiological research on the outcome of Epstein-Barr and non-Epstein-Barr glandular fever. For example, a recent prospective longitudinal study of 250 primary care patients with either Epstein-Barr and non-Epstein-Barr glandular fever or ordinary upper respiratory tract infection has suggested that a distinct post-infectious fatigue syndrome exists after glandular fever (White, Thomas, Amess, Grover, Kangro & Clare, 1995). The fatigue syndrome was distinguishable from psychiatric

disorder and was present in a minority of sufferers six months after the onset of glandular fever. Patients who had had ordinary respiratory tract infection in this study were not found to have developed a distinct fatigue syndrome six months later.

There is some evidence that other less common viral agents such as infectious hepatitus and viral meningitis may also precipitate a post-infectious fatigue syndrome (e.g. Hotopf, Noah & Wessely, 1996). On the other hand, no link has been found between more common viral agents and the development of CFS. A recent controlled prospective study of over 1000 primary care patients with common clinical viral infections found no increased incidence of viral infection among patients who later developed CF or CFS (Wessely, Chalder, Hirsch, Pawlikowska, Wallace & Wright, 1995).

1.3.3. Immunology

Immunological abnormalities are another physical explanation for the illness which has attracted considerable research attention. Some research has investigated whether immune dysfunction plays a primary aetiological role in CFS. Other research has suggested that immune dysfunction mediates between acute infection and the subsequent development of CFS (Strober, 1994).

Reviews of this research have suggested that, although there is evidence for some abnormalities in CFS such as raised circulating immune complexes and decreased natural killer cell function, the results from different studies have generally been inconsistent, and the abnormalities identified have

been non-specific to CFS (e.g. Buchwald & Komaroff, 1991 in Wessely, 1991). It is difficult to draw any conclusions from the results of these studies, because different patient groups and operational definitions of CFS have been used across studies. The influence of confounding variables such as neurohormonal factors, psychiatric morbidity, sleep disorder and inactivity has been inadequately addressed and controlled for in these studies (e.g. Strober, 1994). Finally, much of the research has been based on laboratory studies, and the clinical significance of the findings is unclear.

More rigorous methodology is being used in studies currently being undertaken in research centres in the USA and Australia. Preliminary findings from these studies suggest that a non-specific dysregulation of immune function may occur in a minority of CFS sufferers irrespective of whether or not they also have a psychiatric diagnosis (Wessely, 1991).

1.3.4. Muscle dysfunction

There is no consistent evidence as yet that muscle dysfunction plays a primary role in the development of CFS. However the role of muscular abnormalities in CFS is becoming clearer. A number of studies have found a variety of minor biochemical and structural abnormalities of muscle in CFS sufferers (e.g. Archard, Bowles, Behan, Bell & Doyle, 1988 in Riley, O'Brien, McCluskey, Bell & Nicholls, 1990). Many of these studies lacked control groups, however, and their results may have been partly the result of physical inactivity and deconditioning (e.g. Riley et al, 1990). Research on dynamic

muscle function in CFS sufferers has demonstrated normal muscle strength, endurance and fatiguability, after the confounding effect of physical inactivity has been controlled for (e.g. Lloyd, Gandevia & Hales. 1991, in Wessely, 1991). The clinical relevance and specificity of some of the muscle abnormalities which have been identified have been questioned. It also seems unlikely that CFS is due primarily to muscle abnormalities, because CFS is associated with mental as well as physical fatigue related to mental and physical effort (Wessely & Powell,1989).

1.3.5. Multifactorial models of CFS

Most recently, it has been suggested that CFS is a complex condition which can not be understood in solely physical or psychological terms. It has been argued that the aetiology of CFS may be multifactorial and various interacting physical, psychological and social factors may be involved (e.g.Ware, 1993; Salit, 1996). For example Taerk, Toner, Salit, Garfinkel & Ozersky (1987, in Lewis, Cooper & Bennet, 1994) have suggested that CFS may be due to a physical illness in psychologically vulnerable individuals.

Lewis (1996) has noted several themes and areas of consensus emerging from the recent literature on CFS. One idea is that CFS may not be a unitary, discrete entity, but may instead consist of a number of different conditions (e.g. The 1996 Report on CFS by the Royal College of Physicians, Psychiatrists and General Practitioners). Different aetiological explanations may therefore be relevant to different subgroups of CFS sufferers.

Another recent idea which has emerged from CFS research is that aetiological, perpetuating and maintaining factors in CFS may be different. Factors such as physical illness attributions and catastrophic beliefs may perpetuate CFS illness irrespective of the original cause of illness (e.g. Petrie, Moss-Morris & Weinman, 1995; Powell, Dolan & Wessely, 1990). White (1990) has recently proposed a model for the fatigue syndrome according to which precipitating and maintaining factors are different and change with time. Salit (1996) has also suggested that causal models of CFS need to include predisposing factors (e.g. lifestyle, personality), triggering events (e.g. viral illness) and maintaining factors (e.g. attribution, reduced exercise tolerance) . It is particularly important to include maintaining factors in models of CFS to guide clinical management and treatment of the condition.

A final theme emerging from the recent literature on CFS is that more emphasis and attention needs to be given to exploring the role of psychological processes and psychosocial factors such as stress in CFS.

1.4 Prognosis

There has generally been a lack of long-term studies on the prognosis of CFS, and those studies which have been carried out have used widely varying sample sizes. Studies have also used a wide variety of different case definitions of CFS, and this has made it difficult to compare their findings. These problems aside, the following findings have emerged from research on the prognosis of CFS.

The prognosis for untreated patients with CF and CFS seen in tertiary care settings has been found to be poor. Behan and Behan (1988, p.164) have commented that 'most cases do not improve, give up their work and become permanent invalids'. Schenck and Peterson (1991, in Bonner et al, 1994) similarly found a very poor prognosis for the first year after clinic attendance. None of their series of 62 CFS patients had made a full recovery at one year follow-up.

Slightly more positive findings have emerged from a follow-up study of CFS patients seen at an infectious disease clinic in Belfast, Northern Ireland. Eighteen per cent of those referred to the clinic were found to have improved at follow-up (Hinds & McCluskey,1993, in Wessely, 1995). As many as two-thirds of CFS sufferers seen at an infectious disease clinic in Oxford, England were found to be no longer functionally impaired. Their functioning had not been impaired in the preceding month in any of the activities assessed (i.e. housework, sport, walking, social , hobbies , occupation or studies) at two to four years follow-up after initial clinic attendance (Sharpe, Hawton, Seagroatt & Pasvol, 1992). However only 13 per cent of CFS sufferers seen at the clinic regarded themselves as "fully recovered" at follow-up in this study. The proportion of patients who remained functionally impaired fell significantly with time. Whereas 73 per cent were functionally impaired at six weeks to six months follow-up, only 33 per cent were functionally impaired at two to four years follow-up. An even higher proportion of patients, who had previously enrolled in two treatment trials reported improvement (65 per cent) at 3 year follow-up in a longitudinal outcome study of CFS in Australia (Wilson, Hickie,

Lloyd, Hadzi-Pavlovic, Boughton, Dwyer & Wakefield, 1994). Only 6 per cent of participants had made a full recovery and reported no current symptoms at 3 year follow-up, however, and the majority of patients in this study continued to be impaired carrying out routine activities at follow-up.

In general, these studies suggest that, while many patients with CF and CFS make a significant improvement with time in tertiary care settings, only a small minority make a full recovery. However the results from these tertiary care studies may not be an accurate reflection of the prognosis of CFS because they are likely to be influenced by selection factors.

A better prognosis has been found for CF and CFS patients in primary care and the community (Salit, 1996). Joyce, Hotopf& Wessely (1997) have noted in their systematic review of studies on the prognosis of CF and CFS, that primary care studies which have only included cases with fatigue of less than six months duration, have often found that over 40 per cent of patients made a full or near full recovery during follow-up. When a stricter definition of CFS has been used, and only cases of chronic fatigue have been included (i.e. cases with fatigue for 50 per cent or more of the time, for at least six months) on the other hand, a less favourable outcome has been found in primary care. The natural history of CFS in primary care and the community needs further investigation.

A number of risk factors which have been associated with a poor prognosis include: the strength of attribution of illness to solely physical causes; persistent comorbid psychiatric disorder; the use of avoidant coping strategies (such as reducing activity, and avoiding alcohol); older age;

belonging to a self-help organization; and changing or leaving employment (e.g. Sharpe et al, 1992; Wessely, David, Butler, & Chalder, 1989; Wilson et al, 1994). Chronicity of illness and illness severity (e.g. more severe fatigue and disability) have tended to be associated with a worse outcome in many studies (e.g. Clark, Katon, Russo, Kith, Sintay & Buchwald, 1995), although these associations have not been consistently found (Joyce et al, 1997). Sharpe et al (1992), in their follow-up study of patients presenting with fatigue to an infectious diseases clinic, found no difference in prognosis between patients who had been ill for more than six months at presentation and those with shorter histories of illness. No virological or immunological laboratory markers have been found to be significant predictors of persistent illness (Clark et al, 1995).

Whilst CFS has been associated with a poor prognosis particularly in tertiary care settings, it has not been associated with increased mortality, with the exception of suicide. Also, all the aforementioned studies refer to the prognosis of CFS or CF without treatment. A growing number of studies have recently suggested that the short and medium term prognosis of the condition can be improved through rehabilitation and treatment programmes (e.g. Bonner, Butler, Chalder, Ron & Wessely,1994). The 1996 report on CFS by the Royal Colleges of Physicians, Psychiatrists and General Practitioners has also suggested that the illness may be perpetuated by inadequate clinical management and rehabilitation, and failure to address psychosocial factors.

1.5. Treatment

There is some evidence for a number of different approaches to treating CFS, although treatment remains a controversial issue.

CFS sufferers are commonly prescribed antidepressant drugs. There is some evidence for the effectiveness of these drugs for treating CFS from a number of uncontrolled clinical trials.While a number of uncontrolled studies and case reports have suggested that Fluoxetine is effective for treating CFS, the findings from different studies have not been entirely consistent. For example, Lynch, Seth & Montgomery's (1991) uncontrolled study showed that treatment with fluoxetine for 8 weeks lead to a reduction of at least 50 per cent in the severity of depressive symptoms in a third of mildly to moderately depressed CFS sufferers. More recently however, Vercoulen, Swanink, Zitman, Vreden, Hoofs et al's (1996) randomised, controlled and double-blind study has found no evidence that fluoxetine has a beneficial effect on any of the characteristics of CFS, including severity of depression and functional impairment.

In spite of these inconsistent findings and lack of systematic controlled research, the recent report on CFS by the Royal Colleges of Physicians, Psychiatrists and General Practitioners has recommended that antidepressants continue to be used to treat CFS patients with depression, in view of the considerable evidence from clinical trials showing that antidepressants are effective for treating depressive symptoms in other conditions.

A number of other drug treatments for CFS sufferers have been found to have few if any benefits. There is little systematic evidence suggesting that antiviral agents, immunoglobulin infusions, antihistamine or other immunological treatments are effective (e.g. Straus, 1990). There is some preliminary evidence suggesting, however, that magnesium and essential fatty acids may lead to some improvement in CFS symptoms (Cox, Campbell & Dowson, 1991). There is little empirical support at present for the alternative and complementary therapies and vitamin and dietary supplements which many CFS sufferers currently use to treat their symptoms (Salit, 1996).

CFS sufferers are still frequently advised to rest as a way of managing their symptoms. Self-help groups such as the M.E. association consistently advise sufferers to avoid any physical and mental activity. While resting for long periods may be effective in the short term, if it is used as a long term strategy it may lead to the disuse syndrome (Brena & Chapman, 1985, in Williams, 1993). There is an increasing amount of evidence on the pathophysiology of inactivity (e.g.Greenleaf & Kozlowski, 1982, in Wessely, David, Butler & Chalder, 1989). Inactivity has harmful effects on muscle function, cardiovascular performance and overall fitness, which leads to reduced tolerance for everyday activities, and the development of pain and fatigue at increasingly lower levels of activity. As well as resting for long periods to control symptoms, many sufferers also become very active for short bursts of time in the hope of resuming their premorbid level of activity (Surawy, Hackmann, Hawton & Sharpe, 1995). These sudden bursts of activity after long periods of rest and inactivity inevitably lead to an increase in

pain and fatigue symptoms however. Sufferers typically then respond to this worsening of symptoms by resting again and avoiding activity for further prolonged periods. Thus a vicious cycle of overactivity and underactivity is established. The negative consequences of prolonged rest and patterns of inactivity and overactivity have also been discussed in relation to chronic pain, a condition with many parallels to CFS.

The recent report on CFS from the Royal Colleges of Physicians, Psychiatrists and General Practitioners (1996), has argued that advising CFS sufferers to rest as a way of managing their symptoms is misguided, unless it is only for the short term and one part of a broader treatment strategy. They recommend instead that a crucial aspect of the management of CFS involves addressing the consequences of reduced or variable activity levels through a programme of controlled gradual increases in activity. Wide fluctuations in activity levels should be replaced by a consistent programme of moderate rest and activity, and sufferers should be warned to avoid both prolonged rest as well as sudden bursts of overactivity.

Few studies have evaluated rehabilitation approaches or physical therapy in CFS. A rehabilitation approach involving a programme of graded return to work was found to be effective in one setting however (Peel, 1988, in Salit, 1996). Also two recent randomised controlled trials have demonstrated the effectiveness of graded exercise programmes for treating CFS (e.g. Fulcher, Cleary & White, 1994).

Although many CFS sufferers are anxious about the consequences of becoming more active, there is no evidence that it leads to any long term

damage or disability in CFS sufferers, and there is considerable evidence for the harmful psychological as well as physical effects of inactivity (e.g. Baekeland, 1970). It has been suggested however that patients' fears should be discussed and acknowledged at the outset of treatment. It has also been recommeded that individually-tailored, realistic and achievable goals should be set in exercise programs, which take account of the person's initial level of unfitness and degree of disability (e.g.Wessely, David, Butler & Chalder, 1989).

1.5.1. Cognitive-behavioural treatment approaches

There is now increasing empirical evidence showing that Cognitive-behavioural therapy (CBT) treatment approaches, which aim to change cognitive and behaviour patterns, thought to maintain disability and symptoms in CFS, are effective. Cognitive-behavioural techniques have also been used to treat somatic disorders without any physical explanation, and disorders closely related to CFS such as fibromyalgia and chronic pain (e.g. Deale, Chalder, Marks & Wessely, 1997; Williams 1993). Cognitive and behavioural factors which research suggest play a role in maintaining CFS, and which are addressed in CBT treatment include catastrophic beliefs, dysfunctional cognitions such as the belief that physical symptoms always imply tissue damage, physical illness attributions and avoidance of activity (e.g. Butler, Chalder, Ron & Wessely, 1991; Wessely, David, Butler & Chalder, 1989).

Several studies which have evaluated CBT treatment for CFS have been based on uncontrolled and/or unrandomised research designs. An uncontrolled pilot study by Butler et al (1991) found that CBT led to substantial improvements in overall disability, fatigue, somatic and psychiatric symptoms, and these gains were largely maintained at four year follow-up (Bonner et al, 1994). This study also showed that spontaneous recovery in those who decline or do not respond well to treatment is unlikely. CBT was found to bring about some improvement in depression, but no improvements in disability or fatigue in another non-randomised controlled trial (Freidberg & Krupp, 1994). Deale et al (1997) have suggested that the negative findings in this latter study may have been due to the nature and delivery of the CBT intervention assessed. In particular, graded activity was excluded from the CBT intervention in Freidberg & Krupp's (1994) study, because it provoked relapse.

More recently a randomised controlled trial by Sharpe, Hawton, Simkin, Surawy, Hackmann, Klimes, Peto,Warrell & Seagroatt (1996) compared 16 sessions of CBT to standard medical care. There was satisfactory improvement in 73 per cent of patients in the CBT treatment group, but in only 27 per cent of patients receiving standard medical care. Another randomised controlled trial of CBT also found that 13 sessions of CBT were more effective than 13 sessions of relaxation therapy, for improving physical functioning and fatigue, and this improvement continued during follow-up (Deale et al, 1997). By comparing CBT with relaxation therapy in this study, non-specific treatment factors such as therapist time and attention were

controlled for. Seventy per cent of patients completing CBT in this study, achieved substantial improvement in physical functioning, compared with 19 per cent of patients receiving the relaxation control treatment.

A recent double blind, randomised controlled trial in Australia, on the other hand, found that a brief CBT intervention did not lead to any specific or substantial improvements in sufferers (Lloyd, Hickie, Brockman, Hickie, Wilson, Dwyer & Wakefield, 1993). This trial compared six sessions of CBT with a placebo and immunological therapy and found that although CBT lead to small improvements on self-reported measures of function, these improvements had not been maintained on follow-up, and could be explained in terms of non-specific factors. Deale et al (1997) have suggested that the CBT intervention evaluated in Lloyd et al's (1993) study may have been ineffective because it was too brief. Deale et al (1997) argue that a longer CBT intervention has the advantage of enabling patients to learn about how to prevent relapses, and treat themselves while they are still seeing a therapist.

Chalder, Butler & Wessely (1996) have suggested that CBT treatment can be used to achieve substantial improvements even in patients with severe symptoms and disability who need inpatient treatment. They have described six severe cases of CFS who were treated as inpatients using CBT treatment. In five of the patients there was an improvement in work and social functioning, and mood and a reduction in symptoms of fatigue following treatment. Two of the patients returned to employment following treatment. One patient who dropped out of treatment and failed to improve, had been depressed and did not respond to antidepressant treatment. This patient also held a fixed view

that her illness was physical and could not be improved through therapy. Although this study's findings are promising and suggest that CBT may be of use in treating more severe cases of CFS in an inpatient setting, the cases reported were not part of a randomised controlled trial.

Overall there is now substantial evidence to suggest that CBT is an effective treatment approach for CFS, at least in the context of clinical trials. Randomised, controlled studies have shown that CBT treatment is both more effective than alternative approaches such as standard medical care and relaxation therapy, and brings about a satisfactory improvement in the majority of patients.

High treatment refusal rate

One shortcoming of previous CBT outcome studies pointed out by Lewis (1996) is that the treatment refusal rate has been found to be high and this may have confounded the studies' results. Lewis (1996) also argues that a high treatment refusal rate limits the extent to which the treatment can be said to be applicable to all CFS sufferers.

A high treatment refusal rate and poor treatment adherence was found in Butler et al's (1991) uncontrolled pilot study. Thirty-six per cent of CFS patients referred for CBT in this study, refused the offer of treatment, and 16 per cent of those who accepted the offer of treatment dropped out after treatment had started. This compares to a refusal rate of 10 per cent among the last 50 patients referred by neurologists for CBT for other conditions (Butler et al, 1991). There was a trend for those refusing treatment in Butler et

al's (1991) study, to be female, have lower GHQ scores and to hold solely physical attributions for their illness. The principal reason given for refusing treatment concerned fears about treatment having detrimental effects. It is not possible to draw any conclusions about whether or not treatment would have had harmful effects on these patients, but there were few clinical or symptomatic differences between those who refused and accepted treatment. For example no significant differences were found between those who accepted or rejected treatment in terms of length of illness, fatigue severity, current psychiatric illness or functional impairment.

On the other hand, persuading CFS sufferers to participate in CBT treatment and adhere to the course of treatment was not found to be a problem in several subsequent controlled outcome studies of CBT treament (Deale et al, 1997; Lloyd et al, 1993; Sharpe et al, 1996). For example in Deale et al's (1997) study, only 10 per cent of the CFS patients eligible for trial entry refused treatment and only 3 per cent said they had refused treatment because they did not wish to have cognitive-behaviour therapy. The proportion of treatment dropouts (10 per cent) in this latter study was also low, suggesting that CBT was generally an acceptable and credible treatment approach. Only one of the patients withdrew from CBT treatment because they found it ineffective in this study. Unlike Butler et al's (1991) study, Deale et al's (1997) study found no differences between patients who dropped out, refused and completed treatment, on any demographic variable or pre-treatment outcome measure (including measures of psychological distress and mood, fatigue, functional impairment and illness attributions).

The "efficacy" research method vs the "effectiveness" method

A more important limitation of the previous outcome studies which have supported the efficacy of CBT treatment is that they were clinical trials evaluating the efficacy of CBT treatment under strictly controlled conditions.

The previous clinical trials were evaluating CBT treatment under strictly controlled conditions in the sense that they were only evaluating the treatment on a very selected sample of CFS patients. For example, in Deale et al's (1997) trial, patients were excluded if they met criteria for severe depression (DSM-III-R melancholic subtype) or somatization disorder, or if they were undergoing any physical investigations. Likewise, in Sharpe et al's (1996) trial, patients were excluded if they met criteria for severe depression (melancholia), or had a history of bipolar affective disorder, schizophrenia, or substance misuse (as defined in DSM-III-R). In routine clinical practice, by contrast, particularly in tertiary care settings, the CFS patients who are treated often have multiple problems, diagnoses and unexplained symptoms.

The previous clinical trials were also evaluating CBT under strictly controlled conditions in the sense that therapists participating in the trials were required to adhere closely to a manualised treatment protocol. For example, in Deale et al's (1997) study the therapists followed a detailed session-by-session CBT treatment manual, and the research team met fortnightly to ensure protocol adherence. Likewise, in Sharpe et al's (1996) study, therapy was codified in a manual and supervised by an experienced cognitive therapist. In routine clinical practice, by contrast, therapists do not adhere strictly to a

treatment manual or have their adherence to a specific treatment protocol supervised.

Some of the previous CBT trials (e.g. Friedberg & Krupp, 1994; Lloyd et al, 1993; Sharpe et al, 1996) have also evaluated CBT delivered for a fixed number of sessions. In clinical practice, however, the number of sessions which patients receive varies, and depends on factors such as their progress.

There are therefore a number of important differences between CBT evaluated in clinical trials and CBT as it is actually delivered in clinical practice. These differences limit the extent to which the results from previous clinical trials can be said to be generalisable to CBT in clinical practice, or the external validity of previous clinical trials' results.

Seligman in his article titled "Science as an Ally of Practice"(1996) describes and distinguishes between two research methods which have arisen to evaluate the outcomes of psychotherapy. One method - the *efficacy* method - evaluates a treatment administered according to a manual, for a fixed number of sessions using clinic volunteers with well-diagnosed uncomplicated disorders, who are randomly assigned to different therapists and treatment modalities. Previous outcome studies evaluating CBT treatment for CFS clearly fall into this category. The other method - the *effectiveness* or *clinical utility* method - evaluates the outcome of therapy when it is actually delivered in the field, without a manual, for a variable number of sessions, with patients who may have multiple problems and who choose a particular therapist or treatment modality because they believe in it.

It is often argued that the efficacy method is the superior method which establishes the truth of what works, and that the effectiveness method is only useful for then confirming that it works. Seligman (1992) argues, however, that the effectiveness method has some important advantages over the efficacy method, and that both methods are useful for answering complementary questions. Most importantly, the effectiveness method has high external validity as it tests exactly what it wants to generalise to. The efficacy method, by contrast, evaluates a treatment which differs in many important respects from therapy delivered in actual clinical practice.

While a considerable number of previous studies have evaluated the effectiveness of different treatment approaches for CFS sufferers using what Seligman terms an 'efficacy' method, the only previous study which has evaluated a treament approach for CFS sufferers using a method similar to what Seligman terms an 'effectiveness' method, is Wearden et al's (in press) recent study. Wearden et al (in press) have evaluated the effectiveness of a graded exercise intervention for CFS sufferers as it relates to routine clinical practice, using a heterogenous sample of CFS patients. No previous outcome studies have evaluated CBT treatment as it is actually delivered in routine clinical practice using an effectiveness approach.

The results of previous clinical trials of CBT for CFS are encouraging, and suggest that, under certain conditions, CBT is capable of producing significant improvements for a selected sample of CFS sufferers. Further research is needed, however, to evaluate whether CBT is as effective when it is

delivered in a real clinical setting with a more representative group of CFS patients and scarce resources.

1.6. Factors associated with treatment outcome

A number of recent studies have evaluated factors associated with outcome following CBT treatment. There is considerable overlap between factors which have been associated with a poor treatment outcome and factors associated with a poor prognosis. Butler et al's (1991) study have found an association at follow-up between persistence of psychiatric disorder (e.g. anxiety or depression) and poor treatment outcome. Patients who had a previous psychiatric history at initial assessment were also more likely to continue to fulfill criteria for CFS four years later in Bonner et al's (1994) study. Severity of affective disorder before starting treatment was not found to affect treatment outcome in Butler et al's (1991) and Bonner et al's (1994) studies. Neither were any differences found in the proportion of patients with a psychiatric disorder at pre-treatment, between the group who were improved and the group who were unimproved following CBT treatment in Deale et al's (1997) study.

Contrary to the idea that a more severe initial illness is associated with a worse outcome, clinical features indicating a more severe illness have not been found to be consistently associated with a worse outcome. Clinical features such as severity of fatigue, length of illness, and number of somatic symptoms were not found to be associated with treatment outcome in Butler

et al's (1991) study. Neither was a relationship found between duration of fatigue at initial assessment and persistent CFS at four year follow-up in Bonner et al's (1994) study. On the other hand, patients who continued to fulfill CFS criteria four years after initial diagnosis in Bonner et al's (1994) study were likely to have been more fatigued, and to have had more somatic disorders at the initial assessment.

No associations have been found between treatment outcome and demographic variables, such as age of illness onset (Bonner et al, 1994) and gender (Butler et al, 1991). Membership of the M.E. association has not been found to be associated with outcome at four year follow-up in Bonner et al's (1994) study, despite the association that has been found between this factor and a poor prognosis in Sharpe et al's (1992) study. Other factors that have been found to be associated with a poor treatment outcome include, making a new claim for disability benefit during treatment and taking medical retirement (Deale et al, 1997).

While there is an increasing amount of research on the role of psychosocial variables in the aetiology and perpetuation of the illness, very little research has looked at the relationship between psychosocial variables and treatment outcome. Lewis (1996) has drawn attention to the relationship between psychosocial variables and treatment outcome in saying that failure to address psychosocial stressors such as chronic work and relationship difficulties during treatment may result in a relapse ocurring. CBT approaches already address some psychosocial variables during treatment, such as individuals' illness beliefs and explanations, but there is no conclusive research

evidence yet on how illness beliefs and attributions affect or are related to treatment outcome (e.g. Butler et al, 1991; Deale et al, 1997).

1.7. The role of psychosocial factors in CFS

Research used to focus mainly on the role of clinical and pathological factors such as psychiatric disorder and viral infection, in the development of CFS. More recently, research has begun to look at the influence of psychological processes and various psychosocial factors on both the development and course of CFS. For example the role of various psychosocial variables such as stressful lifestyles, coping strategies, personality, and social support in CFS have been investigated (e.g. Ray, Jefferies & Weir, 1995).

The present study aims to focus on the role of several specific psychosocial variables in CFS, including stressful life-events, social support, illness attributions and perfectionism.

1.7.1. Stressful life-events

An association between psychosocial stress and the development of illness has been recognised for some time. Over the last 30-40 years research has tried to determine the relationship between psychosocial stress (measured by adverse stressful life-events) and various illnesses and health conditions including heart disease, herpes virus infections, various forms of malignancy and cancer (Cooper, Cooper & Faragher, 1989). A great deal of research over

the past 25 years has suggested that a number of adverse life-events (such as divorce, death of a relative, family illness) over a short period of time may be a pre-conditioning factor in stress-related illnesses (Paykel, 1983).

A number of studies have looked at the relationship between stressful life-events and the development of CFS, but the findings so far have been conflicting and inconclusive. Many CFS sufferers in Ware's (1993), Surawy et al's (1995) and Wood et al's (1991) studies, reported stressful life-events preceding the onset of illness, although none of these studies included control groups. In Wood et al's (1991) study 32.4 per cent of CFS patients reported a major stressful life event in the six months preceding the onset of fatigue. This information was not collected using a standardised instrument however and these findings therefore need to be treated with caution. Stress was said to be a contributory factor or the single most probable cause of CFS by nearly half the interviewees in Ware's (1993) study. In Surawy et al's (1995) study patients initially reported that the onset of CFS occurred in association with symptoms of a viral illness. After further enquiry however, most patients reported that major psychosocial stressors and chronic difficulties, such as work and relationship difficulties and bereavement, had occurred prior to the onset of the condition.

CFS sufferers were also found to have experienced more loss related life-events a year prior to the onset of their illness than a healthy control group in Stricklen, Sewell & Austad's (1990) study. Another controlled study found no relationship between the onset of CFS and stressful life-events however (Lewis et al, 1994). Lewis et al (1994) found no differences in the overall

number or severity of life-events recalled, by a CFS group and an irritable bowel syndrome group two years prior to the onset of their illness, and by healthy controls in the previous two years. Two life-events which were reported more frequently by the CFS sufferers than the other groups in this study were related to moving house. Lewis et al (1994) have commented however, that life-events related to moving house may have been reported more frequently by CFS sufferers than the other two groups in their study, because there was a larger number of professionals in the CFS group.

Bruce-Jones,White, Thomas & Clare (1994) have recently looked at the relationship between stressful life-events and the development of CFS, using a more sophisticated measure known as the Life Events and Difficulties Scale. This scale provides qualitative and quantitative information about life-events and ongoing difficulties, and the significance which individuals attach to them (Brown and Harris, 1989). Little association was found in Bruce-Jones et al's (1994) study between the experience of social adversity in the previous six months and the development of the post-infectious fatigue syndrome, using the Life Events and Difficulties Scale. The authors concluded, that although stress was not associated with the onset of CFS in their study, it may be a factor which maintains the syndrome a long time after the initial onset of illness. They argue that this may explain why a closer relationship was found between CFS and measures of stress in patients with chronic fatigue of much longer duration in Stricklen et al's (1990) study.

Surawy et al (1995) have pointed out that life-events and ongoing stressors such as chronic work and relationship difficulties, which preceded

and may have contributed to the development of CFS in the patients in their study, often remained unresolved many months after the start of the illness. The illness does not necessarily resolve these problems and may even exacerbate them. Sufferers themselves, have reported that once the condition has developed, psychosocial stress exacerbates symptoms and brings on relapses (Ray,Weir, Cullen & Phillips, 1992). Further systematic research is needed to assess the role of stressful life-events and chronic ongoing difficulties in perpetuating the illness.

If stressful life events and ongoing difficulties do play a role in maintaining the illness, then it might be expected that failure to resolve these psychosocial stressors may result in relapse, and will be associated with a worse outcome. There is already some evidence that certain stressful life-events such as changing or leaving employment (Sharpe et al, 1992) and taking medical retirement (Deale et al, 1997) as a result of illness, are related to a poor outcome in CFS sufferers. Further research needs to explore the relationship between other stressful life-events and outcome. If an association between stressful life-events and treatment outcome is found, this would provide a justification for including stress management techniques in Cognitive-behavioural treatment for CFS sufferers.

1.7.2 Social support

It has been suggested that a number of variables including social support, coping style and personality modify or buffer against the effects of

potentially stressful situations (e.g. Power, 1988). A considerable amount of research suggests that social support mediates the effects of stress on health and psychological well-being (Cohen & Wills, 1985). Greater social support has been found to have beneficial consequences in a number of life threatening and chronic illnesses. For example Levy, Herberman, Whiteside, Sanzo, Lee & Kirkwood (1990), found that higher natural killer cell activity in breast cancer patients was predicted by the perception of high quality of emotional support from a spouse or intimate other, and perceived social support from the patient's physician. Likewise Revenson, Schiaffino, Majerovitz & Gibofsky, (1991, in Ray, 1992) showed that social support affected depression in rheumatoid arthritis sufferers. However, considerable controversy continues to surround the relationship between social support, emotional adjustment, and health. For example it has not yet been established whether social support has a direct effect on distress, and/or whether it also buffers the effects of stress (Power, 1988). Also, there is still no clear consensus on how the social support construct should be defined and measured (Champion & Goodall, 1993).

A few recent studies have looked at the role of social support in CFS. CFS sufferers in Ware's (1993) study described having experienced a loss or lack of support from colleagues, friends, family and others. Lewis et al's (1994) recent controlled study also found that CFS sufferers reported significantly lower levels of overall perceived social support from 10 different sources ranging from spouse/partner to colleagues, than a group of irritable bowel syndrome sufferers and healthy controls both pre- and post-illness. This

was despite the fact that CFS sufferers reported having used a strategy of 'seeking social support' for coping with stressful life-events, significantly more than the other two groups in this study. This latter study was based on respondents' retrospective reports however. Further longitudinal prospective research is therefore needed to replicate and confirm this study's findings.

Lewis et al (1994) have suggested that low social support may contribute to depression and immunological changes in CFS. There is some evidence that low levels of social support may effect neuroendocrine or immune system functioning, and increase susceptibility to infectious disease (Jemott & Locke, 1984). Several studies have also shown that perception of poor quality of social support predicts natural killer cell activity in breast cancer patients specifically (e.g. Levy et al, 1990; Levy, Herberman, Maluish, Schlien & Lippman, 1985, in Levy et al, 1990). There is no clear evidence for any immunological changes in CFS sufferers however, and the role of immune dysfunction in CFS remains controversial.

A number of researchers have recently drawn attention to the importance of studying negative aspects of social support and social relationships as well as positive aspects of social support. Most research on social support and mental health has until recently focused on positive aspects of social support and has ignored the negative aspects such as other people's negative attitudes and behaviour (Champion & Goodall, 1993; Ray, 1992). However those researchers who have looked at positive as well as negative aspects of social relationships have found that negative aspects have a greater effect on mental health (e.g. Rook, 1984 in Champion & Goodall, 1993). Ray

(1992) has recently drawn attention to the importance of distinguishing between negative and positive forms of social support in relation to chronic illness by developing a measure of social support for sufferers of chronic illness, which assesses both negative and positive aspects of support provided by relationships. The concept of negative social support seems particularly relevant to CFS, in view of the dismissive, critical and misunderstanding way in which other people often respond to their illness.

Lewis (1996) argues that the media are partly responsible for creating a sense of disbelief about CFS in sufferers' families, friends and social support networks. The media have trivialised CFS and made it into a socially unacceptable illness, by promoting stereotypes such as "yuppie flu". This has the effect of reducing the amount of positive social support and/or increasing the criticism and negative support, which sufferers receive.

The experience of having one's subjective sensations and perceptions of illness misunderstood, trivialised, or dismissed as 'not real' by others has a number of detrimental effects. It may exacerbate the stressfulness of symptoms and/or may create feelings of ambiguity, self doubt, lack of control and helplessness (Lewis et al, 1994; Ware, 1992) which in turn maintain and perpetuate the illness. Ware (1992) argues that sufferers also respond to disconfirmation of their experience of illness by others, by developing strategies for challenging the assertion that CFS is 'not real' such as proving that it is an organic disorder. The purely physical illness attributions which this may lead CFS sufferers to adopt however, may be counterproductive as

research suggests that this type of illness attribution is associated with a worse outcome (e.g. Wilson et al, 1994).

No research to date has looked specifically at the relationship between social support and prognosis or treatment outcome in CFS. A relationship might well be expected however on the basis of previous research suggesting that negative types of social support, such as having one's sensations and experience of illness dismissed and misunderstood by others, are related to other factors associated with a poor treatment outcome in CFS, such as physical illness attributions, helplessness and lack of control. An inadequate social support system has also been associated with a poor treatment outcome at 6 months - 2 years follow-up in chronic pain sufferers, whose condition has some close parallels to CFS (Hudgens, 1979 in Payne & Norfleet 1986).

If an association was found between social support and treatment outcome in CFS sufferers, it might suggest that more emphasis should be given to involving close relatives or friends of CFS sufferers in their treatment and improving the social support they receive. This might involve encouraging sufferers and their families and friends to discuss and explore positive and negative types of support and their consequences.

The results from a recent study (Nott, Vedhara & Power, 1995) on the role of social support in HIV infection, suggest that enhancing social support levels may be a gradual process and that social support may be less amenable to change than was previously thought (Cassel, 1974, in Champion & Goodall, 1993). The relevance of the findings from this study to social support in CFS and other illnesses has not been assessed however. An increasing amount of

other research now suggests that individuals can influence the social support they receive. For example Dunkel-Schetter, Folkman & Lazarus (1987) have suggested that a person's social support network are highly responsive to the coping strategies which the person adopts in stressful situations. They found that the level of overall practical, emotional, and informational support received was more strongly associated with an individual's coping behaviour than with other characteristics of the person or stressful situation. These findings suggest that interventions to improve CFS sufferers' social supports, may usefully be aimed at enhancing individuals' skills to elicit support from others.

1.7.3. Illness attributions

Considerable research has shown that in various physical and mental illnesses patients' causal attributions for their illness can affect coping style, length of, and disability associated with, illness, and adherence to treatment (Powell et al, 1990; Cathebras, Jacquin, Le Gal, Fayol, Bouchou & Rousset, 1995). Chalder, Power & Wessely (1996) argue however that the findings from research in this area have been inconsistent, and that all that can be concluded at present is that patients who report a specific explanation for their illness are likely to have a better outcome than patients who report no illness attribution at all.

In relation to CFS, a number of studies on patients in tertiary care settings have noted that most patients prefer physical explanations for their

symptoms rather than psychological explanations (Matthews, Manu & Lane, in Cathebras et al, 1995; Powell et al, 1990). Self-help patient organisations such as the M.E. association also take the view that the condition primarily has a physical basis. Given the lack of any conclusive research evidence on what causes CFS at present, it is impossible to comment on which types of illness attributions are more accurate. However irrespective of the accuracy of people's illness attributions, it is possible and important to consider the consequences of holding different illness attributions.

According to cognitive-behavioural models of CFS, attributing illness to physical causes, has a number of negative consequences. It has been argued that physical illness attributions are a cognitive factor that possibly maintains illness behaviour and perpetuates symptoms by leading to feelings of helplessness; lack of self efficacy; diminsished responsibility for one's own health; and a focus on bodily sensations (e.g. Helman, 1978, in Powell et al, 1990; Pennebaker, 1982 in Surawy et al, 1995). Physical illness attributions are also thought to lead to an avoidance of activity as a way of coping (Wessely, Butler, Chalder & David 1991) and this coping strategy is thought to perpetuate intolerance of physical and mental activity and exacerbate symptoms if used longer term (Butler et al, 1991; Wessely, David, Butler & Chalder, 1989). It has also been suggested that holding physical illness attributions possibly prevents the sufferer addressing psychosocial stressors which may have triggered and be perpetuating the illness (Surawy et al, 1995).

Blaming symptoms on external causes such as a viral infection also has certain advantages. An external style of attribution may protect the individual

against certain cognitive changes associated with depression (Robson, 1988, in Powell et al, 1990). It also protects an individual from the social stigma of having a psychological illness and the loss of self esteem if their illness was seen in terms of a failure to cope or perform (Powell et al, 1990; Surawy et al, 1995). An exploration of why patients resisted psychological explanations for their illness in Surawy et al's (1995) study, revealed that patients viewed psychological illnesses such as depression as indicating weakness, fault or blameworthiness. CFS sufferers may be particularly sensitive to the social stigma associated with psychological disorders because of their tendency as noted by Surawy et al (1995), to evaluate personal worth in terms of achievement and coping.

A number of studies on patients with fatigue in both tertiary care settings and primary care and community settings, have looked at whether physical illness attributions are associated with a poorer prognosis and outcome than other illness attributions.

Several studies on CFS patients in tertiary care settings suggest that physical illness attributions may predict a worse outcome or more delayed recovery. Sharpe et al (1992) found an association between belief in a viral cause of the illness, and persistent functional impairment at follow-up in patients referred to an infectious diseases outpatient clinic in a teaching hospital. Wilson et al (1994) also found that a strong conviction in a physical disease process at initial assessment was predictive of a poor outcome at 3 year follow-up. The findings from these studies need to be interpreted with caution however, as it is not clear whether physical illness attributions were the

result of a more severe form of illness, or a different illness experience (Lewis, 1996). In Sharpe et al's (1992) study for example, illness beliefs were only assessed at follow-up, and were not assessed at the initial clinic assessment. It was therefore not possible to be certain about the direction of causality underlying the association between illness beliefs and persistent functional impairment found in this study. Belief in a viral cause of the illness may have been a factor which maintained and contributed to functional impairment. Alternatively this type of illness belief may have been a consequence of a more disabling and severe illness.

Less consistent findings on the relationship between illness attributions and outcome, have emerged from several other studies (Bonner et al, 1994; Butler et al, 1991; Deale et al, 1997). A poor treatment outcome, measured in terms of self rated global improvement, as well as a tendency to refuse treatment altogether, were associated with the strength of initial attribution of symptoms to exclusively physical causes in Butler et al's (1991) study. Physical illness attributions were not found to be such an important prognostic factor when these patients were followed up four years later however in Bonner et al's (1994) study. There was a trend for physical illness attributions to be associated with a poor treatment outcome at four year follow-up, but this result was not statistically significant. Also, those who had had a good response to treatment originally and who had maintained their gains four years later, had not changed their attributions over time. No significant difference was found either between the pre-treatment illness attributions held by

improved and unimproved patients in Deale et al's (1997) randomised controlled study on CBT treatment for CFS.

The findings from different tertiary care based studies on the relationship between illness attributions and outcome are therefore inconsistent at present. The findings from these tertiary care studies may also have been biased by the fact that the studies were based on a highly selected group of CFS sufferers who tend to have a higher rate of psychological distress, psychiatric disorder and abnormal illness behaviour than patients with fatigue seen in primary care settings or the community

Recently, several other studies have looked at the relationship between illness attributions and outcome, in patients with fatigue in primary care settings and the community. Whereas most CFS patients in tertiary care settings tend to attribute their illness to physical causes, CFS patients in primary care settings and patients with fatigue in primary care and community settings are more likely to attribute their symptoms to psychological and psychosocial factors (e.g.Cathebras et al, 1995; Euba et al, 1996; Pawlikowska et al, 1994). In a study of primary care patients with 'functional' fatigue not due to somatic illness or major depression, Cathebras et al (1995) found that a tendency to attribute fatigue to physical causes initially was not associated with a worse outcome, measured in terms of fatigue, 42 days later, although it was associated with a higher number of reported symptoms. As Cathebras et al (1995) have pointed out however, a longer follow-up period in their study may have revealed some differences in outcome between patients with different illness attributions.

Physical illness attributions have been associated with lower scores on some outcome measures in a longer follow-up study on patients with fatigue in the community (Chalder et al, 1996). Chalder et al (1996) looked specifically at how physical (M.E.), psychological and social illness attributions were related to outcome in terms of fatigue, functional impairment and psychological distress, 18 months later. It was found that patients who attributed their fatigue to M.E. were more fatigued, significantly more disabled, but less psychologically distressed at follow-up, than the other two groups who attributed their fatigue to psychological and social factors. The finding that physical (M.E.) illness attributions are associated with less psychological distress in this study, may support the assertion in previous research (e.g. Powell et al, 1990) that external physical illness attributions protect an individual against the social stigma and negative implications of a psychological explanation for their illness.

Overall, there is no consistent evidence, as yet, that physical illness attributions lead to a worse treatment outcome and prognosis in CFS sufferers in tertiary care or patients with fatigue in primary care and the community.

In line with the cognitive-behavioural theory that physical illness attributions maintain disability and perpetuate symptoms in CFS however, one of the main aims of CBT treatment is to encourage CFS sufferers to consider alternative explanations for their illness in addition to physical causes. The aim is not to persuade CFS sufferers to replace any physical illness attributions which they hold initially, with psychosocial illness attributions. Instead CBT aims to encourage CFS sufferers to adopt a broader range of explanations for

their illness, so that more treatment options become possible (Royal Colleges of Physicians, Psychiatrist and General Practitioners Report on CFS, 1996). Surawy et al (1995) have recently advocated a collaborative CBT approach, which involves building on patients' existing explanatory model, drawing a distinction between factors which precipitate and perpetuate the condition, and then encouraging patients to consider the role which cognitive and behavioural factors, such as illness attributions, play in perpetuating the illness (Surawy et al, 1995).

It seems that further research is needed to clarify the relationship between illness attributions and outcome, in view of the contradictory and inconclusive findings which have emerged from different studies so far, and the treatment implications of these findings.

1.7.4. Perfectionism

A number of empirical studies suggest that personality factors may predispose individuals to developing fatigue and CFS. In a study of healthy college undergraduates, Montgomery (1983) found a positive association betweeen tiredness, emotional instability, introversion, and competitiveness. Kroenke, Wood, Mangelsdorff, Meier & Powell (1988) similarly found that primary care patients experiencing fatigue were more sensitive, inhibited, and less sociable than those not complaining of tiredness. A number of studies on patients with CF or CFS, have also found an increase in histrionic- and emotional-type personality traits. For example, elevations on histrionic and

schizoid personality patterns compared to normative data, were found in 33 per cent and 29 per cent of CFS sufferers respectively in Millon, Salvato, Blaney, Morgan, Mantero-Atienza, Klimas & Fletcher's (1989) study, using the Millon Clinical Multiaxial Inventory. This study failed to include a control group however. Blakey, Howard, Sosich, Murdoch, Menkes & Spears (1991) also found higher levels of emotionality in CFS patients than chronic pain patients and healthy controls using the Minnesota Multiphasic Personality Inventory. The results of this latter study suggest that emotionality is a predisposing factor for CFS, rather than a reaction to illness. A methodological shortcoming of this study however, was that it made no attempt to control for the confounding effect of physical impairment in the assessment of personality (Johnson, DeLuca & Natelson, 1996).

In general, there has been very little systematic empirical research on the role of personality factors in CFS, and far more evidence for the personality characteristics of CFS sufferers has come from qualitative research. Accumulating evidence from qualitative research suggests that CFS sufferers, or those who seek medical help, are hard driving, conscientious, perfectionist high achievers who may be particularly distressed by a disorder which prevents them meeting their own high standards (Abbey & Garfinkle, 1990; Puffer & McShane, 1991, both in Surawy et al, 1995). CFS sufferers in Surawy et al's (1995) study revealed premorbid personality characteristics such as a marked achievement orientation, perfectionism, high and exacting standards for work performance, responsibility and personal conduct. They also reported premorbid lifestyles characterised by persistent striving to meet their own self

imposed high standards, and others' expectations. Many CFS patients interviewed in Ware & Kleinman's (1992) study describe having lead lives of intense activity and involvement before their illness began. CFS sufferers' descriptions of their personalities prior to their illness typically included idioms such as "hyper", "superwoman", "workaholic" and "driven". Patients also used expressions such as "always on the go" and "always pushing myself" to describe their premorbid lifestyle.

These findings on CFS sufferers' personality characteristics and premorbid lifestyles, lead to suggestions that Type A personality traits and behaviour patterns might be associated with CFS. Flett, Hewitt, Blankstein and Dynin's (1994) study has shown that perfectionism shares a number of features in common with Type A personality including setting oneself high personal standards, and having demanding or critical parents. Research on the relationship between Type A personality traits and CFS is therefore relevant to the relationship between perfectionism and CFS. Several small-scale empirical research studies suggest that Type A traits (Woods & Goldberg, 1991) and certain components of the Type A behaviour pattern (Lewis et al, 1994) characterise CFS sufferers, although the findings have not been entirely consistent. For example Lewis et al (1994) found that CFS sufferers rate themselves as better listeners (a Type A characteristic) than irritable bowel syndrome patients and healthy controls, suggesting they set themselves high standards in interpersonal relationships. The global Type A behaviour construct was not found to characterise CFS sufferers in this study however (Lewis et al, 1994).

Other research has focused or commented more specifically on the relationship between perfectionism and fatigue.

Preliminary evidence for a relationship between chronic fatigue and perfectionism comes from Hembry's (1993, in Magnusson, Nias & White, 1996) pilot study of general practice patients experiencing chronic fatigue. The patients in this study were found to tend to view themselves as perfectionists. This association between chronic fatigue and perfectionism has been replicated recently in Magnusson et al's (1996) study using the newly developed Frost Multi-dimensional Perfectionism Scale (Frost et al,1990). Magnuson et al (1996) found an association between negative components of perfectionism and mental and physical fatigue in female nurses. Negative components of perfectionism in this study included doubts about actions, parental expectation, parental criticism, and concern over mistakes, and positive components included high personal standards and organisation. A negative component of perfectionism particularly associated with mental fatigue in this study, was indecision or "doubts about actions". Physical fatigue tended to be reported by those who perceived their parents as having high expectations. There was also a trend for those with high personal standards, a positive component of perfectionism, to be less tired in this study.

Several studies have found an association between negative components of perfectionism and neuroticism (Flett, Hewitt, Blankstein & O'Brien, 1991; Magnusson et al,1996). It is therefore possible that any association found between perfectionism and fatigue is due to the effect of the confounding variable of neuroticism. This possibility was ruled out in

Magnusson et al's (1996) study however, because negative perfectionism was found to be associated with fatigue separately from neuroticism. Another potential confounding variable which was not controlled for in this study however, was depression.

While several studies have looked at the relationship between perfectionism and fatigue, few empirical studies have looked at the relationship between CFS and perfectionism. One of the most common and consistent themes in the illness cognitions elicited from CFS sufferers in Surawy et al's (1995) study however, concerned high standards and the underlying assumption that self respect, and gaining respect from others, depends on achieving high standards in most spheres of life. These cognitions and underlying assumptions are similar to statements which are seen to characterise a more perfectionist personality on measures of perfectionism such as Frost et al's (1990) perfectionism scale. It was not clear from this study whether these cognitions and assumptions are specific to CFS sufferers however, as no comparisons were made with the cognitions of healthy controls or other illness groups.

Wood and Wessely's (unpublished) recent study on the other hand, failed to find any significant differences between the scores of CFS patients in a specialist tertiary referral setting, and the scores of a control group of Rheumatoid Arthritis patients from the same hospital, on Frost et al's (1990) multidimensional measure of perfectionism.

Findings from different studies on the relationship between fatigue, CFS and perfectionism have therefore been inconsistent and no firm

conclusions can yet be made. There is a need for further research to assess whether a perfectionist personality is more characteristic of CFS sufferers than healthy controls or other illness groups and whether it is a factor associated with the development or perpetuation of the illness.

In spite of the lack of empirical evidence that perfectionism plays a role in the illness, some cognitive models of CFS (e.g. Surawy et al, 1995) have already suggested that perfectionist ways of thinking should be included as a factor in the development and maintenance of the condition. Also CBT treatment for CFS sufferers already involves strategies to modify and challenge any perfectionist ways of thinking and assumptions which are thought to play a role in the illness and which may be preventing change (Sharpe et al, 1996; Surawy et al, 1995). This is despite the fact that no empirical research to date has looked at the relationship between perfectionism and outcome in CFS sufferers.

1.8. Rationale for the present study and research questions

There is now considerable evidence from a number of clinical trials that under certain conditions CBT is capable of producing significant improvements in a selected sample of CFS sufferers (e.g. Deale et al, 1997; Sharpe et al, 1996). However no previous research has evaluated whether CBT is effective when it is delivered in routine clinical practice, by therapists with differing levels of experience, for a variable number of treatment sesions, and with a more heterogenous and representative sample of CFS sufferers.

Various factors associated with a poor outcome following CBT treatment have also been identified in previous research, including persistence of psychiatric disorder (Butler et al, 1991), and making a new claim for disability benefit during treatment (Deale et al, 1997). There has been a lack of systematic research or conclusive research findings however, on whether various psychosocial factors such as stress, social support, illness attributions and perfectionism are related to treatment outcome. For example, several studies have looked at the relationship between illness attributions and treatment outcome, but the findings have been contradictory and inconclusive (e.g. Butler et al, 1991; Deale et al, 1997).

The present study aims to address the aforementioned gaps in the research literature firstly by evaluating the effectiveness of CBT treatment as it is delivered in routine clinical practice, and secondly by investigating the relationship between CBT treatment outcome and various psychosocial variables. The specific psychosocial variables which will be focused on in the present study, namely stress, social support, illness attributions and perfectionism, are variables which some research studies have suggested may play a role in the development and maintenance of the condition. It seems important to investigate these psychosocial variables further in order to examine their relationship to treatment outcome. In addition, it will shed light on whether these factors are important variables to address and modify during treatment, to achieve a better outcome and prevent future relapse.

The present study is retrospective and is based on a one group pre-test, post-test design, with follow-ups at immediate post-treatment, one, three

and six months and one year. The study is based on the responses from a number of questionnaires filled in by a group of CFS patients before and after a course of outpatient CBT treatment, assessing various psychosocial and outcome variables.

A preliminary research question is what proportion of patients in routine clinical practice show a clinically significant improvement at 6 month follow-up and at postal follow-up (i.e.1 year follow-up). The main research questions concern the relationship between various psychosocial variables and treatment outcome following CBT in CFS patients.

The hypotheses are that treatment outcome will be associated with :

1) An increased or reduced overall number or severity of stressful life-events.
2) More or less social support
3) Holding a solely physical or psychosocial illness attribution or a mixed illness attribution
4) Higher or lower perfectionism.

CHAPTER 2: METHOD

2.1 Participants

Participants were recruited from 178 CFS sufferers who were assessed for cognitive-behavioural therapy at a specialist CFS clinic at a large teaching hospital in South London between April 1994 and May 1996 and were subsequently offered a course of treatment. Of these CFS sufferers, 98 (55 per cent) accepted the offer and completed seven or more treatment sessions ("Treatment completers"), 22 (12 per cent) dropped out of treatment (i.e. completed less than seven treatment sessions) ("Dropouts"), 43 (24 per cent) refused the offer of treatment and completed no treatment sessions ("Treatment refusers"). Nine (5 per cent) were not granted authorisation for funding for treatment, one (1 per cent) deferred the decision as to whether or not they would accept treatment, and five (3 per cent) completed a course of CBT treatment as part of Deale et al's (1997) clinical trial.

CFS sufferers offered a course of treatment met the following UK diagnostic criteria for CFS (Sharpe et al, 1991): a main complaint of medically unexplained, disabling fatigue of at least 6 months' duration, with impairment of physical and mental activities. In order to make the treatment available to as many patients as possible however, not all patients were required to strictly fulfill all the UK diagnostic criteria for CFS. For example, although the UK diagnostic criteria for CFS exclude individuals with severe psychiatric

diagnoses, some patients who were offered treatment in the present study may have also fulfilled criteria for other psychiatric disorders such as severe melancholic depression or substance abuse.

Those CFS sufferers who were finally included in the present study were those patients who had completed a course of seven or more CBT treatment sessions (i.e. the treatment completers) and had also completed at least some pre-treatment outcome measures prior to the present study (N=86). Treatment completers who had failed to fill out any pre-treatment outcome measures (N=12) were excluded from the present study, because without any data from pre-treatment questionnaires, no baseline data would have been available on these patients from which to assess their degree of improvement since receiving CBT treatment. Those patients who had completed CBT treatment as part of Deale et al's (1997) clinical trial were also excluded from the present study, because it is likely that the treatment these patients received was different from the treatment received by patients in routine clinical practice.

2.2. Clinical procedure

2.2.1. Assessment

Each study participant had received an assessment interview with a psychiatrist after being referred to the CFS clinic. A full history was taken. A diagnosis of CFS was made according to the UK operational case definition

(Sharpe et al, 1991). Psychiatric diagnoses were based on an abbreviated version of the Schedule for Affective Disorders and Schizophrenia (Spitzer & Endicott, 1978 in Deale et al, 1997) and were then made according to DSM-III-R criteria. Information on the age, sex, marital status, socio-economic class, ethnic background and illness duration of the individual was also recorded.

2.2.2. CBT treatment

Participants had then been offered a course of individual CBT treatment with a therapist at weekly or fortnightly intervals on an outpatient basis. Those patients fulfilling operational criteria for depression were also started on antidepressant medication. On average study participants completed 13 sessions of CBT treatment (SD= 3.88) with a range from 7 - 29 sessions. Eighty-five study participants (98.9 per cent) were treated through outpatient sessions at the CFS clinic, but one (1.2 per cent) completed treatment from home, by postal correspondence and telephone appointments at fortnightly intervals.

Eleven therapists were involved in administering the CBT treatment, including five qualified RMN nurses, one clinical psychologist, and five psychiatrists working as senior registrars. These therapists had widely differing levels of expertise and/or training in CBT. The five nurses had each completed an eighteen month full-time course in behavioural psychotherapy. One of the nurses had twelve years of previous experience practising CBT. Two of the

nurses had six years of previous experience of practising CBT and the other two nurses had one year of previous experience of practising CBT. The clinical psychologist was trained in CBT during her two year professional training and had seven years of previous experience of using CBT techniques. The five psychiatrists had only been trained in CBT techniques during several two hour sessions and none of them had any previous experience of using CBT. All of the therapists were supervised by a qualified behavioural psychotherapist at weekly or fortnightly intervals, depending on their level of experience.

The treatment approach that was used has a behavioural and psychoeducational emphasis (Deale et al, 1997). It is derived from a treatment approach that has been used to manage chronic pain, but has been specifically adapted for dealing with chronic fatigue. The aims are to increase individuals' tolerance for activity in a sequence of graded steps and to show individuals that this can be done without causing any long term damage or exacerbation of symptoms.

Initially the presenting problems are assessed and patients are asked to keep a record of their pattern of rest, activity and symptoms. The treatment rationale is then discussed with the patient and the therapist and patient jointly agree upon a planned schedule of consistent graded activity and rest. In this way the patient is encouraged to rest and be active at set times and for set durations rather than in response to symptoms. The goals cover a range of activities such as walking, reading, and visiting friends, which the patient has previously been avoiding, but wishes to resume. The targets are initially set at a level that is modest and achievable, in spite of fluctuations in symptoms.

Once the patient has adopted this structured routine of rest and activity, the activity targets are gradually increased and rest reduced as tolerance to symptoms and exercise improves. At all stages the patients are actively involved in setting their own goals and are encouraged to develop a greater sense of self-efficacy in relation to having control over their symptoms.

To encourage more healthy sleeping habits and prevent insomnia, patients are advised to reduce daytime sleep and to rise at the same time each morning. Cognitive techniques are also incorporated into the treatment. Patients are taught to identify and monitor any unhelpful and distressing thoughts, such as perfectionist thoughts and fears about symptoms and treatment, and to recognise the link between thoughts and behaviour. Patients are then encouraged to generate more constructive alternative thoughts and to practise doing this as a homework task between sessions.

At the end of therapy the patient and therapist prepare for and discuss how the patient can manage any setbacks which might occur, such as a sudden worsening of symptoms, using the principles they have learnt during therapy.

2.3. Design

The present research was based on a one group pre-test, post-test design. The study was based on patients' responses to a number of questionnaires assessing outcome and psychosocial variables, which they were asked to fill in at various stages before and after CBT treatment, specifically at

pre-treatment, immediate post-treatment, one, three and six months and 1 year (postal) follow-ups.

Study participants (N= 86) had already been asked by their therapist to fill out a number of questionnaires at pre-treatment, immediate post-treatment, and at one, three and six month follow-ups. Therapists had sent these questionnaires to patients to fill out shortly before their appointments at the aforementioned stages of treatment, and patients were asked to bring their completed questionnaires with them to their appointment. Patients who failed to bring the relevant completed questionnaires with them to their appointments at these stages of treatment were usually asked to fill in the questionnaires at the clinic after their appointment before going home. Occasionally patients filled in the questionnaires at home after their appointment and returned them by post. Patients who started treatment, but failed to attend their treatment

Table 1. Questionnaires patients filled out at pre-treatment, immediate post-treatment and at 1, 3 and 6 month follow-up.

1. Fatigue Questionnaire (Chalder et al, 1993)
2. Work and Social Adjustment Scale (Marks, 1986)
3. GHQ (Goldberg, 1972)
4. HADS (Zigmond & Snaith, 1983)
5. Illness Attributions Questionnaire
6. Measure of Global Improvement and Satisfaction (filled in at immediate post-treatment, 3 and 6 month follow-up only)

sessions at any of the stages of treatment where they would have been required to fill in these questionnaires, were sent the relevant questionnaires to fill in and return by post. Data collected from these questionnaires had been entered onto a Statistical Package for Social Sciences (SPSS) data file by patients' therapists prior to the present study. This data was included in the analysis of the present study. Table 1 shows which questionnaires patients had been asked to complete by their therapists at different stages of treatment prior to the present study. These measures are described in more detail on p.76-84.

2.3.1. Postal follow-up questionnaires

I sent a letter to all those patients who had been selected for inclusion in the present study (N=86), to ask them whether they would be willing to fill out a further package of postal follow-up questionnaires for use in the present study (see Appendix 1). The package of questionnaires included the six measures shown in Table 2, which had also been administered at previous stages of treatment, as well as four other measures of psychosocial variables which had not been administered at any previous stages of treatment, namely a life-events inventory, perfectionism questionnaire and two social support measures. An addressed pre-stamped envelope was included for the return of the completed replies. In addition to being asked to fill out the package of questionnaires, patients were also asked for information on their current medication, work and marital status, length of their illness and whether they were currently in receipt of any benefits (see Appendix 2).

Those patients who failed to respond to the postal questionnaire were sent a follow-up reminder (see Appendix 3) four weeks later and given a follow-up phonecall 6 weeks later, to ensure that they had received the invitation, and that the address the questionnaire had been sent to was current.

Of those patients who were sent a postal follow-up package of questionnaires, 42 (49 per cent) finally completed and returned the package of questionnaires, whereas 44 (51 per cent) failed to return the questionnaires or declined the invitation to complete the package of questionnaires. Those treatment completers who completed the postal follow-up package of questionnaires filled it in on average 13 months after the last session of CBT treatment (SD=8.11), with a range from 1 month to 31 months. *The postal follow-up is therefore sometimes referred to as a 1 year follow-up in the results section.* However the postal follow-up is not a precise 1 year follow-up due to the variation in when patients filled this package of questionnaires in.

2.3.2. Numbers of questionnaire responders at different follow-up points

Table 2 illustrates how many of those patients who were selected for inclusion in the present study (N=86) had completed a questionnaire at pre-treatment and again at different points after treatment. Information was only included in the present study from the Fatigue, Work and Social Adjustment, GHQ and HAD questionnaires filled out by study participants at points after treatment if the questionnaire concerned had also been filled out by the participant at pre-treatment.

Table 2. Number of questionnaires completed at pre-treatment and at another point after treatment

Questionnaires	Pre-treatment	Immediate Post-treatment	Follow-up (months) 1	3	6	Postal Follow-up
Fatigue	84	64	39	44	45	41
Work and Social Adjustment	86	64	40	45	46	42
GHQ	82	62	38	44	43	40
HAD	84	64	38	44	42	40
Illness Attributions	78				41	39
Global Improvement					33	42

Table 3 illustrates how many of those patients who were selected for inclusion in the present study (N=86) filled out a questionnaire at pre-treatment, at pre-treatment and 6 month follow-up, and at pre-treatment, 6 month follow-up and postal follow-up. This table indicates that only 31 of the patients who filled in the Fatigue Questionnaire at pre-treatment and 6 month follow-up also filled in this questionnaire at pre-treatment and postal follow-up. Likewise, the table indicates that only 32 of the patients who filled in the Work and Social Adjustment Scale at pre-treatment and 6 month follow-up also filled in this scale at pre-treatment and postal follow-up.

Table 3. Number of participants who responded to questionnaires at pre-treatment, at pre-treatment and 6 month follow-up, and at pre-treatment, 6 month follow-up and postal follow-up.

Questionnaires	Pre-treatment	Pre-treatment and 6 month follow-up	Pre-treatment and 6 month and postal follow-ups
Fatigue	84	45	31
Work and Social Adjustment	86	46	32
GHQ	82	43	30
HAD	84	42	29

2.3.3. Demographic and pre-treatment information

I collected considerable demographic and pre-treatment information on those patients who were included in the present study (N=86) from patients' index cards in the CFS unit, patients' assessment letters, and patients' files in medical records. This information was included in the analysis of the present study. In particular, information was included on study participants' marital status, age, gender, socio-economic class, ethnicity, illness duration, and number of treatment sessions, and whether study participants were members of the M.E. self-help association, were in receipt of psychiatric medication and/or had consulted a doctor for emotional problems. Patients' socio-economic class was based on the HMSO Occupational Classification (HMSO, 1991).

I also collected and included in the analysis of the present study demographic information on the following groups of CFS sufferers who were not included in the main analysis of the present study or sent postal follow-up questionnaires: those who refused treatment (treatment refusers); those for whom treatment funding had not been authorised (non-authorised); those who had deferred the decision about whether to precede with treatment (deferred); those who had completed CBT treatment sessions but not filled out any pre-treatment outcome measures; and those who had completed CBT treatment as part of Deale et al's (1997) clinical trial. I collected this demographic information from patients' index cards in the CFS unit, assessment letters and files held in medical records.

2.4. Obstacles encountered during data collection

Whilst most of the data for the present study was collected from self-report questionnaires filled in by patients at various stages of treatment as already detailed above, I also used a number of other sources to collect data on CFS patients in the present study.

In order to classify those patients whose assessment dates fell between the period April '94 - May '96 and who were offered a course of CBT treatment into treatment completers, treatment refusers, non-authorised or deferred, I originally used information recorded on patients' index cards in the CFS unit. Information on the cards was not always clear or complete however, and was augmented where possible by additional information collected from

patients' assessment letters, patients' files held in the medical records, a record of outpatient attendances kept by the NHS trust where I was working, or patients' CBT therapists.

I used patients' cards in the CFS unit to obtain information on patients' assessment and treatment dates and the number of sessions they attended. I checked the accuracy of this information using the NHS trust's record of outpatient attendances. Where there was a discrepancy in the information from these two sources, I referred to a list of treatment and follow-up dates kept in the CFS unit, or to patients' files in the hospital's medical records. If information on the cards was incomplete, I used information from the NHS trust's record of outpatient attendances, and then checked the accuracy of this information using the list of treatment and follow-up dates kept in the CFS unit, or patients' files.

2.5. Ethical procedures

Permission to carry out the study was obtained from the research ethics committee for the institution from which participants were recruited (a copy of the official letter giving ethical approval appears in Appendix 4). In order to ensure that those patients who were sent the postal follow-up package of questionnaires could give informed consent, an information sheet outlining the purpose and nature of the study (see Appendix 5) was sent with a consent form (see Appendix 6) along with the original letter asking them whether they would be willing to fill out the package of postal follow-up questionnaires.

Patients who were interested in participating in the study by completing the package of postal follow-up questionnaires were asked to sign the consent form in the presence of a witness and return it with their completed questionnaires.

Those patients who had filled in questionnaires for their therapists prior to the present study, data from which was included in the present study, were asked for permission to use this data for research purposes at the time they filled out these questionnaires.

2.6. Measures

Questionnaires included several measures of outcome variables:

Work and Social Adjustment Scale (Marks,1986) measured functional impairment (see Appendix 7). This measure has been widely used in clinical outcome trials with a range of populations and has been found to be sensitive to change in CFS (e.g. Butler et al, 1991). Impairment of work, home management, social and private leisure activities are each rated on a visual analogue scale. Respondents rated the degree to which their fatigue impaired each of these areas of their lives on a scale from 0 "Not at all impaired" to 8 "Very severely impaired". A total social adjustment score was derived from the sum of the impairment scores in each of these four areas of their lives.

Fatigue Questionnaire (Chalder et al, 1993): assessed severity of fatigue (see Appendix 8). This questionnaire contains 11 items which measure the severity of subjective mental and physical fatigue. The measure also

includes questions on the duration of fatigue, the percentage of time the respondent feels tired each day, and two questions on muscle pain at rest and after exercise. Respondents are also asked why they think they are feeling tired. Fatigue symptoms were rated on a four option continuum from "Less than usual" to "Much more than usual". The questionnaire was scored using a bi-modal response system now known as the GHQ method, giving a range of scores from 0 to 11: scores of 4 or more indicated caseness or excessive fatigue.

This fatigue scale has been shown to have good reliability and validity in Chalder, Berelowitz, Hirsch, Pawlikowska, Wallace, Wessely & Wright's (1993) study of two hundred and seventy-four new registrations and 100 consecutive attenders at a general practice in Kensington. The total scale as well as the mental and physical fatigue subscales were shown to have a high level of internal reliability using Cronbach's Alpha as well as by assessing the scale's split half reliability. Relative Operating Characteristics (ROC) analysis also revealed that using a cut-off score of 3/4, the scale has good concurrent validity (i.e. good ability to discern between cases and non-cases) (Chalder et al, 1993). The specificity and sensitivity values for the scale using this cut-off score were 75.5 and 74.5 respectively.

General Health Questionnaire (GHQ) - 12 item (Goldberg, 1972): measured level of psychological distress. Respondents had to rate each of the 12 depression- and anxiety-related items on a four option continuum similar to the one on the Fatigue scale. A bimodal scoring system was used giving a range of scores from 0 -12: scores of 4 or above indicated "psychological

caseness". Those scoring above this cutoff score are variously called General Health Questionnaire cases or subjects with a psychiatric disorder.

The GHQ was chosen for this study because it has been specifically recommended for assessing psychological distress in CFS sufferers (Schluederberg et al, 1992). The GHQ-12 has already been used in a considerable number of studies on CFS sufferers (e.g. Butler et al, 1991; Wessely & Powell, 1989) and has the advantage that it does not include questions about any somatic symptoms which may be due to physical illness rather than psychiatric disturbance.

Numerous studies have also confirmed that the GHQ-12 is a reliable and valid measure. A number of studies have confirmed that the GHQ-12 has satisfactory internal consistency. For example, Banks, Clegg, Jackson, Kemp, Stafford & Wall (1980, in Goldberg & Williams, 1988) showed that the GHQ had a high degree of internal consistency in a sample of school leavers, engineering employees and unemployed men. Cronbach's Alpha values were 0.82, 0.82 and 0.90 respectively for these three groups. A number of studies assessing the scale's construct validity have shown that it has a fairly consistent factor structure across a range of different cultural groups and settings (e.g. Politi, Piccinelli & Wilkinson,1994). Numerous studies have also confirmed that the GHQ-12 has good concurrent validity by comparing it to other measures of psychiatric morbidity (e.g. Radanovic & Eric,1983, in Goldberg & Williams, 1988) .

Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983): screened for current anxiety and depressive disorders. This scale was

developed for detecting current anxiety and depression in non-psychiatric medical settings. Items reflecting somatic symptoms that are likely to occur in physical illness are excluded. The scale consists of seven items concerning depression and seven items concerning anxiety, and each item is scored from 0 to 3. It has been suggested that a score of 8 to 10 is used to identify 'borderline' cases, and a score of 11 or more to identify 'definite' cases on each of the subscales.

Like the GHQ, the reliability and validity of the HAD has been extensively tested. The HAD has been shown to be both a reliable and valid instrument for detecting clinically significant anxiety and depression in medical outpatients settings in a number of different European and non-European studies (e.g. Abiodun, 1994; Barczak, Kane, Congdon, Clay, & Betts, 1988; Zigmond & Snaith, 1983). Barczak et al (1988), for example, have shown that the HAD is an effective screening instrument for psychiatric disorder in medical outpatients attending a Genito-urinary clinic. Using a cut-off score of 8 to identify cases gave sensitivities of 82 per cent and 70 per cent and specificities of 94 per cent and 68 per cent for depressive disorders and anxiety disorders respectively in this study.

Global outcome self-ratings were used to assess global improvement (see Appendix 9). Respondents had to rate their global improvement on a 7 point scale from "Very much better" through "Unchanged" to "Very much worse". Respondents also had to rate their satisfaction with treatment outcome on a 7-point scale from "Very satisfied" to "Very dissatisfied". Patients were asked to rate how useful treatment had been on a 5 point scale from "Very

useful" to "Not at all useful". The ratings were then collapsed into two dichotomous categories: scores of 1, 2 or 3 (i.e. representing "better", "satisfied" or "useful") versus scores of 4 or more (i.e. "unchanged/worse", "dissatisfied" or "not useful").

These global wellbeing scales have been recommeded for use with CFS (Schleuderberg, Straus, Peterson, Blumenthal, Komaroff et al, 1992), and have already been used with CFS sufferers in several treatment trials (e.g. Bonner et al, 1994; Deale et al, 1997).

The package of postal follow-up questionnaires also included several measures of psychosocial variables:

Illness attributions measure. Patients were asked to evaluate whether nine different factors played a role in causing their symptoms or making them worse (see Appendix 10). Five of the specified factors were physical, and four were psychosocial. Patients were also asked to write down any factors other than those which had been specified which they thought were relevant to their illness. Patients overall responses were finally categorised as physical, psychosocial or multifactorial. CFS sufferers' illness attributions were also assessed and categorised in a similar way in Deale et al's (1997) study.

Multidimensional Perfectionism Scale (MPS) (Frost, Marten,Lahart & Rosenblate, 1990) measured level of perfectionism (see Appendix 11). This is a 35-item measure which assesses six dimensions of perfectionism: excessive concern over mistakes; high personal standards; the perception of high parental expectations; the perception of high parental criticism; doubting of the quality of one's actions; and a preference for organization and order. The items consist

of statements presented in a Likert-type format with a 5 point response continuum from "Strongly disagree" to "Strongly agree". Higher scores on the scale indicate a higher degree of perfectionism. Six subscale scores were calculated for each of the 6 dimensions of perfectionism. A total perfectionism score was calculated by adding together all the subscale scores except the organisation subscale score.

A number of studies have confirmed that the MPS is both a valid and reliable measure of perfectionism. For example, several studies have confirmed the internal reliablility of the MPS subscales and the total perfectionism scale (e.g. Clavin, Clavin, Gayton & Broida, 1996; Frost et al, 1990; Parker & Adkins, 1995). The organisation items were excluded from the total perfectionism score in the present study however, in view of findings in Frost et al's (1990) study showing that this subscale was least well correlated with each of the other subscales on the MPS, and was also least well correlated with the total of the other items on the perfectionism scale.

There is some evidence for the validity of the MPS from studies showing that the MPS is highly correlated with other measures of perfectionism such as Burn's Perfectionism Scale and Hewitt and Flett's (1991) newly developed multidimensional perfectionism scale (e.g. Frost et al, 1990; Hewitt, Flett, Turnbull-Donovan & Mikail,1991). Several studies have also shown that scores on the MPS are significantly correlated with scores on the Maudsley Obsessive-Compulsive Inventory (e.g. Clavin et al, 1996; Frost et al, 1990). This provides evidence for the scale's construct validity, as perfectionism has long been associated with compulsive behaviour.

Positive and Negative Social Support Questionnaire (Ray, 1992) measured levels of positive and negative support received by participants (see Appendix 12). This measure was developed to be appropriate for those who suffer from a chronic illness. The questionnaire items assess negative and positive aspects of social support, and look at the support received from significant others in general rather than specific others. Respondents rated the degree to which people who are important to them provided them with the type of support described in each item, on a scale from 1 "Never", through 3 "Sometimes", to 6 "Always". Mean scores for positive (PS) and negative support (NS) were then calculated by taking the mean of the individuals' ratings on items assessing positive support and items assessing negative support respectively.

Ray 's (1992) study provides preliminary evidence for the utility of making a distinction between positive and negative types of support in studies of emotional adjustment to chronic illness. Positive social support was found to be related to anxiety, whereas negative social support was related to both anxiety and depression in CFS sufferers in this study.

Significant Others Scale (SOS) - Short form (Power, Champion & Aris, 1988) was adapted for the present study to assess quality of emotional and practical support received by participants (see Appendix 13). This scale was devised originally to assess the quality of emotional and practical support which an individual receives from seven key role relationships. The scale was adapted for the present research to assess the support which an individual receives from their two most significant relationships.

The respondents were asked to rate each significant relationship on two items assessing emotional support and two items assessing practical support, in terms of the level of support received and the ideal level of support they would have liked to receive using a seven point scale from 1 "Never" to 7 "Always".

Total scores for actual and ideal, emotional and practical support were calculated by adding together the scores for both significant relationships. Discrepancies between ideal and actual support levels were calculated by subtracting actual support scores from ideal support scores. As recommended by Power et al (1988), where actual support scores exceeded ideal support scores (i.e. there was an overprovision of support), the discrepancy values were recoded to have a zero discrepancy value. Total discrepancy scores for both emotional and practical support were calculated by adding together the discrepancy scores for both significant relationships. The total scores for actual, ideal and discrepancy levels of emotional and practical support were then divided by the number of significant relationships rated (2), to give mean scores for actual, ideal and discrepancy levels of emotional and practical support.

Power et al (1988) have confirmed that the SOS-long form has good reliability and validity. This study has shown for example, that the SOS-long form has good test-retest reliability over a six month period. Factor analyses in this study also revealed that the distinctions made between ideal and actual support and between emotional and practical types of support on the SOS scale are useful and valid. There is also some evidence that the SOS-short form

has good validity from the findings of Power's (1988) study. The latter study has for example shown that the SOS-short form has good validity in terms of being able to distinguish between a group of depressed and non-depressed respondents.

Stressful life-event Inventory (Cooper et al, 1989) was used to assess participants' level of psychosocial stress (see Appendix 14). Participants had to indicate whether or not they had experienced each life-event since they started treatment. For each event experienced the participants were asked to assess how upsetting the event had been on a scale from 1 to 10.

The checklist used in the present study was originally developed on a UK sample (Cooper et al, 1989). This instrument was used in Cooper et al's (1989) study to look at the relationship between the incidence and perception of psychosocial stress and breast cancer. It was also used in Lewis et al's (1994) study to assess whether there were any differences in the number and severity of life-events experienced by chronic fatigue and irritable bowel syndrome patients prior to illness, and between these groups and healthy controls.

Previous life-event inventories such as the Holmes and Rahe Schedule of Recent Experiences (1967) tended to focus only on the occurrence of life-events. The life-event checklist used in the present study, however, looks at how stressful different life-events were perceived to be by different respondents as well. In asking respondents to rate how stressful they found different life-events, the life-event checklist used in the present study allows

for differences in the importance which different individuals attach to various perceived life-events.

2.7. Statistical Analyses

The first part of the main analyses looked at whether participants had improved after treatment. Improvement or change was assessed on the various outcome measures administered before and after treatment in three ways.

The main way improvement was measured was in terms of the proportion of patients who had made a clinically significant improvement on the Work and Social Adjustment Scale at 6 month follow-up and postal follow-up. The criterion for a "clinically significant improvement" was a 25 per cent reduction or more on the total score of the Work and Social Adjustment Scale (i.e. a reduction of 8 or more points on the total score). This outcome criterion was selected because percentage (rather than mean) change in a specified area is thought to be a more relevant and sensitive determinant of outcome in CFS. Also, the main aim of CBT treatment for CFS is to improve functional impairment, and this was therefore the main outcome variable of interest. A 25 per cent improvement on the Work and Social Adjustment Scale was used as a cutoff in the present study on the basis that Deale et al (1997) found a 25 per cent reduction on the Work and Social Adjustment Scale from pre-treatment to post-treatment in their clinical trial of CBT for CFS sufferers.

The second way improvement was measured was in terms of the proportion of patients who rated themselves as better on global outcome self-ratings.

The third way improvement was assessed was in terms of mean change on two main outcome measures (the Work and Social Adjustment Scale and the Fatigue Questionnaire) and several subsidiary outcome measures (GHQ and HADS).

The second part of the main analysis looked at factors associated with treatment outcome. In particular, the relationship between several psychosocial variables, namely social support, illness attributions, stressful life-events and perfectionism, and treatment outcome was assessed, by comparing patients who had made a clinically significant improvement (improvers) and patients who had not improved (non-improvers) in terms of these psychosocial variables. Correlations were also carried out between these four psychosocial variables and mean change on the Work and Social Adjustment Scale between pre-treatment and postal follow-up.

Significance testing was two-tailed throughout the analysis. Results from statistical tests were considered significant if the probability of them occuring by chance was less than 5 per cent ($p<.05$). All the percentages quoted in the tables are the percentages of CFS patients on whom data was available.

2.8. Statistical power calculations

A power calculation suggested that a sample size of 42 would have 99 per cent power to detect a mean improvement in individual patient's total scores between pre-treatment and 6 month follow-up or between pre-treatment and postal follow-up of 6.4 points on the Work and Social Adjustment Scale, assuming that the standard deviation of patient's improvements was 7.0, using a paired t-test with a 0.05 two-sided significance level.

A second power calculation suggested that a sample size of 41 would have 99 per cent power to detect a mean improvement in patients' total scores between pre-treatment and 6 month follow-up or between pre-treatment and postal follow-up of 3.0 points on the Fatigue Questionnaire, assuming that the standard deviation of patients' improvements is 4.0, using a paired t-test with a 0.05 two-sided significance level.

The first power calculation was based on a mean improvement of 6.4 points (20 per cent) on the Work and Social Adjustment Scale on the basis of the finding in Deale et al's (1997) clinical trial that patients achieved a 25 per cent improvement on this scale between pre-treatment and post-treatment. Patients would be expected to make smaller improvements on the Work and Social Adjustment Scale in the present study than in Deale et al's (1997) study, because the present study is based on routine clinical practice, whereas Deale et al's (1997) study was based on a tightly controlled trial of CBT with a more selected sample of CFS patients.

The second power calculation was based on a mean improvement of 3.0 points on the Fatigue Questionnaire on the basis of the findings in Wearden et al's (in press) study that a graded exercise intervention in routine clinical practice lead to a mean improvement of 2.9 points on the Fatigue Questionnaire 6 months after the start of treatment. Previous randomised controlled trials have found that graded exercise and CBT lead to substantial and similar improvements in fatigue and disability (e.g. Fulcher & White, 1997; Sharpe et al, 1996).

It was assumed that patients' treatment gains at 6 month follow-up would largely be maintained at 1 year follow-up in the power calculations in the present study. This assumption was based on the findings in Bonner et al's (1994) pilot study that treatment gains were maintained over a four year follow-up period.

The assumptions about the standard deviations of patients' improvements on the Work and Social Adjustment Scale and Fatigue Questionnaire were based on the standard deviations found in the present study, as no information was available on the standard deviations of patients' improvements from similar previous studies.

A third power calculation was carried out with respect to the analyses comparing the mean scores of patients who had improved and those who had not improved, on various psychosocial variables including stressful life-events, social support and perfectionism. Cohen (1992) recommends that in a design which compares two groups using a t-test, a sample size of 26 participants per group is needed for significance at the 0.05 level if postulating a large effect in

order to attain a power of 0.80. A sample of 26 participants in each group was therefore needed to have 80 per cent power to detect a difference between improvers' and non-improvers' scores on the stressful life-event inventory and the measures of social support and perfectionism, using independent t-tests with a 0.05 two-sided significance level.

No previous studies have examined the relationship between treatment outcome and psychosocial variables such as social support, perfectionism, or stressful life-events. It was therefore not possible for a precise estimation of the effect size (i.e. the degree to which my hypotheses were false) to be made. However, Cohen defines a large effect as being one 'likely to be visible to the naked eye of a careful observer' (i.e. without statistical analysis) (Cohen, 1992, p.156). A large effect has therefore been assumed in the power calculations in the present study for the analyses on the relationship between treatment outcome and psychosocial variables.

CHAPTER 3: RESULTS

3.1. Patient characteristics

3.1.1. Characteristics of treatment completers

Table 4. Demographic characteristics of treatment completers

Marital Status	Married	29 (34.1%)
	Not married	56 (65.9%)
Age		M= 35.65, SD=10.44
Gender	Male	37 (43%)
	Female	49 (57%)
Socio-economic Class	Class I or II:	49 (73.1%)
	Class III - VI:	18 (26.9%)
Ethnicity	White	75 (90.4%)
	Non-white	8 (9.6%)
Member of the ME association	Member	23 (29.5%)
	Non-member	55 (70.5%)
Active member of ME association	Active:	4 (5.2%)
	Non-active	73 (94.8%)
Taking Psychiatric Medication	Medicated	35 (46.7%)
	Non-medicated	40 (53.3%)
Consulted Doctor for Emotional Problems	Consulted:	37 (46.8%)
	Have not Consulted:	42 (53.2%)

Table 4 illustrates the demographic characteristics of treatment completers included in the main analysis of the present study (N=86). As Table 4 shows, treatment completers included in the present study were

predominantly white, female, middle aged and from higher socio-economic classes. Roughly half the treatment completers were taking psychiatric medication and/or had consulted a doctor for emotional problems, and the majority did not belong to the ME self-help organisation.

Table 5 illustrates the pre-treatment psychological and illness characteristics of treatment completers included in the main analysis of the present study (N=86). Treatment completers had near maximum scores on both the Fatigue Questionnaire and Work and Social Adjustment scale and had been ill for three and a half years on average at pre-treatment. Treatment completers had moderate scores on the GHQ, and although their scores on the

Table 5. Pre-treatment illness and psychological characteristics of treatment completers

	M	SD
Illness Duration (Yrs)	3.49	(2.39)
Total Score on Fatigue Questionnaire	9.20	(2.71)
Total Work and Social Adjustment Score	22.74	(6.75)
Total GHQ Score	6.45	(3.64)
Anxiety Subtotal on HAD	8.76	(4.36)
Depression Subtotal on HAD	7.99	(3.94)
Illness Attributions		
Solely Physical	7 (9.0%)	
Solely Psychosocial	2 (2.6%)	
Mixed	69 (88.5%)	

anxiety and depression subscales of the HAD were not marked, a high proportion of patients were definite or borderline cases of depression and anxiety, as measured by the HAD. In all 24 (28.6 per cent) treatment completers were borderline cases of depression and 20 (23.8 per cent) were definite cases of depression as measured by the HAD. Seventeen (20.2 per cent) treatment completers were borderline cases of anxiety and 28 (33.3 per cent) were definite cases of anxiety on the HAD. The majority of treatment completers in the present study held mixed illness attributions (i.e. they attributed their symptoms to both physical and psychosocial factors), rather than solely physical or solely psychosocial illness attributions.

3.1.2. Characteristics of CFS sufferers excluded from the present study

Table 6 illustrates the demographic and pre-treatment characteristics of CFS sufferers excluded from the present study, either because funding for treatment was not authorised for them, because they deferred the decision as to whether or not to accept treatment, or because they received CBT treatment as part of Deale et al's (1997) clinical trial. As is shown in Table 6, the characteristics of these three groups of CFS sufferers are similar to those of treatment completers included in the present study. The sample sizes of each of these three groups of CFS sufferers who were excluded were too small for it to be possible to statistically compare their characteristics to those of the treatment completers included in the present study.

Table 6. Characteristics of CFS sufferers excluded from the present study.

		Non- Authorised (N=9)	Deferred (N=1)	In Trial (N=5)
Marital Status	Married	0 (0%)	0 (0%)	2 (40%)
	Not-married	9 (100%)	1 (100%)	3 (60%)
Age	M	31.33	22.00	35.40
	(SD)	(5.48)		(11.28)
Gender	Male	3 (33.3%)	1 (100%)	1 (20%)
	Female	6 (66.7%)	0 (0%)	4 (80%)
Socio-economic Class	Class I or II:	2 (33.3%)		5 (100%)
	Class III - VI:	4 (66.7%)		0 (0%)
Ethnicity	White	7 (87.5%)	1 (100%)	
	Non-white	1 (12.5%)	0 (0%)	
Member of the ME association	Member	1 (16.7%)	0 (0%)	
	Non-member	5 (82.3%)	1 (100%)	
Active member of ME association	Active:	0 (0%)	0 (0%)	
	Non-active:	6 (100 %)	1 (100%)	
Illness Duration (years)	M	3.14	3.00	
	(SD)	(2.80)		
Consulted Doctor for Emotional Problems	Consulted:	4 (57.1%)	0 (0%)	
	Have not Consulted:	3 (42.9%)	1 (100%)	

3.1.3. Comparison of characteristics of treatment refusers, completers and dropouts

Twenty-six per cent of those patients who were offered a course of CBT treatment as part of routine clinical practice, and had funding for treatment authorised, refused the offer. Eighteen per cent of those CFS

patients who started CBT treatment dropped out before they had completed seven treatment sessions.

One-way ANOVA and chi-square statistical tests were used to compare the pre-treatment and demographic characteristics of treatment refusers (N=43), treatment completers (N=98), and treatment dropouts (N=22). *This was the only part of the analyses where those treatment completers who failed to fill in any pre-treatment outcome measures were included in the group of "Treatment Completers".*

The distribution of the three CFS groups' scores on the illness duration variable had to be normalised before carrying out a one-way ANOVA on this variable, because the kurtosis and skewness were greater than 2.0 on the treatment refusers' illness duration scores. This was done by log transforming treatment refusers', dropouts' and completers' scores on the illness duration variable before carrying out any analyses.

No significant differences were found between those CFS sufferers who refused treatment (refusers), completed treatment (completers) and dropped out of treatment (dropouts) in terms of marital status, age, gender, or illness duration. There was a trend for treatment refusers, completers and dropouts to differ in terms of age ($F(2,158) = 2.87$, $p < 0.1$) although the difference between these three groups was not significant or large enough to be clinically meaningful.

It was not possible to use statistical analyses to compare these three groups on other demographic and pre-treatment variables such as socio-economic class, ethnicity, membership of the ME association, receipt of

psychiatric medication and whether they had consulted a doctor for emotional problems. This was mostly because more than a third of the data was missing in one of the three groups on a variable.

It was not possible to statistically compare the three groups in terms of ethnicity using a chi-square test, because too few people fell into the non-white category amongst treatment refusers and dropouts.

There were however a number of interesting differences between the three groups on several of these variables that it was not possible to analyse. In terms of socio-economic class, whereas refusers tended to be fairly evenly distributed between the higher and lower socio-economic classes (52.4 per cent in Class I or II, 47.6 per cent in Class III-VI), treatment completers and dropouts were more likely to come from the higher than the lower socio-economic classes (75.3 per cent and 72.7 per cent of treatment completers and dropouts were from Class I or II respectively, and 24.7 per cent and 27.3 per cent of completers and dropouts were from Class III-VI respectively).

Another interesting difference was that, whereas a roughly equal number of refusers were members of the ME association (a self-help group for CFS sufferers) as were non-members (45 per cent were members, 55 per cent were non-members), amongst completers and dropouts there were many more non-members than members of the ME association (72 per cent and 84.2 per cent of completers and dropouts were non-members respectively, and 28 per cent and 15.8 per cent of completers and dropouts were members respectively).

3.2. Outcome

3.2.1. Proportion of patients improved

Table 7. Patients improved at 6 month follow-up and postal follow-up

	6 month follow-up	Postal follow-up
No. of treatment completers who improved	16 (34.8%)	14 (33.3%)
No. of treatment completers and dropouts who improved (in an intention to treat analysis)	33 (41.8%)	37 (46.3%)

Table 7 shows the proportion of treatment completers (N=86) who achieved a clinically significant improvement in terms of functional impairment on the Work and Social Adjustment Scale at 6 month and postal follow-up. The criterion for a "clinically significant improvement" was a 25 per cent reduction or more on the total score of the Work and Social Adjustment Scale (i.e. a reduction of 8 or more points on the total score), as specified in the overview of the statistical analyses on p.85. At 6 month follow-up 34.8 per cent (16) of treatment completers had made a clinically significant improvement on the Work and Social Adjustment Scale. At postal follow-up a similar percentage of treatment completers (33.3 per cent (14)) had achieved a clinically significant improvement on the Work and Social Adjustment Scale. However these analyses were only based on the 46 patients who filled in the Work and Social Adjustment Scale at 6 month follow-up and the 42 patients

who filled in the measure at postal follow-up, out of the 86 treatment completers who had filled in this measure at pre-treatment.

An intention to treat analysis was carried out in which treatment completers who had not responded to the Work and Social Adjustment Scale at 6 month follow-up and/or postal follow-up and treatment dropouts were included. These patients were rated as improved or unimproved at 6 month follow-up and postal follow-up on the basis of the difference between their pre-treatment score on the Work and Social Adjustment Scale and their last reported score on this scale as at 6 month follow-up and as at postal follow-up respectively. Forty two per cent and 46.3 per cent of the patients included in these intention to treat analyses had made a clinically significant improvement by 6 month and postal follow-up respectively (see Table 7).

This intention to treat analysis was based on a total of 79 patients, including 28 of the 40 treatment completers who failed to fill in the Work and Social Adjustment Scale at 6 month follow-up, and five of the twenty-two treatment dropouts, in addition to the 46 treatment completers who filled in this measure at 6 month follow-up. At postal follow-up the final analysis was based on a total of 80 patients, including 33 of the 44 treatment completers who failed to fill in the Work and Social Adjustment Scale at postal follow-up, and five of the twenty-two treatment dropouts, in addition to the 42 treatment completers who filled in this measure at postal follow-up. Treatment completers and dropouts who had not filled in the Work and Social Adjustment Scale at pre-treatment and at another stage after treatment were not included in this intention to treat analysis.

Of the five treatment dropouts who were included in the intention to treat analysis at 6 month and postal follow-up, four (80 per cent) had achieved a clinically significant improvement at 6 month follow-up and postal follow-up based on the their last reported scores on the Work and Social Adjustment Scale as at 6 month and postal follow-up respectively.

Of the 28 treatment completers who failed to fill in the Work and Social Adjustment Scale at 6 month follow-up and were included in the intention to treat analysis, 13 (46.4 per cent) had achieved a clinically significant improvement since pre-treatment based on their last reported score on this measure as at 6 month follow-up.

Of the 33 treatment completers who failed to fill in the Work and Social Adjustment Scale at postal follow-up and were included in the intention to treat analysis, 19 (57.6 per cent) had achieved a clinically significant improvement since pre-treatment based on their last reported score on this measure as at postal follow-up.

3.2.2. Self rated global outcome

The proportions of treatment completers who rated themselves as better at 6 month and postal follow-up (91.0 per cent and 88.1 per cent respectively) were much higher than the proportions of treatment completers who had achieved a clinically significant improvement on the Work and Social Adjustment Scale at 6 month and postal follow-up (34.8 per cent and 33.3 per cent respectively). As shown in Table 8, a high percentage of treatment

Table 8. Treatment completers' self rated global improvement at 6 month and postal follow-up

	6 month follow-up N=33	Postal follow-up N=42
1. **Global Improvement**		
Better/much better	30 (91.0%)	37 (88.1%)
Unchanged/worse	3 (9.1%)	5 (11.9%)
2. **Satisfaction with global outcome**		
Satisfied/Very satisfied	27 (81.8%)	34 (81.0%)
Neither/dissatisfied	6 (18.2%)	8 (19.0%)
3. **How useful has treatment been to you?**		
Useful/very useful	31 (93.9%)	38 (90.5%)
Not useful	2 (6.1%)	4 (9.5%)

completers also rated themselves as satisfied with their level of improvement, and rated treatment as useful at 6 month follow-up and postal follow-up.

These analyses were only based on the 33 treatment completers who filled in the global improvement and satisfaction measure at 6 month follow-up and the 42 treatment completers who filled in this measure at postal follow-up.

An intention to treat analysis was carried out in which treatment completers who had not filled in the global improvement and satisfaction measure at 6 month follow-up and/or postal follow-up and treatment dropouts were included (see Table 9). These patients were assigned the last values they recorded on the global improvement measure, prior to 6 month follow-up and postal follow-up respectively.

Table 9. Treatment completers and dropouts self rated global improvement at 6 month and postal follow-up

	6 month follow-up N=69	Postal follow-up N=76
1. **Global Improvement**		
Better/much better	63 (91.3%)	69 (90.8%)
Unchanged/worse	6 (8.7%)	7 (9.2%)
2. **Satisfaction with global outcome**		
Satisfied/Very satisfied	57 (82.6%)	63 (82.9%)
Neither/dissatisfied	12 (17.4%)	13 (17.1%)
3. **How useful has treatment been to you?**		
Useful/very useful	62 (89.9%)	69 (90.8%)
Not useful	7 (10.1%)	7 (9.2%)

A very similar proportion of patients rated themselves as improved, satisfied with their improvement and rated treatment as useful at 6 month and postal follow-up in an intention to treat analysis.

This intention to treat analysis was based on a total of 69 patients, including 30 of the 53 treatment completers who failed to fill in the global improvement self-ratings at 6 month follow-up, and six of the twenty-two treatment dropouts, in addition to the 33 treatment completers who filled in this measure at 6 month follow-up. At postal follow-up the intention to treat analysis was based on a total of 76 patients, including 28 of the 44 treatment completers who failed to fill in the global improvement self-ratings at postal follow-up, and six of the twenty two treatment dropouts, in addition to the 42 treatment completers who filled in this measure at postal follow-up. Treatment

completers and dropouts who had not filled in the global improvement and satisfaction measure at any point after treatment were not included in this intention to treat analysis.

Of the six treatment dropouts included in the intention to treat analysis, five (83.3 per cent) rated themselves as improved and satisfied with their level of improvement at 6 month and postal follow-up, and three (50 per cent) had found treatment useful. Of the 30 treatment completers who failed to fill in the global improvement self-ratings at 6 month follow-up and were included in the intention to treat analysis, 28 (93.3 per cent) rated themselves as having improved, 25 (83.3 per cent) rated themselves as satisfied with their improvement, and 28 (93.3 per cent) rated treatment as having been useful, based on their last score on the global improvement and satisfaction measure. Of the 28 treatment completers who failed to fill in the global improvement self ratings at postal follow-up, 27 (96.4 per cent) rated themselves as improved, 24 (85.7 per cent) rated themselves as satisfied with their level of improvement, and 28 (100 per cent) rated treatment as having been useful.

3.2.3. Mean changes on outcome measures

Table 10 indicates the pattern of change in treatment completers' mean scores on various outcome measures completed at a number of stages before and after treatment. The scores on each outcome measure only include those of patients who filled in the outcome measure at pre-treatment. The mean score at each follow-up point after pre-treatment on a measure also only

includes the scores of patients who responded to the measure at that follow-up point.

For example, while 84 patients filled in the Fatigue Questionnaire at pre-treatment and were included in the mean score at pre-treatment on this measure, only 64 of those original 84 patients filled in the questionnaire again at immediate post-treatment, so only these 64 were included in the mean score at immediate post-treatment. Likewise, only 45 of the original 84 patients filled in this measure at 6 month follow-up, so only these 45 were included in the mean score at 6 month follow-up, and so on.

This means that any apparent trends in the mean scores on the measures over time from one follow-up point to the next should be interpreted with caution. These apparent trends may have been influenced not only by the way in which patients' conditions have progressed over time, but also by changes in the mix of patients filling in the measure from one follow-up point to the next. This caveat should be borne in mind in reading the following description of the results.

On all the outcome measures, treatment gains appeared to have been concentrated largely in the period between pre-treatment and immediate post-treatment. For each measure there were some further treatment gains in at least one of the subsequent time periods between follow-ups, but there were also some retracements of these gains over other subsequent time periods as well.

On the Fatigue Questionnaire and Work and Social Adjustment Scale the greatest treatment gains had been made by 3 month follow-up, but some of

Table 10.Treatment completers' scores on outcome measures before and after treatment

	M	SD	N
Fatigue Questionnaire:			
Pre-	9.20	(2.71)	84
Immediate post-	6.00	(4.40)	64
1mfup	6.15	(3.97)	39
3mfup	5.18	(4.40)	44
6mfup	5.40	(4.29)	45
1yr fup	6.73	(3.86)	41
Work and Social Adjustment:			
Pre-	22.74	(6.75)	86
Immediate post-	17.61	(7.52)	64
1mfup	17.43	(9.38)	40
3 mfup	15.78	(9.19)	45
6 mfup	16.74	(9.80)	46
1yr fup	17.31	(9.73)	42
GHQ:			
Pre-	6.45	(3.64)	82
Immediate post-	4.03	(3.85)	62
1 mfup	3.32	(3.26)	38
3 mfup	3.71	(3.77)	44
6 mfup	3.26	(4.07)	43
1yr fup	4.08	(4.26)	40
HAD anxiety subscale:			
Pre-	8.76	(4.36)	84
Immediate post-	7.27	(3.78)	64
1 mfup	6.11	(3.62)	38
3 mfup	7.07	(3.96)	44
6 mfup	6.31	(4.06)	42
1 yr fup	7.13	(4.47)	40
HAD depression subscale:			
Pre-	7.99	(3.94)	84
Immediate post-	6.39	(4.01)	64
1 mfup	5.90	(4.41)	38
3 mfup	6.14	(4.28)	44
6 mfup	5.88	(4.10)	42
1 yr fup	6.70	(4.27)	40

Pre- = Pre-treatment, Immediate post- = Immediate post-treatment,
1mfup= 1 month follow-up, 3mfup= 3 month follow-up,
6mfup= 6 month follow-up, 1 yr fup= 1 year (i.e. postal) follow-up

these gains were then lost by 6 month follow-up and 1 year (i.e. postal) follow-up. On the GHQ and HAD depression subscale, the greatest treatment gains had been made by 6 month follow-up, although some of these gains were lost by postal follow-up. On the HAD anxiety subscale, the greatest treatment gains had been made by 1 month follow-up.

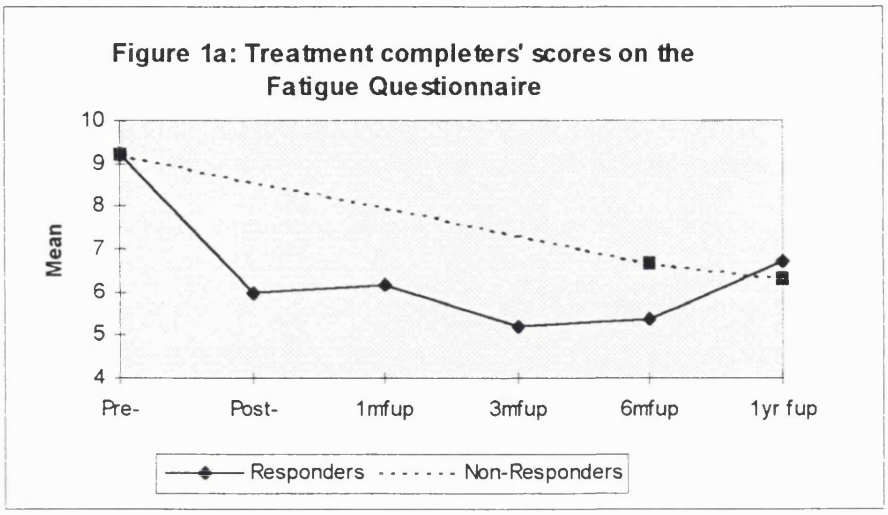
Figures 1a to 1e on pages 106-107, provide a graphical representation of the trends in treatment completers' mean scores on various outcome measures over time discussed above. The continuous line on each graph indicates the trend from one follow-up point to the next in the mean scores of those treatment completers who responded to the measure at each time point. A dotted line has also been included on each of these graphs to provide a broad indication of how patients who had originally filled in the measure at pre-treatment but who failed to fill in the measure at 6 month and/or postal follow-up may have scored if they had filled the measure in at this stage of follow-up, based on their score from the last time they filled the measure in.

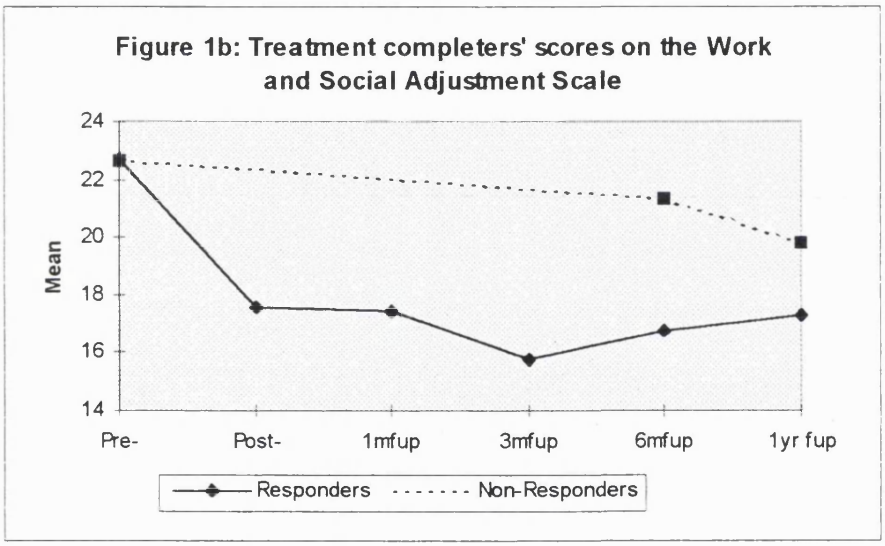
The first point on the dotted line shows the mean score at pre-treatment of all treatment completers who had filled out the scale at pre-treatment. There were no non-responders at pre-treatment on any scale because, as explained in the method section on p.71, information was only included from the Fatigue, Work and Social Adjustment, GHQ and HAD questionnaires filled out by study participants at points after treatment if the questionnaire concerned had also been filled out by the participant at pre-treatment. The second point on the dotted line in each figure shows the mean of the last reported scores as at 6 month follow-up, for treatment completers

who did not fill out the relevant measure at 6 month follow-up. The third point on the dotted line in each figure is the mean of the last reported scores on this measure as at postal follow-up, for treatment completers who did not fill out the measure at postal follow-up.

The majority of non-responders at 6 month follow-up on each outcome measure had last filled in the measure at pre-treatment or immediate post-treatment. Therefore the mean score indicated by the point on the dotted line at 6 month follow-up is mainly a reflection of patients' scores at pre-treatment or immediate post-treatment. This probably at least partly accounts for why, on each of the outcome measures, the means of the last reported scores for non-responders at 6 month follow-up are much higher than the mean scores of actual responders at 6 month follow-up.

By contrast, non-responders at postal follow-up on each measure did include reasonable numbers of patients who had responded at 6 month follow-up. This fact probably accounts for why the estimated mean scores of non-responders at postal follow-up fall in between the estimated mean scores of non-responders at 6 month follow-up, and the mean scores of actual responders at 6 month follow-up.





Responders = Mean scores of treatment completers who *responded* to the questionnaire at various points before and after treatment

Non -Responders = Mean scores of treatment completers who *did not respond* to the questionnaire at 6month follow-up and/or postal follow-up (based on the score they achieved on the questionnaire at the last time point when they filled in the questionnaire)

Figure 1c: Treatment completers' scores on the GHQ

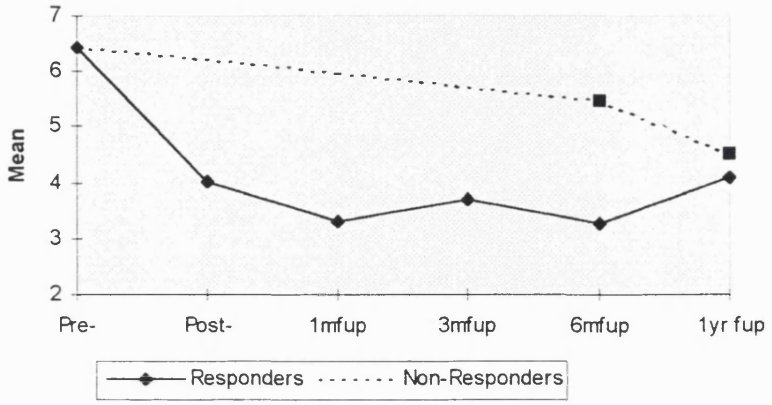


Figure 1d: Treatment completers' scores on the HAD anxiety subscale

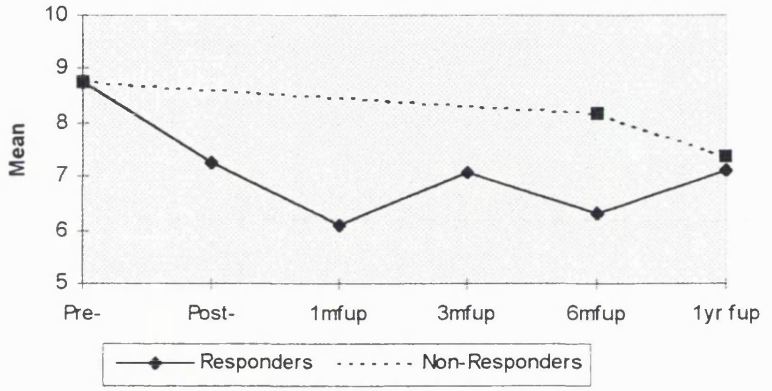
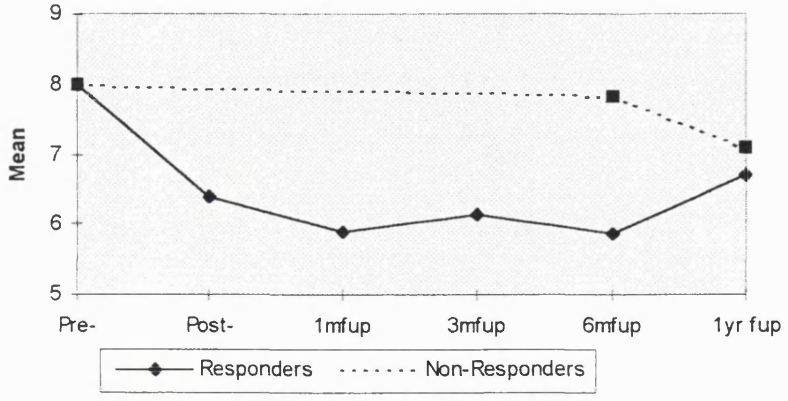


Figure 1e: Treatment completers' scores on the HAD depression subscale



Responders = Mean scores of treatment completers who *responded* to the questionnaire at various points before and after treatment

Non -Responders = Mean scores of treatment completers who *did not respond* to the questionnaire at 6month follow-up and/or postal follow-up (based on the score they achieved on the questionnaire at the last time point when they filled in the questionnaire)

The apparent trend towards delayed improvement between 6 month and postal follow-up amongst questionnaire non-responders on each measure may therefore have been nothing more than a delayed measure of treatment gains that had actually occurred much earlier.

Table 11 shows the results of a repeated measures ANOVA of treatment completers' mean scores on outcome measures which they filled in at pre-treatment, 6 month follow-up and postal follow-up. The analysis on each outcome measure was only based on treatment completers who had responded to the measure at all three time points (i.e. pre-treatment, 6 month follow-up and postal follow-up).

Table 11 shows that, for treatment completers who filled in an outcome measure at pre-treatment, 6 month follow-up and also postal follow-up, treatment gains achieved at 6 month follow-up were largely maintained at postal follow-up. Moreover, on the Work and Social Adjustment Scale and HAD anxiety subscale these patients made further treatment gains between 6 month follow-up and postal follow-up.

The distribution of scores on the Fatigue Questionnaire had to be normalised before carrying out a repeated measures ANOVA, because the kurtosis and skewness were greater than 2.0 on the Fatigue Questionnaire at pre-treatment. This was done by log transforming the scores on the Fatigue Questionnaire at all time points. The distribution of scores on the HAD depression subscale at 6 month follow-up also had to be normalised before carrying out a repeated measures ANOVA, because the kurtosis was greater

Table 11. Treatment completers' scores on outcome measures at three different stages of treatment

	M	SD	N	F value (df) a.
Fatigue Questionnaire:				
Pre-Treatment	9.13	(2.49)	31	b.11.38 (2,60)***
6 month follow-up	5.74	(4.36)		
Postal follow-up	6.23	(4.09)		
Work and Social Adjustment:				
Pre-Treatment	22.84	(9.50)	32	21.95 (1.6, 51.0)***
6 month follow-up	17.63	(9.99)		
Postal follow-up	16.72	(9.95)		
GHQ:				
Pre-Treatment	5.93	(3.32)	30	6.77 (1.6, 46.9)**
6 month follow-up	3.26	(4.07)		
Postal follow-up	3.47	(4.02)		
HAD anxiety subscale:				
Pre-Treatment	8.45	(4.09)	29	7.42 (1.6, 44.0)**
6 month follow-up	6.55	(4.23)		
Postal follow-up	6.28	(4.47)		
HAD depression subscale:				
Pre-Treatment	7.76	(4.14)	29	c.4.37 (2, 54)*
6 month follow-up	5.89	(3.53)		
Postal follow-up	6.21	(4.71)		

a. Age was entered as a covariate in all analyses
b. Data log transformed over all time points
c. 1 outlier excluded from the subscale scores at 6 mfup
*p<.05, ** p<.01, *** p< .001

than 2.0. This was done by excluding one outlier on the subscale at 6 month follow-up.

As Table 11 shows, there was an overall significant improvement across these three time points on the Fatigue Questionnaire, Work and Social Adjustment Scale, GHQ and HAD anxiety and depression subscales. The

Table 12. Treatment completers' scores on outcome measures at pre-treatment and 6 month follow-up

	M	SD	N	t (df)
Fatigue Questionnaire:				
Pre-Treatment	9.09	(2.49)	45	a.5.20 (44)***
6 month follow-up	5.40	(4.29)		
Work and Social Adjustment:				
Pre-Treatment	22.02	(7.17)	46	5.04 (45)***
6 month follow-up	16.74	(9.80)		
GHQ:				
Pre-Treatment	5.58	(3.37)	43	3.41 (42)**
6 month follow-up	3.26	(4.07)		
HAD anxiety subscale:				
Pre-Treatment	8.26	(4.09)	42	3.70 (41)**
6 month follow-up	6.31	(4.06)		
HAD depression subscale:				
Pre-Treatment	7.79	(4.00)	42	b. 3.85 (40)***
6 month follow-up	5.51	(3.37)		

a. Data log transformed at both time points
b. 1 outlier excluded from the subscale scores at 6 mfup before carrying out the analysis
** p<.01, *** p<.001

levels of significance did however vary, with the improvements on the Fatigue Questionnaire and Work and Social Adjustment Scale being the most significant, and the improvement on the HAD depression subscale being the least significant.

Table 12 shows the results of paired t-tests assessing whether there were any significant improvements on outcome variables between pre-treatment and 6 month follow-up. Only those treatment completers who had completed an outcome measure at both pre-treatment and 6 month follow-up were included in the analyses on each outcome measure.

It was necessary to normalise the distribution of scores on the Fatigue Questionnaire at all time points by log transforming the data, before carrying out a paired t-test, because the kurtosis on the Fatigue Questionnare at pre-treatment was greater than 2.0. It was also necessary to normalise the distribution of scores on the HAD depression subscale at 6 month follow-up by excluding one outlier before carrrying out a paired t-test, because the kurtosis was greater than 2.0.

The results of the paired t-tests, as shown in Table 12, confirm that there were significant improvements between pre-treatment and 6 month follow-up on all outcome measures. The overall improvement on the Fatigue and Work and Social Adjustment measures and HAD depression subscale was more significant than on the GHQ or HAD anxiety subscale.

Table 13 shows the results of paired t-tests assessing whether there were any significant improvements on outcome variables between pre-treatment and postal follow-up. Once again the analyses on each outcome

measure were based only on those treatment completers who had completed an outcome measure at both pre-treatment and postal follow-up. It was necessary to normalise the distribution of scores on the Fatigue Questionnaire at all time points by log transforming the data before carrying out a paired t-test, because the kurtosis on the Fatigue Questionnaire at pre-treatment was greater than 2.0.

Table 13. Treatment completers' scores on outcome measures at pre-treatment and postal follow-up

	M	SD	N	t (df)
Fatigue Questionnaire:				
Pre-Treatment	9.51	(2.28)	41	a.5.03 (40)***
Postal follow-up	6.73	(3.86)		
Work and Social Adjustment:				
Pre-Treatment	23.02	(6.97)	42	5.92 (41)***
Postal follow-up	17.31	(9.73)		
GHQ:				
Pre-Treatment	6.43	(3.28)	40	3.49 (39)**
Postal follow-up	4.08	(4.26)		
HAD anxiety subscale:				
Pre-Treatment	8.70	(3.72)	40	2.78 (39)**
Postal follow-up	7.13	(4.47)		
HAD depression subscale:				
Pre-Treatment	7.59	(3.86)	40	1.56 (39)
Postal follow-up	6.70	(4.27)		

a. Data log transformed at both time points
** p<.01, *** p<.001

As Table 13 shows, significant improvements were found between pre-treatment and postal follow-up on all the outcome measures except the HAD depression subscale using paired t-tests. The improvement on the Fatigue and Work and Social Adjustment measures was once again more significant than the improvement on the GHQ and HAD anxiety subscale.

3. 3. Factors associated with treatment outcome

Patients who had made a clinically significant improvement on the Work and Social Adjustment Scale ("Improvers") at postal follow-up were compared to those who had not made a clinically significant improvement on this scale ("Non-improvers") on a range of demographic, pre-treatment and postal follow-up variables, as well as in terms of various psychosocial factors.

Initially these comparisons were carried out using chi-square and independent t-tests, without controlling for any potential confounding variables. However, a variable which may have confounded the results of these comparisons was the duration of follow-up at which patients had filled in the postal questionnaire. In order to assess whether this variable was having a confounding effect, the comparisons between improvers and non-improvers on continuous variables such as age were recalculated using a simple factorial ANOVA and the duration of follow-up at which patients filled in the postal questionnaire was controlled for by entering it as a covariate in the analyses. An attempt was also made to control for this potential confounding variable in comparisons between improvers and non-improvers on categorical variables

such as marital status. This was done by carrying out chi-square tests comparing improvers and non-improvers on categorical variables, for those patients who had filled in the postal questionnaire more and less than 12 months since the end of treatment, separately. The results of these latter chi-square tests are not reported as the expected cell frequencies in all the analyses were too low for a chi-square test to be used validly.

No significant differences were found between improvers and non-improvers on any of the pre-treatment or demographic variables before controlling for potential confounding variables using chisquare and independent t-tests. For example, there were no significant differences between improvers and non-improvers in terms of gender, age, socio-economic class, ethnicity, illness duration, receipt of psychiatric medication, and membership of the ME association.

Nor were there any significant differences between improvers and non-improvers in terms of their scores on any outcome measures at pre-treatment. For example, improvers did not differ significantly from non-improvers in terms of their degree of fatigue, functional impairment (i.e. Work and Social Adjustment Scale score), or psychological distress (GHQ and HAD anxiety and depression scores) at pre-treatment. However, there was a trend for more improvers than non-improvers to be married at pre-treatment ($\chi_2(1) = 3.08$, $p<0.1$).

When the aforementioned comparisons between improvers and non-improvers on continuous pre-treatment variables were recalculated using simple factorial ANOVA tests, and the duration of follow-up at which patients

had filled in the postal questionnaire was entered as a covariate, the same pattern of significant results emerged. However the covariate was not found to have a significant confounding effect in any of these analyses.

Table 14 shows the results of chi-square tests and independent t-tests which were carried out to compare treatment improvers to non-improvers on various postal follow-up variables, before controlling for any potential confounding variables. There was a trend for non-improvers to be more likely to be in receipt of benefits than improvers at postal follow-up ($\chi_2(1)=3.08$, $p<.1$). Also, while there were no significant differences between improvers and

Table 14. Postal follow-up characteristics of treatment "Improvers" and "Non-improvers"

		Improvers N=14	Non-improvers N=28	Statistical Test
Employment Status	Working	8 (57.1%)	9 (33.3%)	$\chi2$ (1) =2.15
	Not-working	6 (42.9%)	18 (66.7%)	
In receipt of Psychiatric Medication	Yes	5 (35.7%)	12 (44.4%)	$\chi2$ (1)=0.29
	No	9 (64.3%)	15 (55.6%)	
In receipt of Benefits	Yes	5 (35.7%)	18 (64.3%)	$\chi2$ (1)=3.08
	No	9 (64.3%)	10 (35.7%)	
No. of Treatment sessions	M (SD)	14.14 (3.44)	13.18 (3.35)	t(40)=0.87
Total GHQ score	M (SD)	2.07 (2.84)	5.18 (4.39)	t (40)=2.40*
HAD Anxiety Subtotal	M (SD)	5.71 (4.58)	7.57 (4.32)	t (40)=1.29
HAD Depression Subtotal	M (SD)	4.29 (3.15)	8.00 (4.34)	t (40)=2.84**

* $p<.05$, ** $p<.01$

non-improvers in terms of psychological distress, as measured by the GHQ and HAD at pre-treatment, there was a difference between the levels of psychological distress and particularly depression of these two groups at postal follow-up. Non-improvers had significantly higher total scores on the GHQ than improvers at postal follow-up ($t(40)=2.40$, $p<.05$). Non-improvers also had significantly higher scores than improvers on the Depression subtotal on the HAD at postal follow-up ($t(40)=2.84$, $p<.01$). However there was no significant difference between improvers and non-improvers on the Anxiety subtotal of the HAD at postal follow-up.

When comparisons between improvers and non-improvers on continuous variables at postal follow-up were recalculated using a simple factorial ANOVA and the duration of follow-up at which patients filled in the package of postal follow-up questionnaires was entered as a covariate, a similar pattern of results emerged. Non-improvers had significantly higher total scores than improvers on the GHQ at postal follow-up ($F(1,37)=5.26$, $p<.05$). Non-improvers also had significantly higher scores than improvers on the HAD depression subscale ($F(1,37)=6.31$, $p<.05$). The significant differences on these two variables between improvers and non-improvers were not as significant as the differences which were found on these variables before controlling for the duration of follow-up at which patients filled in postal follow-up questionnaires. However, the covariate was not found to have a significant confounding effect in any of the analyses.

The findings shown in Table 15 are related to the main hypotheses of the present research, i.e., whether there is a relationship between poor

treatment outcome and various psychosocial variables including social support, a high level of stressful life-events, higher perfectionism and physical illness attributions. Table 15 shows the results of chi-square tests and independent t-tests which were used to test these hypotheses by comparing improvers' and non-improvers' scores on measures of various psychosocial variables, including social support, stressful life-events, perfectionism and illness attributions, at postal follow-up. As Table 15 shows, none of the differences that were found between improvers' and non-improvers' scores on any of the measures of psychosocial variables were significant. No significant differences were found between improvers' and non-improvers' scores on any of the subscales of the perfectionism scale, although these results are not presented in Table 15. Also, there was little difference between the proportion of improvers (18 per cent) and non-improvers (14 per cent) who reported instances of receiving more emotional or practical support than they ideally wanted (i.e. over-provision of support), on the Significant Others Scale of social support, and who therefore had to have their discrepancy scores recoded to a value of zero. There was a trend, however, for improvers to have experienced a lower mean severity of stressful life-events since the start of treatment than non-improvers ($t(39)=1.70$, $p<0.1$).

The numbers of patients who held solely physical or psychosocial illness attributions at pre-treatment and postal follow-up were too small to carry out chi-square tests comparing improvers' and non-improvers' illness

Table 15. Comparison of treatment "Improvers" and "Non-improvers" in terms of several psychosocial variables

		Improvers N=14	Non-improvers N=28	Statistical Test
Stressful Life-Events Inventory				
Total no. of Stressful Life-Events	M (SD)	5.07 (3.67)	6.14 (3.62)	t (40)=0.90
Total Severity of Stressful Life-Events	M (SD)	29.57 (31.37)	38.24 (25.62)	t (39)=0.95
Mean Severity of Stressful Life-Events	M (SD)	4.54 (3.01)	6.09 (2.63)	t (39)=1.70
Perfectionism Scale				
Total Perfectionism Score	M (SD)	74.82 (25.38)	72.44 (20.68)	t (36)= 0.30
Positive and Negative Social Support Scale				
Mean Positive Social Support	M (SD)	4.86 (1.05)	4.49 (0.98)	t (40)= 1.12
Mean Negative Social Support	M (SD)	2.29 (0.78)	2.47 (0.66)	U=167.5 a.
Significant Others Scale				
Actual Emotional Social Support	M (SD)	10.83 (2.15)	11.56 (2.44)	t (34)=0.88
Ideal Emotional Social Support	M (SD)	12.82 (1.31)	12.89 (1.25)	t (32)=0.16
Actual Practical Social Support	M (SD)	9.14 (2.63)	10.26 (2.84)	t (32)=1.11
Ideal Practical Social Support	M (SD)	11.09 (2.22)	11.80 (1.65)	t (31)=1.03
Discrepancy between Ideal and Actual Emotional Support	M (SD)	1.82 (1.93)	1.27 (1.67)	t (33)= 0.86
Discrepancy between Ideal and Actual Practical Support	M (SD)	2.14 (1.99)	1.68 (2.29)	t (31)= 0.56
Illness Attributions Measure				
Illness Attributions at Pre-treatment	Solely Physical	2 (15.4%)	3 (11.5%)	
	Solely Psychosocial	0 (0%)	0 (0%)	
	Mixed	11 (84.6%)	23 (88.5%)	
Illness Attributions at Postal- follow-up	Physical	2 (14.3%)	2 (7.1%)	
	Psychosocial	0 (0%)	1 (3.6%)	
	Mixed	12 (85.7%)	25 (89.3%)	

a. non-parametric Mann Whitney test used

attributions. Even when the categories of solely physical and psychosocial illness attributions were grouped together and compared to mixed illness attributions, there were still too few patients who held either solely physical or solely psychosocial illness attributions at pre-treatment and postal follow-up to carry out chi-square tests. The majority of both improvers and non-improvers held mixed illness attributions at pre-treatment and postal follow-up. There were no obvious differences between the illness attributions of improvers and non-improvers at pre-treatment or postal follow-up either.

These comparisons between improvers' and non-improvers' scores on various psychosocial variables at postal follow-up may have been confounded by the duration of follow-up at which patients had filled in the postal follow-up questionnaire. Previous research has also suggested that there is a relationship between level of psychological distress and/or affective disorder and psychosocial variables such as perceived stress, social support and perfectionism (e.g. Bruce-Jones et al, 1994). Therefore patients' level of psychological distress or severity of depression and anxiety at postal follow-up may also have confounded the results of the comparisons between improvers' and non-improvers' scores on various psychosocial variables. Comparisons between improvers and non-improvers on continuous psychosocial variables (i.e. stress, social support and perfectionism) were therefore recalculated using a simple factorial ANOVA. The duration of follow-up at which patients filled in the postal questionnaire, as well as patients' total GHQ, HAD depression and anxiety subscale scores at postal follow-up, were controlled for by entering them as covariates in the analyses.

A very similar pattern of results emerged from these re-analyses, although trends were found for improvers and non-improvers to differ in terms of the total number as well as the mean severity of stressful life-events experienced since the start of treatment. There was a trend for improvers to have experienced a lower overall number of stressful life-events since the start of treatment than non-improvers ($F(1,33) = 3.67$, $p < .1$). There was also a trend for improvers to have experienced a lower overall mean severity of stressful life-events since the start of treatment than non-improvers ($F(1,32) = 2.93$, $p < .1$). However, there was no trend for improvers and non-improvers to differ in terms of the total severity of stressful life-events they had experienced since the start of treatment. Nor were there any significant differences between improvers and non-improvers on any of the total or subscale scores of the other psychosocial variables.

The duration of follow-up at which patients filled in postal follow-up questionnaires was found to have a significant confounding effect in the analyses looking at the relationship between treatment outcome and the number and severity of stressful life events experienced, total perfectionism scores and the level of actual emotional social support received. The latter covariate was also found to have a significant confounding effect in the analyses looking at the relationship between treatment outcome and several dimensions of perfectionism assessed by the subscale scores on the perfectionism scale, including excessive concern over mistakes, high personal standards and preference for organization and order. The other covariates (i.e. GHQ, HAD anxiety and depression scores) were not found to have a

significant confounding effect in any of the analyses on the relationship between treatment outcome and psychosocial variables.

The relationship between treatment outcome and various psychosocial variables was analysed further by carrying out bi-variate correlations between treatment completers' mean improvement on the Work and Social Adjustment Scale between pre-treatment and postal follow-up and their total and subscale scores on measures of stressful life-events, perfectionism and social support.

Several significant findings emerged from the correlational analyses. A significant association was found between greater improvement between pre-treatment and postal follow-up and a lower mean severity score on the stressful life-event inventory (corr (41)= -0.38, $p<.05$). A significant association was also found between greater improvement and a lower total severity score on the stressful life-event inventory (corr (41)= -0.36, $p<.05$). Greater improvement was also significantly associated with a lower total number of stressful life-events (corr (42)= -0.34, $p<.05$).

When these correlations were recalculated using partial correlations and controlling for the duration of follow-up at which patients had filled in the postal follow-up questionnaires as well as patients' total GHQ, HAD anxiety and depression subscale scores at postal follow-up, the same pattern of significant findings emerged. There was a significant association between greater improvement and a lower mean severity score on the stressful life-event inventory (corr (32)=-0.35, $p<.05$). There was also a significant association between greater improvement and a lower total severity score on the stressful life-event inventory (corr (32)=-0.47, $p<.01$). Greater

improvement was also significantly associated with a reduced overall number of stressful life-events (corr (33)=-0.54, p<.01).

3.4. How the study's results may have been biased by questionnaire non-responders

There are a number of potential sources of bias which may have affected the main analyses, due to the exclusion of treatment completers who failed to fill in outcome measures at different stages of treatment.

3.4.1. How the main analyses may have been biased by excluding non-responders to pre-treatment outcome measures

One potential source of bias was that those treatment completers who failed to fill in any pre-treatment outcome measures (N=12) were excluded from all the main analyses. In order to assess this source of bias, the demographic and pre-treatment characteristics of this group of treatment completers were compared with those of treatment completers who did fill in some pre-treatment outcome measures (N=86), and were therefore included in the main analyses. It was only possible to statistically compare these two groups in terms of marital status, gender age and illness duration, because more than a third of the data on the demographic and pre-treatment variables was missing for patients who didn't fill in any outcome measures at pre-

treatment. No significant differences were found between these two groups from these comparisons.

3.4.2. How the analyses on patients' mean improvement on outcome measures may have been biased by questionnaire non-responders

Another potential source of bias is that not all patients who filled in the the main two outcome measures (i.e. the Fatigue Questionnaire and Work and Social Adjustment Scale) at pre-treatment also filled them in at 6 month and postal follow-ups. The paired t-tests assessing the significance of patients' mean change on these two main outcome measures between pre-treatment and 6 month follow-up only included those patients who filled in the measure at both pre-treatment and 6 month follow-up. Those treatment completers who filled in an outcome measure at pre-treatment only were excluded from the latter analyses. Similarly, the paired t-tests assessing the significance of patients' mean change on the two main outcome measures between pre-treatment and postal follow-up only included those patients who filled in the measure at both pre-treatment and postal follow-up.

This potential source of bias was assessed by making four sets of comparisons between different groups of treatment completers in terms of various demographic and pre-treatment variables. The variables examined were marital status, gender, age, socio-economic status, ethnicity, illness duration, receipt of psychiatric medication, membership of the ME association, whether they had consulted a doctor for emotional problems, and pre-treatment scores

on the Fatigue Questionnaire, Work and Social Adjustment Scale, GHQ and HAD anxiety and depression scales. The following four sets of comparisons were made:

1. Treatment completers who filled in the Work and Social Adjustment Scale at pre-treatment and 6 month follow-up were compared with treatment completers who filled in this questionnaire at pre-treatment but not at 6 month follow-up.
2. Treatment completers who filled in the Work and Social Adjustment Scale at pre-treatment and postal follow-up were compared with treatment completers who filled in this questionnaire at pre-treatment but not at postal follow-up.
3. Treatment completers who filled in the Fatigue Questionnaire at pre-treatment and 6 month follow-up were compared with treatment completers who filled in this questionnaire at pre-treatment but not at 6 month follow-up.
4. Treatment completers who filled in the Fatigue Questionnaire at pre-treatment and postal follow-up were compared with treatment completers who filled in this questionnaire at pre-treatment but not at postal follow-up.

Table 16 shows the significant results and trends that emerged from the first two sets of comparisons. The pattern of significant results and trends which emerged from the third and fourth sets of comparisons was identical to that which emerged from the first two sets of comparisons. This arose because

Table 16. Significant results and trends from comparisons between responders and non-responders to the Work and Social Adjustment Scale at 6 month and postal follow-ups.

		Treatment completers who filled in Work and Social Adjustment Scale at pre-treatment but not at 6 month follow-up N=40	Treatment completers who filled in Work and Social Adjustment Scale at pre-treatment and 6 month follow-up N=46	Statistical Test
Age	M (SD)	32.23 (9.50)	38.63 (10.39)	t(84)=2.97***
Consulted doctor for emotional problems	Yes	21 (52.5%)	16 (34.8%)	$\chi 2(1)=3.51$*
	No	15 (37.5%)	27 (58.7%)	
GHQ score at pre-treatment	M (SD)	7.37 (3.77)	5.66 (3.37)	t(80)=2.17**
		Treatment completers who filled in the Work and Social Adjustment Scale at pre-treatment but not at postal follow-up N=44	Treatment completers who filled in the Work and Social Adjustment Scale at pre-treatment and postal follow-up N=42	Statistical Test
Marital Status	Married	10 (22.7%)	19 (45.2%)	$\chi 2(1)=4.57$**
	Unmarried	33 (75%)	23 (54.8%)	
Age	M (SD)	33.27 (10.02)	38.14 (10.39)	t(84)=2.21**

*p<0.10, **p<0.05, ***p<0.01

the groups of patients involved in the third and fourth sets of comparisons were identical to the groups of patients involved in the first and second sets, apart from one patient who filled in the Work and Adjustment Scale but not the Fatigue Questionnaire at 6 month follow-up, and one other patient who filled in the Work and Social Adjustment Scale but not the Fatigue

Questionnaire at postal follow-up. The results from the third and fourth sets of comparisons have therefore not been presented separately in Table 16.

The results of the first and third sets of comparisons indicated that, among the treatment completers who filled in the Fatigue or Work and Social Adjustment questionnaires at pre-treatment, those who also filled in these questionnaires at 6 month follow-up were both significantly older and significantly less psychologically distressed at pre-treatment, as measured by their GHQ scores, than those who did not. There was also a trend for the group who filled in the questionnaires at 6 month follow-up to be less likely to have consulted a doctor for emotional problems at pre-treatment than those who did not.

The results of the second and fourth sets of comparisons indicated that, among the treatment completers who filled in these questionnaires at pre-treatment, those who also filled in the questionnaires at postal follow-up were both significantly older and significantly more likely to be married than those who did not.

3.4.3. How the analyses of the proportion of patients who made a clinically significant improvement may have been biased by non-responders

The analyses of the proportion of patients who had made a clinically significant improvement on the Work and Social Adjustment Scale between pre-treatment and 6 month follow-up, and between pre-treatment and postal follow-up, was only based on those treatment completers who filled in this

measure at both pre-treatment and the relevant follow-ups. These analyses may have been biased by excluding treatment completers who failed to fill in this measure at the relevant follow-ups. The aforementioned comparisons between treatment completers who filled in the Work and Social Adjustment Scale at pre-treatment only and those who also filled in this measure at 6 month and postal follow-ups are therefore also relevant for assessing this potential source of bias.

3.4.4. How the analyses of factors associated with treatment outcome may have been biased by questionnaire non-responders

Those treatment completers who filled in the Work and Social Adjustment Scale at both pre-treatment and postal follow-up are the same group of treatment completers who were included in the analyses concerning factors associated with treatment outcome. Treatment completers who filled in the Work and Social Adjustment Scale at pre-treatment but failed to fill the measure in at postal follow-up were excluded from the latter analyses, and this may have introduced a further source of potential bias. The aforementioned results from the comparisons between treatment completers who filled in the Work and Social Adjustment Scale at both pre-treatment and postal follow-up and those who only filled in the measure at pre-treatment are therefore also relevant for assessing this further potential source of bias.

3.5. How the study's results may have been biased by excluding treatment dropouts

3.5.1. How the treatment outcome results may have been biased by excluding dropouts

Treatment dropouts were another group of patients who were excluded from the analyses of the proportions of patients who had made a clinically significant improvement at 6 month follow-up and postal follow-up in the present study. This may have introduced a source of bias into the results of these analyses. The analyses of patients' mean improvement on the Fatigue Questionnaire and Work and Social Adjustment Scale between pre-treatment and 6 month follow-up, and between pre-treatment and postal follow-up, may also have been biased by excluding these treatment dropouts.

In order to assess this potential source of bias, the demographic and pre-treatment characteristics of treatment dropouts were compared to those for treatment completers who completed the Fatigue Questionnaire and/or Work and Social Adjustment Scales at both pre-treatment and 6 month and/or postal follow-up, and were therefore included in the analyses referred to above. In particular, these groups of patients were compared in terms of age, marital status, gender, socio-economic class, illness duration, membership of the ME association, whether they had consulted a doctor for emotional problems, and pre-treatment scores on the Fatigue Questionnaire, Work and Social Adjustment Scale, GHQ and HAD anxiety and depression subscales using chi-square tests and independent t-tests.

It was not possible to carry out comparisons between these groups of patients in terms of receipt of psychiatric medication or ethnicity using chi-square tests, because the expected cell frequencies in these analyses were too low to validly use chi-square tests. The findings from the comparisons between these groups of patients in terms of socio-economic class should be interpreted with caution, as information was only available on 12 of the 22 treatment dropouts (i.e. slightly more than half of the dropouts). Likewise, the findings from the comparisons between these groups of patients in terms of pre-treatment scores on the Fatigue Questionnaire, Work and Social Adjustment Scale, GHQ and HAD should also be interpreted with caution, as only 13 or 14 of the 22 treatment dropouts (i.e. less than two-thirds) had filled out these pre-treatment questionnaires.

Table 17 shows the significant results and trends which emerged from the comparisons between the pre-treatment and demographic characteristics of dropouts and treatment completers who responded to the Work and Social Adjustment Scale at pre-treatment and 6 month follow-up and/or at pre-treatment and postal follow-up. The pattern of significant results which emerged from the corresponding set of comparisons in relation to the Fatigue Questionnaire was identical to the pattern of significant results found from these latter comparisons. This was because, as already explained, the groups of patients involved in the two sets of comparisons were almost identical to each other. The results from the comparisons between dropouts and treatment completers who responded to the Fatigue Questionnaire at pre-treatment and 6

Table 17. Significant results and trends from the comparisons between treatment dropouts and treatment completers who responded to the Work and Social Adjustment Scale at 6 month and/or postal follow-up

		Dropouts N=22	Treatment completers who responded to Work and Social Adjustment scale at pre-treatment and 6 month follow-up N=46	Statistical Test
Age	M (SD)	31.09 (10.98)	38.63 (10.39)	t (66)= 2.75***
Pre-treatment HAD anxiety score	M (SD)	4.23 (2.74)	8.11 (4.08)	t (55)= 3.22***

		Dropouts N=22	Treatment completers who responded to Work and Social Adjustment scale at pre-treatment and postal follow-up N=42	Statistical Test
Age	M (SD)	31.09 (10.98)	38.14 (10.39)	t (62)= 2.53**
Pre-treatment HAD anxiety score	M (SD)	4.23 (2.74)	8.70 (3.72)	t (51)= 3.98****
Pre-treatment GHQ score	M (SD)	4.54 (2.85)	6.43 (3.28)	t (51)= 1.86*

*p,0.10, **p<0.05, ***p<0.01, ****p<0.001

month follow-up and/or at pre-treatment and postal follow-up have therefore not been presented in Table 17.

The results of these comparisons indicated that treatment dropouts were significantly younger, and had significantly lower scores on the HAD

anxiety subscale at pre-treatment, than treatment completers who responded to the Work and Social Adjustment Scale and/or Fatigue Questionnaire at pre-treatment and 6 month follow-up. No other significant results or trends emerged from the comparisons between treatment dropouts and treatment completers who responded to either of the two measures at pre-treatment and 6 month follow-up.

Treatment dropouts were also found to be significantly younger, and to have significantly lower scores on the HAD anxiety subscale at pre-treatment, than treatment completers who responded to the Work and Social Adjustment Scale and/or Fatigue Questionnaire at pre-treatment and postal follow-up. There was also a trend for treatment dropouts to have lower scores on the GHQ at pre-treatment than treatment completers who responded to the Work and Social Adjustment Scale and/or Fatigue Questionnaire at pre-treatment and postal follow-up.

3.5.2. How the analysis of factors associated with treatment outcome may have been biased by excluding dropouts

The analysis of factors associated with treatment outcome in the present study was also based only on those treatment completers who responded to the Work and Social Adjustment Scale at both pre-treatment and postal follow-up. Treatment dropouts were excluded from this analysis and may have therefore introduced a source of bias into it. The results from the aforementioned comparisons between treatment dropouts and treatment

completers who responded to the Work and Social Adjustment Scale at pre-treatment and postal follow-up are therefore also relevant for assessing this latter source of bias.

3.6. How the results fit with the research hypotheses

A preliminary research question of the present study was what proportion of patients show a clinically significant improvement at 6 month follow-up and postal follow-up. The present study's results suggest that 34.8 per cent of treatment completers achieved a clinically significant improvement on the Work and Social Adjustment Scale between pre-treatment and 6 month follow-up, and 33.3 per cent achieved a clinically significant improvement between pre-treatment and postal follow-up. A much higher percentage of patients rated themselves as improved however on global outcome measures at 6 month follow-up (91 per cent) and postal follow-up (88.1 per cent).

In relation to the main research questions of the present study, the only hypothesis for which the present study's results provide some support is the first hypothesis - that treatment outcome will be associated with an increased or reduced overall number or severity of stressful life-events. At postal follow-up there was a trend for patients who had made a clinically significant improvement and patients who had not improved to differ in terms of the total number and mean severity of stressful life-events they had experienced since the start of treatment, after controlling for the duration of follow-up at which

patients filled in the postal follow-up questionnaires, total GHQ and HAD anxiety and depression subscale scores.

Also, significant associations were found between patients' mean improvement between pre-treatment and postal follow-up on the Work and Social Adjustment Scale, and the total number, total severity, and mean severity of stressful life-events they had experienced since the start of treatment, before and after controlling for potentially confounding variables.

The present study's results provide no evidence to support the second hypothesis that treatment outcome will be associated with more or less social support. No significant differences were found between those patients who had made a clinically significant improvement at postal follow-up and those patients who had not improved, in terms of their mean positive and negative social support scores on Ray's (1992) measure of positive and negative social support. Nor were there any differences between improved and non-improved patients' actual, ideal or discrepancy social support scores on Power et al's (1988) Significant Others Scale at postal follow-up, or between patients' mean improvement on the Work and Social Adjustment Scale between pre-treatment and postal follow-up and their subscores on either of the two social support measures.

There was no evidence to support the third hypothesis, that treatment outcome will be associated with holding solely physical, solely psychosocial or mixed illness attributions from the study's results. It was not possible to statistically analyse whether there were any signficant differences in the number of improvers and non-improvers who held solely physical or

psychosocial or mixed illness attributions at pre-treatment and postal follow-up using chi-square tests, as too few patients held solely physical and/or psychosocial illness attributions. There were no obvious differences between the illness attributions of improved and non-improved patients at pre-treatment or postal follow-up either.

Finally, there was no evidence to support the fourth hypothesis that CBT treatment outcome is associated with higher or lower perfectionism from the results of the present study. No significant differences were found between improved and non-improved patients' total and subscale scores on the perfectionism scale at postal follow-up, before or after controlling for potentially confounding variables. Also, there was no association between patients' mean improvement on the Work and Social Adjustment Scale between pre-treatment and postal follow-up and their total or subscale scores on the perfectionism scale at postal follow-up.

CHAPTER 4: DISCUSSION

The present research is an effectiveness study of CBT treatment for CFS sufferers referred to a specialist CFS clinic at a teaching hospital in London. The main focus was on assessing the relationship between various psychosocial factors, namely stressful life events, social support, illness attributions, and perfectionism, and outcome following CBT treatment.

4.1. Characteristics of treatment completers

Those treatment completers who were included in the main analysis of the present study were similar to CFS patients seen in other specialist care settings. Like CFS patients encountered in other specialist care settings, treatment completers in the present study were predominantly white, female and from higher socio-economic classes (Butler et al, 1991; Sharpe et al, 1992; Wessely, 1995). Treatment completers in the present study had also been ill for a long time and were severly functionally impaired and fatigued, similar to CFS patients seen in other specialist care settings (Butler et al, 1991; Friedberg & Krupp, 1994; Sharpe et al, 1996). A high proportion of treatment completers, roughly half, were also definite or borderline cases of depression and anxiety, as measured by the HAD.

4.2. Comparison of treatment refusers, dropouts and completers

A fairly high treatment refusal rate (26 per cent) was found in the present study. This refusal rate is lower than the treatment refusal rate (36 per cent) found in Butler et al's (1991) uncontrolled pilot study of CBT treatment, but much higher than the treatment refusal rate found in Sharpe et al's (1996) and Deale et al's (1997) controlled clinical trials of CBT (10 per cent and 3 per cent respectively). Butler et al (1991) note that the high treatment refusal rate for CBT treatment among CFS sufferers in their study contrasts with a 10 per cent refusal rate among the last 50 patients referred by neurologists for CBT for conditions other than CFS. The refusal rate found in the present study only refers to the proportion of patients who refused CBT treatment after an initial assessment for CBT treatment. A much higher refusal rate may have been found if patients who had refused to attend even an assessment for CBT treatment had also been included in the figures.

The high treatment refusal rate found in the present study may have biased the treatment outcome results of the present study, as treatment refusers may have benefited more or less from CBT treatment, if they had accepted it, than the CFS sufferers who completed treatment and were included in the analyses in the study. From the comparisons between treatment refusers, dropouts and completers which it was possible to make in the present study, there was no evidence that refusers would have biased the study's treatment outcome results. No significant differences were found between treatment refusers, dropouts, and completers in terms of length of illness,

marital status, or gender. There was a trend for them to differ in terms of age, but this difference was not large enough to be clinically meaningful.

A similar lack of significant differences between refusers, dropouts, and completers in terms of demographic and pre-treatment variables was found in Deale et al's (1997) study. No significant difference was found betweeen those who accepted and refused CBT treatment in terms of length of illness in Butler et al's (1991) study either, although there was a trend for those refusing treatment to be female in the latter study.

Some interesting differences were found between refusers, dropouts, and completers on several pre-treatment variables in the present study which it was not possible to statistically analyse, due to a problem of missing data.

Firstly, a noticeably higher proportion of treatment completers and dropouts came from the higher socio-economic classes (i.e. classes I and II) than refusers. This is in contrast to the finding of no differences in socio-economic class between treatment completers, refusers and dropouts in Deale et al's (1997) study. However a number of other studies have noted that there is an overrepresentation of high socio-economic classes among CFS sufferers in tertiary referral settings (e.g. Wessely & Powell, 1989). It has been suggested that this reflects selection and referral biases, and the greater tendency for CFS sufferers from higher socio-economic classes to seek treatment (e.g. Euba et al, 1996). The trend for a greater proportion of those who refused than accepted treatment to come from lower socio-economic classes in the present study is therefore interesting, as it suggests that not only are CFS sufferers from lower socio-economic classes less likely to seek help or

be referred to a tertiary referral setting in the first place, but when they are referred to a tertiary referral setting they are more likely to refuse treatment when it is offered to them. A possible explanation for why CFS sufferers from lower socio-economic classes are more likely to refuse treatment is that they have too many competing demands and worries and this makes it difficult for them to focus on treatment.

There is no evidence from the present study's findings or any previous outcome studies' findings, such as the findings in Deale et al's (1997) study, that socio-economic status has any relationship to outcome in CFS sufferers. It is therefore unlikely that the tendency for a higher proportion of treatment refusers to come from lower socioeconomic classes than treatment completers, in the present study, would have meant that excluding treatment refusers biased the treatment outcome results in the present study at all.

A second difference between treatment refusers, completers, and dropouts which was noted from the present study's findings was that the proportion of treatment refusers who were members of the ME association was higher than for treatment completers and dropouts. This finding is unsurprising in view of the fact that much of the literature being published by self-help organisations at present is ambivalent about the value of CBT, although it does recognise the importance of pacing. Also, self-help organisations such as the ME association take the view that the condition primarily has a physical basis. Members of these organisations are therefore possibly more likely to attribute their illness to physical causes and more likely to refuse an offer of treatment based on psychological principles such as CBT.

At present there is no firm evidence that membership of the ME association has any relationship to outcome following CBT treatment. While a relationship was found between membership of a self-help organisation and a poor prognosis in Sharpe et al's (1992) study, Bonner et al (1994), like the present study, found no relationship between membership of the ME association and outcome following CBT treatment. It therefore seems unlikely that the relatively higher proportion of treatment refusers than treatment completers who were members of the ME association would have biased the outcome results of the present study.

Also, while the aforementioned differences between those who accepted and refused treatment in terms of socio-economic status and membership of the ME association may have been found to be significant if there had been sufficient data available to statistically analyse them, this can not be assumed to be the case.

4.3. Dropouts

The number of dropouts from CBT treatment in the present study (18 per cent) was slightly higher than the dropout rate in previous clinical trials of CBT treatment (e.g.10 per cent in Deale et al's (1997) study). A possible explanation for the higher dropout rate in the present study than in previous clinical trials of CBT treatment is that clinical trials use more selective criteria for who they include in the study. Many of the dropouts in the present study may have been problematic cases with multiple problems and diagnoses.

As already described above, there was no evidence from the comparisons which were made between treatment completers, refusers and dropouts that the treatment dropouts differed significantly in terms of any demographic and pre-treatment variables from treatment completers and refusers. On those variables where there were differences between these three groups, which it was not possible to statistically analyse, a greater difference was found between refusers and those who had completed at least one session of CBT treatment (i.e. dropouts and completers) than between dropouts and completers. There was therefore no evidence from the comparisons between treatment dropouts, completers and refusers that excluding dropouts from all the main analyses in the present study would have biased the results.

4.4. CBT outcome

4.4.1. CBT outcome results of the present study

Thirty-five per cent of treatment completers achieved a clinically significant improvement in functional impairment on the Work and Social Adjustment Scale between pre-treatment and 6 month follow-up in the present study, and 33.3 per cent achieved a clinically significant improvement between pre-treatment and postal follow-up. Significant treatment gains at 6 month follow-up were therefore largely maintained at postal follow-up.

A much higher proportion of treatment completers rated themselves as improved ("better" or "much better") at 6 month follow-up (91 per cent) and

postal follow-up (88.1 per cent) on global self-rating scales. A high percentage of patients also rated themselves as satisfied with their level of improvement at 6 month follow-up and postal follow-up (81.8 per cent and 81.0 per cent respectively) and rated treatment as useful at 6 month follow-up and postal follow-up (87.2 per cent and 82.4 per cent).

There was an overall significant mean improvement between pre-treatment, 6 month follow-up and postal follow-up on all the outcome measures (i.e. the Fatigue Questionnaire, Work and Social Adjustment Scale, GHQ and HADS) in the present study. There were also significant improvements on all the outcome measures between pre-treatment and 6 month follow-up and between pre-treatment and postal follow-up, except on the HAD depression subscale between pre-treatment and postal follow-up. There were generally less significant improvements on the GHQ and HADS however, than on the Fatigue Questionnaire and Work and Social Adjustment Scale.

4.4.2. A comparison of the main outcome results of the present study with previous CBT outcome studies' results

In relation to the main measure of outcome (i.e. the proportion of patients who had made a clinically signficant improvement) a much lower proportion of patients were found to have significantly improved following CBT treatment than in several previous controlled trials of CBT treatment. Whereas only a third of patients achieved a clinically significant change on the

Work and Social Adjustment Scale of functional impairment in the present study at 6 month follow-up and postal follow-up, slightly more than two-thirds of patients achieved a significant improvement on the Karnofsky scale of functional impairment at 7 month follow-up in Sharpe et al's (1996) CBT trial, and on the Medical Outcomes Study Short-Form General Health Survey physical functioning scale at 6 month follow-up in Deale et al's (1997) study.

On the other hand, a similar proportion of patients had made a clinically significant improvement at 6 month follow-up and postal follow-up in the present study, suggesting that treatment gains at 6 month follow-up had largely been maintained at postal follow-up (i.e. 1 year follow-up). No previous CBT outcome studies have included as long a follow-up as the present study with the exception of Bonner et al's (1994) study. Bonner et al (1994) found that treatment gains at the end of treatment and at 3 month follow-up had been maintained at 4 year follow-up. The present study's findings are therefore consistent with those of Bonner et al's (1994) study that CBT leads to improvements which are maintained long term.

There were also smaller improvements in patients' mean scores on the two main outcome measures in the present study (i.e. the Work and Social Adjustment Scale and Fatigue Questionnaire) than in Deale et al's (1997) previous CBT outcome study. Deale et al (1997) found larger percentage improvements between pre-treatment and 6 month follow-up on patients' mean scores on Chalder et al's (1993) Fatigue Questionnaire and the Work and Social Adjustment Scale than were found in the present study.

On the other hand, the outcome results of the present study were better than those of Lloyd et al's (1993) study. CBT treatment lead to no specific or substantial improvements at 3 month follow-up in Lloyd et al's (1993) controlled trial. While CBT treatment did lead to some small improvements on self reported measures of function in Lloyd et al's (1993) study, these improvements had not been maintained by 3 month follow-up.

4.4.3. Explanations for differences between the present study's main outcome results and previous studies results

The nature and length of the CBT intervention

A possible explanation for the poorer outcome results in Lloyd et al's (1993) study than the present study and other CBT outcome studies is that they were evaluating a much shorter CBT intervention (i.e. only six sessions of CBT treatment) than other studies including the present study.

There are a number of possible explanations for the better outcome results in terms of fatigue and functional impairment in Deale et al's (1997) and Sharpe et al's (1996) clinical trials than the present study.

Stricter criteria for a clinically significant improvement

One possible explanation is that the criteria for a clinically significant improvement adopted in the present study were slightly stricter than the criteria used in Sharpe et al's (1996) study and Deale et al's (1997) study.

Patients were only defined as having achieved a clinically significant improvement in the present study if they had made a 25 per cent improvment on the Work and Social Adjustment Scale. By contrast, patients were defined as having achieved a clinically significant improvement, if they had only achieved a 10 per cent improvement on the Karnofsky scale of functional status in Sharpe et al's (1996) study. It is therefore possible that Sharpe et al (1996) achieved better outcome results than the present study because they classified patients as having achieved a clinically significant improvement when they had made smaller percentage changes on a scale of functional impairment than the present study.

It is possible that Deale et al (1997) also achieved better outcome results than the present study because the criteria for a clinically significant improvement in their study were in some respects more lenient than the criteria used in present study. While Deale et al (1997) defined patients as having significantly improved when they had achieved a 50 per cent (rather than a 25 per cent) change on a scale of functional impairment, unlike the present study, Deale et al (1997) also defined patients as improved if they had achieved a score above a certain cutoff on the functional impairment scale.

Pre-treatment characteristics of study participants

Another possible explanation for why there were better outcome results in Sharpe et al's (1996) study than the present study was that the patients in the former study were slightly less chronically ill. The average duration of illness at pre-treatment in the present study was 42 months,

whereas the average duration of illness at pre-treatment in Sharpe et al's (1996) study was 34 months.

Aside from chronicity of illness, there were no other differences between the pre-treatment characteristics of patients included in the present study and patients included in Deale et al's (1997) and Sharpe et al's (1996) studies which could account for the different outcome results in these studies.

CBT in routine clinical practice

Possibly one of the most significant differences between the present study and Sharpe et al's (1996) and Deale et al's (1997) clinical trials of CBT treatment which explains the discrepancy between the findings of the present study, and these other studies, is that the present study was a retrospective effectiveness study of CBT treatment in routine clinical practice. The other studies, by contrast, were clinical trials evaluating the efficacy of CBT treatment under strictly controlled conditions.

For example, the clinical trials were evaluating treatment on a more selected and homogenous sample of CFS patients than the present study. Unlike the present study, patients were excluded from Sharpe et al's (1996) trial if they were currently receiving psychotherapy, receiving antidepressant drugs (unless they had been taking the same dose for three months or more without improvement), or met criteria for severe depression (DSM-III-R melancholic subtype). Similarly, patients were excluded from Deale et al's (1997) study if they were receiving concurrent new treatment, if they were unable to attend all treatment sessions, were receiving ongoing physical

investigations, had severe depression (melancholia) or if they were taking antidepressant medication or anxiolytics (at a dose greater than 10mg/day of diazepam or equivalent) and if the dose had not been stable for three months before and during the trial.

The therapists participating in previous clinical trials were also adhering more strictly to a treatment protocol than the therapists in routine clinical practice who were included in the present study. Moreover, therapy was administered by a small number of trained and experienced therapists in previous clinical trials, whereas in the present study therapy was administered by a large number of trained and untrained therapists with widely differing levels of experience.

A similar discrepancy has emerged between the findings of a recent study by Wearden et al (in press), evaluating the effectiveness of a graded exercise intervention for CFS sufferers as it relates to clinical practice and a previous clinical trial by Fulcher and White (1997), which evaluated the efficacy of a graded exercise intervention under strictly controlled conditions. Fulcher and White's (1997) clinical trial showed that graded exercise lead to substantial and similar improvements in fatigue and disability to those found following CBT treatment in several previous clinical trials (Deale et al, 1997; Sharpe et al, 1996). Like the present study, however, Wearden et al's (in press) trial evaluating graded exercise as it relates to routine clinical practice, found more modest treatment effects.

4.4.4. A comparison of the results on subsidiary outcome measures in the present study with previous studies' results

Improvements in psychological distress and mood

Several controlled trials of CBT treatment have found that CBT treatment only leads to similar or slightly larger improvements than alternative interventions such as relaxation or medical care on measures of psychological distress, anxiety and depression (Deale et al, 1997; Sharpe et al, 1996). CBT treatment has been found to lead to similar improvements on measures of psychological distress, anxiety and depression in the present study to these previous controlled trials. Also, like previous studies, the present study's results suggest that CBT generally leads to less improvements on measures of mood and psychological distress than on measures of fatigue and functional impairment.

Patients who had completed CBT treatment were found to have made similar modest improvements on the GHQ-12 and a measure of depression (the Beck depression inventory) between pre-treatment and 6 month follow-up in Deale et al's (1997) study to the present study, although unlike the present study, the significance of this improvement was not measured. Patients who had completed CBT treatment in Sharpe et al's (1996) study were also found to have made similar improvements on the HAD anxiety and depression subscales at 7 month follow-up to the improvements, made by patients on the same subscales, at 6 month follow-up after CBT treatment in the present study.

Improvements in self-rated global outcome

A much higher proportion of patients rated themselves as having made an overall improvement in the present study than in previous CBT outcome studies (e.g. Butler et al, 1991; Sharpe et al, 1996). In the present study 91 per cent and 88 per cent of patients rated themselves as "better" or "much better" at 6 month follow-up and postal follow-up respectively. In Butler et al's (1991) study by contrast only 70 per cent of patients rated themselves as "better" or "much better" at the end of treatment. In Deale et al's (1997) study only 70 per cent of patients rated themselves as "better" or "much better" at 6 month follow-up. Similarly in Sharpe et al's (1996) study only 60 per cent of patients reported significant subjective improvement ("much improved" or "very much improved") at 7 month follow-up after CBT treatment.

Also, the proportion of patients who rated themselves as having improved, was much higher than the proportion that had achieved a clinically significant improvement on the Work and Social Adjustment Scale at 6 months follow-up and postal follow-up in the present study. If self-rated global outcome had been the main measure of outcome in the present study, as it was in Butler et al's (1991) study, the present study's results would have suggested that CBT was more effective than the results of previous clinical trials of CBT treatment. Unlike the present study, previous trials of CBT treatment, have found considerable consistency between the proportion of patients who rated themselves as having made an overall improvement, and the proportion of patients who have made a clinically significant improvement on a scale of functional impairment (e.g. Deale et al, 1997; Sharpe et al, 1996).

4.4.5. Explanations for differences between the present study's self-rated global outcome results and previous studies' results

Lower expectations

One possible reason why more patients rated themselves as improved in the present study than in previous CBT trials, is that patients seen in routine clinical practice, might have lower expectations of how much improvement they will make following treatment, than patients participating in a clinical trial of CBT treatment. If so, then patients treated in routine clinical practice are more likely to rate themselves as improved when they have made less improvement than patients participating in treatment trials. This could also at least partly explain the considerable discrepancy between the proportion of patients who were found to have made a clinically significant improvement on the Work and Social Adjustment Scale, and the proportion of patients who rated themselves as having made an overall improvement at 6 months and postal follow-up in the present study.

Bias due to non-responders

Possibly the high percentage of treatment completers who failed to fill in the Work and Social Adjustment Scale at 6 month follow-up and postal follow-up (47 per cent and 51 per cent respectively) and the global improvement scale at 6 month follow-up and postal follow-up (62 per cent and 51 per cent respectively) also biased the results in the present study. Those

patients who felt they had made less improvement following treatment, irrespective of their level of improvement on outcome measures such as the Work and Social Adjustment Scale, may have been more unwilling to fill out follow-up questionnaires. This source of bias may have inflated the proportion of patients who were found to rate themselves as improved at follow-up in the present study.

Overly strict criteria for a clinically significant improvement

Another possible explanation for the discrepancy found in the present study between the proportion of patients who rated themselves as improved and the proportion of patients who were found to have made a clinically significant improvement is that the criteria for a clinically significant improvement adopted in the present study (i.e. a 25 per cent improvement on the Work and Social Adjustment Scale) are overly strict. The present study's findings suggest that patients themselves feel they have improved, feel their improvement has been satisfactory, and that treatment has been useful when they have achieved far less than a 25 per cent improvement on the Work and Social Adjustment Scale. Patients' subjective experience of having improved is arguably a relevant and meaningful indicator of treatment outcome. Also, as already discussed, it could be argued that the criteria for a clinically significant improvement adopted in the present study were slightly stricter at least in some respects than the criteria used in previous studies such as Deale et al's (1997) and Sharpe et al's (1996) studies.

4.5. Demographic and clinical factors associated with treatment outcome

No significant differences were found between those patients who had improved by a clinically significant amount on the Work and Social Adjustment Scale at postal follow-up ("Improvers"), and those patients who had not improved ("Non-improvers"), in terms of any demographic or pre-treatment variables in the present study. There was a trend however, for improvers and non-improvers to differ in terms of marital status. Deale et al (1997) similarly found no significant differences between patients who had improved by a clinically significant amount on a functional impairment scale at 6 month follow-up and patients who had not improved, in terms of any pre-treatment or demographic variables.

4.5.1. Marital status

There was a trend in the present study for a higher proportion of improvers than non-improvers to have been married at pre-treatment. A possible explanation for this finding might be that CFS sufferers who are married, receive more or better social support due to the support they were receive from their spouse, and this higher level of support helps them to benefit more from CBT treatment. This finding should be interpreted with caution however, as no previous studies have found a relationship between marital status and outcome in CFS sufferers (e.g. Deale et al, 1997; Sharpe et al, 1992). Also, it was not possible to control for the duration of follow-up at

which patients filled in the postal questionnaires when assessing the relationship between marital status and treatment outcome in the present study.

4.5.2. Illness duration and severity

No significant relationships were found between treatment outcome and clinical indicators of a more severe illness at pre-treatment including, severity of fatigue and functional impairment and illness duration in the present study. Patients who had not improved by a clinically significant amount at postal follow-up were no more severely fatigued or functionally impaired, and had not been ill for longer at pre-treatment, than patients who had improved.

The findings on the relationship between illness severity and treatment outcome in previous studies have been inconsistent. No relationship has been found between length of illness at initial assessment and outcome in any previous studies of CBT treatment (e.g.Butler et al, 1991, Bonner et al, 1994; Deale et al, 1997). Other clinical features indicating a more severe illness at pre-treatment have been inconsistently associated with CBT treatment outcome in previous studies however. For example, Butler et al (1991), like the present study, found no association between severity of fatigue and functional impairment at pre-treatment and treatment outcome following CBT. By contrast, Bonner et al (1994) found that patients who continued to fulfill criteria for CFS at 4 year follow-up (i.e. those with a poor treatment

outcome), were significantly more fatigued, and perceived themselves as experiencing greater somatic discomfort at pre-treatment.

The aforementioned discrepancy between the findings of Butler et al's (1991) study, the present study and Bonner et al's study could be due to the fact that the latter study was assessing the relationship between severity of fatigue at pre-treatment, and treatment outcome at a much longer follow-up period after treatment (four years), than the former two studies. The discrepancy in findings could also be due to the fact that a good treatment outcome was defined using much stricter criteria in Bonner et al's (1994) study than the other two studies. Whereas Bonner et al (1994) defined patients as having improved if they no longer fulfilled the Oxford criteria for CFS, Butler et al (1991) defined patients as improved if they described themselves as "better" or "much better" after treatment, and the present study defined patients' as improved if their scores on the Work and Social Adjustment Scale had improved by 25 per cent.

4.5.3. Psychological distress and mood disturbance

Like previous studies (eg. Butler et al, 1991; Bonner et al, 1994; Deale et al, 1997) no differences were found between improved and unimproved patients in terms of their level of psychological distress or severity of affective disorder before starting CBT treatment in the present study. However, and also in line with previous studies, (e.g. Bonner et al, 1994; Butler et al, 1991; Sharpe et al, 1992) significant differences were found between patients who

had improved and not improved in terms of their level of psychological distress and depression at postal follow-up in the present study.

These findings may suggest that greater psychological distress and depression at postal follow-up are a cause and/or are a consequence of lack of improvement in terms of functional impairment following treatment.

Patients who fail to significantly improve following treatment and remain severely functionally impaired and fatigued are likely to experience a number of adverse psychological consequences as a result, particularly if they have been ill for a considerable time. There is evidence that lack of physical activity and exercise have adverse psychological effects (Wessely, David, Butler & Chalder, 1989). Also, restricting one's activity will result in a loss of social and other rewards (Ray, 1991). The ambiguity surrounding the illness and the factors which cause and maintain the condition, as well as a tendency for other people to dismiss CFS sufferers' symptoms, may also contribute to depression in CFS sufferers (Lewis, 1996).

On the other hand depression may play a role in maintaining the condition and preventing change. For example, patients whose psychological distress and depression does not improve during treatment may have more difficulty recognising any small improvements they do make and may be more likely to become demoralised by setbacks. Patients who continue to feel psychologically distressed may also have more difficulty attending sessions regularly and completing homework tasks.

Another possible explanation is that at least some patients who fail to benefit significantly from CBT treatment have a psychiatric illness which

predominantly manifests itself as fatigue. There is considerable overlap between the symptomatology of CFS and depression, and it is possible that some patients may have been incorrectly diagnosed as having CFS rather than depression.

4.5.4. Membership of the ME association

Although an association was found between a tendency to refuse CBT treatment and membership of the ME association in the present study, as already discussed, no relationship was found between membership of the ME association and treatment outcome in the present study. These findings suggest that while those who refuse an offer of CBT treatment at the outset are more likely to be members of the ME association, those who complete a course of CBT treatment but do not subsequently improve, are no more likely to be members of the ME association than those who do improve.

In line with the present study, no association was found between membership of the ME association and outcome following CBT treatment at 4 year follow-up in Bonner et al's (1994) study. Sharpe et al (1992) however, found a relationship between membership of a patient organisation and ongoing disability at two year follow-up in patients who had not been treated with CBT treatment. It has been suggested that Sharpe et al's (1992) findings may suggest that patient organisations such as the ME association provide advice that maintains disability (Lewis, 1996). While this may be true and patients who belong to these organisations and do not receive CBT treatment

may be less likely to get better, in line with Sharpe et al's (1992) findings, those patients who are members of a patient organisation but who agree to participate in a course of CBT treatment may well adhere to the principles on which CBT treatment is based and benefit as much as non-members from treatment, explaining the findings of the present study, and Bonner et al's (1994) study. Thus the findings of Sharpe et al's (1992) study may not be in conflict with the findings of the present study or Bonner et al's (1994) study.

4.5.5. Receipt of benefits

There was a trend for improvers to be less likely to be in receipt of benefits than non-improvers at postal follow-up in the present study. This finding is consistent with the finding in Deale et al's (1997) study that making a new claim for disability-related benefit during treatment was significantly related to a poor treatment outcome.

One possible explanation for this finding is that unimproved patients were significantly more functionally impaired, fatigued and more psychologically distressed than patients who had improved at postal follow-up. All these factors would have made unimproved patients more likely to be entitled to claim benefits such as disability-related benefits. It is also possible that claiming benefits may have contributed to patients' difficulties benefiting from CBT treatment. For example patients who were in receipt of benefits may have been less motivated to do well from treatment and improve in case it threatened their entitlement to benefits.

4.6. Psychosocial factors associated with treatment outcome

4.6.1. Stressful life-events

The only hypothesis in the present study for which there was some support from the present study's findings was the hypothesis that treatment outcome will be associated with an increased or reduced overall number or severity of stressful life-events. There was considerable evidence from the present study's results that a better treatment outcome is associated with having experienced a lower overall number and severity of stressful life-events since the start of treatment.

At postal follow-up there were trends for patients who had improved by a clinically signficant amount to have experienced fewer stressful life-events, and a lower mean severity of stressful life-events, than non-improved patients since the start of treatment. Also, significant associations were found between patients' mean improvement between pre-treatment and postal follow-up on the Work and Social Adjustment Scale, and the total number, total severity, and mean severity of stressful life-events they had experienced since the start of treatment.

The findings from different studies to date on the relationship between stressful life-events and the development of CFS have been conflicting and inconclusive (e.g. Lewis et al, 1994; Surawy et al, 1995). However, there is some evidence that, even if stressful life-events are not associated with the onset of the condition, they may be one of the factors which maintains the

illness a long time after onset (Bruce-Jones et al, 1994). No previous research has directly examined the relationship between stressful life-events after the onset of illness and outcome in CFS, although several studies have found a link between specific stressful life-events, such as changing and leaving employment, and a poor prognosis or treatment outcome (e.g. Sharpe et al, 1992). The present study's findings go further, therefore, in showing that there is a relationship between the overall number and severity of stressful life-events which a person has experienced since the start of treatment and their treatment outcome.

The relationship between the number and severity of stressful life-events experienced and treatment outcome found in the present study could suggest that stress leads to lack of improvement. There is some evidence that stress maintains symptoms and prevents improvement in CFS from CFS sufferers' reports that stress exacerbates symptoms and triggers relapses after the condition has developed (Ray et al, 1992). Lewis (1996) has also suggested that unless premorbid and ongoing sources of stress such as work and relationship difficulities are addressed during patients' treatment, it is more likely that they will relapse.

Another possible explanation for the relationship found between stressful life-events and treatment outcome in the present study is that lack of improvement during treatment causes CFS sufferers to experience more stressful life-events, and to perceive the life-events they do experience as having a greater impact on them. For example, patients who fail to improve during treatment, and who continue to experience severe fatigue, are more

likely to have an impaired capacity to work, and this may result in employment events occurring such as loss of job. Continuing fatigue and functional impairment is also likely to put an increased strain on interpersonal relationships, and lead to relationship events such as marital difficulties. Patients who fail to improve over the course of treatment are also likely to perceive stressful life-events which happen to them, such as moving house, getting married, and having a baby, as more stressful due to their continuing fatigue and functional impairment.

One shortcoming of the present research on life-events is that it relies on retrospective reporting, which may be unreliable and confounded by the experience of illness. The considerable ambiguity surrounding CFS and the lack of acceptable explanations for the condition may make patients with this illness particularly inclined to search for explanations in the form of stressful life-events.

Patients' recall of events may also have been particularly biased by factors such as depression and demoralisation (Paykel, 1983). It has been noted by Brown (1974, in Bruce-Jones et al, 1994) that depressed individuals tend to remember more negative or threatening life-events than non-depressed individuals. The trend for improved and non-improved patients to differ in terms of the number and severity of stressful life-events they had experienced since the start of treatment in the present study, could therefore be explained in terms of improved, and non-improved patients' differing degrees of depression and demoralisation. Improved patients were significantly less psychologically distressed and depressed, as measured by their total GHQ and HAD

depression scores, than non-improved patients, and it is likely that non-improved patients would have been more demoralised due to their lack of improvement. However there were trends for improved and non-improved patients to differ in terms of the number and mean severity of stressful life-events they had experienced since the start of treatment after controlling for patients' level of psychological distress and depression in the present study.

Patients' recall of events in the present study may also have been biased by their state of health when filling out the questionnaire. Patients who had improved less, like depressed individuals, may have had a tendency to recall more stressful life-events, and to recall these life-events as having had a greater impact on them, than patients who had made greater improvement. Patients may also, albeit unconciously, have been to some extent communicating the severity of their present condition through their responses to the questionnaire, particularly as the researcher who sent the questionnaires was not someone known to them.

4.6.2. Social support

There was no evidence for a relationship between higher or lower social support and treatment outcome from the present study's findings. There were no significant differences between improved and non-improved patients' level of positive or negative social support received from significant others in general, as measured by Ray's (1992) positive and negative social support scale. Also, there were no significant differences between improved and non-

improved patients' actual and ideal levels of practical and emotional support received from their two most significant relationships, as measured by Power et al's (1988) Significant Others Scale (SOS). Nor were there any differences between improved and non-improved patients' discrepancies between ideal and actual levels of emotional and practical support, after adjusting for over-provision of support. No significant association was found either between patients' mean improvement between pre-treatment and postal follow-up on the Work and Social Adjustment Scale, and any of the social support scores derived from the two measures of social support.

While social support is one of a number of variables which are thought to buffer against the effects of potentially stressful life-events (e.g. Power et al, 1988), the present results suggest that those who improved less from treatment were not found to have experienced a greater severity and overall number of stressful life-events in the present study because they were receiving less positive or more negative social support.

No previous studies have looked at the relationship between social support and outcome in CFS with which to directly compare the results of the present study. However, previous literature has suggested that CFS patients experience a sense of loss or lack of support from others and experience considerable negative social support such as having their illness misunderstood or dismissed as all "in the mind" by others. It has been suggested that this lack of positive social support and presence of negative support may have a number of detrimental consequences which maintain and perpetuate the illness. For example it leads to feelings of ambiguity, self-doubt, lack of control and

helplessness, and exacerbates the negative effects of stressful life-events (e.g. Lewis et al, 1994; Ware, 1992). There was no evidence from the present study's findings that patients who failed to significantly improve by postal follow-up, did so because they experienced more negative social support than those who had significantly improved. Also, there was no evidence that patients failed to improve because they were in receipt of a lower level of perceived emotional or practical support or were more dissatisfied with the level of emotional and practical support they were receiving (as measured by the discrepancy between their actual and ideal levels of emotional and practical support on the SOS). This does not necessarily suggest that CFS sufferers don't experience less positive support and more negative social support than patients with other illnesses, only that some CFS patients can improve following CBT treatment, despite receiving as much negative social support and positive social support from others as non-improvers.

Possibly a more significant difference would have been found between improvers' and non-improvers' levels of social support on the SOS if patients had been asked about the support received from a larger range and number of key relationships. Whereas the original short form of the SOS assesses the support received from seven significant others, the adapted version of this scale used in the present study, only assessed the support received from two significant others.

Another shortcoming in the way social support was assessed in the present study is that it was only measured at postal follow-up, and not at pre-treatment. It is therefore possible that there could have been a significant

difference between improvers' and non-improvers' levels of perceived social support at pre-treatment, which could have accounted for their different responses to treatment. There may also have been a significant difference between their degree of change on social support measures between pre-treatment and postal follow-up which could have accounted for or been a consequence of their different responses to treatment. It seems unlikely however, that patients' social support scores would have changed very much between pre-treatment and postal follow-up, because the CBT intervention did not directly try to enhance patients' social support levels, and there is evidence that social support levels tend to remain relatively stable at least over 6 month periods (e.g. Nott et al, 1995; Power et al, 1988).

Another possible explanation for the present findings could be that there isn't a simple relationship between social support and treatment outcome and higher levels of social support don't necessarily lead to a better outcome in CFS. The previous literature on the role of social support in CFS has tended to emphasise the detrimental consequences of low levels of social support both before and after the condition has developed. For example, Lewis (1996) has pointed out that low social support may increase the negative effects of potentially stressful life-events (e.g. Lewis 1996). Also, Lewis et al (1994) have suggested that low perceived social support prior to the onset of the illness may increase vulnerability to this condition by contributing to depression and/or immunological changes. There is some evidence from the literature on chronic pain however, a chronic condition with close parallels to

CFS, that once the condition has developed, social support can reinforce and maintain the condition as well as having beneficial consequences.

According to a behavioural perspective, chronic pain consists of a number of learned behaviours that can be reinforced by family members and significant others, for example through support and attention (e.g. Fordyce, 1978 in Payne & Norfleet 1986). A number of clinical reports have provided support for this theory that family members can reinforce chronic pain. Also, Block, Kremer, & Gaylor (1980) found that pain patients who reported their spouses as relatively solicitous when they were in pain, experienced pain for a longer period of time (15.5 years as opposed to 4.5 years) than patients who reported their spouses as relatively unsolicitous when they were in pain. These findings may suggest that having a solicitous spouse is a factor in the development of long term pain. On the other hand, these findings may suggest that spouses respond to the chronic pain by getting a divorce, or by becoming more solicitous as the condition develops (Block et al, 1980). There is also some evidence that chronic pain patients with highly solicitous spouses, are more likely to have problems making changes and maintaining the changes they have made (Fordyce, 1976; Benjamin, 1989, both in Williams, 1993).

The previous literature on the relationship between social support and CFS may therefore have overlooked the more negative consequences of social support once the condition has developed. Possibly no differences were found between improvers' and non-improvers' levels of support at postal follow-up in the present study, because support has both positive and negative consequences in relation to treatment outcome.

Power et al (1988) found that depressed cases on the GHQ-28 had higher ideal levels of emotional and practical support, and higher discrepancies between their ideal and actual emotional and practical support scores, than non-depressed cases on the SOS. Patients' level of depression could not have confounded the results of the present study however, as no difference was found between improved and non-improved patients' social support scores, after controlling for their level of psychological distress and depression. It is surprising however that while improvers had significantly lower scores than non-improvers on the GHQ-12 and the HAD depression subscale at postal follow-up in the present study, there were no differences between improvers' and non-improvers' ideal or discrepancy scores on the SOS before controlling for levels of psychological distress and depression.

A possible explanation for the discrepancy between the findings of the present study and Power et al's (1988) study is that while Power et al (1988) were comparing depressed and non-depressed cases on the GHQ-28, the improvers and non-improvers in the present study only differed significantly on their total scores on the GHQ-12 and HAD depression subscale. Also, Power et al (1988) used the long form of the SOS, whereas the present study was using an adapted version of the short form of the SOS.

4.6.3. Illness attributions

It was not possible to statistically compare improvers' and non-improvers' illness attributions at pre-treatment, or postal follow-up, in the

present study because too few patients held solely psychosocial and/or solely physical illness attributions. However, there were no obvious differences in the proportion of improvers and non-improvers who held solely psychosocial, solely physical or mixed illness attributions at pre-treatment and postal follow-up. The majority of both improvers and non-improvers held mixed illness attributions at pre-treatment and postal follow-up. Also a similar proportion of improvers (14 per cent) and non-improvers (7 per cent) changed from holding a physical illness attribution before starting treatment, to holding a mixed illness attribution at postal follow-up. Therefore the illness attributions held by patients at pre-treatment, and postal follow-up, did not seem to have any relation to whether or not they benefited from treatment.

Up until now modifying patients' illness attributions by encouraging them to adopt broader explanations for their illness than simple disease explanations, and encouraging them to consider the role of psychological and social factors as well, has been a key aspect of CBT treatment (e.g. Sharpe et al, 1996). This is based on the theory that physical illness attributions have a number of negative consequences which maintain illness behaviour and symptoms. For example, illness attributions are thought to lead to a focus on bodily sensations (Pennebaker, 1982 in Surawy et al, 1995), and coping strategies such as avoidance of activity, which perpetuate intolerance of activity and exacerbate symptoms if used longer term (e.g. Wessely, Butler, Chalder & David, 1991). However there is no consistent research evidence as yet that physical illness attributions are related to a poor treatment outcome and the advantages of physical illness attributions, such as that they protect the

individual from the stigma of having a psychological illness, may have been overlooked. The results from previous studies looking at the relationship between illness attributions and treatment outcome have been conflicting and inconclusive.

A number of previous CBT outcome studies found no relationship between illness attributions and treatment outcome as was the case with the present study. For example, Deale et al (1997) found no difference between the pre-treatment illness attributions of patients who improved and did not improve at 6 month follow-up after CBT treatment. Butler et al (1991) by contrast found that a poor outcome immediately following CBT treatment was significantly associated with the strength of attribution of illness to physical causes. However, when the patients in Butler et al's (1991) study were followed up four years later in Bonner et al's (1994) study, no statistically significant association was found between a poor treatment outcome, and holding physical illness attributions. Also, those patients who had a good outcome at four year follow-up were not found to have changed their physical illness attributions over the four year period.

In contrast with the present study's findings, two previous studies which looked at the long-term outcome for CFS patients, who had not received CBT treatment, found a significant association between physical illness attributions and a poor outcome. Sharpe et al (1992) found an association between belief in a viral cause of illness and persistent functional impairment at follow-up, and Wilson et al (1994) found that the strength of the belief in a physical rather than psychological disease origin predicted a poor

outcome. Lewis (1996) has argued that the significance of the findings from the latter two studies is unclear however, as patients' illness attributions may have been the result of a more severe illness, or a different illness experience.

A possible explanation for the discrepancy between Sharpe et al's (1992) and the CBT outcome studies' findings is that whereas the CBT outcome studies, including the present study, were looking at the relationship between patients' overall illness attributions and treatment outcome, Sharpe et al's study was looking at the relationship between whether or not patients held a specific illness attribution and outcome. While Sharpe et al (1992) showed an association between belief in a viral cause of illness and outcome, at least some of the patients who believed that a virus had been a factor in their illness in this study also felt "stress" had played a role in their illness (i.e. they held mixed illness attributions).

Another finding that is of interest in the present study, is that very few patients held solely physical illness attributions at pre-treatment or postal follow-up. Unlike the present study, previous studies have noted that CFS sufferers seen in specialist care settings prefer physical to psychosocial explanations for their symptoms. Powell et al (1990) for example, found that 80 per cent of the CFS sufferers referred for neurological assessment to a tertiary referral centre for neurology, who were included in their study, attributed their illness to a physical cause (mainly post-viral fatigue). Deale et al (1997) likewise found that 65 per cent of CFS sufferers included in their clinical trial of CBT treatment held physical illness attributions as opposed to psychological or multi-factorial illness attributions at pre-treatment.

In the present study by contrast, only 9 per cent of the treatment completer group as a whole (N=86) held solely physical illness attributions at pre-treatment. Also only 12.8 per cent of those patients who filled in the postal follow-up questionnaire, and were included in the analysis on the relationship between illness attributions and treatment outcome, held solely physical illness attributions at pre-treatment, and only 11.9 per cent held solely physical illness attributions at postal follow-up. The majority of CFS patients in the present study held complex, multi-factorial and mixed illness attributions and explained their symptoms in terms of both physical and psychosocial factors.

Similar to the present study, Sharpe et al (1992) also noted that patients' illness attributions were often complex and many patients attributed their illness to more than one cause. Although a high percentage of patients believed that a virus had played a role in their illness in Sharpe et al's (1992) study, many patients also referred to the role of "stress" (i.e. a psychosocial factor) in their illness. Unlike the present study however, Sharpe et al (1992) do not provide figures on how many patients held solely physical, psychosocial or mixed illness attributions.

A possible explanation for the much lower proportion of CFS sufferers who held solely physical illness attributions in the present study, than in previous studies, is the high number of treatment refusers in the present study. There was no information available on treatment refusers' illness attributions, and it is possible that if they had been included in the present study's figures, a higher proportion of the CFS sufferers would have been found to have held physical illness attributions.

It seems possible that a higher proportion of treatment refusers than treatment completers would have held solely physical illness attributions in the present study. This is because patients who believe their illness is entirely due to physical factors would have been more likely to refuse a treatment based on psychological priniciples such as CBT. In line with this argument, Butler et al (1991) found a trend for those refusing treatment to be more likely to attribute their illness to entirely physical factors. Also, as discussed above, the finding that a higher proportion of those who refused CBT treatment were members of the ME association than those who accepted CBT treatment in the present study could suggest that refusers were more likely to attribute their illness to physical factors, particularly as self-help organisations such as the ME association take the view that the illness primarily has a physical basis.

4.6.4. Perfectionism

No significant differences were found between improved patients and non-improved patients in terms of any of the subscale, or total scores on the perfectionsism scale, at postal follow-up in the present study. Improvers had slightly higher total perfectionism scores than non-improvers at postal follow-up, but this difference was not statistically significant. Neither were any significant associations found between patients' subscale or total scores on the perfectionism scale at postal follow-up and their mean improvement on the Work and Social Adjustment Scale between pre-treatment and postal follow-up. These findings cannot be directly compared to those of previous research

as no previous studies have looked at the relationship between perfectionism and treatment outcome in CFS.

There are a number of possible explanations for the present study's findings on the relationship between perfectionism and treatment outcome. The findings may suggest that a person's level of perfectionism is not an important determinant of whether or not they achieve a significant improvement after CBT treatment. However there was no information available on CFS sufferers' level of perfectionism at pre-treatment in the present study, and, particularly as CBT treatment includes strategies to reduce excessive perfectionism, it cannot be assumed that patients' perfectionism scores did not change over the course of treatment. It is therefore possible that improvers' perfectionism scores were reduced by a greater amount than non-improvers' perfectionism scores over the course of treatment, and this greater improvement in their perfectionism scores partly accounts for their better treatment outcome.

On the other hand, perfectionism may convey certain advantages as well as disadvantages in relation to CBT treatment outcome. An explanation for the non-significant trend for improvers to have slightly higher total perfectionism scores than non-improvers, at postal follow-up, may be that while perfectionism may play a role in maintaining the condition, it may also convey certain advantages in relation to CBT treatment which counteract any negative effects it has. For example, more perfectionist CFS sufferers may be more likely to benefit from CBT treatment because they apply themselves better to treatment and are more conscientous about attending sessions and

completing homework tasks. They may also be more conscientous about adhering to the principles of CBT treatment and using the techniques they have learnt after treatment has ended. This may result in them maintaining their treatment gains and coping better with any relapses.

The lack of any significant findings to suggest that treatment outcome is associated with perfectionism in the present study could suggest that perfectionism plays no role in CFS, or only plays a role in a subgroup of CFS sufferers. This would support the findings of Wood and Wessely's (unpublished) recent study, which found that CFS patients were no more perfectionist than patients with other chronic physically disabling illnesses such as rheumatoid arthritis, as measured on Frost's (1990) multi-dimensional perfectionism scale. As Wood and Wessely argue, media representations of CFS sufferers as perfectionist in nature may reflect an atypical subgroup of CFS sufferers and/or a media stereotype. Little empirical research, to date, has looked directly at whether perfectionism is a pre-morbid risk factor, or maintaining factor in CFS, and the findings so far have been conflicting and inconclusive (e.g. Lewis et al, 1994). Most of the evidence suggesting that perfectionism does play a role in CFS comes from qualitative or uncontrolled studies (e.g. Surawy et al, 1995; Ware & Kleinman, 1992).

4.7. Limitations of the research

4.7.1. High treatment refusal rate

One of the limitations of the present research is the high treatment refusal rate (26 per cent). The high treatment refusal rate limits the extent to which the treatment can be said to be applicable and acceptable to all CFS sufferers. Also, treatment refusers may have differed in some respect from the group of treatment completers on whom the analysis was finally based, and this may have biased the study's results.

As already discussed, no significant differences were found between treatment refusers and treatment completers in terms of any of the demographic or pre-treatment characteristics that were analysed in the present study, including marital status, age, gender and illness duration. Also, while some differences were noted between treatment refusers and completers in terms of socio-economic class and membership of the ME association, it was not possible to statistically analyse the significance of these differences due to a problem of missing of data. Moreover, even if these differences had been significant, there is no evidence that either socio-economic class or membership of the ME association at pre-treatment are related to outcome following CBT treatment, from either the present study's findings or the findings of previous CBT outcome studies on CFS sufferers (e.g. Bonner et al, 1994; Deale et al, 1997). Therefore, even if refusers had been shown to be significantly more likely to come from lower socioeconomic classes and to be

more likely to be members of the ME association than treatment completers, this would not suggest that excluding refusers would have biased the treatment outcome results of the present study.

4.7.2. Bias due to exclusion of questionnaire non-responders

Another principal limitation is that the exclusion from the analysis of patients who failed to fill in measures at different stages of treatment may have biased the study's results.

Bias due to non-responders to outcome measures at pre-treatment

It could be argued that the exclusion of treatment completers who failed to respond to any outcome measures at pre-treatment from all the main analyses in the present study introduced a source of bias. However there was no evidence from the demographic and pre-treatment data to suggest that excluding these treatment completers would have biased the results. No significant differences were found between this latter group of treatment completers and the treatment completers who were included in the main analysis of the present study in terms of marital status, age, gender or illness duration.

Differences between the demographic and pre-treatment characteristics of responders and non-responders to outcome measures at 6 month and postal follow-up

It could also be argued that the exclusion of treatment completers who failed to respond to the two main outcome measures (the Work and Social Adjustment Scale and Fatigue Questionnaire) at 6 month follow-up and/or postal follow-up may have affected both the results on the proportion of patients who achieved a clinically significant improvement at these follow-ups and the results of the paired t-tests assessing the significance of patients' mean improvement on these outcome measures between pre-treatment and 6 month follow-up or postal follow-up.

Non-responders to both the Fatigue Questionnaire and the Work and Social Adjustment Scale at 6 month follow-up or postal follow-up were found to be significantly younger than those patients who responded to these questionnaires, and were therefore included in the aforementioned treatment outcome analysis. However a number of previous outcome studies (e.g. Bonner et al, 1994; Deale et al, 1997; Sharpe et al, 1992) have, like the present study, found no relationship between patient's age and outcome. It therefore seems unlikely that this age difference between treatment completers who responded and failed to respond to the two main outcome measures at 6 month follow-up and postal follow-up would have biased either the results on the proportion of patients who had achieved a clinically significant improvement, or the results of patients' mean improvement on the two main outcome measures at 6 month and postal follow-up.

Non-responders to the Work and Social Adjustment Scale and Fatigue Questionnaire at postal follow-up were also significantly less likely to be married than those patients who responded. As with age, however, no previous outcome studies have found a relationship between marital status and outcome in CFS sufferers. A trend was found for improvers to be more likely to be married than non-improvers in the present study however, although this difference was not significant. It is therefore possible that the difference in terms of marital status between responders and non-responders to the Work and Social Adjustment Scale and Fatigue Questionnaire at postal follow-up would have inflated the results to a modest extent.

A difference between those who responded and failed to respond to the Work and Social Adjustment Scale and Fatigue Questionnaire at 6 month follow-up which may have introduced more of a bias was a trend for non-responders to be more likely than responders to have consulted a doctor for emotional problems at pre-treatment. Moreover, treatment completers who failed to respond to the Work and Social Adjustment Scale and Fatigue Questionnaire at 6 month follow-up were also found to be significantly more psychologically distressed, as measured by their GHQ scores at pre-treatment, than treatment completers who responded.

No relationship was found in the present study between whether a patient had consulted a doctor for emotional problems at pre-treatment and treatment outcome. There is no direct evidence either for a relationship between treatment outcome and having consulted a doctor for emotional

problems at pre-treatment from any previous studies, as no studies have directly assessed the relationship between these factors.

However, a relationship between a poor treatment outcome at four years follow-up and having had a previous psychiatric history at initial assessment was found in Bonner et al's (1994) study. It could be argued that having consulted a doctor for emotional problems at pre-treatment is an indicator that a person may have had a previous psychiatric history. Therefore, the trend for non-responders to have been more likely to have consulted a doctor for emotional problems at pre-treatment than responders in the present study suggests that excluding non-responders might possibly have inflated the treatment outcome results to a modest extent.

It is also difficult to be certain how excluding patients who were more psychologically distressed, as measured by their GHQ score at pre-treatment, may have biased the outcome results of the present study. Intuitively, it might be expected that patients who were more psychologically distressed, and particularly patients who were more depressed at pre-treatment, would benefit less from CBT treatment because they would have more difficulty attending treatment sessions regularly and carrying out homework tasks between sessions. However previous empirical outcome studies (e.g. Bonner et al, 1994; Butler et al, 1991; Deale et al, 1997) have, like the present study, shown that patients' level of psychological distress or mood disturbance at pre-treatment is not related to their treatment outcome at follow-up. Having said that, a number of previous outcome studies have, like the present study, shown that patients who are more psychologically distressed or whose mood is more

disturbed at follow-up after treatment have a poorer treatment outcome (e.g. Bonner et al, 1994; Sharpe et al, 1992).

No information was available on non-responders' level of psychological distress at follow-up in the present study, but these latter findings suggest that, if non-responders had continued to have a higher level of psychological distress than responders at follow-up, excluding them may have inflated the present study's treatment outcome results.

Possible impact of excluding questionnaire non-responders on the analysis on the proportion of patients who achieved a clinically significant improvement at 6 month and postal follow-ups

A higher proportion of patients were found to have achieved a clinically significant improvement at 6 month and postal follow-up in an intention to treat analysis in which treatment completers who had not filled in the Work and Social Adjustment Scale at 6 month and/or postal follow-up and treatment dropouts were included and rated as improved or unimproved on the basis of the difference between their pre-treatment score on the Work and Social Adjustment Scale and their last reported score on this scale after treatment. Whereas 34.8 per cent and 33.3 per cent of treatment completers were found to have achieved a clinically significant improvement at 6 month and postal follow-up respectively before carrying out the intention to treat analysis, 41.8 per cent and 46.3 per cent of patients were found to have achieved a clinically significant improvement at 6 month and postal follow-up respectively in the intention to treat analysis.

Of the 28 treatment completers who had failed to fill in the Work and Social Adjustment Scale at 6 month follow-up, but who were included in the intention to treat analysis, 13 (46.4%) had achieved a clinically significant improvement at 6 month follow-up based on the difference between their pre-treatment score on this measure and their last reported score on this measure as at 6 month follow-up. Also, of the 33 treatment completers who had failed to fill in the Work and Social Adjustment Scale at postal follow-up, but who were included in the intention to treat analysis, 19 (57.6%) had achieved a clinically significant improvement at postal follow-up based on the difference between their pre-treatment score on this measure and their last reported score on this measure as at postal follow-up.

The latter findings could be seen to suggest that excluding treatment completers who failed to respond to the Work and Social Adjustment Scale at 6 month and/or postal follow-up may have lead to an underestimate of the number of patients who had achieved a clinically significant improvement at 6 month and postal follow-up in the present study. However, not all patients who failed to fill in the Work and Social Adjustment Scale at 6 month and/or postal follow-up were included in the intention to treat analysis. Only those patients who had filled in the Work and Social Adjustment Scale at pre-treatment and at another stage of treatment were included. It could be argued that those questionnaire non-responders at 6 month and postal follow-up who were included in the intention to treat analysis because they had filled in the Work and Social Adjustment Scale at pre-treatment and at at least one other stage of treatment were a select group that was not representative of all the

treatment completers who failed to respond to this measure at 6 month and postal follow-ups respectively. Arguably, patients who had made greater improvements since pre-treatment may have been more willing to cooperate with filling out the Work and Social Adjustment Scale at pre-treatment and at at least one other stage of treatment. Having said this, it is worth noticing that approximately two thirds of the treatment completers who failed to respond to the Work and Social Adjustment Scale at both 6 month and postal follow-up were included in the intention to treat analysis.

Possible impact of excluding questionnaire non-responders on the analyses on patients' self-rated global outcome

In an intention to treat analysis in which treatment completers who had not filled in the global improvement self-ratings at 6 month and/or postal follow-up and treatment dropouts were included and given their last global outcome self-ratings as at 6 month follow-up and postal follow-up respectively, a similar pattern of global outcome results emerged to those which were obtained before carrying out an intention to treat analysis.

Also, of the 30 treatment completers who had failed to fill in the global improvement self-ratings at 6 month follow-up, but who were included in the intention to treat analysis, a similar proportion rated themselves as improved, satisfied with their improvement and rated treatment as useful at 6 month follow-up based on their last reported score on the global improvement and satisfaction measure. The intention to treat analysis did however reveal slightly better global outcome results for non-responders at postal follow-up than for

responders. Of the 42 patients who were included in the analysis at postal follow-up before carrying out an intention to treat analysis, 37 treatment completers (88.1 per cent) rated themselves as improved, 34 (81 per cent) rated themselves as satisfied with their improvement, and 38 (90.5 per cent) rated treatment as useful. However, of the 28 treatment completers who failed to fill in the global outcome self-ratings at postal follow-up but who were included in the intention to treat analysis, 27 (96.4 per cent) rated themselves as improved, 24 (85.7 per cent) were satisfied with their improvement, and 28 (100 per cent) rated treatment as useful.

The latter findings could be seen to suggest that excluding treatment completers who failed to fill in the global outcome self-ratings at postal follow-up may have inflated the proportions of patients who rated themselves as improved, were satisfied with their improvement and had found treatment useful at postal follow-up in the present study. However only 28 of the 44 treatment completers who failed to fill in the global outcome self-ratings at postal follow-up were included in the intention to treat analysis at postal follow-up. It could be argued that those questionnaire non-responders at postal follow-up who were included in the intention to treat analysis because they had filled in global outcome self-ratings at a previous stage of treatment were a select group that was not representative of all the treatment completers who failed to respond to this measure at postal follow-up. Arguably, patients who had made greater improvements since pre-treatment may have been more willing to cooperate with filling out the global outcome self-ratings at a stage of treatment prior to postal follow-up for research purposes.

4.7.3. Bias due to exclusion of treatment dropouts

It could also be argued that the exclusion of treatment dropouts from the main analyses in the present study may have introduced a source of bias. The various ways in which this could potentially have biased the results are discussed in detail below.

Differences between the demographic and pre-treatment characterisitcs of treatment dropouts and treatment completers who were included in treatment outcome analyses

One way in which the extent to which excluding dropouts may have biased the treatment outcome results of the present study was assessed was by comparing the demographic and pre-treatment characteristics of treatment dropouts with those of treatment completers who were included in different aspects of the treatment outcome analyses. In particular, the demographic and pre-treatment characteristics of treatment dropouts were compared with those of treatment completers who were included in the analysis on the proportion of patients who achieved a clinically significant improvement on the Work and Social Adjustment Scale at 6 month or postal follow-up, and with those who were included in the analysis on patients' mean improvement on the Fatigue Questionnaire and Work and Social Adjustment Scale between pre-treatment and 6 month or postal follow-up.

The results of these comparisons consistently revealed that treatment dropouts were significantly younger and less anxious, as measured by their HAD anxiety subscale scores at pre-treatment, than treatment completers who had been included in these analyses. There was also a trend for treatment dropouts to be less psychologically distressed, as measured by their pre-treatment GHQ scores, than treatment completers who were included in the analysis on the proportion of patients who had made a clinically significant improvement by postal follow-up, and those who were included in the analyses on patients' mean improvement on the Work and Social Adjustment and Fatigue Scales between pre-treatment and postal follow-up.

As discussed earlier, a number of previous outcome studies (e.g. Bonner et al, 1994; Deale et al, 1997) have, like the present study, found no relationship between patient's age and outcome. It therefore seems unlikely that the significant age difference betweeen treatment dropouts and treatment completers who were included either in the analysis on the proportion of patients who achieved a clinically significant improvement, or in the analysis on patients' mean improvement on the two main outcome measures, would have biased the results of these two areas of analyses on treatment outcome.

It is more difficult to be certain that the differences found between treatment dropouts and treatment completers included in the analyses in terms of their GHQ and HAD anxiety scores at pre-treatment would not have biased the results of these analyses. As already discussed, previous studies have shown, like the present study, that patients' level of psychological distress or mood disturbance at pre-treatment, as measured by their GHQ or HAD scores,

is not related to their treatment outcome at follow-up (e.g. Bonner et al, 1994; Butler et al, 1991; Deale et al, 1997). Although previous studies have tended to only assess the relationship between patients' overall score on the HAD scale at pre-treatment and their treatment outcome, the present study has specifically shown that patient's HAD anxiety scores at pre-treatment are not related to their treatment outcome at postal follow-up.

On the other hand, a number of studies have shown that patients who are more psychologically distressed after treatment have a poorer treatment outcome (e.g. Bonner et al, 1994; Butler et al; Sharpe et al, 1992). These findings suggest that, if dropouts had continued to have lower GHQ scores at follow-up than treatment completers included in the analysis, excluding treatment dropouts may have lowered the study's treatment outcome results.

However there is less consistent evidence that patients who are more anxious after treatment have a poorer outcome. Whereas Bonner et al (1994) found that a poor treatment outcome was associated with a higher HAD anxiety score at postal follow-up, no relationship was found between patients' HAD anxiety scores and their outcome at postal follow-up in the present study. It is therefore difficult to be certain whether differences between the pre-treatment HAD anxiety scores of treatment dropouts and treatment completers included in the analysis suggest that excluding treatment dropouts would have biased the study's treatment outcome results.

In any case, the apparent differences betweeen treatment dropouts and treatment completers included in the analyses in terms of GHQ and HAD anxiety subscale scores at pre-treatment should be interpreted with caution, as

slightly less than two-thirds of treatment dropouts filled out the GHQ and HAD anxiety subscale at pre-treatment.

Possible impact of excluding treatment dropouts on the analysis on the proportion of patients who achieved a clinically significant improvement

As already explained on p.178 in section 4.7.2., a higher proportion of patients were found to have achieved a clinically significant improvement at 6 month and postal follow-up in an intention to treat analysis in which treatment completers who had not filled in the Work and Social Adjustment Scale at 6 month and/or postal follow-up, and treatment dropouts were included and rated as improved or unimproved on the basis of the difference between their pre-treatment score on the Work and Social Adjustment Scale and their last reported score on this scale after treatment. Whereas 34.8 per cent and 33.3 per cent of treatment completers were found to have achieved a clinically significant improvement at 6 month and postal follow-up respectively before carrying out the intention to treat analysis, 41.8 per cent and 46.3 per cent of patients were found to have achieved a clinically significant improvement at 6 month and postal follow-up respectively in the intention to treat analysis.

Of the five treatment dropouts who were included in an intention to treat analysis four (80 per cent) were found to have achieved a clinically significant improvement between pre-treatment and 6 month follow-up and between pre-treatment and postal follow-up based on their last reported scores on the Work and Social Adjustment Scale as at 6 month follow-up and postal follow-up respectively.

The latter findings could be seen to suggest that excluding dropouts may have lead to an underestimate of the number of patients who had achieved a clinically significant improvement at 6 month and postal follow-up after CBT treatment in the present study. However, only five of the twenty-two treatment dropouts had filled out the Work and Social Adjustment Scale at both pre-treatment and at another point after treatment and were therefore included in the intention to treat analysis, and four of these five had achieved a clinically significant improvement. It could be argued that this group of five dropouts was a select group that was not representative of all of the dropouts. Arguably, dropouts who had made more improvements since pre-treatment may have been more satisfied with the treatment that they had been given, and therefore more willing to cooperate with filling out the Work and Social Adjustment Scale at different stages of treatment for research purposes.

Possible impact of excluding treatment dropouts on the analyses on patient's self-rated global outcome

As already explained on p.180 in section 4.7.2., in relation to the self-rated global outcome results at 6 month and postal follow-up in the present study, in an intention to treat analysis in which treatment completers who had not filled in global outcome self-ratings at 6 month and/or postal follow-up and treatment dropouts were included, a similar pattern of global outcome results emerged to those which were obtained before carrying out an intention to treat analysis. Of the six treatment dropouts who were included in the intention to treat analysis, five (83.3 per cent) rated themselves as improved and satisfied

with their level of improvement but only three (50 per cent) rated treatment as useful at 6 month and postal follow-up.

These results could be seen to suggest that excluding dropouts may have inflated the proportion of patients who rated treatment as useful at 6 month and postal follow-up in the present study. However only six of the twenty two treatment dropouts had filled out the global outcome self-ratings at any stage of treatment and were therefore included in the intention to treat analysis. It could be argued that this group of six dropouts was a select group that was not representative of all the dropouts.

4.7.4. Retrospective nature of study

One of the reasons why there was so much missing data in the present study was because the research was carried out retrospectively and was based on some data which had been collected from patients at their assessment or at various stages of treatment prior to the present study. The completeness of the data which had been collected varied considerably. For example, much less information had been recorded on the demographic and clinical characteristics of treatment refusers and dropouts than treatment completers. This limited the extent to which it was possible to evaluate how refusers and dropouts may have biased the results of the present study, and to find out more about factors associated with a tendency to refuse and drop out of treatment.

Another consequence of the retrospective design of the present research is that three of the four psychosocial variables analysed in the present

research, namely social support, stressful life-events and perfectionism, were only measured at postal follow-up. It was therefore not possible to assess whether these psychosocial variables were predictive of a poorer treatment outcome. While an association was found between stressful life-events and treatment outcome in the present study, it was not possible to determine whether stressful life-events are a factor which contributes to a poor treatment outcome and/or are a consequence of a more disabling illness.

4.7.5. Lack of a control group

Previous controlled clinical trials have shown that CBT is more effective than no intervention, standard medical care or relaxation (Deale et al, 1997; Friedberg & Krupp, 1994; Sharpe et al, 1996). The lack of a control group in the present study meant that it was not possible to verify whether the treatment effects found in this study were significantly greater than those that would have occurred with an alternative intervention such as relaxation, or without any intervention. The improvements found in the present study may have been due to non-specific treatment factors such as therapist time and interest, support and homework practice rather than factors specific to CBT treatment. The improvements may also have reflected natural remission in the disorder. Also, it was not possible to separate out the effects of psychiatric medication from the effects of CBT in the present study.

Comparisons with outcome following no intervention

It is difficult to assess whether CBT treatment in the present study was more effective than no intervention at all by comparing the present study's findings to data on the outcome of untreated CFS patients. Very few studies have looked at the untreated prognosis for fatigue patients in tertiary referral settings. Also, those outcome studies on untreated fatigue patients which have been carried out have used different measures of outcome, different follow-up durations, and CFS patients with different durations of illness to the present study. These difficulties aside, there are some comparisons that can be made.

The proportion of patients in the present study who were found to have made a clinically significant improvement in terms of functional impairment at 6 month and 1 year follow-up after CBT treatment (i.e. 35 per cent and 33 per cent respectively), was similar to the proportion (31 per cent) who no longer reported functional impairment without any intervention after a similar follow-up period (1 to 2 years after initial assessment, which is comparable with 6 to 12 months after completion of treatment) in Sharpe et al's (1992) study.

It could be argued that the outcome following CBT treatment in the present study was poorer than the outcome with no treatment in Sharpe et al's (1992) study because, while the proportions of patients who had improved were similar across the two studies, Sharpe et al's (1992) definition of improvement was stricter. While the present study defined patients as having improved if they had achieved a percentage change (25 per cent) in functional

impairment, Sharpe et al (1992) only defined patients as having improved if their functioning had reached a certain level (i.e. if their functioning had not been impaired in the preceding month in one or more activities including housework, sport, walking, social, hobbies, occupation or studies).

There are however some reasons why one would have expected the outcome in the present study to be poorer, notwithstanding the differences between the way that outcome was assessed in the two studies. Firstly, the present study was based on patients who had been fatigued for at least 6 months at inital assessment, whereas Sharpe et al's (1992) study also included patients who had been fatigued for durations down to only 6 weeks. Secondly, the present study was based on patients referred to a specialistic tertiary referral CFS clinic, where more severely ill patients who have not responded to other types of treatment are likely to be referred. Sharpe et al's (1992) study on the other hand was based on patients referred to an infectious diseases outpatient clinic. Bearing these points in mind, it is arguable that the outcome following CBT treatment in the present study was in fact superior to the outcome when patients were given no treatment in Sharpe et al's (1992) study.

Comparison with outcome following medical care only

The proportion of patients in the present study who achieved a clinically significant improvement in functional impairment at 6 month follow-up after CBT treatment (35 per cent) was also higher than the proportion of patients who achieved a clinically significant improvement in functional impairment at 7 month follow-up following medical care only (23 per cent) in

Sharpe et al's (1996) study. Medical care comprised assessment, advice to increase their level of activity as much as possible and follow up in general practice in this latter study.

The better outcome in the present study arose despite the fact that, as already discussed, the criteria for a clinically significant improvement in Sharpe et al's (1996) study were less strict, and the patients in the latter study were less chronically ill at pre-treatment than in the present study. Moreover, the present study, unlike Sharpe et al's (1996) study, did not exclude patients with severe depression or a history of bipolar affective disorder, schizophrenia or substance abuse, whose prognosis was likely to be worse.

Comparison with outcome following a relaxation intervention

CBT lead to clinically significant improvements in functional impairment in 35 per cent of patients at 6 month follow-up in the present study, which was substantially higher than the 19 per cent of patients achieving a clinically significant improvement at 6 month follow-up after a relaxation intervention in Deale et al's (1997) study.

It could be argued that the outcome results following CBT treatment in the present study are not strictly comparable with the outcome results following relaxation in Deale et al's (1997) study however, because the two studies were based on different criteria for a clinically significant improvement. As already discussed, the criteria for a clinically significant improvement in Deale et al's (1997) study were stricter in some respects but more lenient in other respects than the present study's criteria. This problem aside, there are a

number of reasons why one would have expected poorer outcome results in the present study.

Firstly, the present study, unlike Deale et al's (1997) study, did not exclude patients who fulfilled criteria for other psychiatric diagnoses such as somatization disorder and severe depression, whose prognosis was likely to be poorer. Secondly, it is likely that the therapists conducting relaxation treatment in Deale et al's (1997) study adhered more strictly to a treatment protocol than the CBT therapists in the present study, particularly as therapists' protocol adherence was checked on a fortnightly basis by the research team in Deale et al's (1997) study.

Bearing these points in mind, it is arguable that the outcome following CBT treatment in the present study was considerably better than the outcome following relaxation in Deale et al's (1997) study. Comparing CBT to a psychological treatment based on relaxation controls for non-specific treatment factors such as therapist time and interest, support and homework practice. Therefore the finding that CBT lead to a better outcome in the present study than relaxation in Deale et al's (1997) study suggests that the gains following CBT treatment in the present study were due to factors specific to CBT, rather than being solely due to non-specific treatment factors.

Research implications of these comparisons

The aforementioned comparisons suggest that CBT treatment in the present study was more effective than no intervention or basic medical care. They also imply that the improvements following CBT treatment in the present

study were not simply a reflection of natural remission in the disorder or the result of non-specific treatment factors. Further research is needed however, using a controlled study of CBT treatment in routine clinical practice, to verify the findings from these comparisons.

4.7.6. Sample size and statistical power

The sample size which it was possible to attain in the present study for different aspects of the analyses was limited by some practical constraints. As explained in the method section, participants were recruited from all those CFS sufferers who were assessed for treatment between April '94 and May '96 and subsequently completed a course of seven or more treatment sessions. It would not have been possible to have recruited any more patients by including patients who had been assessed before April '94, as very few patients had been assessed and offered a course of CBT treatment prior to that date at the clinic. Patients who had been assessed more recently than May '96 were more likely to still be filling out other standard treatment follow-up questionnaires and as a result would have been less likely to be willing to fill out a further postal follow-up package of questionnaires for the present study than patients who were included in the present study.

The sample sizes obtained for different aspects of the analyses were also limited by the low response rate to questionnaires administered at different stages of treatment. A number of factors may account for the poor questionnaire response rate at various stages of treatment.

A possible reason why there was a low response rate to the questionnaires which therapists had administered to patients at pre-treatment, immediate post-treatment, and at 1, 3, and 6 month follow-ups, may have been that at the time that a lot of the data was being collected the data was not being specifically used for any research. Therapists, with their limited time available, may therefore have placed a relatively low priority on ensuring that all patients filled out these questionnaires fully, and on following up patients who did not respond to the questionnaries initially.

While the 49 per cent response rate to the postal follow-up package of questionnaires in the present study was about average for a postal questionnaire (Heberlein & Baumgartner, 1978), there were a number of factors which may have lowered the response rate to this package of questionnaires. One factor was that patients had already been asked to fill out a number of similar packages of questionnaires at previous stages of treatment. Also, at least some of the patients who were sent a postal follow-up package of questionnaires in the present study were also being asked to participate in other research studies being undertaken at the CFS unit at the same time that the present study was being undertaken. Another reason why a number of patients had not responded to the package of postal follow-up questionnaires was that they had moved from the address to which the questionnaires had been sent and had not left a forwarding address.

Due to the practical constraints discussed above, the final sample sizes obtained for some aspects of the analysis were fairly small, and this may have limited the power of the results obtained from these analyses. For example, an

original power calculation (see p. 88) suggested that a sample of 26 participants in each group was needed to have 80 per cent power to detect a difference between improvers' and non-improvers' scores on the stressful life-event inventory and measures of social support and perfectionism using independent t-tests with a 0.05 two-sided significance level. The final sample of improvers and non-improvers who were included in the analysis in the present study (14 improvers and 28 non-improvers) was less than this in one of the groups however. It is therefore possible that, although no significant differences were found between improvers' and non-improvers' mean scores on the stressful life-event inventory, social support measures and perfectionism scale in the present study, some significant differences may have become evident if a larger sample of improvers had been included in this analysis.

Also, while the necessary sample size in the original power calculation was calculated on the assumption that the relationship between treatment outcome and psychosocial variables would be a "large effect", the relationship between treatment outcome and psychosocial variables, if it exists, may only be a "medium effect". If so, a much larger sample size (64 in each group) would have been needed to detect the relationship between treatment outcome and psychosocial variables. Clearly there is a need to replicate the present study's findings on the relationship between social support, perfectionism, stressful life-events and treatment outcome with a larger participant group before the findings can be accepted with any degree of confidence.

On the other hand, the samples obtained for the paired t-tests assessing the significance of the improvement in patients' mean scores on the Work and

Social Adjustment Scale and Fatigue Questionnaire between pre-treatment and 6 month or postal follow-up in the present study were sufficiently large to have more than 80 per cent power to detect an improvement if one had occurred based on the power calculations specified on p. 87. A power calculation specified that a sample of 42 patients would have 99 per cent power to detect an improvement of 6.4 points in patients' mean scores on the Work and Social Adjustment Scale between pre-treatment and 6 month or postal follow-up, assuming the standard deviation of patients' improvement was 7.0, using a paired t-test with a 0.05 two-sided significance level. Therefore the final samples of 46 patients and 42 patients who were included in the paired t-tests assessing the significance of patients' improvement on the Work and Social Adjustment Scale between pre-treatment and 6 month or postal follow-up in the present study were both sufficiently large to have more than 99 per cent power and 99 per cent power respectively to detect an improvement if one had occurred.

Also, a power calculation specified that a sample size of 41 patients would have 99 per cent power to detect an improvement in patients' mean scores of 3.0 points on the Fatigue Questionnaire between pre-treatment and 6 month or postal follow-up, assuming that the standard deviation of patients' improvements is 4.0, using a paired t-test with a 0.05 two-sided significance level. Therefore the final samples of 45 patients and 41 patients who were included in the paired t-tests assessing the significance of patients' improvement on the Fatigue Questionnaire between pre-treatment and 6 month or postal follow-up in the present study were both sufficiently large to

have more than 99 per cent power and 99 per cent power respectively to detect an improvement if one had occurred.

In summary, the sample sizes were large enough for the results of the analyses on the improvement in patients' mean scores on the Work and Social Adjustment Scale and Fatigue Questionnaire between pre-treatment and 6 month or postal follow-up in the present study to be accepted with a high degree of confidence. However, the practical constraints discussed above resulted in the sample sizes for the analyses of factors associated with treatment outcome being lower than they would have needed to be to give a similar level of confidence in the results of these analyses.

4.7.7. Type I errors

The large data set in the present study meant that it was often possible to carry out multiple tests. For example numerous comparisons were made between improvers' and non-improvers' demographic and pre-treatment characteristics. It is therefore possible that some of the significant results obtained in the present study were Type I errors.

4.7.8. Potential confounding variables

Evaluating the effectiveness of a treatment as it is delivered in routine clinical practice rather than under tightly controlled conditions has the advantage of realism and high external validity. However, using this type of

research method also introduces a number of potentially confounding variables that have not been controlled for in the original design of the study.

The number of treatment sessions which patients received and therapists' level of expertise/experience were two factors which were not held constant in the original design of the present study. This was because in routine clinical practice patients receive differing lengths of treatment and are treated by therapists with differing levels of experience and expertise. These variables - number of treatment sessions and therapists' level of experience/expertise - may have been associated with treatment outcome, and, if so, they could have confounded the results of the analysis on factors associated with treatment outcome in the present study. Ideally, these potentially confounding factors should therefore have been controlled for in the analysis on factors associated with treatment outcome in the present study.

4.8. Research implications

4.8.1. Factors associated with treatment outcome

The findings on factors associated with treatment outcome in the present study should be interpreted with caution, as the number of treatment completers on whom this analysis was based were small. Further research is needed to verify the findings found in the present study on factors associated with treatment outcome using a larger sample size. Also, three of the four

psychosocial variables whose relationships to treatment outcome were assessed in the present study, namely social support, perfectionism and stressful life-events, were only measured at follow-up in the present study. Further prospective research is therefore needed which includes measures of these psychosocial variables at pre-treatment, to assess whether these variables are predictive of treatment outcome.

4.8.2. The need for a more sophisticated measure of stress

In view of the considerable evidence from the present study's results that there is a relationship between the number and severity of stressful life-events experienced since the start of treatment and outcome following CBT treatment in CFS sufferers, it would be worth investigating the relationship between stress and treatment outcome further in future research. One way in which the present study's findings could be strengthened would be by assessing the relationship between stress and treatment outcome in CFS sufferers using a different measure of stress, as different measures can produce varying results.

The self-report checklist which was used to measure stress in the present study had the obvious advantage that it could be administered to a large number of patients with relatively little research effort and was not time consuming for patients to fill in. However this method of data collection also has a number of shortcomings.

One shortcoming is that it is only a checklist of the incidence and severity of major life-events. The checklist does not assess other sources of stress such as more minor everyday stressors (e.g. a parking ticket, or experiencing delays in transport to work on a particular morning) or chronic ongoing stressors (e.g. caregiving, several months of unemployment). However there is considerable evidence suggesting that minor everyday stressors and chronic ongoing stressors may predict ill health better than major life-events (e.g. Kanner et al, 1981, in Lewis, 1994; Moos, 1995).

Future research could therefore usefully employ a broader framework that focuses not only on the relationship of more acute stressors such as major life-events, but also on the relationship of chronic ongoing stressors and minor everyday stressors to treatment outcome in CFS sufferers. A more sophisticated measure of stress such as Brown and Harris's (1989) Life Events and Difficulties Schedule (LEDS) could be used to assess these relationships, as it produces data not just on major stressful life-events, but also on more minor everyday stressors and chronic ongoing stressors.

Another important advantage of using the LEDS is that it uses a different system for rating the severity of events and difficulties to self-report checklists, which reduces the subjectivity of the assessment. When the LEDS is used to assess stress, the impact or importance of a stressor is estimated in a specific context for the average person by independent investigators. Using observer-based ratings of events avoids many of the biases and confounds inherent in methods which rely on subjects' own ratings of events such as the method used in the present study. In fact, when administering and coding the

LEDS, interviewers are trained specifically to edit out respondents' subjective reaction and emotional responses to an event so that this doesn't confound the event's contextual rating.

Also, investigators administering the LEDS have clear pre-defined criteria which guide which events and difficulties to rate as severe. By contrast, self-report checklists do not specify the criteria for including a stressor as a major life-event on the inventory, for the sake of brevity. It is therefore left up to the respondent to decide whether an event is severe enough to warrant recording it as an event on the checklist, a method which is clearly open to bias.

Data collection methods which rely on an interview such as the LEDS are also better able to ensure that patients are only reporting events which occurred within a specified time period, by establishing the exact timing of events with respondents during the interview.

Using investigator-based ratings of the severity of events, and clear pre-defined criteria for which events and difficulties to include, as well as precise timing of events, would help to overcome a number of the sources of bias which may have affected the results on the relationship between stress and treatment outcome in the present study. For example, it would overcome a source of bias highlighted by Creed (1985) - an "effort after meaning" phenomenon - whereby ill people tend to seek an explanation for their illness. It might also help to overcome the tendency for a person's health status and degree of distress at the time of filling out the measure to bias their recall of events.

Interview methods such as the LEDS are also able to reduce measurement error by enabling more effective probing of event reports. For example, the interviewer can probe to see whether a respondent has tended to exaggerate the number of stressful life-events to which they've been exposed by mentioning the same event more than once in response to different questions.

A disadvantage of the LEDS in its original form which might make it less suitable for future studies along the lines of the present study is that it requires the use of highly trained interviewers, long personal interviews and an elaborate coding system to distinguish subjective components from more objective contextual information. It is therefore time consuming and expensive to administer and code. However, several shortened and more standardised versions of the LEDS have been developed recently such as the Structured Life Events Inventory to try to overcome the aforementioned problems (Wethington, Brown & Kessler, 1995).

4.8.3. Generalisability of findings

The clinical characteristics of the sample of treatment completers included in the present study were largely similar to the characteristics of CFS sufferers seen in other specialised tertiary referral centres. The findings from the present research can therefore be said to be generalisable to other CFS patients seen in specialist tertiary referral clinics.

Also, previous controlled trials of CBT treatment evaluated CBT under strictly controlled conditions which arguably bore little resemblance to therapy in routine clinical practice. For example, they evaluated CBT administered according to a manual, for a fixed number of sessions, with a small number of experienced therapists and a highly selected group of CFS sufferers. By contrast, the present study evaluated CBT treatment as it is delivered in routine clinical practice - without a manual, for a variable number of sessions, with a large number of therapists of differing levels of experience, and with a more heterogenous sample of CFS sufferers. The findings from the present study could therefore be argued to be more generalisable to actual clinical practice than the results of previous controlled clinical trials of CBT treatment.

It has been argued, however, that CFS patients in tertiary care settings are a highly selected group of patients who have a much higher rate of psychological distress, psychiatric diagnoses and abnormal illness behaviour than patients with fatigue seen in primary care settings or in the community (Cathebras et al, 1995). The findings from the present study can therefore not be assumed to be generalisable to patients with fatigue in the general population or primary care.

4.8.4. How the questionnaire response rate could be improved in future research

A larger sample size could have been attained for the various analyses in the present study if there had been a higher response rate to the 6 month and postal follow-up questionnaires.

It could be argued that interviewing patients in their own homes rather than sending them a package of questionnaires in the post might lead to a better response rate to the postal (1 year) follow-up package of questionnaires. However this could prove to be very time-consuming if, as was the case in the present study, there was a high number of extra-contractual referrals. In any case, it is probably easier and less tiring for CFS patients to fill out a package of questionnaires in their own time and return them by post than to fill out the questionnaires all at once during an interview in their home which might last forty to fifty minutes.

Possibly a better way in which the response rate to at least the two main outcome measures (i.e. the Fatigue and Work and Social Adjustment Scales) at postal follow-up could be improved in future research would be by telephoning patients who fail to respond to the postal questionnaires initially, and asking them if they would be willing to fill out these questionnaires over the phone.

Another way of improving the response rate to the package of postal follow-up questionnaires might be to time the study so that patients are not also being asked to participate in other research studies at the same time.

Reducing the number of questionnaires included in the postal follow-up package of questionnaires, and thereby reducing the time it takes patients to fill in all the questionnaires, might be a further way of improving the response rate in future research.

The response rate to the questionnaires which therapists administered at pre-treatment, immediate post-treatment and at 1, 3, and 6 month follow-up might be improved if therapists were to agree a plan for how patients who fail to respond to questionnaires administered at different stages of treatment should be systematically followed up.

4.8.5. Independent assessments of outcome

A methodological weakness of the present study was its reliance on patients' questionnaire responses. Although there are no objective measures for assessing fatigue, disability and mood in CFS sufferers, it would be worthwhile in future research to carry out interviews with patients' therapists or patients' significant others to make a more independent assessment of patients' improvement and validate patients' self reports. The considerable discrepancy found between the proportion of patients who rated themselves as improved and the proportion of patients who achieved a clinically significant improvement on the Work and Social Adjustment in the present study particularly highlights the importance of including multiple measures of outcome and independent assessments of patients' improvement in future CFS outcome studies.

4.9. Clinical and professional implications

4.9.1. Efficacy of CBT treatment

There is considerable evidence that CBT is potentially an effective treatment for CFS sufferers from a number of previous clinical trials which have evaluated the treatment under strictly controlled conditions, with a selected sample of CFS sufferers (Butler et al, 1991; Bonner et al, 1994; Deale et al, 1997; Sharpe et al, 1996). The present study's findings suggest that, in routine clinical practice, and with a more heterogenous sample of CFS sufferers, CBT treatment has more modest effects. CBT treatment was not found to have produced significant clinical improvements in as high a proportion of patients in the present study as in previous controlled trials of CBT treatment.

However, CBT treatment was found to lead to clinically significant improvements in functional impairment in at least a third of patients, as well as subjective improvement in the majority of patients at 6 month follow-up and 1 year follow-up in the present study. Most previous CBT outcome studies, with the exception of Bonner et al (1994), have not followed up the effects of treatment for longer than six or seven months. The present study therefore shows that CBT leads to treatment gains which are maintained for a longer follow-up period than has been demonstrated in most previous studies.

An intention to treat analysis suggested that excluding questionnaire non-responders and treatment dropouts in the present research may have lead

to an underestimate of the proportion of patients who had achieved a clinically significant improvement at 6 month and postal follow-up. A second intention to treat analysis also suggested that excluding questionnaire non-responders may have lead to an underestimate of the proportion of patients who rated themselves as improved, satisfied with their improvement and who rated treatment as useful at postal follow-up in the present study. An intention to treat analysis also suggested that excluding treatment dropouts may have inflated the proportion of patients who rated treatment as useful at 6 month and postal follow-up in the present study.

4.9.2. Adherence to treatment protocol

One of the differences between the CBT intervention evaluated in previous clinical trials and the present research which possibly explains the better outcome results in those previous clinical trials is that the therapists delivering CBT treatment in the clinical trials adhered more strictly to a treatment protocol. Therapists in routine professional practice, as were included in the present study, are unlikely to have their adherence to any treatment protocol checked as it was in Deale et al's (1997) study, and are likely to adopt a more flexible approach. While it may be important to tailor cognitive and behaviour techniques to the individual patient, as suggested by Deale et al (1997), the present study's findings also suggest that CBT might possibly be made more effective by ensuring that therapists adhere more strictly to a treatment protocol.

4.9.3. Modification of psychosocial factors during CBT treatment

The findings in the present study concerning the relationship between treatment outcome and various psychosocial variables need to be verified in future research with a larger sample size. Future research also needs to include measures of psychosocial variables at pre-treatment in order to clarify whether these psychosocial variables are predictors of treatment outcome. With these caveats in mind, the clinical significance of the present study's findings on the relationship between treatment outcome and various psychsocial variables will briefly be considered.

Modification of stress during CBT treatment

A possible explanation for the significant relationship found between the number and severity of stressful life-events experienced and treatment outcome in the present study is that stressful life-events perpetuate patients' symptoms, prevent them improving and lead to a poorer treatment outcome. If this is the case, it would suggest that CBT treatment in clinical practice could be made more effective by helping sufferers to identify sources of stress and teaching them stress management techniques.

For example, patients could be taught which coping style is most appropriate to use in different situations (Lewis, 1996). In the general coping literature, problem-focused coping strategies are distinguished from emotion-focused coping strategies (Carver, Sheier & Weintraub, 1989; Folkman & Lazarus, 1985, both in Ray et al, 1995). Whereas problem-focused strategies

involve directly thinking about, confronting and resolving the problem, and are often more effective in situations where the individual has some control, emotion-focused coping strategies may be more appropriate in situations where it is important to reduce stress and arousal by directing attention away from the problem (Lewis et al, 1994).

More emphasis could also be given to teaching patients to apply the cognitive techniques for challenging and replacing unhelpful patterns of thinking, which are already an established part of CBT treatment for CFS, to changing patterns of thinking which contribute to and exacerbate stress. For example, patients could be taught to recognise and challenge any tendency to exaggerate the importance of events which may lead them to get trivial situations out of proportion and become stressed.

Progressive relaxation techniques and rapid stress control techniques, such as slow diaphragmatic breathing and regularly checking for signs of physical tension, could also be easily integrated into CBT treatment to help paitents manage stress better.

Incorporating these stress management techniques into treatment may help CFS patients to cope better with stressful life-events when they do occur, so that stressful life-events have less of an impact on them, and it may even help to prevent certain stressful life-events occurring such as marital difficulties and work-related problems.

Modification of social support during CBT treatment

One possible explanation for the lack of relationship found between treatment outcome and social support in the present study is that social support has both positive and negative consequences in relation to treatment outcome. For example, as well as having beneficial consequences, social support may also reinforce and maintain the condition. The present study's findings do not therefore necessarily imply that CBT in routine clinical practice should not try to enhance patients' social support levels by, for example, enhancing individuals' skills to elicit support from others, in order to improve treatment outcome. However it may also be important to ensure that the social support patients receive from others is not playing a role in reinforcing and perpetuating their condition during CBT treatment.

It would be interesting in future research to assess whether social support does play a role in reinforcing and maintaining the condition. If a relationship was found it might suggest that it would be beneficial to involve families and significant others in CFS sufferers' clinical treatment, to change relationship patterns which are playing a role in maintaining their condition.

Modification of illness attributions in CBT treatment

One of the main aims of CBT treatment at present is to encourage patients to adopt broader explanations for their illness than simple physical explanations (e.g. Sharpe et al, 1996). Patients are encouraged to also consider the role of social and psychological factors in their illness. However, the findings of previous CBT outcome studies, as well as the findings of the

present study, cast doubt on whether changing patients' physical illness attributions is an effective or necessary aspect of CBT treatment. There were no obvious differences between the pre-treatment and postal follow-up illness attributions held by improvers and non-improvers in the present study. Also, several previous CBT outcome studies (Bonner et al, 1994; Deale et al, 1997) have found no relationship between illness attributions and treatment outcome. There is clearly a lack of consistent research evidence at present that patients who hold less physical or broader illness attributions achieve a better treatment outcome, and that modifying patients' physical illness attributions should be an important aspect of CBT treatment.

Modification of perfectionism during CBT treatment

The modification of perfectionist assumptions and ways of thinking is already an established part of CBT treatment for CFS. However there is little consistent evidence from empirical research as yet that perfectionism is a pre-morbid risk factor or maintaining factor in the condition (e.g. Lewis et al, 1994; Woods & Wessely (in press)). The lack of relationship found between perfectionism and treatment outcome in the present study implies that perfectionism is not an important factor to address during CBT treatment in routine clinical practice. If anything, the trend for improvers to have higher perfectionism scores than non-improvers suggests that more perfectionist individuals are better able to benefit from CBT treatment.

4.9.4. Reducing the refusal rate for CBT treatment

The high treatment refusal rate found in the present study and Butler et al's (1991) study limits the extent to which the treatment can be said to be applicable to all CFS sufferers and an acceptable and credible treatment. In order to reduce the refusal rate and make CBT more acceptable to a wider number of CFS sufferers, future research needs to find out more about any factors associated with a tendency to refuse treatment.

In the present study those who refused treatment were found to be more likely to come from lower socio-economic classes, and to be members of the ME association, than those who accepted treatment. However, it was not possible to statistically analyse the significance of these differences between those who accepted and rejected treatment, due to a problem of missing data. These findings must therefore be interpreted with caution. If these findings could be confirmed through further research however, they would have some important clinical and professional implications.

Firstly the finding that those refusing treatment tend to come from lower socio-economic classes than those accepting CBT treatment implies that CBT needs to be altered to be made more accessible and acceptable to people from lower socio-economic classes. For example, therapists should avoid using vocabulary which would not be used or readily comprehended by the patient.

A possible explanation for the finding that treatment refusers were more likely to be members of the ME association is that self-help organisations such as the ME association are ambivalent about the value of CBT treatment.

Also, self-help organisations take the view that the condition has a physical basis, and members of these organisations may see this as in conflict with engaging in a treatment approach such as CBT, which is based on psychological principles and techniques. It may therefore be particularly important to address and discuss any fears or reservations about CBT treatment which members of these organisations have at the initial assessment, and to discuss in detail what treatment will involve. It may also be important to stress to members of these organisations at the initial assessment that CBT treatment is not based on any assumptions about whether the illness is caused by physical or psychological factors.

4.9.5. Aetiology

The outcome results following CBT treatment in the present study do not shed any light on the aetiology of the condition. Although CBT is concerned with modifying perpetuating cognitive and behavioural factors in the condition, the aetiological and maintaining factors in the condition are not necessarily the same, and may change over time (White, 1990). Therefore, if a CFS sufferer benefits from CBT treatment this does not necessarily imply that their condition was not originally caused by physical factors such as viral or immunological factors. The findings that CBT is an effective treatment for CFS sufferers should not therefore be interpreted as grounds for assuming that physical factors bear no relationship to the aetiology of the condition. In fact, to do so in clinical practice could increase the likelihood of members of self-

help organisations, such as the ME association, who tend to take the view the condition has a physical basis, refusing CBT treatment on the grounds that it does not acknowledge the possible role of physical factors in the aetiology of their condition.

4.10. Conclusions

4.10.1. CBT treatment outcome in routine clinical practice

In summary, the present study has shown that CBT in routine clinical practice leads to clinically significant improvements in a lower proportion of patients and/or smaller improvements in patients' mean scores on measures of fatigue and functional impairment than has been found in previous CBT clinical trials which have evaluated a similar nature and length of intervention.

The more modest outcome results found in the present study than in previous clinical trials of CBT are possibly best explained in terms of the fact that previous trials were evaluating CBT under more strictly controlled conditions. CBT treatment may be less effective in routine clinical practice than in clinical trials due to scarce resources, a wider sample of CFS patients with multiple diagnoses, and a larger number of therapists with differing levels of experience. The discrepancy between the findings of the present study and previous clinical trials of CBT treatment highlights the importance of carrying out effectiveness studies to evaluate treatment interventions in routine clinical

practice, as well as evaluating an intervention's potential efficacy under tightly controlled conditions.

The present study did however demonstrate that the gains following CBT treatment are maintained for a longer follow-up period (one year) than had been demonstrated in most previous trials. Also, the proportion of patients who reported subjective improvement in the present study was much higher than in previous clinical trials of CBT (e.g. Butler et al, 1991; Deale et al, 1997; Sharpe et al, 1996), as well as being much higher than the proportion of patients who had improved by a pre-determined clinically significant amount on a measure of functional impairment in the present study. This suggests that it is worthwhile to include multiple measures of outcome and independent assessments of outcome when evaluating treatment interventions.

A principal limitation of the present research was that the low response rate to the 6 month and postal follow-up questionnaires, and the exclusion of treatment dropouts may have biased the treatment outcome results to some extent. A better questionnaire response rate might be achieved in further research by ensuring that all patients who fail to fill in questionnaires initially are systematically followed up. Patients who are unwilling to fill out the full package of questionnaires could be asked to fill out some of the main measures over the phone. The questionnaire packages which patients are asked to fill out could also be shortened, and the research could be timed so that patients are not also being asked to participate in other research studies at the same time.

The lack of a control group in the present study meant that it was not possible to evaluate the efficacy of CBT treatment relative to no treatment at

all or relative to an alternative intervention which controls for non-specific treatment factors. However it was possible to make some very broad comparisons with outcomes reported in other studies which suggested that CBT treatment in the present study was more effective than no intervention, basic medical care or relaxation only. These comparisons suggested that the treatment gains following CBT in the present study were not simply a reflection of natural remission in the disorder or the result of non-specific treatment factors.

4.10.2. Relationship between treatment outcome and psychosocial variables

There was considerable evidence for a relationship between treatment outcome and the experience of stressful life-events in the present study, although there was no evidence for a relationship between treatment outcome and the other main psychosocial variables assessed, namely social support, perfectionism and illness attributions. However, the findings on the relationship between psychosocial factors and treatment outcome in the present study should be interpreted with caution as they were only based on a small sample of CFS patients.

Further prospective research is required to determine the aetiological significance of the association found between stressful life-events experienced and treatment outcome. If it was shown that stress is a factor which contributes to a poor treatment outcome, it would suggest that CBT could be made more effective by incorporating stress management techniques. Further

research could also usefully assess the relationship between stress and treatment outcome using a more sophisticated measure of stress such as Brown and Harris's (1989) Life Events and Difficulties Schedule (LEDS). Using such a measure would help to overcome some of the biases inherent in data collection methods which rely on subjects' own ratings of events such as the self-report checklist used in the present research. The LEDS could also be used to assess the relationship between treatment outcome and other sources of stress such as chronic ongoing difficulties and minor everyday stressors. These other sources of stress might be found to be just as strongly predictive of treatment outcome as major stressful life-events, if not more so.

The lack of relationship between patients' illness attributions and treatment outcome in the present study and several previous studies (e.g. Bonner et al, 1994; Deale et al, 1997) casts doubt on the importance of modifying patients' physical illness attributions during CBT treatment as is done at present. The lack of relationship between perfectionism and treatment outcome also suggests that modifying patients' perfectionist ways of thinking may not be an important component of CBT treatment at present. If anything the present study's findings suggest that perfectionism may convey certain advantages in relation to CBT treatment outcome.

The lack of relationship between treatment outcome and social support found in the present study may reflect the fact that social support and particularly solicitousness has detrimental as well as beneficial consequences. For example, social support may play a role in maintaining the condition and preventing change. Further research is needed to assess whether CBT could be

made more effective by including family members and signficant others in order to address relationship patterns which may be reinforcing and maintaining the condition.

In conclusion, while the present study findings suggest that CBT is more effective than no intervention and has specific treatment effects, it casts doubt on the relative importance of some specific components of CBT treatment which have been considered important until now. For example the present study's findings suggest that changing patients' illness attributions and perfectionist ways of thinking are not important components of CBT currently, but that CBT could possibly be made more effective by incorporating stress management techniques. Finally, prospective research based on a larger sample of CFS patients to investigate the relationship between psychosocial factors and treatment outcome further would be very worthwhile.

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APPENDIX 1. : Letter to participants inviting them to fill out a postal follow-up package of questionnaires

, 1997

Dear

I understand that you have recently completed a course of behavioural therapy with one of the therapists at the Chronic Fatigue Syndrome unit at . I hope that you have maintained the gains you made at the clinic and are now doing well.

As is explained in the enclosed information leaflet, I am presently carrying out a research study to find out more about who does well from treatment and how we can further improve the treatment that is currently being offered. I am therefore following up and contacting all those who have completed a course of therapy at the unit, to ask them if they would be willing to take part in this study.

I very much hope you will agree to help us, by filling in the enclosed pack of questionnaires, and returning them both in the stamp addressed envelope provided. I would also be grateful if you could sign and return the enclosed consent form, which gives us permission to use your questionnaire responses in our study. You will notice that the consent form also needs to be signed by a witness, and I'd be grateful if you could ask a friend, relative or neighbour to do this. There will be no other committment other than to complete these forms. Should you wish to see the results of the study when it has been completed, I will be more than happy to send you a copy of the final report.

Thankyou very much for your help and support,

With best wishes,

Clinical Psychologist in Training

APPENDIX 2. : Front sheet of the package of postal follow-up questionnaires

CHRONIC FATIGUE SYNDROME

QUESTIONNAIRE PACK

The enclosed package of questionnaires asks you about different aspects of your illness. These questionnaires will be used to look at how various psychosocial factors such as life events, predict how well people with Chronic fatigue benefit from a cognitive-behavioural programme.

Please answer ALL the questions, choosing the answer which you think most closely applies to you.

Your answers will be kept strictly confidential

Thankyou for your co-operation!

Name: .....

Date: .....

Age: ..... Sex: .....

Marital Status: Single /Married /Cohabiting/Divorced /Separated /Widowed (Please circle as appropriate)

Work Status: Unemployed / Employed / Student (Please circle as appropriate)

Occupation: (If none or a housewife please enter your partner's or parents' occupation. If unemployed please enter your occupation when last employed): .....

Current Medication: .....

How long have you had your illness? ..... months

No. of months since first appointment on behavioural programme: ..... months

No. of months since last appointment on behavioural programme: ..... months

Please state any benefits you are currently receiving (e.g. invalidity benefits): .....

APPENDIX 3. : Reminder letter to participants

Dear

I do hope you received my letter dated regarding a research project which I'm presently carrying out. I should be most grateful if you could find the time to complete and return the questionnaires and consent form which I sent you with my previous letter, if you have not already done so. I have enclosed a stamp addressed envelope for this purpose. We really need as many people as possible, who have received treatment at the CFS unit, to join in this study.

If you have any queries regarding the research project or questionnaires, I would be very pleased to discuss them with you and I can be contacted directly on the number above. If it would be easier for me to phone you however, please send me a note to let me know in the enclosed stamp addressed envelope, stating a daytime telephone number you can be contacted on.

I look forward to hearing from you.

With best wishes,

Clinical Psychologist in Training

APPENDIX 4. : Official letter from the research ethics committee giving ethical approval

ETHICAL COMMITTEE (RESEARCH)

Tel: (0171 919) 2892

31 July, 1997

Prof S Wessely
Dept. of Psychological Medicine
KCH

Dear Prof Wessely

Re: The relationship between psychosocial variables and treatment outcome in chronic fatigue syndrome (094/97)

The Ethical Committee (Research) considered and confirmed Chair's action to approve Study No. 94/97 from an ethical point of view, at its meeting on 25 July 1997.

Yours sincerely

Margaret Chambers
Committee Administrator

cc G Bent

APPENDIX 5.

CHRONIC FATIGUE SYNDROME STUDY
INFORMATION LEAFLET

The following information leaflet describes the research study, we would like to invite you to take part in, in more detail.

Chronic Fatigue Syndrome (CFS) also known as Myalgic Encephalitis (ME) or Post Viral Fatigue Syndrome is a common, distressing condition and affects people in different ways. It is unlikely that a single cause of CFS will ever be identified and therefore finding a single drug to alleviate the problems is doubtful. Over the past few years, cognitive behaviour therapy (CBT) has been found to be an effective rehabilitation programme for people with this condition. However, little research has explored whether psychosocial factors such as support from others, and stressful life events, play a role in how people respond to treatment.

The main purpose of the present study is to investigate whether various psychosocial variables such as support from others, beliefs held about the illness, and stressful life events, predict how well people benefit from CBT . The study will be based on patients who have completed CBT treatment.

As a participant, you will be asked to fill out a postal questionnaire consisting of a number of different measures of treatment outcome and psychosocial factors. The questionnaire will include a measure of impairment of work and social activities, fatigue, psychological distress and mood and overall improvement. It will also include measures of psychosocial factors such as support from others, stressful life events, beliefs about the illness, and perfectionism. The postal questionnaire can be returned by post and will not involve you attending any additional outpatient appointments. You may have already filled in some of the measures included in the postal questionnaire before and after treatment, and this previous data will be used in the study in addition to the data from the postal questionnaire, to look at pre-treatment post-treatment changes.

We realise that you may have already filled out a number of questionnaires at different stages of treatment and that the questionnaire for our study will involve more of your time. The postal questionnaire will however, help us to understand more about factors which predict how well people respond to treatment. If appropriate, these factors will then be used to modify or change the way CBT is delivered to achieve the best possible treatment outcome.

If you wish to discuss this further, please contact:

Georgina Bent (Clinical Psychologist in Training) : 0171 7405078

APPENDIX 6.

CHRONIC FATIGUE SYNDROME STUDY
CONSENT FORM

It has been explained to me that a research study is being conducted evaluating whether various psychosocial factors such as support from others, and stressful life events predict how well people benefit from Cognitive behaviour therapy (CBT).

I have been informed that participants will be sent a postal questionnaire to fill out, which includes various measures of improvement and psychosocial variables. I understand that I may already have filled out some of these measures before and after treatment and that this previous data will also be used in the study.

I have been informed that I can withdraw from the study at any time without giving a reason, and any further treatment will not be affected. I understand that this study has been reviewed by the Ethical Committee and that the rules of confidentiality will apply to all information provided by me during the course of the study.

I understand that participation in this trial is voluntary and non participation will not in any way influence any treatment that would be offered to me.

NAME:..... DATE:.....

SIGNATURE:.....

WITNESSED BY

NAME:..... DATE:.....

SIGNATURE:.....

APPENDIX 7. : Work and Social Adjustment Scale

1. BECAUSE OF MY ILLNESS MY ABILITY TO WORK IS IMPAIRED								
0	1	2	3	4	5	6	7	8
NOT AT ALL	SLIGHTLY		DEFINITELY	MARKEDLY			VERY SEVERELY IMPAIRED/ I CANNOT WORK	

2. BECAUSE OF MY ILLNESS MY HOME MANAGEMENT IS IMPAIRED (cleaning, shopping, cooking, child-care, paying bills)								
0	1	2	3	4	5	6	7	8
NOT AT ALL	SLIGHTLY		DEFINITELY	MARKEDLY			VERY SEVERELY IMPAIRED	

3. BECAUSE OF MY ILLNESS MY SOCIAL LEISURE ACTIVITIES ARE IMPAIRED (with other people e.g. outings, visitors, parties, pubs, clubs)								
0	1	2	3	4	5	6	7	8
NOT AT ALL	SLIGHTLY		DEFINITELY	MARKEDLY			VERY SEVERELY IMPAIRED	

4. BECAUSE OF MY ILLNESS MY PRIVATE LEISURE ACTIVITIES ARE IMPAIRED (done alone e.g. reading, gardening, walking alone, collecting, sewing)								
0	1	2	3	4	5	6	7	8
NOT AT ALL	SLIGHTLY		DEFINITELY	MARKEDLY			VERY SEVERELY IMPAIRED	

5. BECAUSE OF MY ILLNESS MY ABILITY TO FORM AND MAINTAIN RELATIONSHIPS IS IMPAIRED								
0	1	2	3	4	5	6	7	8
NOT AT ALL	SLIGHTLY		DEFINITELY	MARKEDLY			VERY SEVERELY IMPAIRED	

APPENDIX 8. : Fatigue Questionnaire

We would like to know whether or not you have been having any problems with feeling tired, weak or lacking in energy in the last month. Please answer ALL the questions simply
by underlining or circling the answer which you think most nearly applies to you. We would like you to answer the questions whether or not you have these symptoms. We also would like to know how you feel either at the moment or recently, rather than a long time ago. (If you have been feeling tired for a long time, we want you to compare yourself to how you felt when last well).

1. Do you have problems with tiredness?	Less than usual	No more than usual	More than usual	Much more than usual
2. Do you need to rest more?	Less than usual	No more than usual	More than usual	Much more than usual
3. Do you feel sleepy or drowsy?	Less than usual	No more than usual	More than usual	Much more than usual
4. Do you have problems starting things?	Less than usual	No more than usual	More than usual	Much more than usual
5. Do you lack energy?	Better than usual	No more than usual	More than usual	Much more than usual
6. Do you have less strength in your muscles?	Better than usual	No more than usual	More than usual	Much more than usual
7. Do you feel weak?	Less than usual	Same as usual	More than usual	Much more than usual
8. Do you have difficulty concentrating?	Less than usual	Same as usual	Worse than usual	Much worse than usual
9. Do you make slips of the tongue when speaking?	Less than usual	No more than usual	Worse than usual	Much worse than usual
10. Do you find it more difficult to find the correct word?	Less than usual	No more than usual	Worse than usual	Much worse than usual

11. How is your memory?	Better than usual	No worse than usual	Worse than usual	Much worse than usual

THE NEXT QUESTIONS ASK ABOUT MUSCLE PAIN

12. Do your muscles hurt at rest?	Less than usual	No more than usual	Worse than usual	Much worse than usual

13. Do your muscles hurt after exercise?	Less than usual	No more than usual	Worse than usual	Much worse than usual

14. If you are tired at the moment please indicate approximately how long this has lasted.
(Please underline or circle the answer which applies to you).

Not Applicable	Less than 1 week	Less than 3 months	Between 3 & 6 months	6 months or more

15. Overall what percentage of the time do you feel tired? (Please underline or circle the
answer which applies to you).

None of the time	25% of the time	50% of the time	75% of the time	All the time

16. Why do you think you are feeling tired? (Please try to give one reason).

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.....

APPENDIX 9. : Self Rated Global Outcome Measure

1. Overall, how are you compared to before treatment?
   a. Very much better
   b. Much better
   c. A little better
   d. About the same
   e. A little worse
   f. Much worse
   g. Very much worse

2. How is your fatigue compared to before treatment?
   a. Very much better
   b. Much better
   c. A little better
   d. About the same
   e. A little worse
   f. Much worse
   g. Very much worse

3. How handicapped/restricted are you compared to before treatment?
   a. Very much better
   b. Much better
   c. A little better
   d. About the same
   e. A little worse
   f. Much worse
   g. Very much worse

4. How satisfied are you with the outcome of treatment?
   a. Very satisfied
   b. Moderately satisfied
   c. Slightly satisfied
   d. Neither satisfied or dissatisfied
   e. Slightly dissatisfied
   f. Moderately dissatisfied
   g. Very dissatisfied

5. How useful has treatment been to you?
   a. Very useful
   b. Moderately useful
   c. Useful
   d. Not particularly useful
   e. No use at all

APPENDIX 10. : Illness Attributions Measure

FACTORS WHICH HAVE CONTRIBUTED TO YOUR PROBLEM

Which of the following do you currently consider important, in having caused your symptoms or made them worse. Tick as many as you wish.

	Not A Factor	Might be A Factor	Definitely A Factor
A. Previous viral infection			
B. Current or continuing infection			
C. Work Stress			
D. Stress from Relationship Difficulties			
E. Emotional Upset or Distress			
F. Food Allergy			
G. Other Allergy			
H. Hormonal Disorder			
I. A Major Event in Your Life			

Please give any further details and indicate any other factors you think are relevant to your illness.

.....
.....
.....
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.....

APPENDIX 11. : Multidimensional Perfectionism Scale

Please circle the number that best corresponds to your agreement with each statement below, at present. Use this rating system:

Strongly disagree 1 2 3 4 5 Strongly agree

	Strongly disagree....Strongly agree
1. My parents set very high standards for me	1 2 3 4 5
2. Organisation is very important to me	1 2 3 4 5
3. As a child I was punished for doing things	
less than perfectly	1 2 3 4 5
4. If I do not set the highest standards for	
myself, I am likely to end up a second	
rate person	1 2 3 4 5
5. My parents never tried to understand my mistakes	1 2 3 4 5
6. It is important to me that I be thoroughly	
competent in everything I do	1 2 3 4 5
7. I am a neat person	1 2 3 4 5
8. I try to be an organised person	1 2 3 4 5
9. If I fail at work/school, I am a failure as a	
person	1 2 3 4 5
10. I should be upset if I make a mistake.	1 2 3 4 5
11. My parents wanted me to be the best at	
everything	1 2 3 4 5
12. I set higher goals than most people	1 2 3 4 5
13. If someone does a task at work/school	
better than I, then I feel like I failed the	
whole task	1 2 3 4 5
14. If I fail partly, it is as bad as being a	
complete failure	1 2 3 4 5
15. Only outstanding performance is good	
enough in my family	1 2 3 4 5
16. I am very good at focusing my efforts	
on attaining a goal	1 2 3 4 5

	Strongly disagree....Strongly agree				
17. Even when I do something very carefully, I often feel					
that it is not quite right	1	2	3	4	5
18. I hate being less than best at things.	1	2	3	4	5
19. I have extremely high goals.	1	2	3	4	5
20. My parents have expected excellence from me.	1	2	3	4	5
21. People will probably think less of me if I make a					
mistake	1	2	3	4	5
22. I never felt like I could meet my parents' expectations	1	2	3	4	5
23. If I do not do as well as other people, it means I am					
an inferior human being	1	2	3	4	5
24. Other people seem to accept lower standards from					
themselves than I do	1	2	3	4	5
25. If I do not do well all the time, people will not					
respect me	1	2	3	4	5
26. My parents have always had higher expectations					
for my future than I have	1	2	3	4	5
27. I try to be a neat person	1	2	3	4	5
28. I usually have doubts about the simple					
everyday things I do	1	2	3	4	5
29. Neatness is very important to me.	1	2	3	4	5
30. I expect higher performance in my daily tasks than					
most people	1	2	3	4	5
31. I am an organised person.	1	2	3	4	5
32. I tend to get behind in my work because I repeat					
things over and over.	1	2	3	4	5
33. It takes me a long time to do something "right".	1	2	3	4	5
34. The fewer mistakes I make, the more					
people will like me.	1	2	3	4	5
35. I never felt like I could meet my parents' standards.	1	2	3	4	5

APPENDIX 12. : Positive and Negative Social Support Questionnaire

Think of the PEOPLE IN YOUR LIFE WHO ARE IMPORTANT TO YOU. The questions below refer to feelings that you might have about them and about the ways that they respond to you now that you are ill. Please say to what extent each description applies at present, in your view, to the people in your life who are important to you.

Do this by circling a number from 1 to 6, where

1 = never **4 = quite often**
2 = almost never **5 = very often**
3 = sometimes **6 = always**

1. Can you lean on and turn to them when things are difficult? 1 2 3 4 5 6

2. Can you get a good feeling about yourself from them? 1 2 3 4 5 6

3. Do they put pressure on you to do things? 1 2 3 4 5 6

4. Do they take over your chores when you feel ill? 1 2 3 4 5 6

5. Do they express concern about how you are? 1 2 3 4 5 6

6. Do they misunderstand the way you think and feel about things? 1 2 3 4 5 6

7. Can you trust, talk to frankly, and share your feelings with them? 1 2 3 4 5 6

8. Can you get practical help from them? 1 2 3 4 5 6

9. Do they argue with you about things? 1 2 3 4 5 6

10. Do you feel they are there when you need them? 1 2 3 4 5 6

11. Do they press you to say that you are feeling better? 1 2 3 4 5 6

1 = never **4 = quite often**
2 = almost never **5 = very often**
3 = sometimes **6 = always**

12. Do they listen when you want to confide about things that are important to you? 1 2 3 4 5 6

13. Do they express irritation with you? 1 2 3 4 5 6

14. Do they accept you as you are, including your "bad" as well as good points? 1 2 3 4 5 6

15. Do they help out when things need to be done? 1 2 3 4 5 6

16. Do they show you affection? 1 2 3 4 5 6

17. Do they make helpful suggestions about what you should do? 1 2 3 4 5 6

18. Are they critical of the way you respond to your illness? 1 2 3 4 5 6

19. Do they do things that conflict with your own sense of what should be done? 1 2 3 4 5 6

20. Do they give you useful advice when you want it? 1 2 3 4 5 6

21. Do they express frustration with you? 1 2 3 4 5 6

22. Do they treat you with respect? 1 2 3 4 5 6

23. Do they disagree with you about what is best for you to do? 1 2 3 4 5 6

APPENDIX 13. : (Adapted Version of) Significant Other's Scale-Short Form

Instructions:

Please state below the two people who are closest to you in your life currently (for example your partner, mother, father, child, sibling, close friends etc). For each person please circle a number from 1 to 7 to show how well he or she provides the type of help that is listed, at present.
The second part of each question asks you to rate how you would like things to be if they were exactly as you hoped for. As before, please put a circle around one number between 1 and 7 to show what your rating is.

Person 1:.....

	Never Sometimes Always
1 a. Can you trust, talk to frankly and share your feelings with this person?	1 2 3 4 5 6 7
b. What rating would your ideal be?	1 2 3 4 5 6 7
2. a. Can you lean on and turn to this person in times of difficulty?	1 2 3 4 5 6 7
b. What rating would your ideal be?	1 2 3 4 5 6 7
3. a. Does he/she give you practical help?	1 2 3 4 5 6 7
b. What rating would your ideal be?	1 2 3 4 5 6 7
4. a. Can you spend time with him/her socially?	1 2 3 4 5 6 7
b. What rating would your ideal be?	1 2 3 4 5 6 7

Person 2: .....

1 a. Can you trust, talk to frankly and share your feelings with this person?	1 2 3 4 5 6 7
b. What rating would your ideal be?	1 2 3 4 5 6 7
2. a. Can you lean on and turn to this person in times of difficulty	1 2 3 4 5 6 7
b. What rating would your ideal be?	1 2 3 4 5 6 7
3. a. Does he/she give you practical help?	1 2 3 4 5 6 7
b. What rating would your ideal be?	1 2 3 4 5 6 7
4. a. Can you spend time with him/her socially?	1 2 3 4 5 6 7
b. What rating would your ideal be?	1 2 3 4 5 6 7

PLEASE CIRCLE ONE NUMBER ONLY FOR EACH QUESTION

APPENDIX 14. : Stressful Life-Events Inventory

Please circle the number 1 in the 'Yes' column for each event which has taken place since you started treatment. Then circle a number on the scale which best describes how
upsetting the event circled was to you e.g. 10 for death of husband

EVENT	NO	YES	SCALE
1. Bought house	0	1	1 2 3 4 5 6 7 8 9 10
2. Sold house	0	1	1 2 3 4 5 6 7 8 9 10
3. Moved house	0	1	1 2 3 4 5 6 7 8 9 10
4. Major house renovation	0	1	1 2 3 4 5 6 7 8 9 10
5. Separation from loved one	0	1	1 2 3 4 5 6 7 8 9 10
6. End of relationship	0	1	1 2 3 4 5 6 7 8 9 10
7. Got engaged	0	1	1 2 3 4 5 6 7 8 9 10
8. Got married	0	1	1 2 3 4 5 6 7 8 9 10
9 Marital problem	0	1	1 2 3 4 5 6 7 8 9 10
10. Awaiting divorce	0	1	1 2 3 4 5 6 7 8 9 10
11. Divorce	0	1	1 2 3 4 5 6 7 8 9 10
12. Child started school/nursery	0	1	1 2 3 4 5 6 7 8 9 10
13. Increased nursing responsibilities	0	1	1 2 3 4 5 6 7 8 9 10
for elderly or sick person	0	1	1 2 3 4 5 6 7 8 9 10
14. Problem with relatives	0	1	1 2 3 4 5 6 7 8 9 10
15. Problems with friends/neighbours	0	1	1 2 3 4 5 6 7 8 9 10
16. Pet related problems	0	1	1 2 3 4 5 6 7 8 9 10
17. Work related problems	0	1	1 2 3 4 5 6 7 8 9 10
18. Change in nature of work	0	1	1 2 3 4 5 6 7 8 9 10
19. Threat of redundancy	0	1	1 2 3 4 5 6 7 8 9 10
20. Changed job	0	1	1 2 3 4 5 6 7 8 9 10
21. Made redundant	0	1	1 2 3 4 5 6 7 8 9 10
22. Unemployed	0	1	1 2 3 4 5 6 7 8 9 10
23. Retired	0	1	1 2 3 4 5 6 7 8 9 10
24. Increased or new bank loan/mortgage	0	1	1 2 3 4 5 6 7 8 9 10

EVENT	NO	YES	SCALE
25. Financial difficulty	0	1	1 2 3 4 5 6 7 8 9 10
26. Insurance problem	0	1	1 2 3 4 5 6 7 8 9 10
27. Legal problem	0	1	1 2 3 4 5 6 7 8 9 10
28. Emotional or physical illness of close family or relative	0	1	1 2 3 4 5 6 7 8 9 10
29. Serious illness of close family or relative requiring hospitalisation	0	1	1 2 3 4 5 6 7 8 9 10
30. Surgical operation experienced by family member or relative	0	1	1 2 3 4 5 6 7 8 9 10
31. Death of husband	0	1	1 2 3 4 5 6 7 8 9 10
32. Death of family member or relative	0	1	1 2 3 4 5 6 7 8 9 10
33. Death of close friend	0	1	1 2 3 4 5 6 7 8 9 10
34. Emotional or physical illness of yourself	0	1	1 2 3 4 5 6 7 8 9 10
35. Serious illness requiring hospitalisation of yourself	0	1	1 2 3 4 5 6 7 8 9 10
36. Surgical operation on yourself	0	1	1 2 3 4 5 6 7 8 9 10
37. Pregnancy	0	1	1 2 3 4 5 6 7 8 9 10
38. Birth of baby	0	1	1 2 3 4 5 6 7 8 9 10
39. Birth of grandchild	0	1	1 2 3 4 5 6 7 8 9 10
40. Family member left home	0	1	1 2 3 4 5 6 7 8 9 10
41. Difficult relationship with children	0	1	1 2 3 4 5 6 7 8 9 10
42. Difficult relationship with parents	0	1	1 2 3 4 5 6 7 8 9 10