Sick and Tired: Understanding and Managing Sleep Difficulties in Fibromyalgia Syndrome

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Attestation of Authorship

"I hereby declare that this submission is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person (except where explicitly defined in the acknowledgements), nor material which to a substantial extent has been submitted for the award of any other degree or diploma of a university or other institution of higher learning".

Signature: Date:

Co-authored Works

Although the studies included within this thesis were primarily my own ideas and work, they would not have been possible without the advice and support of my supervisors and a number of collaborators.

The first three studies incorporated within this thesis were completed in the UK under the supervision of Dr Mark Cropley. All three supervisors have provided support with the data analysis and interpretation of the findings for this thesis.

My contribution to each of the studies forming part of the overarching thesis was as follows:

For the study described in Chapter Four, I was responsible for developing the research proposal, project materials and ethics committee application, which were refined through consultation with one of my supervisors Dr Mark Cropley. I would like to acknowledge the contribution of Kirsty Humphrey, an MSc student, from the University of Surrey, UK, who helped me with the participant recruitment, collation of the questionnaires and data entry for the study described in Chapter Four. I conducted the data entry checks, cleaning of the data and data analysis. The results were discussed with my supervisors who contributed to their interpretation and in the publication of the findings within this thesis and the published paper.

For the two studies which are outlined and discussed in Chapters Five and Six, I was primarily responsible for the completion of all aspects of the projects including writing the research proposals, obtaining ethical approval, recruiting participants, completing the data collection (including conducting all the interviews for the qualitative study) and data analysis. All aspects of the development of the studies were discussed with my supervisor Dr Mark Cropley to ensure the study was conducted to be best possible standard.

For the fourth study, described in Chapter Seven, the project was developed as a joint collaboration with Dr Mark Cropley. Dr Cropley lead the grant application for funding from the University of Surrey and I provided input into the design of the study and refinement of the intervention used to ensure this met the needs of people with FMS. I

was also responsible for preparing the study documentation and facilitating participant recruitment. On success of the grant application we appointed a part-time research assistant to provide support with the administration of the project. I would like to acknowledge the valuable contribution of Joanna Rodriquez, an MSc student, from the University of Surrey, UK. Joanna's role involved providing administrative support, such as sending out the materials to eligible participants, ensuring follow up data was received and entering the data into the SPSS database. On completion of the data collection, I completed the data entry checks and data analysis.

A letter confirming my contribution to the studies incorporated within this thesis from Dr Mark Cropley is contained in the appendices (see Appendix R).

Acknowledgments

This thesis would not have been possible without the volunteers who kindly gave up their time to take part in this research and who were willing to share their experiences. I would like to express my sincere gratitude to the study participants and the Fibromyalgia Association, UK.

I am also extremely grateful to have worked with such a supportive team of supervisors, who not only helped to guide me through this thesis, but have facilitated my development as a health professional. They have always been there to talk ideas through, to provide an encouraging word and offer timely feedback. Above all, I offer them my sincere thanks for their belief in me, which has helped me to believe in myself.

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Research Equipment

Cambridge Neurotechnoloy UK who provided technical support with the actigraphy equipment.

Intellectual Property Rights

There are no intellectual property rights associated with this thesis.

Ethical Approval

Ethics approval was obtained from the University of Surrey, Committee of Ethics for the four research studies encompassed in this thesis.

Study One, described in Chapter Four: 'An investigation into the relationship between sleep, pain, fatigue and quality of life in Fibromyalgia patients' (Ref: EC/2005/24/PSYCH). Ethics approval received on 3rd June 2005 (see Appendix C).

Study Two, described in Chapter Five: This study analysed additional data collected from participants in Study One. 'An investigation into the relationship between sleep, pain, fatigue and quality of life in Fibromyalgia patients' (Ref: EC/2005/24/PSYCH). An extension to administer the same assessment measures to a sample of healthy controls was applied for and approved on 10th October 2005 (see Appendix G).

Study Three, described in Chapter Six: 'Exploring the role of sleep in Fibromyalgia Syndrome' (Ref: EC/2007/48/Psych). Ethics approval received on 28th June 2007 (see Appendix L).

Study Four, described in Chapter Seven: 'Effects of a guided relaxation routine on sleep and quality of life in people with Fibromyalgia Syndrome' (Ref: 133-PSY-07). Ethical approval received on 6th June 2007 (see Appendix P).

Confidential Material

No participant identifying material is contained within this thesis. Participants will be identified using their unique study registration number to protect anonymity.

Abstract

Sleep disturbance has been highlighted as one of the key difficulties for people diagnosed with Fibromyalgia Syndrome (FMS). Objective findings have revealed that there may be underlying changes in the sleep structure for this population. However, there is little evidence regarding how people perceive their sleep quality, the nature of the specific difficulties they experience or how sleep affects their daily lives. The purpose of this thesis was to explore the nature and extent of sleep difficulties in people with FMS, the psychological factors that may contribute to poor sleep quality and the impact of sleep on people's lives. The thesis also aimed to explore a possible strategy for the management of sleep disturbance in FMS.

After completion of a literature review of research focusing on sleep and FMS, mixed research methods were applied to address the aims of this thesis. Two quantitative studies, (one utilising a cross-sectional questionnaire and the other using a case-control design), explored the sleep quality in people with FMS and the links between sleep and other symptoms of FMS. A qualitative study using interpretative phenomenological analysis was employed to elaborate on these quantitative findings, to explore what sleep disturbance means to people with FMS. A pilot study was then conducted to explore a possible intervention to improve sleep quality for people with FMS based on the findings of the previous three studies.

Sleep disturbance was found to affect a greater number of people with FMS than previously identified. Poor sleep quality had a profound effect on people's lives, affecting other symptoms of the condition such as pain and fatigue, as well as reducing their ability to engage in daily activities. Night-time awakenings and feelings of high levels of arousal on awakening were found to have the most profound impact in FMS, with people experiencing 'blocks of sleep' lasting several hours throughout the night. Psychological factors such as negative affect, perceived levels of stress and beliefs about sleep were found to be significantly associated with poor sleep quality. A brief mindfulness based intervention aiming to reduce stress and cognitive arousal, proved to be feasible and showed positive trends in sleep quality post-intervention in comparison to a progressive muscle relaxation control group intervention, and may be a potential treatment intervention for people with FMS.

The role of sleep in FMS appears to be more complicated than previously described, with sleep, psychological factors and health outcomes highly interlinked. A revised model displaying the relationships between sleep and pain is proposed based on the findings of this thesis. Non-pharmacological interventions specifically aimed at improving perceived sleep quality should form an important component to treatment approaches for people with FMS.

Introduction

Sleep disturbance has a substantial impact on functioning and quality of life for people with Fibromyalgia Syndrome (FMS), however little is known about the nature of the sleep disturbance experienced or how sleep quality can be improved in this population. In order to improve healthcare provision and quality of life, a greater understanding about the nature of the sleep disturbance experienced and the role of sleep in FMS is needed.

The purpose of this thesis was to extend the current knowledge base using a mixed methods approach.

The specific objectives of this thesis were to:

- Describe the nature and extent of self-reported sleep difficulties in FMS
- Explore the psychological factors that may contribute to poor sleep quality in patients with FMS
- Explore how sleep quality affects patients' symptoms and daily lives
- Pilot a possible intervention to improve sleep quality for patients with FMS

The first step of this thesis was to review the existing literature on FMS and sleep (see Appendix A for search strategy). To extend the current knowledge base, and to answer the overall research question and objectives of this thesis, a combination of quantitative and qualitative research methods needed to be employed. Psychological processes (such as the experience of physical illness) are highly complex, and can be influenced by a number of causative and influential factors. A concurrent mixed methods design (where the methods are used to complement each other) offers the best approach to understanding such a complex phenomenon. In addition, to address the aims of this thesis, exploring both the extent and the nature of sleep disturbance in FMS and possible management approaches, a mixed methods approach forms the framework of this thesis.

Four interlinked, but distinct research studies are discussed within this thesis. Each study explores a different objective, with the findings combined into a cohesive whole in order to address the overarching research question. The studies completed as part of this thesis were developed over a five year period. At the onset of this thesis in 2005

little information was available as to the underlying cause of the condition, let alone the types of sleep difficulties people perceived they were experiencing. Over the duration of this thesis, there have been significant advances in our understanding of the condition, including a movement towards FMS being considered as a neurological, rather than a rheumatological condition. Consequently, it was important to ensure that the most current literature was used to inform the interpretation of the findings. Literature available up until March 2010 has, therefore, been included within this thesis where most appropriate to make sense of the field and the research. The overall thesis has been structured into eight chapters following the development of the work completed:

- Chapter One explores the literature on FMS, its impact on both individuals and society and current treatment approaches.
- In Chapter Two, the current knowledge base on sleep and insomnia, and the factors affecting sleep quality in the general population are discussed.
- Chapter Three integrates and extends the information within the first two chapters by reviewing the literature specifically focusing on sleep in FMS.
- In response to the findings of the literature review outlined in the first three chapters, Chapter Four aims to address some of the gaps identified in the current literature by exploring the links between sleep quality, coping and other symptoms of FMS such as pain and fatigue.
- Chapter Five extends the findings of the study described in Chapter Four by examining the psychological factors that may influence sleep quality in FMS, by comparing people with FMS with healthy controls.
- Using a qualitative approach to elaborate on the quantitative findings of the studies in Chapters Four and Five, Chapter Six examines people's experiences of sleep, the role of sleep on quality of sleep and the meaning of poor sleep quality for people with FMS. This chapter aims to explore the needs of patients with FMS, to identify the key areas that would need to be addressed in a proposed intervention to improve sleep quality.
- Chapter Seven pilots an intervention to improve sleep quality for people with FMS based on the results of the previous studies within this thesis.
- The discussion in Chapter Eight combines evidence from the existing literature with the research conducted within this thesis. Implications of the research findings for clinical practice and future research are proposed.

Each of the four research studies incorporated within this thesis, will be described in a separate chapter of this thesis. A discussion of the issues relating specifically to each study will also be included within the chapter. The findings are then synthesised in the final chapter (Chapter Eight) with a discussion of the issues relating to the thesis as a whole.

Defining Terms Central to the Thesis

The term Fibromyalgia Syndrome will be shortened to FMS (a commonly used acronym) throughout this thesis, to increase the readability of the text. A glossary of acronyms and terms has been provided at the end of this thesis for ease of reference.

Insomnia is often used interchangeably to describe both a symptom (e.g. lack of sleep) and a sleep disorder (primary insomnia). There are three different diagnostic classification systems for insomnia; The International Classification of Disease (ICD-10), Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition and the International Classification of Sleep Disorders (2001). In the presence of an underlying medical condition, insomnia is referred to as 'secondary insomnia', although the different guidelines propose different classification criteria. The diagnosis of secondary insomnia is further complicated as there is a need to identify whether the underlying medical condition is causal or co-morbid to the insomnia (McCrae & Lichstein, 2001). Indeed, the ICD-10 only recognises secondary insomnia as a disorder if the complaint of insomnia is the primary concern above the underlying medical condition (World Health Organization, 1992). Consequently, secondary insomnia is often not diagnosed and treatment continues to focus on the underlying medical condition, even though the insomnia may be partially independent of the underlying condition and may require specific intervention.

Other common sleep disorders occurring in adulthood include:

- Periodic limb movement disorder which is characterized by 'periodic episodes of repetitive and highly stereotyped limb movements that occur during sleep' associated with night-time awakening and daytime sleepiness (American Academy of Sleep Medicine, 2001);

- Psychophysiologic insomnia which is a disorder where poor sleep is the result of tension and learned associations leading to decreased functioning during the daytime. It is observed that most patients are light sleepers even before developing psychophysiologic insomnia (American Academy of Sleep Medicine, 2001) and;
- Paradoxical insomnia (sleep state misperception) is a disorder where there is no objective evidence of insomnia or excessive daytime sleepiness (American Academy of Sleep Medicine, 2001).

Due to the interchangeability of the term 'insomnia', the difficulties of diagnosing 'secondary insomnia' and the fact that many people have significant sleep difficulties that do not meet the diagnostic classifications for insomnia (Ohayon & Reynolds, 2009), the terms 'sleep disturbance' and 'poor sleep quality' will be used throughout this thesis instead of the term 'insomnia'. The specific types of sleep disturbance (e.g. problems falling sleep or waking up during the night) will be referred to as 'sleep difficulties'.

A further distinction that needs to be outlined when reading this thesis, is the distinction between fatigue and perceptions of feeling sleepy (daytime sleepiness). These two terms have previously been used interchangeably in the literature, within current assessment scales and by both health professionals and patients. However, the terms may hold different meanings and interpretations for different people (Pigeon, Sateia, & Ferguson, 2003). In an attempt to distinguish between the two terms, Pigeon et al (2003) proposed that, sleepiness refers to feelings of drowsiness, decreased alertness and an urge to return to sleep, and fatigue relates to feelings such as weariness, weakness and depleted energy. The terms fatigue and sleepiness will be used within this thesis based on these definitions by Pigeon et al (2003).

Chapter One. The Context of Fibromyalgia Syndrome (FMS)

This chapter will first review the evidence of the clinical presentation and underlying cause of FMS, and will then describe the history of the condition and diagnostic criteria. The current literature on the extent and effect of FMS on individuals, their families and society will then be reviewed, before exploring how the condition is currently managed in clinical practice.

Clinical Presentation of FMS

FMS is a chronic medical condition where the most prominent symptom is widespread chronic pain. Additional symptoms include fatigue, sleep disturbance and cognitive difficulties (Mease, 2005). Emerging evidence suggests that the condition may arise from irregularities in the neuroendocrine and autonomic nervous systems (Mease et al., 2007). People with FMS have been found to have increased sensitivity to stimuli (such as temperature and pressure) in comparison to controls (Berglund, Harju, Kosek, & Lindblom, 2002; Lautenbacher, Rollman, & McCain, 1994). Although these initial studies were based on people's subjective interpretations of the term 'painful', more recent advances in functional magnetic resonance imaging (fMRI) have provided objective, supporting evidence of this finding. For example, studies using fMRI have shown that people with FMS have increased blood flow in a greater number of areas of the brain in response to the application of painful pressure or heat stimuli in comparison to controls. The higher levels of activation are reported to occur in the areas of the brain involved in processing pain and twice as much pressure was needed to yield the same levels of activation in the control group (Cook et al., 2004; Gracely, Petzke, Wolf, & Clauw, 2002). In a subsequent study using magnetic resonance imaging, people with FMS were found to have significantly lower gray matter volume in the cingulo-frontal cortex and the amygdala (areas associated with the modulation of pain processing) in comparison to controls, although the authors noted that these differences in gray matter volume could be a result of medication taken to relieve symptoms rather than linked to FMS directly (Burgmer et al., 2009).

Lower levels of the neurotransmitters, serotonin and norepinephrine, which are involved in the inhibition of pain responses, have also been observed in people with FMS (Russell, 1998). This suggests that people with FMS have both augmented sensitivity

and are less able to inhibit the pain response (Mease, 2005). Genetic factors, depression and the experience of stressful life events (such as surgery, childbirth or traffic accidents) have been linked to an increased risk of developing FMS, although the evidence is often inconsistent (Al-Allaf et al., 2002; Arnold et al., 2004; Forseth, Husby, Gran, & Forre, 1999; Kato, Sullivan, Evengard, & Pedersen, 2006; McBeth, 2005).

No physiological marker for FMS has been identified and diagnosis is usually made after the exclusion of other possible causes of pain (such as rheumatoid arthritis, systemic lupus erythematosus and polymyalgia rheumatica) (Marcus, 2009). Although no specific risk factors have been identified, smoking (Yunus, Arslan, & Aldag, 2002b), high Body Mass Index (Yunus, Arslan, & Aldag, 2002a), lower levels of education and unemployment (White, Speechley, Harth, & Ostbye, 1999b) have all been associated with increased severity of symptoms.

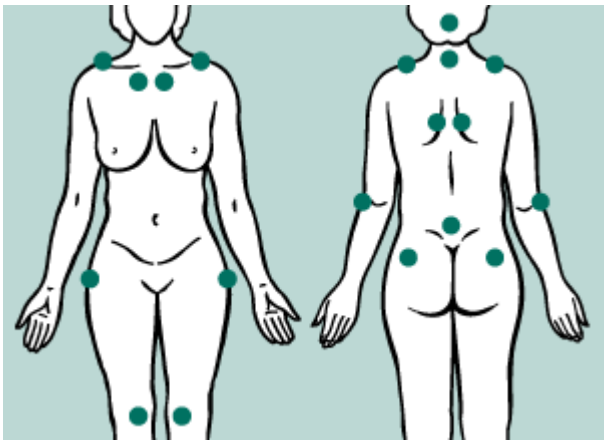
FMS was first described by clinicians, in the 1800s, as muscular rheumatism. At the beginning of the following century the condition became known as 'fibrositis' (suggesting inflammation of the fibrous tissue); until the term was changed to 'Fibromyalgia Syndrome (FMS)' in 1976, to reflect the lack of evidence of inflammation within the condition. It was not until 1987 that the condition was recognised by the American Medical Association. The term FMS continues to suggest that FMS is a rheumatological condition and patients are most commonly diagnosed and treated by rheumatologists, however, as indicated above, the latest evidence points to the fact that symptoms of FMS have a neurological, rather than a rheumatological basis (Moldofsky, 2009).

Diagnosis

The most commonly applied diagnostic criteria is the American College of Rheumatology (ACR) criteria (Wolfe et al., 1990), which defines FMS as persistent widespread pain (across four quadrants of the body) for >3 months and pain in ≥11 out of 18 tender points on digital palpitation, using the amount of pressure sufficient to blanch a finger nail or approximately 4kg pressure (see Figure 1, p. 7) (Wolfe et al., 1990). High tender point scores have been be found to correlate with higher levels of disability (Lundberg & Gerdle, 2002) and the criteria have been found to have 88%

sensitivity and 81% specificity to distinguish people with FMS from controls (Wolfe et al., 1990).

Figure 1. Tender point sites according to the ACR (1990) diagnostic criteria



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The ACR criteria (Wolfe et al., 1990) offered a more refined approach to diagnosis in comparison to previously proposed criteria (Smythe & Moldofsky, 1977; Yunus, Masi, & Aldag, 1989a). However, the ACR criteria have received wide criticism due to their reliance on patients' subjective views of pain and inability to account for the observed high variability in symptoms. For example, someone who may meet the criterion number of tender points on one day, may not meet the criteria the following day; and patients are often diagnosed with less than 11 tender points (Bennett, 1998). The ACR criteria may also be criticised for not acknowledging the wide range of symptoms that patients with FMS experience, including fatigue, cognitive difficulties (such as difficulty concentrating and word retrieval) and sleep disturbance (Mease, 2005). It has also been argued that tender points may not be measuring a discrete entity, as many people without FMS have increased sensitivity in these areas of the body. One study has revealed that the ACR criteria are not reliable in their ability to distinguish people with FMS from those with chronic widespread pain, and that the criteria only distinguishes patients with more severe pain symptoms (Bidari, Ghavidel-Parsa, & Ghalehbaghi, 2009).

MacFarlane, Croft, Schollum, and Silman (1996) proposed more stringent criteria proposing that pain should be experienced in two or more sections of the "contralateral limbs and axial pain" in order to be defined as FMS. However, this criterion is not

widely applied in clinical practice and continues to be subject to similar criticisms of the ACR criteria, such as not being sensitive to the high variability in symptoms and being reliant on patient self-report. Consequently, despite the known limitations, the ACR criteria is the current recommended diagnostic criteria for FMS and is the most commonly applied criteria in clinical practice.

Despite the fact that the ACR criteria has been the recognised diagnostic criteria for two decades, in view of its critique it is perhaps not surprising that recognition and diagnosis of FMS remains highly variable between clinicians (Hughes, Martinez, Myon, Taieb, & Wessely, 2006). The high co-morbidity observed with other conditions such as chronic fatigue syndrome (CFS), irritable bowel syndrome (Hudson, Goldenberg, Pope, Keck, & Schlesinger, 1992) systematic lupus erythematosus (Gladman, Urowitz, Gough, & MacKinnon, 1997) and rheumatoid arthritis (Weir et al., 2006) makes diagnosis difficult. The most common confusion occurs between CFS and FMS which have many overlapping symptoms. Based on comparison of the two diagnostic criteria (ACR, Wolfe et al., 1990), and the US Centers for disease control criteria for CFS, it appears that the main distinction relates to the most prominent symptom experienced by the patient; pain is a core criteria for FMS with the possible co-occurrence of fatigue, while fatigue is the essential criteria for CFS with the possible co-occurrence of pain. The high degree of overlap between symptoms of these two conditions, and indeed others, has led some clinicians to argue that FMS may not be a distinct medical condition but rather that these conditions may lie on a spectrum of pain and fatigue. This has resulted in some clinicians questioning the legitimacy of FMS (Schaefer, 2003). In light of the recent evidence, described at the beginning of this chapter, implicating the central nervous system for the symptoms experienced by people with FMS, it appears that FMS may be a distinct clinical entity from CFS (which is believed to linked to a hyper-reactive immune system and triggered by viral or other infectious agents) and that the two conditions should therefore be studied separately to avoid possible contamination of the findings.

In recent qualitative studies, many FMS patients have described that the diagnosis of FMS appears ‘empty’ due to the lack of recognition, respect, knowledge and effective treatment options for the condition (Madden & Sim, 2006; Sim & Madden, 2008; Undeland & Malterud, 2007). This has important implications for patients for whom it may take several years to receive a diagnosis to explain the symptoms that they are experiencing (which will be discussed further in the exploring the impact of FMS

section, following the discussion of the prevalence of FMS, p. 9) (Arnold et al., 2008). Due to the wide variability in diagnosis, limitations of the diagnostic criteria and risk of misdiagnosis, the classification of FMS therefore needs to be interpreted with some caution in research.

Prevalence

Prevalence estimates of FMS vary considerably from 0.7% up to 11% (Branco et al., 2010; Kivimaki et al., 2007; Lindell, Bergman, Petersson, Jacobsson, & Herrstrom, 2000; White, Speechley, Harth, & Ostbye, 1999c; Wolfe, Ross, Anderson, Russell, & Hebert, 1995). In a general population study conducted in New Zealand, the prevalence of FMS has been estimated to be 1.1% in Maori and 1.5% in New Zealand European (Klemp, Williams, & Stansfield, 2002). In Europe, prevalence estimates of 0.18% and 2.8% have been estimated (Branco et al., 2010; Hughes et al., 2006). Research has consistently revealed that FMS predominantly affects females (female: male ratio of 6-10:1), with prevalence estimates of between 3-5% in females and 0.5-1.6% in males (Wolfe et al., 1990; Yunus, 2001). The wide variability in prevalence estimates may be due to the differences in: 1) the sample population (for example in different age groups); 2) the type of setting (e.g. general population or hospital setting); 3) the diagnostic criteria used to classify FMS (as not all studies based their inclusion criteria on the ACR criteria); and 4) the research methodology applied (e.g. retrospective or prospective designs may yield different results). For example, a study conducted in the UK reported lower prevalence estimates of 0.18%, using a retrospective design within a primary care setting (Hughes et al., 2006). The lower prevalence estimates are likely to be affected by poor data recording in clinical practice and by the regional variation in diagnostic patterns observed within the study.

Impact of FMS

FMS can affect people of any age, including children, although onset most commonly occurs in working age adults, with the highest prevalence rates between 30 and 60 years of age (Hughes et al., 2006; White et al., 1999c). The diagnostic criteria for diagnosing children with FMS is different to that applied to adults, as it is based on the occurrence

of fewer tender points; usually between 5 and 11 tender points (Yunus & Masi, 1985). Children have been found to have a more favourable prognosis than adults (Buskila, 2009) and the consequences of their symptoms due to the different daily demands placed on them, are likely to be different to that of adults, therefore making comparisons difficult. Consequently this thesis will focus specifically on adults (>18 years of age) with FMS.

Longitudinal studies have revealed that there is little or no change in the health status of people with FMS, with symptoms persisting at the same level of severity for as long as 15 years after diagnosis (Kennedy & Felson, 1996; Ledingham, Doherty, & Doherty, 1993; Mengshoel & Haugen, 2001; Wolfe et al., 1997). Although one study has revealed that older age was associated with lower levels of pain, fatigue and depression in FMS (Reisine, Fifield, Walsh, & Forrest, 2008). It should be noted that the earlier studies showing little change in symptom severity over time were conducted before a change in recommended clinical treatment, as described in the current management section at the end of this chapter (Carville et al., 2008).

FMS is associated with significantly high societal and health care costs (Bernatsky, Dobkin, De, & Penrod, 2005; Hughes et al., 2006; Penrod et al., 2004; Sicras-Mainar et al., 2009). For example, in the UK, FMS patients have been found to make more than double the number of visits to health care services than non-FMS controls and have higher prescription rates (Hughes et al., 2006). This increased level of health care use has been found to remain stable over the course of the illness, despite an initial decrease in service utilisation during the year following diagnosis (White et al., 1999c). FMS is also associated with high indirect costs to society, as many people with FMS are forced to leave employment, reduce their working hours or have increased absence from work as a result of their FMS symptoms (Burckhardt, Clark, & Bennett, 1992; Kivimaki et al., 2007; Sicras-Mainar et al., 2009; White, Speechley, Harth, & Ostbye, 1999a). The UK findings are supported by a survey conducted in the US which found that 26% of people with FMS were receiving some form of disability benefit. Considering that FMS predominantly affects working age adults and that the long term prognosis remains poor, the costs of FMS to society are considerable.

On an individual basis, FMS can have a profound effect on peoples' lives (Arnold et al., 2008). Research has shown that people with FMS report significantly lower quality of

life in comparison to the general population (Epstein et al., 1999; Martinez et al., 2001) and experience higher levels of pain and quality of life than people with other chronic pain conditions, such as rheumatoid arthritis (Callahan, Smith, & Pincus, 1989). People with FMS frequently report that their experience of symptoms varies over the course of a day, with greater levels of pain and fatigue in the late afternoon/evening (Arnold et al., 2008). People with FMS have described that the fluctuating and unpredictable nature of pain, fatigue and cognitive impairment can make planning and pacing activities difficult (Arnold et al., 2008; Cunningham & Jillings, 2006). The fluctuating natures of symptoms can lead to difficulties in maintaining social relationships and reducing their engagement in activities as they unable to commit to scheduled arrangements (Arnold et al., 2008; Cunningham & Jillings, 2006; Lofgren, Ekholm, & Ohman, 2006). Symptoms appear to be interconnected, with pain, fatigue, poor sleep and cognitive difficulties each being affected by the other (Arnold et al., 2008).

As mentioned, earlier in this chapter, the impact of the symptoms of the condition may be perpetuated by a feeling of the lack of credibility, the invisibility of symptoms and low public awareness (Arnold et al., 2008; Lempp, Hatch, Carville, & Choy, 2009; Madden & Sim, 2006; Sim & Madden, 2008; Undeland & Malterud, 2007). Qualitative studies have revealed that many people with FMS experience negative interactions with the medical profession and are perceived to be 'difficult patients' by clinicians (Lempp et al., 2009). This may reflect the frustrations of both the patients and the medical profession due to the lack of availability of effective treatment options and only recent advances in understanding the pathophysiology of the condition (Arnold et al., 2008). Due to the lack of understanding about the condition and few treatment options, social relationships can become strained, and many people with FMS have described losing their self confidence, sense of personal control over their lives and experiencing social isolation and loss of intimacy with others (Arnold et al., 2008; Lempp et al., 2009; Sim & Madden, 2008). The burden extends to families and partners who also need to adapt to the person's illness by taking on additional tasks, experiencing a change in social roles and learning to adapt to the variable nature of the person's symptoms (Soderberg, Strand, Haapala, & Lundman, 2003).

Current Management Strategies

The treatment of FMS has changed dramatically over the last five to 10 years, and indeed during the duration of the work completed as part of this thesis. Previously, treatment of FMS focused on the use of medication to manage specific symptoms (such as prescribing pain killers for symptoms of pain), rather than acting on an identified physiological cause. Recent advances in our understanding of the pathogenesis of the condition has lead to treatments focusing on the use of serotonin noradrenaline reuptake inhibitors (such as milnacipran and duloxetine) and medications for neuropathic pain (such as pregabalin and gabapentin). These medications have demonstrated moderate efficacy in the treatment of FMS (Arnold et al., 2007; Choy et al.; Hauser, Bernardy, Uceyler, & Sommer, 2009; Mainguy, 2009) and all four medications have recently been approved for the treatment of FMS by the Food and Drug Administration in the US; although the availability of these medications for FMS in the UK and NZ is more restricted.

Despite their limited reported efficacy, many patients with FMS often find the side effects of the above named medications (such as drowsiness and dizziness), difficult to tolerate. For example, in a meta-analysis of pregabalin it was reported that between one in three, and one in 10 participants with FMS discontinued the use of pregabalin because of adverse side effects (Moore, Straube, Wiffen, Derry, & McQuay, 2009). In another clinical trial, it was reported that 33% of participants dropped out of the study due to treatment related adverse events (Mease, Russell et al., 2008).

The European League Against Rheumatism (EULAR) stipulate that in addition to pharmacotherapy, exercise should form an important part of a multi-disciplinary treatment approach for people with FMS (Carville et al., 2008). In a Cochrane review of 34 studies of exercise for people with FMS (Busch, Barber, Overend, Peloso, & Schachter, 2007), it was revealed that aerobic exercise had moderate positive effects on physical functioning, psychological well-being, pain and the number of tender points. However, only one study was deemed to be of high quality in the meta-analysis and sample sizes for all studies in the analysis were small (with intervention group sample sizes ranging from 16 -51). In addition, Busch et al (2007) commented that participant adherence to the exercise interventions appeared to be poor, with many participants reporting that they experienced an exacerbation of symptoms during the intervention

period. This was reflected in the high attrition rates, with 13-44% of participants withdrawing from the intervention. The authors deemed there to be insufficient evidence to explore the effects of muscle strengthening or flexibility training (Busch et al., 2007). These findings have been supported by qualitative research which has revealed that many patients struggle to complete daily activities requiring physical effort (such as housework), as they exacerbate symptoms of pain and fatigue (Cunningham & Jillings, 2006).

These findings have significant clinical implications. Although prescribed a programme of exercise in accordance with management guidelines, many patients may find it difficult to adhere to exercise programmes both due to the fluctuating nature of their symptoms, making engagement in a regular exercise routine difficult and managing the resulting increases in pain and fatigue after an exercise session (Jones, Clark, & Bennett, 2002). As FMS is believed to result from central sensitisation to pain, it may be the case that different types and intensities of physical activity have different effects. Emerging evidence suggests that people with FMS need tailored low intensity exercise programmes that focus on using concentric contraction activities (movements completed slowly and allow the body to return to its resting state before completing further movements such as slow stretching) to avoid intensifying the pain signals sent from the muscles to the nervous system and increasing perceptions of pain. Therefore activities using repetitive movement or movements against a force (such as resistance training or swimming) which can aggravate pain signals, need to be completed for very short periods of time (for example, less than 10 minutes) and include regular rest periods with a focus on avoiding over-stretching (Jones & Liptan, 2009).

This has lead to an increase in research exploring the effects of less intense exercise approaches in people with FMS. Promising improvements in health outcomes have been found for pool based exercise (Calandre et al., 2009; Mannerkorpi, Nordeman, Ericsson, & Arndorw, 2009), Pilates (Altan, Korkmaz, Bingol, & Gunay, 2009), vibration exercise (Alentorn-Geli, Padilla, Moras, Lazaro Haro, & Fernandez-Sola, 2008; Gusi, Parraca, Olivares, Leal, & Adsuar), Qi-gong (Haak & Scott, 2008) and increasing lifestyle activities (Fontaine, Conn, & Clauw, 2010). However, the findings continue to be limited by small sample sizes, and full clinical trials that are powered to detect significant differences in health outcomes are needed to provide support for these initial findings (Thomas & Blotman, 2010). The effectiveness of exercise interventions are

also likely to depend on a number of individual factors, such as current level of physical condition, age, BMI and presence of other co-morbid conditions. Consequently FMS patients may need individually tailored exercise programmes to help them, both in terms of being able to complete everyday life activities, as well as physical exercise to improve their quality of life and reduce the experience of symptoms.

Barriers to engaging in physical activity may also arise from psychological factors, such as fear of aggravating symptoms, low motivation and difficulties understanding and adjusting to living with FMS. To support people with FMS to manage their emotional reactions to the condition and to support them to overcome the challenges they face integrating recommended treatments into their lives (Carville et al., 2008), psychological interventions may be beneficial in FMS. However, systematic reviews of non-pharmacological interventions have not yet been conducted and the effectiveness of approaches focusing on psychological factors remains unclear. Due to the complex nature of symptom presentation in FMS and limitations of current pharmacological treatments, current management guidelines suggest the need for a multi-disciplinary treatment approach to improve patient outcomes and quality of life (Carville et al., 2008; Hauser, Thieme, & Turk, 2009). However, further investigation of the role of psychological factors and interventions addressing these factors is required to inform treatment.

Conclusion

FMS is a common, chronic pain condition where people may experience a wide range of symptoms including pain, fatigue, cognitive difficulties and sleep disturbance. Due to the lack of an objective diagnostic tool and high degree of symptom overlap with other conditions such as chronic fatigue syndrome, the validity of the diagnosis of FMS continues to be questioned. Current management guidelines suggest the need for a multidisciplinary approach to treatment incorporating pharmacological, exercise and psychological treatments due to the complex clinical presentation of the patient group. However, current treatment approaches have low reported efficacy. The profound impact that the condition has on people's lives, in addition to the high health care and societal costs, means that a greater understanding of the condition is needed to improve treatment and quality of life for people with FMS.

Chapter Two. The Role of Sleep

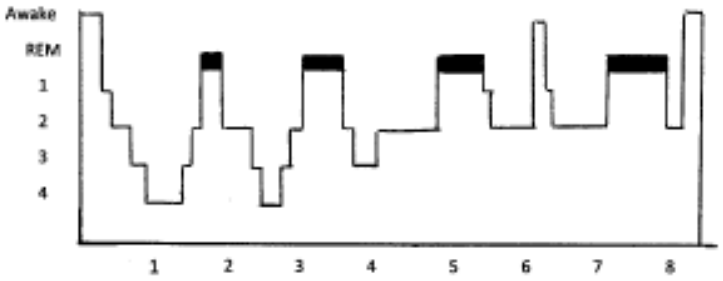
The Normal Sleep Process

Sleep is considered to be the most important recovery mechanism available to humans, and good sleep is essential for optimal well-being, daily functioning and health (Morin & Espie, 2003). Poor sleep quality can lead to increased fatigue, negative mood changes and in extreme cases, can even lead to impaired immune function (Lorton et al., 2006; Rogers, Szuba, Staab, Evans, & Dinges, 2001). Even moderate sleep loss is associated with deficits in alertness and performance on cognitive and physical tasks (Jewett, Dijk, Kronauer, & Dinges, 1999). The amount people sleep has also been linked with life expectancy, with too little or too much sleep associated with increased mortality risk (Doghramji, 2006; Gallicchio & Kalesan, 2009). Sleep may be as important as diet, exercise and genetics (Hublin, Partinen, Koskenvuo, & Kaprio, 2007).

The sleep process usually consists of five sleep stages; four stages of Non-Rapid Eye Movement (NREM) sleep, and one stage of Rapid Eye Movement (REM) sleep (Morin & Espie, 2003). Stage one sleep is a transitional stage, lasting approximately five minutes, where the body prepares itself for sleep. This stage is a state of drowsiness and if woken up during this stage, the person may not feel that they have been to sleep at all. Stage two sleep is a light sleep stage where brain activity, heart rate and breathing slow down, and muscle tension is reduced. Sleep becomes progressively deeper through stages three and four (also referred to as slow wave sleep). It is thought that the body has the opportunity to rejuvenate and repair itself during stage four. From stage four sleep people then return back through the sleep stages to the lighter stage of sleep (stage two) before entering REM sleep (stage five). REM sleep is characterised by observed rapid eye movements as if the person is awake, with increased brain activity, heart rate and breathing rates. It is thought that this is the stage where dreaming occurs and the brain processes and stores new information to aid long term memory, although this remains unclear (Morin, 1993). It has been suggested that the brain blocks signals to the muscles in this stage to prevent people from acting out their dreams. People move through each sleep stage in a cycle (see Figure 2, p. 16) lasting approximately 90 minutes which is repeated approximately five times over the course of the night. The length of each sleep stage within a cycle changes over the course of the night, with most

deep sleep (stages three and four) occurring at the beginning of the night and more REM sleep towards the end of the night. It therefore assumed that sleep must be continuous to enable the body to adequately repair and restore itself (Walsh & Lindblom, 1997).

Figure 2. The cycle of sleep stages



■ = REM Sleep

Source: Morin, CM (1993). Insomnia: Psychological Assessment and Management, p. 17, New York Guildford Press. Reprinted with authors permission.

The sleep process is regulated by the hypothalamus which acts as a biological clock controlling states of being awake and sleepiness (known as circadian rhythms). There are variations in people's circadian rhythms, with some people preferring to go to bed earlier and awakening earlier, whereas others may prefer to go to bed later and wake up later (Randler, 2008). These preferences (known as sleep chronotype) may be affected by personality (Cavallera & Giudici, 2007) or mood (Chelminski, Ferraro, Petros, & Plaud, 1999). Further, there is some evidence that these preferences may be heritable (Hur, 2007) and are influenced by the person's underlying circadian rhythm (Duffy, Rimmer, & Czeisler, 2001).

Circadian rhythms involve natural variations in core body temperature, secretion of melatonin and hormones, appetite and alertness over the course of the day. Changes in these physiological processes prepare the body for the onset of sleep or wakefulness (Morin, 1993). Levels of melatonin increase before sleep onset which increases feelings of drowsiness and has a role in reducing the body temperature to facilitate sleep onset.

Cortisol is a hormone that is released throughout the day and regulates the amount of energy required by the body to meet the demands placed upon it at a given time. Levels of cortisol naturally fluctuate throughout the day, with higher levels in the morning and decreasing in the evening when there are fewer demands placed on the body. However, cortisol is also released in response to stress to enable the body to mobilise its resources to cope with the stressor, therefore higher levels of cortisol are associated with higher levels of stress and physiological arousal. Consequently high levels of cortisol may have a role in preventing sleep onset at night if the body is prepared for action. A growth hormone releasing hormone (somatocrinin) also increases during the night, with secretion levels at their peak just before the onset of deep sleep (stages three and four). In addition to increasing muscle mass, it appears that this hormone has a direct influence on promoting deep sleep. For example, one study has revealed that administration of growth hormone releasing hormone in participants during REM sleep has been found to result in a 10-fold increase in deep sleep and is therefore likely to have an important role in the sleep experience (Kerkhofs et al., 1993).

If people do not experience sufficient sleep, there is an increased biological drive for the body to sleep, in order to fulfil the sleep debt. However, the feeling of sleepiness does not consistently increase after a period of sleep deprivation as it is strongly influenced by the natural underlying circadian rhythm. For example, if a person has been awake throughout the night, they may find it difficult to sleep during the day when their natural circadian rhythm has resulted in a higher core body temperature, levels of cortisol and low levels of melatonin, making sleep onset more difficult for the body. This can be a particular issue for people who work night shifts and need to sleep during the day or for those who move between time zones on a long flight resulting in the experience of ‘jet lag’. For some people their natural circadian rhythm is unsynchronised with the schedules determined by society. For example, their body clock ‘may be ahead of society’ (advanced sleep phase syndrome) in which case the person will awaken in the early hours of the morning (e.g. at 3am) and need to fall asleep earlier (e.g. 6pm) (Morin, 1993). If people with circadian rhythm sleep disorders are left to follow their natural circadian rhythms they usually experience good sleep quality, however, the need to adhere with societal routines and timescales can cause these people significant integration difficulties.

Although sleep moves through the sleep stages (as described in Figure 2, p. 16) over the course of the night, there is wide variation in the amount of sleep that people need. Some people may need to sleep for nine or more hours each night to function at their optimum level the following day, while other people function well on less than six hours of sleep per night. On average, people in the western world sleep for approximately 7-8.5 hours per night (Kripke, Simons, Garfinkel, & Hammond, 1979) and take less than 30 minutes to fall asleep (Morin & Espie, 2003). In addition to the individual differences in sleep need between people, the amount of sleep needed also changes over the course of the lifespan. For example, babies need 16-18 hours of sleep across a 24 hour period (and spend nearly 50% of their sleep in the REM sleep stage); children and adolescent need around 9.5 hours of sleep reducing to around 8.5 hours in early adulthood. There is some evidence that as adults become older (over 70 years of age) the amount of sleep needed has been found to reduce even further to around seven hours of sleep per night (with decreased time spent in stage 4 deep sleep) (Morin & Espie, 2003; Redline et al., 2004). However, a meta-analysis of studies that used objective measures of sleep quality over the course of the human lifespan have found that sleep quality does not necessarily decline in a linear relationship and that only minimal changes to the sleep architecture occur after 60 years of age (Ohayon, Carskadon, Guilleminault, & Vitiello, 2004). It has been proposed that it may be the risk factors associated with older age, such as an poorer physical health and reduced levels of physical activity, that may be linked to changes in sleep quality rather than an effect of age itself (Fetveit, 2009).

The underlying mechanisms and natural sleep cycle can easily become unbalanced by a range of external and internal factors that may contribute to chronic sleep disturbance. Physical illness and the experience of pain have been found to significantly disrupt the natural sleep cycle and this will be discussed in more detail later in this chapter. Environmental factors such as the invention and the availability of electricity means that people are now exposed to artificial light and cognitive stimulation (e.g. television and computers) in the evening, which can affect the natural biological clock which responds to light cues and stimulation.

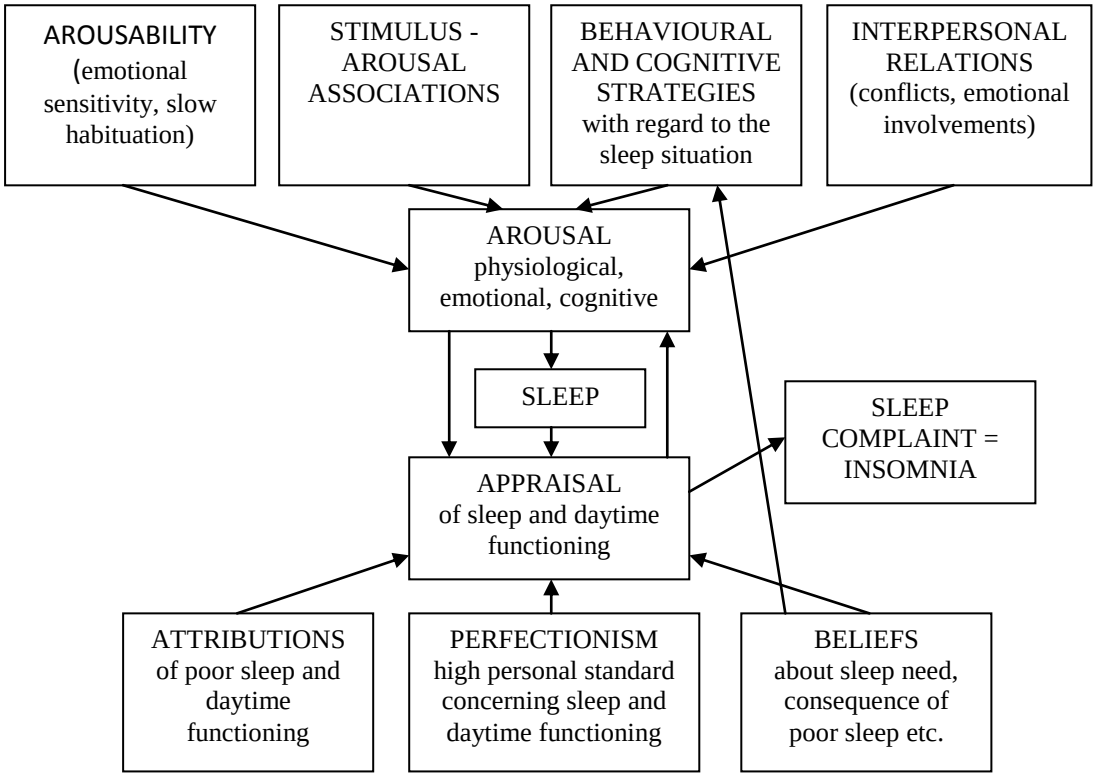
Sleep can also be affected by psychological factors such as expectations of sleep, levels of stress, physical factors such as symptoms of illness and some types of medication,

particularly some pain relieving medications that contain high levels of caffeine. As a stimulant, caffeine can lead to poor sleep quality particularly if ingested close to bedtime. Even moderate amounts of caffeine can affect sleep. For example in one study, adult men were given a 200mg single dose of caffeine (equivalent to one to two cups of regular coffee) or a non active placebo before 7.30 in the morning and were asked not to consume any further caffeine products for the remainder of the day. The results revealed that on the day participants were given the caffeine, they experienced reduced sleep efficiency (total sleep time/time in bed x 100), total sleep time, and increased latency to stage two sleep (Landolt, Werth, Borbely, & Dijk, 1995). This suggests that even a relatively small dose of caffeine can have a considerable effect on sleep.

Bootzin and Nicassio (1978) highlighted the importance of behaviours on sleep quality in their stimulus control theory. They proposed that over time the sleeping environment (e.g. the bedroom) becomes associated with wakefulness and other activities un-associated with sleep. For example, people may also use their bedroom for watching television, working or using a computer or reading, making the bedroom a stimulating environment and therefore increasing arousal. If people experience difficulty sleeping they may also begin to associate being in bed with feeling agitated and frustrated about not being able to sleep and these associations may therefore prevent sleep onset or further disrupt sleep.

Amalgamating the research evidence on the factors affecting sleep quality in people with insomnia, Lundh and Broman (2000) proposed the integrative model of the interaction between sleep-interfering and sleep-interpreting processes. The four boxes at the top of Figure 3 (p. 20) represent the sleep interfering processes and the three boxes at the bottom of Figure 3 highlight the sleep interpretation processes that impact on sleep quality. As shown by the model, these processes are likely to influence each other with beliefs about sleep also directly influencing behaviour and cognitive coping strategies.

Figure 3. The Integrative Model of the interaction between sleep-interfering and sleep-interpreting processes (Lundh & Broman, 2000)



Consequently, as highlighted by the model, people's behaviours, thoughts, environment and physical health all have an important influence on sleep quality. Maintaining the sleep equilibrium can therefore be difficult and it has been estimated that up to 45% of the adult population may experience some form of sleep disturbance (Lugaresi, Zucconi, & Bixler, 1987). The role of these factors on sleep in FMS will be discussed in more detail in Chapters Three, Four and Five.

Measuring Sleep

Objective Measures

Polysomnography provides a comprehensive and objective measure of sleep quality. Electrodes are placed onto the scalp and skin before sleep onset, which monitor and record brain activity. Sensors are also used to monitor air flow (nasal or oral), respiratory effort, oxygen saturation, heart rate and eye movements, muscle tension and

movements in the leg and or face. Polysomnography is often considered to be the 'gold standard' measure of sleep quality. The main benefit of these objective measurements taken in polysomnography is that specific disturbances or sleep disorders (such as sleep apnea and restless legs syndrome) can be detected, even if the person or clinician may not be aware of them. Furthermore, the value of polysomnography was revealed in a study by Jacobs et al (1988) who found that the diagnosis of sleep disorders made solely through clinical evaluation of a cohort of patients who had experienced poor sleep for at least one year, was not supported by polysomnography findings in 49% of cases. Polysomnography evidence was also able to provide evidence of the existence of sleep disorders that had not been identified based solely on clinical evaluation (Jacobs et al., 1988).

Polysomnography is expensive, which limits its use both clinically and in research. Since the Jacobs et al study (1988) a number of reliable and valid measurement tools have been developed specifically to identify cases of sleep apnoea or restless legs syndrome. It is also becoming more routine to interview a patient's bed partner to describe the clinical picture, therefore the added value of polysomnography may now have been reduced. In a clinical context, polysomnography cannot be used in isolation to diagnose insomnia, as a full description of a person's sleep history and how poor sleep affects them is fundamental to all diagnostic and treatment plans (Morin, 1993). Acceptance of the measure by patients is low as people are often required to spend several nights in a sleep clinic for the measures to be taken. Several nights of recordings are needed as the person's sleep quality may be affected by sleeping in a new and unfamiliar environment, as well as being affected by the need to be attached to the equipment throughout the night. Technological advances have now enabled the equipment to be used within a person's home, although this introduces difficulties of ensuring that the equipment is used appropriately to ensure that the recordings are accurate. Another disadvantage of assessing sleep at home is that there is no direct observation of the sleeper, which is usually performed by a technician in a sleep clinic (Morin, 1993).

Core body temperature, melatonin and cortisol levels can also be taken as objective measures when exploring sleep quality. They are particularly useful in assessing for the presence of circadian rhythm disorders. Melatonin and cortisol are secreted into the blood and their levels can be measured with a blood test (Benloucif et al., 2005).

However, conducting a blood test is invasive and could in itself affect a person's sleep quality when taken at night. This approach is therefore difficult to implement in clinical research (Mayer, Leonhard, Krieg, & Meier-Ewert, 1998).

Another objective measure that can be used to detect movement, as an indicator of sleep quality, is actigraphy. Actigraphy monitors levels of physical activity during the night using a non-invasive device (actigraph) worn on the non-dominant arm. Natural movements of the arm are detected by a sensor and each movement is stored as an activity count, which can be summed over epoch intervals of one minute or more. Although actigraphs are fitted to the arm, they have been shown to adequately assess whole body movements (Kop et al., 2005). Actigraphs can be worn during the day and night, and offer the advantage of being able to be used in the person's natural environment for long periods, thus enabling the measurement of the variability of sleep quality over time. Formulas are applied to the collected data to calculate the total amount of time spent asleep, time taken to fall asleep (sleep onset latency), sleep efficiency and the number of night-time awakenings. Actigraphs have been used effectively to monitor both nocturnal and day-time activity levels for patients with FMS (Kop et al., 2005; Korszun et al., 2002) and have been found to correlate well with self-reported sleep quality and polysomnography (Hauri & Wisbey, 1992; Landis et al., 2003). The disadvantage of actigraphy is that it relies on movement as an indication of being awake. If a person is awake but remains motionless e.g. watching TV or resting, actigraphy is unable to distinguish this lack of activity from being asleep and is therefore likely to overestimate the time recorded as asleep (Hauri & Wisbey, 1992; Menefee et al., 2000). This may be particularly problematic in people with chronic pain conditions who are more likely to be sedentary (Kop et al., 2005).

Based on the strengths and weaknesses of objective measures of sleep quality, it is now widely recommended that a combination of objective and subjective measures are used in the measurement of sleep quality (Morin & Espie, 2003)

Subjective Measures

A wide range of subjective measures are currently available to assess nocturnal sleep quality and daytime sleepiness. Each measure has its own strengths and weaknesses and some of the most widely used measures are considered below.

Epworth Sleepiness Scale (Johns, 1991)

The Epworth Sleepiness Scale (ESS) has been widely used in research studies exploring sleep quality (Smith et al., 2008). This scale explores levels of daytime sleepiness by asking people to rate how likely they are to doze or fall asleep in eight specified situations. Ratings are based on a scale of 0 (no chance of dozing) to 3 (high chance of dozing). The ratings for each item are then summed to yield a total score between 0-24 with scores of >10 indicating high daytime sleepiness and that the person is getting an inadequate amount of sleep, with 93.5% sensitivity and 100% specificity to distinguish between high and low levels of daytime sleepiness (Johns, 2000). The ESS has been found to be a reliable measure of excessive daytime sleepiness with good internal consistency (Johns, 2002), and is a useful tool for identifying people who require investigation into possible underlying sleep disorders (Schwartz, 2010). However, confirmatory factor analysis failed to confirm a one factor solution for the scale, and it has been recommended that two items should be revised or removed from the scale as they were only relevant to people with severe daytime sleepiness and to improve the psychometric properties of the scale (Smith et al., 2008). As the ESS was designed for measuring daytime sleepiness, it does not explore the quality of the person's sleep during the night. As this thesis aims to focus on the sleep difficulties that people experience, it was decided that a measure focusing specifically on nocturnal sleep quality was needed.

Numerical Response Scales

A number of previous research studies have measured sleep quality by asking people to rate their quality of sleep on a scale of either 0-10 or 0-100, with verbal prompts offered at each extreme of the scale (e.g. very poor sleep quality at one end and excellent sleep quality at the other). Numerical response scales have been found to be a reliable measure of sleep quality and offers the advantages of being easily understood by participants and being quick and easy to administer (Salaffi, Sarzi-Puttini, Ciapetti, & Atzeni, 2009). However, concepts such as sleep and fatigue may be multidimensional and therefore single numerical response scales offer little description as to any variation between the different components of sleep quality. There is also low consistency in the exact wording used in numerical response scales, suggesting they may be exploring different components of sleep quality or daytime sleepiness making direct comparisons difficult.

As sleep is a complex process involving a number of different physiological processes, sleep is considered to be a multidimensional concept (Davies et al., 2008). There are several different types of sleep difficulties that people can experience such as taking a long time to fall asleep (known as poor sleep latency), awakening during the night (sleep maintenance difficulties) and spending time in bed when not asleep (poor sleep efficiency), as outlined in Chapter Two. It is important to identify what the specific sleep difficulties people experience are, to inform treatment. Therefore measures of sleep quality need to address these different components of sleep quality (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989). A number of subjective measures have been developed to assess the different components of sleep quality which will be described below.

Medical Outcomes Study Sleep Scale (Hays, Martin, Sesti, & Spritzer, 2005; Hays, Sherbourne, & Mazel, 1993b)

The Medical Outcomes Study Sleep Scale (MOS-SS) aims to explore the different components of sleep quality and consists of 12 items exploring six components of sleep quality: sleep disturbance, total sleep time, snoring, awakening with physical symptoms, sleep adequacy and somnolence. Each item has different response scales which are then recoded to yield a score between 0-100. These recoded items are then summed in different combinations to yield the six sub-scale scores and the overall total score. Higher scores indicate poorer sleep quality; except for the sleep adequacy scale where a higher score indicates more adequate sleep. The MOS-SS has revealed good test-retest reliability over one (r =0.81) and four (r = 0.8) week periods for people with fibromyalgia (Sadosky, Dukes, & Evans, 2009). The sub-scales have also revealed adequate inter-item consistency of between 0.73 and 0.87 (Lau, Morlock, & Hill, 2006) and demonstrated sensitivity to change (effect sizes above 0.8 obtained) (Viala-Danten, Martin, Guillemin, & Hays, 2008). On review of the measure, with participants with FMS, it was revealed that two items were deemed to be irrelevant to people with FMS, (snoring and awakening short of breath), and that the measure did not address waking up in the morning which is an issue of particular concern for people with FMS (S. A. Martin, Chandran, Zografos, & Zlateva, 2009).

Pittsburgh Sleep Quality Index (PSQI)

Another measure which also explores the different components of sleep quality is the Pittsburgh Sleep Quality Index (PSQI) (Buysse et al., 1989). The PSQI is based on people's self-reports of sleep quality and contains 19 items measuring the quality and pattern of sleep over the past month. The PSQI has seven components: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. Each component score of the PSQI ranges from 0 (no impairment) to 3 (maximum impairment). These component scores can be summed to yield a global PSQI score ranging between 0–21, with higher scores indicating poorer sleep quality. A PSQI global score of >5 has been recommended to be used to indicate significant disturbance (Moul et al., 2002), however, others have proposed a more stringent score of >6 (Sayar, Arikan, & Yontem, 2002). The PSQI has been used effectively in both clinical (Carpenter & Andrykowski, 1998) and non-clinical samples (Gray & Watson, 2002), and has been found to be more significantly associated with symptom ratings and sleep diary measures than the ESS. The PSQI has also demonstrated acceptable internal consistency with cronbach's alpha coefficients between 0.77 to 0.83 revealed (Buysse et al., 1989; Carpenter & Andrykowski, 1998). The measure has been found to have sensitivity for identifying those with poor sleep quality at the level of >6, 93.4% of the time (Backhaus, Junghanns, Broocks, Riemann, & Hohagen, 2002). A test-retest correlation of 0.85 (Buysse et al., 2008b) has been revealed for overall sleep quality and the measure has demonstrated sensitivity to treatment related change six-eight weeks post-intervention (Germain, Shear, Hall, & Buysse, 2007). The PSQI has demonstrated ability to reveal differences in perceived sleep quality between two populations, for example, revealing that patients with cancer report significantly poorer overall sleep quality and daytime dysfunction than healthy controls (Owen, Parker, & McGuire, 1999). Despite revealing changes in sleep quality between young and older adults, the PSQI retains the ability to distinguish between good and poor sleepers in people even over the age of 80 years (Buysse et al., 1991). However, as is commonly the case, the measure has not always been found to correlate well with polysomnographic measures of sleep quality (Buysse et al., 2008a; Buysse et al., 1991). The PSQI and the ESS have been found to have low correlations with each other and only the daytime dysfunction subscale of the PSQI appears to be linked to the same construct of daytime sleepiness as measured by the ESS; suggesting the two distinct constructs of sleep assessed by these two measures (Buysse et al., 2008a).

Sleep Diaries

Sleep diaries are a key part of the evaluation of sleep quality as they provide an overview of the person's sleep pattern over time (Morin, 1993). Sleep diaries are completed each morning and consist of small number of questions about the previous nights sleep. Questions typically refer to the time the person went to bed, the time they fell asleep, the number of times that they awoke each night, the time they woke up in the morning, and a rating of the quality of their sleep and how refreshed they felt in the morning (Morin, 1993). Diaries have been found to be of value in both clinical practice and research. In clinical practice diaries are helpful to identify factors that may be influencing sleep quality, e.g. sleep is consistently poorer on certain nights of the week, as well as providing a tool to show people that they are getting more sleep than they thought or highlighting improvements in sleep quality during and after a course of treatment (Morin, 1993).

Overall, previous research studies comparing self-reports of sleep quality with objective measures of sleep (actigraphy) have revealed that people with chronic pain conditions are reliable in their reports of the total amount of time they spend asleep and their sleep efficiency (Wilson, Watson, & Currie, 1998). However, the amount of time it takes to fall asleep (sleep onset latency) is often overestimated (Carskadon et al., 1976). It may be argued that it is a person's perception of sleep quality that is most important for treatment as even if no sleep difficulties are identified using objective measures, if the person reports experiencing poor sleep and feeling un-refreshed in the morning then this needs to be addressed. For example, if a person experiences seven hours of sleep a night, with only two disturbances during the night, this may not indicate a sleep disturbance using objective measures. However, it may be that the person has a natural sleep need of 9 hours for optimal daytime functioning (or has an increased sleep need due to recovery from illness or injury) and they describe feeling un-refreshed after sleep and spending long periods of time in bed lying still but awake. These aspects of sleep quality are more easily picked up using subjective measures of sleep quality. Indeed, subjective measures have been found to be a reliable and valid measure of sleep quality even though they do not always correlate with objective measures (Morin & Espie, 2003).

Affects of Poor Sleep

Research into the affects of sleep deprivation date back to late 19th century when it was observed that after approximately 90 hours of sleep deprivation, participants demonstrated reduced sensory acuity, slower reaction times and poorer memory and motor skills (Patrick & Gilbert, 1896). Although the sample size in this early study was small (N=3), research findings have consistently revealed that even short periods of sleep deprivation or poor sleep quality can lead to significant impairments, including slower information processing (through poor concentration and memory), increased feelings of pain, fatigue, daytime sleepiness, increased morbidity and mortality, absenteeism from work, likelihood of being involved in an accident and reduced engagement and enjoyment of daily activities (Gander, Marshall, Harris, & Reid, 2005; Kripke, Garfinkel, Wingard, Klauber, & Marler, 2002; Morin & Espie, 2003; Totterdell, Reynolds, Parkinson, & Briner, 1994; Zammit, 1988). The effects of poor sleep quality are important to recognise given that in the general population, poor sleep quality is reported by 56% of people in the US, 36% in the UK, 34% in France, 33% in Germany, 30% in Italy, 23% in Spain and 23% in Japan (Leger, Poursain, Neubauer, & Uchiyama, 2008). Consequently, poor sleep is now considered to be a significant public health problem (Gander, 2003).

The Links between Sleep and Pain

As previously highlighted, one of the affects of poor sleep quality appears to be increased sensitivity to pain. Cooperman et al (1934) were one of the first to explore this phenomena by observing that all six healthy participants who were deprived of sleep for approximately 60 hours, revealed an increase in reported pain sensitivity using the Hairs of von Frey procedure (Cooperman et al., 1934). The Hairs of Von Frey procedure consists of a collection of very thin nylon filaments (hairs) tied together. It is based on the assumption that the same amount of pressure is needed to bend the hairs when the hairs are pressed against the skin and this can then be used to test skin sensitivity when the hairs are pressed against different areas of the body. To further investigate the finding by Cooperman et al (1934), a number of studies have explored the effect of depriving participants with specific stages of sleep to explore the effect on perceived sensitivity using dolorimetry (a device which applies heat or electrical stimulation to a specific area at different intensities until it produces a sensation of

pain). Lentz et al (1999) revealed that after three nights of disrupted stage four (deep) sleep, participants reported increased pain sensitivity. However, this finding was not replicated in a similar study by Older (1998). Onen et al (2001) found that only total sleep deprivation (and not specifically stage four or REM sleep deprivation), was associated with increased pain sensitivity. The inconsistent findings between these studies may, however, be a reflection of the lack of statistical power in the three studies which only included between 9 and 13 participants (Smith & Haythornthwaite, 2004). Generalisation of the findings for people with chronic sleep disturbance may also be difficult, as the effects of acute induced sleep deprivation may not be directly comparable to the effects of chronic poor sleep quality (Smith & Haythornthwaite, 2004).

Using a different approach, Chiu (2005) investigated pain sensitivity in 424 participants who completed a questionnaire about their sleep quality, and revealed that those who reported experiencing sleep difficulties were significantly associated with increased pain sensitivity, as measured by dolorimetry. These findings were subsequently supported in a similar study of patients with rheumatoid arthritis (Lee et al., 2009) where higher sleep disturbance reported using the MOS-SS was significantly associated with increased pain sensitivity using dolorimetry. This suggests that pain and sleep are linked, although the cross-sectional nature of the studies prevents any sense of causality being explored.

Further evidence of the links between sleep and pain is revealed through the high prevalence of self-reported poor sleep quality in patients with chronic pain conditions. Although the percentage of patients with poor sleep quality does vary between chronic pain conditions, the percentage of people with chronic pain reporting poor sleep ranges between 50-70% (Morin, Gibson, & Wade, 1998; Pilowsky, Crettenden, & Townley, 1985; Smith, Perlis, Smith, Giles, & Carmody, 2000), with one study revealing up to 89% of patients reporting at least one difficulty with sleep (McCracken & Iverson, 2002). These are substantially higher rates than those reported in the general population (23-56%) (Leger et al., 2008).

Poor sleep quality has consistently been found to correlate significantly with perceptions of pain severity in a number of chronic pain conditions (Pilowsky et al., 1985). McCracken (2002) revealed that in a sample of 287 participants, who completed

a questionnaire exploring perceived sleep quality, pain severity, depression and physical disability, after controlling for pain and depression, sleep disturbance explained 29% of the variance in physical disability, 58% of psychosocial disability, and 31% of physical symptoms. In addition, Stone, Broderick, Porter, & Kaell (1997) revealed that perceptions of pain were significantly correlated with perceptions of sleep quality recorded, using an electronic sleep diary over one week in participants with rheumatoid arthritis. A similar finding has also been revealed in patients with acute pain after a burn injury (Raymond, Nielsen, Lavigne, Manzini, & Choiniere, 2001). Significant associations have also been found between perceptions of pain severity and objective measures of sleep quality (Wilson et al., 1998). These finding suggest that despite the use of different measures, sleep quality has a consistent independent effect on health outcomes in chronic pain conditions.

Nature of Sleep Disturbance in Chronic Pain

Exploring the types of sleep difficulties that people with chronic pain conditions experience, Smith et al (2000) asked 51 participants receiving treatment for a variety of chronic pain conditions to complete the PSQI (described above), asking about their perceived sleep quality over the previous month. It was revealed that participants slept on average six hours per night, with a mean sleep onset latency of 48 minutes (in comparison to 7-8.5 hours sleep per night and sleep onset latency of <30 minutes for the general population). When asked about the reason for their sleep disturbance, 60% of participants attributed their poor sleep quality to the experience of pain, and just over half of participants stated that they did not experience sleep difficulties prior to the onset of their chronic pain. This once again suggests that pain may have a direct effect on sleep quality. These findings were subsequently supported in a cross-sectional study of 3,246 participants, across five European countries, who were interviewed about their sleep quality over the telephone. For the participants who reported some form of chronic pain (including rheumatic conditions, musculoskeletal pain, backache, headaches and painful gastrointestinal diseases) the most common sleep difficulties experienced were difficulties falling asleep (increased sleep onset latency) and reduced time spent asleep (total sleep time) due to awakening during the night (night-time awakenings) and waking up early in the morning (Ohayon, 2005).

These results have also been supported in studies using objective measures of sleep quality. In a recent case-control study (O'Donoghue, Fox, Heneghan, & Hurley, 2009) 15 participants with chronic low back pain and 15 age and gender matched controls were asked to complete the PSQI and a measure of health related quality of life (Short Form Medical Outcomes Survey SF-36). In addition, participants completed a daily sleep diary and wore an actigraph for three consecutive nights. Findings revealed that participants with chronic back pain had significantly lower sleep efficiency, but that there was no difference in the total sleep time or sleep onset latency between the two groups based on both the subjective and objective measures of sleep quality. However, the sample size in this study was too small to ensure statistical power to detect a significant difference between the two groups. Using polysomnographic recordings, Wittig et al (1982) revealed that patients with a range of chronic pain conditions spent less time asleep, displayed lower sleep efficiency and longer sleep onset latencies, in comparison to a group of patients reporting insomnia, once again highlighting the severity of the sleep disturbance in patients with chronic pain (Wittig et al., 1982).

As illustrated by the studies described above, the main issues for patients with chronic pain are difficulties falling asleep, a short time spent asleep and sleep efficiency, although the type of sleep difficulties experienced does vary between studies (Abad, Sarinas, & Guilleminault, 2008). These differences could suggest that sleep quality may be condition specific and future studies could explore sleep quality in specific disease groups, rather than in samples of a variety of chronic pain conditions. The differences may also reflect the different assessment methods and study designs used, making direct comparisons between the study findings difficult. The cross-sectional designs of the studies described also prevent any notion of causality to be determined.

Two longitudinal studies exploring pain and sleep, one which followed patients with rheumatoid arthritis at baseline and two years later (N = 242) (Nicassio & Wallston, 1992), and the other which focused on orofacial pain patients and followed them up over eight months (N = 128) (Riley et al., 2001), revealed that sleep quality assessed at baseline, was not independently associated with levels of pain at follow up, suggesting that sleep may not be predictive of pain in the longer term. However, both studies highlighted that baseline levels of pain severity were independently predictive of sleep quality at follow up. These findings suggest that pain may have an important influence on long term sleep quality, and is supported by the 90% of people stating that the start

of their sleep difficulties coincided with the onset of pain (Morin, Kowatch, & Wade, 1989). However, it is unlikely that these relationships of complex constructs are linear (Call-Schmidt & Richardson, 2003) and longitudinal studies exploring the interplay between these factors over time are needed to draw strong inferences.

In addition to the higher rates of sleep difficulties reported in people with chronic pain conditions, there is also emerging evidence of a higher prevalence of specific sleep disorders with an underlying organic cause that is not directly related to the chronic pain condition. In a study utilising polysomnography in patients with rheumatoid arthritis, it was revealed that 8 of the 13 patients (62%) studied were found to have sleep apnoea, periodic leg movement disorder, or a combination of the two (Lavie et al, (1991). These findings were supported by Mahowald, Mahowald, Bundlie and Ytterverg (1989) who found that in a sample of 16 patients with rheumatoid arthritis, all participants displayed frequent movements of their arms and legs indicative of periodic limb movement disorder, and two participants were diagnosed with sleep apnoea. However, these findings are limited by the very small sample sizes employed and the lack of age and gender matched controls (Menefee et al., 2000). Further, the above studies do not explore the possible mechanisms that may be causing the higher levels of sleep difficulties within the chronic pain population. The use of polysomnography for research, and clinical purposes, is also reduced due to the cost and difficulties accessing polysomnographic equipment.

Factors Affecting Sleep Quality in Chronic Pain

As described earlier in this chapter, a number of factors can affect sleep quality and these may be of particular importance in patients with chronic pain. For example, older adults are at greater risk of experiencing a chronic pain condition and poor sleep and that the aging process seems to affect changes to the underlying sleep structure. Because higher levels of physical activity have been found to be associated with better sleep quality (Brand et al., 2010) it may also be the case that as chronic pain can reduce engagement in physical activity (through the need to rest or take a daytime nap to relieve symptoms of pain), that the reduced physical activity may consequently affect sleep quality (Cohen, Menefee, Doghramji, Anderson, & Frank, 2000). Although this interpretation was not supported in a cross-sectional study of 287 chronic pain patients

(McCracken & Iverson, 2002) which showed that few (only 16%) participants reported napping during the daytime.

Depression and anxiety have been consistently found to be higher in people with chronic pain, possibly due to the demands of living with a chronic condition (Fishbain, Cutler, Rosomoff, & Rosomoff, 1997), and there is evidence that mood may also have an influential role in people's perceptions of sleep quality. In a sample of 51 participants with chronic low back pain, Atkinson et al (1988) revealed that perceived poor sleep quality was more highly correlated with depression than disease severity. This finding was supported by the objective polysmonographic evidence recorded for a sub-sample of the participants, which indicated that mood has an important role in the experience of sleep. In people with chronic non-malignant pain conditions (including headache, back ache and neck ache), Sayar et al (2002) revealed that depression was the most significant factor associated with poor sleep quality in the regression analysis. However, this finding was not supported in a sample of patients seeking outpatient treatment for a range of chronic pain conditions in the study conducted by Morin et al (1998) which found that there was no significant difference in mood between participants classified as good or poor sleepers, as defined by the participants themselves. The validity of these findings may be questioned as the study did not utilise standardised measures of sleep or mood. The role of mood and sleep disturbance therefore warrants further investigation, to explore if the inconsistent findings may just be a reflection that the difference in study findings is due to different pain populations investigated.

Medications to relieve the symptoms of chronic pain or antidepressants can alter the underlying sleep architecture. Increased night-time awakenings and levels of nocturnal arousal and insomnia can be side effects of taking such medication (McCrae & Lichstein, 2001). Indeed McCraken and Iverson (2002) revealed that poor sleep quality was significantly associated with use of anti-depressants, although it is unclear whether this was directly related to the medication itself or to the underlying depression. Evidence from studies of rats have also revealed that sleep disturbance (particularly disturbance to REM sleep), may interfere with opiod analgesic medication by inhibiting opiod protein synthesis and opiod receptors, and reducing the ability of the serotonin system to inhibit pain (Lautenbacher, Kundermann, & Krieg, 2006; Shapiro &

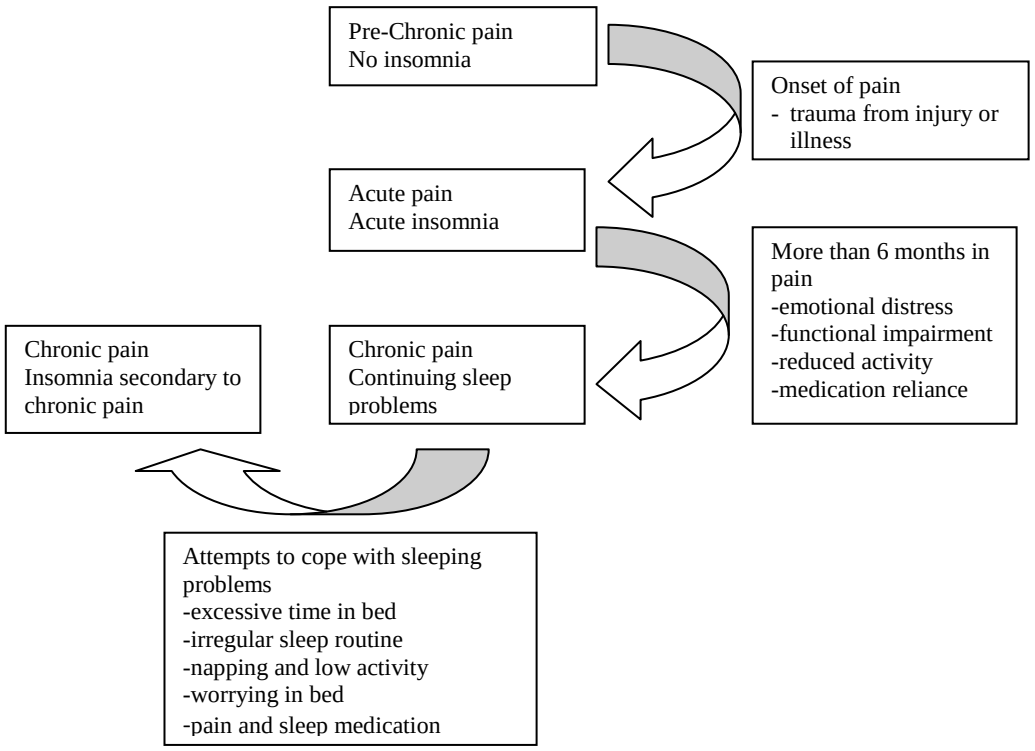
Girdwood, 1981). This effect of poor sleep may be occurring in people with chronic pain, although these effects need further exploration in humans.

The Development and Maintenance of Sleep Difficulties in Chronic Pain

The emerging evidence suggests that there is a reciprocal relationship between sleep and pain and that a number of factors may influence this relationship. Psychological models have been proposed to try to explain how these factors may influence pain and sleep quality. The models are all based on the concept that the link between sleep and pain is bi-directional and that a vicious cycle of poor sleep, pain and fatigue develops, resulting in the chronicity of symptoms.

In their conceptual model of the psychological development of sleep problems in people experiencing chronic pain, Currie et al (2000) proposed that although pain may be a major factor leading to sleep difficulties, the ways people respond to their pain and initial sleep difficulties can either assist in the resolution or exacerbation of their sleep difficulties. For example, reducing physical activity levels during the day, worrying about the consequences that a poor nights sleep may have on their ability to function the next day and using medication, may all lead to chronic sleep disturbance (see Figure 4, p. 34).

Figure 4. Conceptual model of the development of sleep difficulties in chronic pain (Currie et al., 2000)

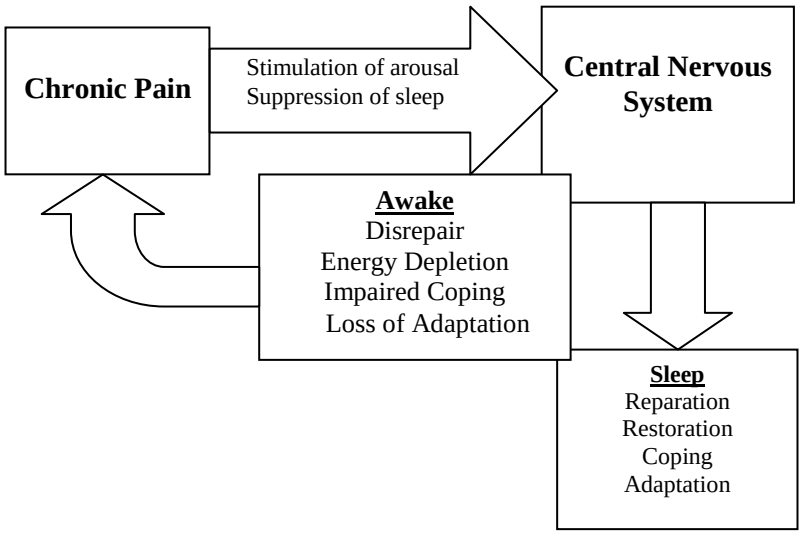


Masi et al (2002) have criticised this model by highlighting that other factors have been found to affect sleep quality, such as anxiety and depression, are not incorporated into the conceptual model. However, the model has been effectively used to inform treatment of insomnia for people with chronic pain, based on cognitive behavioural techniques which support the use of adaptive coping strategies in response to pain and sleep difficulties (Currie et al., 2000).

Despite the wealth of evidence suggesting a bi-directional relationship between sleep and pain, there is little research exploring the potential physiological mechanisms underlying the link. In a review of the sleep and chronic pain literature, Smith and Haythornthwaite (2004) highlighted that areas of the brain involved in the onset and maintenance of sleep (such as the mesencephalic periaqueductal gray and the thalamus), are also involved in the modulation of pain. Neurotransmitters such as acetylcholine are also involved in both sleep and pain regulation, suggesting that a neurological dysfunction may underlie both chronic pain severity and sleep disturbance (Lautenbacher et al., 2006). Incorporating theses physiological processes in their conceptual framework of sleep and pain, Call-Schmidt and Richardson (2003) propose

that there are recursive links between pain, central nervous system arousal and psychological factors, such as the reduced ability to cope and sleep (see Figure 5). They suggested that the experience of pain activates areas of the brain responsible for maintaining arousal and suppresses the areas that are responsible for initiating and maintaining sleep.

Figure 5. Conceptual framework of pain and sleep (Call-Schmidt & Richardson, 2003)



These models offer useful descriptions as to how chronic sleep disturbance may occur in chronic pain based on the research evidence. However, when applied to more complex pain conditions such as FMS, these models do not take into account other symptoms, such as fatigue and cognitive difficulties that have been associated with poor sleep (Dinges & Kribbs, 1991; Moldofsky, 2001; Nicassio, Moxham, Schuman, & Gevirtz, 2002). These models suggest that although pain may precede some sleep difficulties, once sleep difficulties are established they may then become self sustaining and require specific intervention (Cohen et al., 2000).

Clinical Implications

Despite the profound implications of poor sleep on health and daily functioning, people rarely seek advice from clinicians for their poor sleep (Tubtimtes, Sukying, & Prueksaritanond, 2009) and if suspected or reported, poor sleep is often not specifically treated, even with hypnotic medication (National Institute of Health, 2005). However, as the models and research evidence suggests, there is a reciprocal relationship between sleep and pain. Treating only the pain may help to improve sleep quality but may not fully resolve chronic sleep difficulties which will continue to affect levels of pain. Studies exploring the course of sleep problems in chronic illness have revealed that in 88% of cases, if left untreated, sleep difficulties can persist for up to two years (Ganguli, Reynolds, & Gilby, 1996; Katz & McHorney, 1998). This suggests that sleep difficulties need to be specifically addressed in treatment for chronic pain (Roehrs, 2009).

In instances where a sleep disturbance is identified in clinical practice, hypnotic medications are the most frequent treatment, despite little evidence to support the continued efficacy of hypnotic medication with prolonged use, and as expected, any positive effects of the medication only continue for as long as the medication is taken (Morin, Belanger, Bastien, & Vallieres, 2005). Hypnotics have been associated with increased mortality and long term use of the medication is not recommended (Mallon, Broman, & Hetta, 2009). In addition, medications do not address the psychological and behavioural factors that have been found to be important in the development and maintenance of chronic sleep difficulties.

Non-pharmacological interventions, comprising of cognitive and behavioural therapy strategies designed for the treatment of primary insomnia (insomnia occurring without the existence of a co-morbid medical condition), have demonstrated consistent improvements in sleep quality (Morin, Culbert, & Schwartz, 1994; Murtagh & Greenwood, 1995), with 70-80% of participants experiencing beneficial effects from treatment (Morin & Wooten, 1996) and with significant improvements still evident after several years (Backhaus, Hohagen, Voderholzer, & Riemann, 2001). However, access to full programmes of cognitive behavioural interventions delivered by sleep specialists is expensive and highly limited in current clinical practice. Therefore alternative

treatments to improve interventions to address sleep difficulties in patients with chronic pain are needed.

Chapter Three. Sleep in FMS

As highlighted in Chapter One, the experience of poor sleep quality is common in FMS with between 70-90% of patients reporting some form of sleep disturbance (Osorio, Gallinaro, Lorenzi-Filho, & Lage, 2006; Rao & Bennett, 2003; Yunus, Masi, & Aldag, 1989b) and feeling un-refreshed in the mornings (Landis, Lentz, Tsuji, Buchwald, & Shaver, 2004). Using focus groups to elicit the key symptoms of FMS that had the most impact on people's lives, Arnold et al (2008) revealed that sleep disturbance was one of the greatest concerns for people with FMS. Many participants stated that their other symptoms of pain and fatigue would be more manageable if they could improve their sleep "if I can get sleep, I can fix all the rest" (Arnold et al., 2008, p. 117). In the same study, participants also reported that their symptoms were worse first thing in the morning, as they woke up in pain. The importance of sleep for people with FMS has been supported in a study by Kolar et al (1989), who found that in a regression analysis, sleep disturbance was more strongly associated with severe pain than tender points; suggesting that sleep is an important contributory factor in the experience of pain in FMS.

In a large internet survey of 2,569 participants with FMS in the US, participants reported that their most severe symptoms in the past week were morning stiffness, fatigue and non-restorative sleep. Pain was only rated fourth in order of severity. Participants also identified sleep problems as one of the most exacerbating factors of FMS symptoms (Bennett, Jones, Turk, Russell, & Matallana, 2007). Although the study sample may not be representative of the FMS population as a whole (as only people with access to the internet who were registered with the National Fibromyalgia Association were able to participate), this study strengthens the evidence base on the importance of sleep for people with FMS. It also appears that the prevalence of sleep disturbances is even higher in people with FMS than patients with other chronic pain conditions. For example, in FMS Osorio et al (2006) revealed that 90% of participants had a PSQI global score that indicated clinically significant poor sleep quality. This compares to an average of 50-70% of participants with other chronic pain conditions (Morin et al., 1998; Pilowsky et al., 1985; Smith et al., 2000) and 23-56% of people in the general population (Leger et al., 2008), as revealed in previous studies. However, different ways of defining 'poor sleep' quality in each of these studies makes direct comparisons difficult. To address this difficulty, a recent study directly compared

participants with FMS and participants with rheumatoid arthritis. Findings revealed that participants with FMS were five times more likely to have poor sleep (Belt, Kronholm, & Kauppi, 2009).

Possible Underlying Physiological Mechanisms of Poor Sleep in FMS

Early research exploring sleep in FMS focused on identifying possible physiological factors (such as abnormalities in the sleep architecture) of people with FMS. Initial work exploring nocturnal brain waves conducted by Moldofsky, Scarisbrick, England, & Smythe, (1975), using EEG showed that seven out of 10 people with FMS displayed alpha wave intrusions (brain waves that are associated with wakefulness) during sleep stages one to four of sleep (NREM, which is usually characterized by delta brain waves) leading to increased arousal and awakenings. These findings were later supported in another study revealing that nine out of 10 participants with FMS displayed alpha wave intrusions during NREM sleep (Branco et al., 2010). Exploring the phenomena in more detail, a subsequent study revealed that the alpha wave intrusions occurred in three different patterns during NREM sleep. The authors classified the three patterns as: 1) phasic – where the alpha waves occurred simultaneous with the delta waves; 2) tonic – where the alpha waves were evident continuously during NREM sleep stages; and 3) low alpha activity – where there were some but not many alpha waves evident. The FMS participants were more likely to display phasic alpha wave activity (50% of the FMS sample) than controls, and this alpha wave pattern was associated with higher levels of pain, tender points, reduced time spent asleep and reduced stage 4 restorative (slow wave). In comparison 84% of healthy controls experienced low alpha activity, with only 30% of participants with FMS experiencing low alpha activity (Roizenblatt, Moldofsky, Benedito-Silva, & Tufik, 2001). These studies therefore highlight a possible physiological abnormality causing sleep disturbance in FMS.

However, as highlighted in the Roizenblatt et al (2001) study, alpha wave intrusions were also evident in 16% of healthy controls and the existence of the alpha wave intrusion has not always been found to be significantly different between people with FMS and controls. Consequently the phenomena may not be unique to people with FMS and may not be directly linked to FMS symptoms such as pain and fatigue (Carette, Oakson, Guimont, & Steriade, 1995; Horne & Shackell, 1991; Manu et al., 1994; Rains

& Penzien, 2003), although alpha wave intrusions may contribute to increased arousals during the night and exacerbate existing sleep difficulties (Perlis, Giles, Bootzin et al., 1997).

Other studies using polysomnography have identified other potential differences in the sleep architecture of people with FMS. For example, Branco et al (1994) revealed that participants with FMS spent less time in deep sleep (stages three and four) and spent more time awake than controls. The authors proposed that reduced time spent in these stages of sleep (believed to be involved in helping the body to restore and repair itself), may contribute to the exacerbation of symptoms in FMS (Branco et al., 1994). This finding was supported by Sergi et al (1999) who observed that people with FMS spent increased time in stage one (light) sleep, in comparison to controls. Indeed, this increase in stage one sleep, in people with FMS, has been the most consistent polysomnographic finding across studies (Cote & Moldofksy, 1997; Landis et al., 2004; Shaver et al., 1997). Additional research suggests that the increase in light sleep may be linked to an observed increase in nocturnal arousals and sleep fragmentation throughout the night (Jennum, Drewes, Andreasen, & Nielsen, 1993; Sergi et al., 1999; Shah, Feinberg, & Krishnan, 2006; Shaver et al., 1997).

The findings from studies using polysomnography have also been supported through the use of actigraphy in people with FMS. One study exploring activity levels over the course of the day and through the night over five consecutive days, revealed that people with FMS displayed more activity during the night (despite equivalent levels of daytime activity) in comparison to controls (Korszun et al., 2002). Korszun et al (2002) also revealed that people with FMS experienced significantly more nocturnal awakenings during the night than controls. These findings are suggestive that people with FMS experienced increased time in the lighter stages of sleep (Kop et al., 2005; Korszun et al., 2002) and have a greater number of nocturnal awakenings supportive of the polysomnographic findings. However, the findings were not supported in a study by Landis et al (2003), although this study only explored actigraphy recordings taken over three consecutive days and therefore may not have accounted for the variability in sleep quality over time. The control group used within this study was also not matched for age and gender making direct comparisons difficult. In addition, as previously highlighted, studies using polsysomnography and actigraphy have been limited by small sample sizes and the inconsistent findings may therefore reflect methodological issues

and a lack of power of the studies to detect any differences between FMS patients and healthy controls.

There does not appear to be any changes in the circadian rhythms of people with FMS, with studies revealing no significant changes in levels of cortisol, melatonin and core body temperature measured over the course of three days in comparison to controls (Chervin et al., 2009; Klerman, Goldenberg, Brown, Maliszewski, & Adler, 2001). Studies have highlighted that people with FMS have abnormal levels of neurotransmitters and neurons that may be interlinked and involved in sleep regulation, such as nocturnal growth hormone secretion (Landis et al., 2001), lower levels of serotonin (Russell et al., 1992; Vaeroy, Helle, Forre, Kass, & Terenius, 1988a) and increased levels of substance P (Vaeroy, Helle, Forre, Kass, & Terenius, 1988b). These abnormalities may be partially responsible for the observed reduced time spent in deep sleep at night and increased nocturnal arousals (Lashley, 2003). However, these findings need further investigation to explore their role on sleep quality and other health outcomes in FMS.

Consequently, it would appear from the various objective studies of sleep in FMS, that there is evidence of increased lighter (stage one) sleep, nocturnal activity and awakenings during the night. It has been proposed that the need to change positions during the night to relieve physical discomfort may interrupt sleep, leading to fragmented and non refreshing sleep (Boissonnault & Fabio, 1996), although the cause of these changes in the underlying sleep architecture and how the sleep disturbance manifests in FMS remains unclear.

Sleep Disorders in FMS

The findings that there are potentially fundamental changes in the sleep architecture of people with FMS, may be further supported through evidence of a higher prevalence of specific sleep disorders with an identified physical cause in people with FMS. For example, Shah et al (2006) revealed that 19 out of 23 (83%) participants with FMS displayed pauses in breathing, lasting 10 seconds or more, at least 15 times over an hour, which is indicative of sleep apnoea (known as the apnoea hypopnea index). Although other studies have found that the number of pauses in breathing have not reached the level required for a formal diagnosis of the disorder sleep apnoea (e.g.

pauses in breathing indicative of sleep apnea are considered to be between 20-30 seconds asc classified by the International Classification of Sleep Disorders, Second Edition (American Academy of Sleep Medicine, 2001), they have revealed high prevalence of nocturnal pauses in breathing (known as periodic breathing) in FMS participants (Gold, Dipalo, Gold, & Broderick, 2004; Jennum et al., 1993; Sarzi-Puttini et al., 2002; Sergi et al., 1999). Periodic breathing has been linked to increased nocturnal arousals and daytime sleepiness in FMS (Sarzi-Puttini et al., 2002; Shah et al., 2006) and has been found to occur more often in stage one light sleep (Jennum et al., 1993; Sergi et al., 1999). Risk factors for sleep apnoea include age, obesity and gender, and indeed the frequency of sleep apnoea has been found to be higher in obese women and for men with FMS (May, West, Baker, & Everett, 1993; Shah et al., 2006). Sleep apnoea and disordered breathing are unlikely to directly influence the onset of FMS, as high levels of disordered breathing have also been found in other musculoskeletal conditions (Hyyppa & Kronholm, 1995) and many people with sleep apnoea do not have FMS (Alvarez Lario et al., 1992; Molony et al., 1986). Although disordered nocturnal breathing patterns and sleep disorders may not be directly causal to FMS, they may be linked and contribute to poor sleep quality and symptoms of FMS.

High frequency of restless legs syndrome, (a disorder displayed by involuntary movement of the limbs occurring at 20-40 second intervals both during the day and at night, has also been revealed in people with FMS (Yunus & Aldag, 1996). However, the lack of control groups in these studies makes it difficult to compare rates of these disorders in FMS, with levels experienced in the general population based on equivalent measures. As effective treatments are available for sleep apnoea and restless legs syndrome, further research is needed to identify if treatment of these sleep disorders can also help to improve symptoms of FMS for patients with a sleep disorder and FMS (Moldofsky, 2010).

As sleep is primarily a subjective experience, people's perceptions of their sleep difficulties are likely to be of key importance to the way people understand and manage their sleep and daily activities. As outlined at the beginning of this chapter, a high proportion of people with FMS perceive that they experience some type of sleep disturbance.

Types of Sleep Difficulties Experienced in FMS

Baseline analysis of participants with FMS in a clinical trial of hydrotherapy revealed that participants (N=50) reported sleeping for a total of five hours per night. This is comparable to patients with insomnia, less than participants with chronic pain and significantly worse than the general population as described in Chapter Two (Vitorino, Carvalho, & Prado, 2006).

A key study published during the completion of this thesis, explored the nature of perceived sleep disturbances in patients with FMS using the PSQI. Findings revealed that participants with FMS perceived their overall sleep quality to be poor, with over 90% of participants obtaining a PSQI global score >10 (Osorio et al., 2006). As described in Chapter Two, PSQI global scores of >5 are considered to be indicative of poor sleep quality in need of treatment, however for this study the authors set the cut-off score as 10 for reasons that were unspecified. This change in scoring makes comparisons to other studies about the extent of sleep difficulties based on the PSQI scores problematic. Despite these limitations, on exploring the components of sleep quality within this sample, it was revealed that people with FMS reported significantly more night-time awakenings, difficulties falling asleep and reduced daytime dysfunction, in comparison to matched healthy controls. This suggests that the reduction in total sleep time observed by Vitorino et al (2006) may be caused by difficulties both with sleep onset and sleep maintenance.

The findings of the study by Vitorino et al (2006) were also limited by its ability to generalize to the FMS population due to its small sample size (N=30) and because of sampling participants solely from a rheumatology clinic (which may not be representative of the whole FMS population). The study did not explore the influence of sleep quality on illness outcome. Consequently further research is needed to explore people's perceptions of sleep quality in FMS and how poor sleep may impact on their illness experience and daily living in people with FMS.

Relationships between Sleep and Pain in FMS

Comparable to the findings from research into chronic pain, sleep, pain and mood have been found to be significantly correlated in FMS. The initial study exploring perceived sleep quality in FMS assessed sleep quality using the PSQI and found that poor sleep quality, sleep efficiency, increased night-time awakenings and poor overall scores of sleep quality as assessed by the PSQI global score, were all associated with increased sensitivity to pain, as assessed by dolorimetry (Agargun et al., 1999). However, this study did not explore the effect of poor sleep on other symptoms of the condition.

Nicassio et al (2002) asked participants to complete a questionnaire exploring levels of pain, fatigue, depression and sleep quality for the period of one week. Analysis of the baseline data revealed that as expected, high levels of pain were associated with high levels of depression and fatigue, and that there was a negative association with sleep quality. The data collected over the course of the week was then aggregated to explore the effect of pain on subsequent sleep quality and fatigue. It was revealed that the prior day's pain was associated with poor sleep quality and increased fatigue. Interestingly, sleep quality appeared to mediate the relationship between pain and the following day's fatigue. This suggests that interventions to improve sleep quality, that have been effective in improving symptomology in other chronic conditions (Lobbezoo, Tanguay, Thon, & Lavigne, 1996), may improve the experience of FMS symptoms. The measures used in this study however, have limitations. For example, sleep was measured using only one item from the sleep subscale of the FIA questionnaire (Mason, Silverman, Weaver, & Simms, 1992) which focused on feelings on awakening from sleep, rather than asking directly about perceived sleep quality. It would be expected that feelings on awakening are very likely to be associated with perceived pain, mood and fatigue that day. In addition, completing the assessments on a daily basis did not enable the above studies to account for how symptoms may vary over the course of day, therefore the role of sleep on subsequent symptoms remains unclear.

In contrast to the research conducted by Nicassio et al (2002), which found that pain impacts on subsequent sleep quality, studies that have been conducted over longer periods of time have revealed different relationships between pain and sleep. In a daily diary study using palm top computers to record mood, sleep and fatigue over 30 consecutive days by 89 women with FMS, it was revealed that perceived total sleep

time and sleep quality were associated with negative affect and fatigue the following day. The effects of poor sleep on low mood and fatigue become more pronounced after two to three successive nights of poor sleep, suggesting that the effects of poor sleep are cumulative (Hamilton et al., 2008). These findings also indicate that poor sleep may lead to increased negative affect and fatigue, rather than the other way around. However, the study did not explore the effect of sleep on pain.

A study which did explore the relationships between sleep and pain was conducted by Affleck et al (1998). Participants were asked to monitor their perceived pain, sleep, fatigue, and the amount of progress they felt they had made towards their rehabilitation goals, three times per day when prompted by the computer over a 30 consecutive day period. They revealed that poor sleep quality was associated with increased attention towards pain, reduced effort towards physical rehabilitation goals and increased pain severity the following day. The relationship between pain and sleep however did not appear to be bi-directional, as pain was not associated with poor sleep quality the subsequent night (Affleck et al., 1998). In support of these short term follow up findings, a longitudinal study exploring sleep and pain in patients with FMS over the course of one year, found that poor sleep quality at baseline was predictive of pain and sleep quality at one year, but baseline pain did not significantly predict sleep quality at one year (Bigatti, Hernandez, Cronan, & Rand, 2008). These findings support the conceptual framework of pain and sleep outlined in Chapter Two (Call-Schmidt & Richardson, 2003) suggesting that poor sleep may increase low mood and impair the person's ability to cope with subsequent pain. This in turn leads to increased attention towards the pain and pain severity as a result. Sleep disturbance may therefore have an important role in both the aetiology and maintenance of symptoms for patients with FMS, possibly through the lack of the restorative functions of good quality sleep and psychological impact. However, the findings of these studies are limited as only one of these studies used a standardised assessment of sleep quality such as the MOS-SS or PSQI, therefore the reliability and validity of the findings may be questioned. The potential difference in sleep disturbance may have important implications for treatment and further investigation into the exact nature of the sleep difficulties and factors that may be linked to the maintenance of sleep difficulties in people with FMS is needed.

Managing Sleep Disturbance in FMS

Despite the chronicity of the difficulties experienced and the high prevalence of sleep disturbance in FMS (as is the case for patients with other chronic pain conditions), poor sleep quality often receives little attention in current treatment of the condition, and the most common treatment approach is the prescription of hypnotic or tricyclic antidepressant medications. Clinical trials have demonstrated the efficacy of these medications to reduce symptoms of sleep disturbance in the short term for FMS. For example, tricyclic medications have been found to improve sleep for one month (Moldofsky, 2002). However, there is little evidence of the efficacy of medications after prolonged use as the treatment effects disappear after discontinuation. The prolonged use of medications to aid sleep may also lead to impaired daytime functioning and may change the underlying sleep architecture. For example, benzodiazepines can reduce stages three and four of sleep (Morin, 1993) and indeed some people experience 'rebound insomnia' after discontinuing their hypnotic medication, stating that their sleep quality is more impaired than before they started the medication. This can often lead to, or trigger dependence on taking hypnotic medications (Soldatos, Dikeos, & Whitehead, 1999).

Common side effects of hypnotic and tricyclic medication (such as drowsiness and confusion) can also exacerbate other symptoms of FMS such as fatigue and cognitive difficulties, and may not be well tolerated by some patients (Lautenschlager, 2000; Moldofsky, 2002; Shaver et al., 1997). In addition to the limitations of pharmacotherapy, there is also wide variation in patients' adjustment to FMS, suggesting that psychological factors are important to the course and outcome of the condition (Burckhardt et al., 1992; Rao & Bennett, 2003). Consequently, there is an urgent need to explore the effectiveness of non-pharmacological interventions to improve sleep for people with FMS. Promising findings were observed in a pilot study of cognitive behaviour therapy to improve sleep quality for people with FMS (Edinger, Wohlgemuth, Krystal, & Rice, 2005). In comparison to participants randomized to receive sleep hygiene advice and usual care, participants who received the cognitive behaviour intervention on an individual basis for six weeks demonstrated almost a 50% reduction in the number of night-time awakenings experienced. A current full randomized controlled trial is underway to explore the efficacy of cognitive behaviour therapy, however some may argue that the costs of individual therapy may be too

expensive to apply in clinical practice. Promising findings have also been revealed for other non-pharmacological approaches. For example, a pilot study revealed that Ai Chi (water based exercises aimed at strengthening and toning the body and promoting relaxation) significantly improved sleep quality in participants with FMS (Calandre et al., 2009). These findings suggest that non-pharmacological therapies have the potential to help improve sleep quality for people with FMS and exploration of other more cost effective approaches is warranted.

Summary

As highlighted in Chapter Two, the implications of poor sleep quality for healthy people are profound, with poor sleep linked to increased morbidity, risk of accidents, absenteeism from work, increased health care costs and mortality (Gander et al., 2005; Kripke et al., 2002). For people with FMS the effects of poor sleep may be even more extreme through the exacerbation of symptoms such as pain, fatigue, cognitive impairment and difficulties in maintaining social relationships and engaging in rehabilitation (Fictenberg, Putnam, Mann, Zafonte, & Millard, 2001).

The evidence described within this chapter highlights that poor sleep quality has been found to take on primary significance in the course of FMS (Mease, Arnold et al., 2008) and that if left untreated, sleep disturbance may persist for many years. Specific interventions to improve poor sleep quality should therefore form a core part of the management of FMS. The importance of sleep quality in FMS has recently been recognised by the international Outcome Measures in Rheumatology Clinical Trials Working Group (OMERACT) who proposed that sleep should be one of the key outcome variables in clinical trials in FMS and recommend that sleep disturbance should be a core criteria for the diagnosis of FMS (Mease et al., 2009).

The research completed as part of this thesis aims to address some of the limitations of previous research in the area of FMS and to extend the current knowledge base by exploring the nature of sleep difficulties experienced in this population, the psychological aspects that may contribute to the maintenance of sleep difficulties and investigate the potential efficacy of a non-pharmacological intervention for people with FMS. Sleep disturbances have largely been an underestimated and neglected aspect of FMS. With a greater understanding of the effect of sleep on health outcomes in FMS, it

may be possible to help patients improve their sleep quality, and consequently their quality of life, by identifying interventions to address their specific individual needs. The work completed as part of this thesis will therefore yield an original contribution to the current knowledge base and will help to inform clinical management of FMS.

Chapter Four. The Nature and Effect of Sleep Difficulties on Quality of Life in FMS

Previous studies exploring sleep and FMS have revealed a high prevalence of sleep disturbances, and that poor sleep quality is significantly associated with increased pain in patients with this condition. As discussed in Chapter Two, in order to establish a comprehensive understanding of the role of sleep and its effect on quality of life in FMS, it is important to fully explore patients' perceptions and experiences of sleep quality. As outlined in Chapter Three, studies into perceptions of sleep quality undertaken to date have rarely been based on standardised assessment measures, explored the separate components of sleep quality or the effect of sleep disturbance on other health outcomes in FMS. Therefore our understanding on the effect of sleep on people's perceptions of sleep quality is limited.

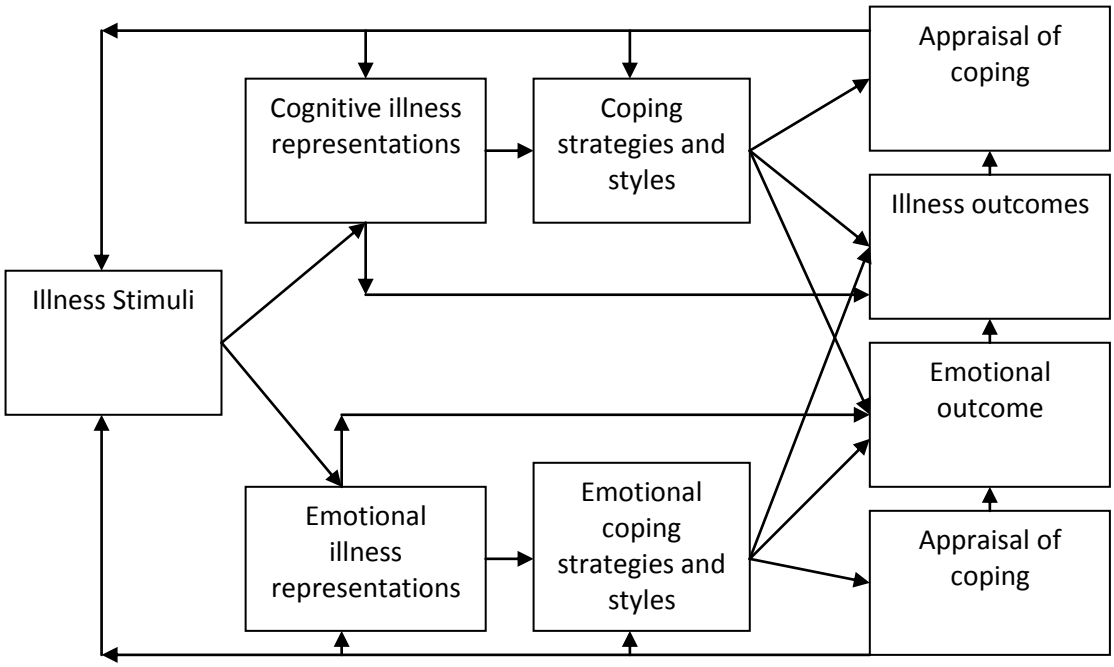
As proposed by the conceptual model of the development of sleep difficulties (Currie et al., 2000) and the conceptual framework of pain and sleep (Call-Schmidt & Richardson, 2003) as described in Chapter Two, there are many factors that are likely to influence the link between sleep quality and pain severity, and a greater understanding of these factors is needed to understand the role of sleep in FMS. One factor identified in the models of pain and sleep, that may influence sleep and pain in FMS, is people's ability to cope with chronic pain and sleep difficulties. Poor sleep may reduce patients' ability to successfully use cognitive coping strategies in response to pain so that individuals become more attentive to the pain (Lawson, Reesor, Keefe, & Turner, 1990) and it is likely that mechanisms regulating attention to pain may also be disrupted by poor sleep (Affleck, Urrows, Tennen, Higgins, & Abeles, 1996).

Coping has been defined as "purposeful efforts to manage the negative impact of stress" (Jensen, Turner, Romano, & Karoly, 1991, p. 250). Managing a chronic condition can be stressful and therefore coping strategies are used by people to manage the everyday demands of living with a chronic illness, such as managing chronic pain. Coping strategies are often classified as either 'problem focused' (where the person confronts the problem directly, such as coming up with a strategy to resolve the problem), or 'emotion focused' (where the person focuses on controlling their emotional reactions, such as talking to family and friends) (Folkman & Lazarus, 1988). However, other researchers prefer to classify coping in terms of 'active' styles of coping which require a

person to initiate an action (such as planning and pacing activities), or 'passive' coping strategies which involves the withdrawal or reliance on an external factor (such as resting and taking medication) (Jensen et al., 1991).

The idea that coping may have a significant influence on health outcomes is supported by the Self Regulatory Model which explores adjustment and outcomes for people with a chronic illness. The Self Regulatory Model proposes that coping has a direct link to health outcomes and may also mediate between peoples' beliefs about their illness (illness representations) and their illness outcomes, such as pain and disability (see Figure 6).

Figure 6. The Self-Regulatory Model (Leventhal, Meyer, & Nerenz, 1980; Leventhal, Nerenz, & Steele, 1984)



Research evidence consistently reveals that active coping strategies, such as using coping self statements or diverting attention, are associated with improved illness outcomes (Brown, Nicassio, & Wallston, 1989; Keefe & Williams, 1990; Manne & Zautra, 1992), and that the use of passive coping strategies are associated with increased pain and disability across a range of chronic pain conditions (Anie, Steptoe, & Bevan, 2002; Brown et al., 1989; Covic, Adamson, & Hough, 2000; Snow-Turek, Norris, & Tan, 1996; Steultjens, Dekker, & Bijlsma, 2001). However, the evidence surrounding

the mediational role of coping in the relationship between illness representation and health outcomes is weak (Carlisle, John, Fife-Schaw, & Lloyd, 2005).

Due to the unique demands of different medical conditions, the effectiveness of coping strategies may be dependent on their appropriateness for the situation or illness. Indeed, research focusing on coping and FMS specifically, has revealed that higher use of active coping strategies is associated with increased disability, pain and poor physical functioning. Nicassio et al (1995) explored the use of coping at baseline and 3 months later using the Pain Coping Strategies Questionnaire (CSQ, Rosenstiel & Keefe, 1983) to explore the effect of coping on pain in FMS. In the regression analysis they revealed that higher use of active coping strategies were associated with higher levels of pain and lower quality of well-being. Their study also found that higher use of passive coping strategies was associated with increased levels of depression. This was partially supported by a study conducted by Martin et al (1996) looking at the use of coping attempts (rather than active or passive coping). Martin et al (1996) revealed that coping attempts and catastrophizing were both related to higher disability, and coping attempts were associated with psychosocial disability. Therefore, it appears that in contrast to other chronic pain conditions, such as arthritis, active coping may be detrimental in FMS (Nicassio et al., 1995).

Although both of the aforementioned studies used the CSQ, different underlying factors of the CSQ were revealed. In the Nicassio et al (1995) study there were two underlying factors: 'coping attempts' and 'pain control and rational thinking'; whereas Martin et al (1996) also found two factors but these were: 'coping attempts' and 'catastrophizing'. Differences in the underlying factors of the CSQ may reflect differences in the methods of the two studies, a longitudinal study by Nicassio et al (1995) and a cross-sectional study by Martin et al (1996) and differences between the two study populations (one recruiting through rheumatology clinics, the other recruiting through the community and patient support groups.) The inconsistent findings may also reflect that coping is a more complex phenomenon than these measures suggest. There is evidence that the use of coping strategies is not stable and may change over time. For example, in a review of the literature on coping and chronic pain, Jensen et al (1991) stated that "some coping strategies in the CSQ are related to adjustment, only in patients reporting low levels of pain severity" (p. 277). It should also be noted that these studies by Martin et al (1996)

and Nicassio et al (1995) only explored the use of coping strategies specifically in response to pain. It may also be the case that different coping measures explore the use of different types or aspects of coping. For example, the CSQ explores coping specifically in relation to pain, whereas other measures explore the application of more generic, trait coping strategies, such as the COPE scale (Carver, Scheier, & Weintraub, 1989). Therefore using different coping measures may reveal different results. Thus caution is needed when comparing the findings from studies using different assessments of coping. As FMS and coping are complex phenomena it may be necessary to explore the use of more generic coping strategies using a different measure of coping, such as the COPE, on a range of outcomes in addition to pain, to understand the effect of coping in FMS.

Coping has been found to have links with sleep in the general population. For example, Harvey (2002) suggested that behaviours, such as reducing physical activity, can be an exacerbating factor in the maintenance of sleep difficulties. (Sadeh, Keinan, & Daon, 2004) suggested that a passive coping approach (such as using disengagement), may be related to increased sleep, as a way of escaping the stressor. They also propose that some strategies (such as cognitive rumination) may lead to increased arousal, preventing sleep onset and therefore poor sleep may be indicative of the use of less effective coping strategies (Sadeh et al., 2004). It should be noted however that this finding was not statistically significant. Active coping strategies such as seeking information may be a useful strategy to reduce stress and improve mood (Felton, Revenson, & Hinrichsen, 1984), however, the use of information seeking has also been associated with increased physiological arousal preventing sleep onset and insomnia (Sadeh et al., 2004; Voss, Kolling, & Heidenreich, 2006).

Another factor that may be linked with sleep, coping and health outcomes in FMS (although not specified in the models of sleep and pain) is mood, such as depression and negative affect. As described in Chapter Two, sleep and mood are highly correlated (Haythornthwaite, Hegel, & Kerns, 1991; Wells, Day, Carney, Freedland, & Duntley, 2004) and mood has been related to a wide range of physical and psychological problems in FMS (Burckhardt et al., 1992; Thieme, Turk, & Flor, 2004). Indeed in a cross-sectional study of people with FMS, Nicassio et al (2002) revealed that depression was linked to pain, fatigue and sleep in FMS. However, it is unclear if depression (often

associated with chronic illness conditions), influences coping and health outcome, or if it is the result of living with a chronic illness. Negative affect is thought to influence the relationship between self-reports of stressors and strain (Brett, Brief, Burke, George, & Webster, 1990; Griffith, Steptoe, & Cropley, 1999; Stansfeld, North, White, & Marmot, 1995). Indeed, one study has revealed that patients with FMS find it more difficult to sustain positive affect in response to stressful situations (Zautra et al., 2005). Therefore both positive and negative affect need to be controlled for when exploring coping in patients with FMS.

It was revealed in the literature review of sleep, coping and health outcomes (Chapters One, Two and Three) that there is a need to explore the nature of the sleep difficulties and factors that may contribute to poor sleep quality in FMS. In order to explore the nature and frequency of perceived sleep difficulties in FMS, a number of different methodologies were considered to inform the design of this study. A retrospective cohort study design was considered as this would offer the most cost-effective, yet reasonably robust approach, to determine the incidence of sleep difficulties within the population and enable to the exploration of potential risk factors. However, due to low awareness and common misdiagnosis of FMS (as discussed in Chapter One) and low recognition and treatment of sleep difficulties in health care services, a retrospective study using health care databases would incur difficulties in ensuring the reliability of FMS diagnosis and would be likely to underestimate the extent of sleep difficulties in this population. A prospective cohort study would not have been feasible due to financial constraints and difficulties in accessing a population of people with FMS. This is because some people with FMS self manage their condition, while others are managed in primary care or are treated by specialist hospital services. To address these weaknesses a cross-sectional design was chosen for this study. This study design offered the opportunity to use a standardised measure to assess the components of sleep quality, as well as enabling the advantage of accessing a wider population of FMS patients, encompassing the spectrum of symptom severity and including those treated both in the community and in secondary care services within a short timeframe.

To ascertain the extent and nature of sleep difficulties in FMS, and the role of sleep in FMS, this study aimed to explore the components of sleep quality and relationships between sleep, mood, coping and health outcomes in FMS. Based on the review of the previous literature it was hypothesised that:

1) Poor sleep quality, defined by the PSQI global score >6, will be highly prevalent in FMS;
2) The most significant sleep difficulties will relate to problems falling asleep (sleep onset latency) and reduced total sleep time;
3) Higher levels of negative affect will be significantly associated with poor sleep quality and pain in FMS;
4) High use of mental and behavioral disengagement will be associated with poor sleep quality and pain in FMS.

Methods

A cross-sectional questionnaire design was used to explore the frequency and nature of sleep difficulties in patients diagnosed with FMS.

Power Calculations

A priori power analysis was undertaken using G*power 3.1.0 (Faul, Erdfelder, Lang, & Buchner, 2007), to identify how many participants would be needed for the study, to ensure enough statistical power and avoid an ambiguous result. The calculation was based on a correlation analysis of overall negative affect and overall sleep quality using a bivariate normal model. A moderate correlation of 0.3 was chosen, as this was revealed in a previous study of depression and sleep in FMS patients (Nicassio et al., 2002). Using a power of 0.8 and a 0.05 significance level, as recommended by Cohen (1992), a test for a two tailed bivariate correlation revealed that a minimum of 84 participants were needed for this study to have sufficient statistical power to detect a medium correlation.

Participant Recruitment

An opportunistic sample of participants was recruited from community based Fibromyalgia Syndrome Support Groups in the South East of England. Due to a lack of treatment options for FMS and dissatisfaction with current health service provision in the UK (and indeed in New Zealand), many patients self manage their condition or seek

private medical treatment. Therefore in order to recruit a sample of FMS patients with a range of illness severity and who have received different health care service provision, participants were recruited through community based support groups rather than through hospital or UK national health care services. Advertisements were placed in support group newsletters, and oral presentations about the study were made at patient meetings. This approach enabled participants of different ages and with a range of FMS severity to take part in the study.

All members of the participating support groups were approached by handing out invitation letters explaining the study, consent forms and the questionnaires for participants to complete. Those unable to attend the meeting were sent the information by post. The researcher asked for 'volunteers' to complete a questionnaire about their sleep patterns and FMS symptoms. Participants were given the opportunity to complete the questionnaire in their own time at home, and were asked to return the completed questionnaire and one signed copy of the consent form, in the freepost envelope provided.

The inclusion criteria were: 1) diagnosis of FMS by a GP or clinician; 2) FMS as the primary medical diagnosis and; 3) aged 18 years or over. Participants were excluded from the study if: 1) they had been diagnosed with a sleep disorder or; 2) if >20% of the questionnaire data was missing (to limit the impact of missing data on the findings). Although the study was described as looking at the effect of sleep in FMS, participants were advised that they did not need to be experiencing sleep difficulties in order to participate.

Outcome Measures

The choice of assessment measures used within this thesis was based on several factors: 1) identifying a measure that was designed to explore each variable under investigation as defined within the thesis; 2) the psychometric properties of the measure (Cronbach's alpha of 0.6 and test-retest of 0.7 were used to define acceptable internal consistency and reliability) and; 3) published recommendations of measures suitable for use with people with FMS to aid in the comparison of findings with other research studies. Although the convention is to consider adequate internal consistency at the 0.7 level, Kline (1999) proposed that as psychological constructs are diverse and that the internal consistency is affected if there are only a small numbers of items in the scale, values

below 0.7 are acceptable. Therefore measures demonstrating internal consistency at or above the 0.6 level were considered to be acceptable within this thesis (Loewenthal, 2001).

Demographic information on age, gender, diagnosis of FMS, employment (including shift work) and use of medication was requested. In addition, participants completed assessment measures focusing on negative affect, sleep quality, use of coping strategies and quality of life over the past month.

Negative Affect

Negative affect was measured using the Positive and Negative Affect Schedule (PANAS) (Watson, Clark, & Tellegen, 1988). The PANAS consists of 10 negative or 10 positive adjectives describing feelings and emotions. Participants were asked to rate the extent to which they had felt each feeling or emotion, in the past month, on a scale from 1 (very slightly or not at all) to 5 (extremely). Scores are summed to yield two scale scores; a positive affect and a negative affect scale, with high scores indicative of higher levels of positive and negative affect. This scale was chosen as the two sub-scales of the PANAS have been found to share only 9% of the variance, suggesting they are relatively independent of each other (Crawford & Henry, 2004). The PANAS has good internal consistency with a Cronbach's alpha of 0.88 for the positive affect scale, and 0.87 for the negative affect scale (Kalpakjian, Lam, Toussaint, & Merbitz, 2004). The measure has shown high correlations with other measures of distress, anxiety and depression, for example correlations of 0.85 to 0.91 have been found with the Profile of Mood States (Crawford & Henry, 2004).

Sleep Quality

Based on the review of available sleep measures in Chapter Two, sleep quality was assessed using the PSQI (Buysse et al., 1989). This measure was chosen as it explores different dimensions of perceived sleep quality, including time to fall asleep (sleep onset latency) and total sleep duration.

Coping

The Coping Orientation of Problem Experience Inventory (The COPE Scale, Carver et al., 1989) is a theoretically guided multi-dimensional coping measure that has been widely used in the health field. The COPE has 15 component scales, each containing four items. Participants were asked to indicate how often they use different types of coping on a scale, ranging from 1 (I usually don't do this at all) to 4 (I usually do this a lot). The items for each scale are summed to give the score for each of the 15 scales. The 15 subscales include: Positive reinterpretation and growth, Mental disengagement, Focus on and venting of emotions, Use of instrumental social support, Active coping, Denial, Religious coping, Humour, Behavioural disengagement, Restraint, Use of emotional social support, Substance use, Acceptance, Suppression of competing activities and Planning. Higher scores are indicative of higher use of the coping strategy. The COPE scale has been widely used to explore coping behaviour, and the planning, restraint coping, seeking instrumental support, seeking emotional support, turning to religion, focus on venting emotion and denial sub-scales have revealed Cronbach's alphas between 0.71-0.92, although the mental disengagement, active coping, positive reinterpretation and behavioural disengagement scales revealed internal consistency co-efficients (Cronbach's alphas) below 0.7 (0.45, 0.62, 0.68 and 0.63 respectively). Test-retest reliability over an 8 week period was found to be between 0.46-0.86 which was considered to be poor, however this may reflect the transient nature of the use of coping strategies over time (Carver et al., 1989).

Quality of Life

Health related quality of life was assessed using the RAND 36-item Health Survey (SF - 36) (Hays, Sherbourne, & Mazel, 1993a; Ware & Sherbourne, 1992). For this questionnaire participants were asked to describe how they felt and how able they were to carry out their usual activities over the past month. Scores for the individual items were recoded and summed to create eight component scales. Scores ranged from 0-100, a higher score indicating higher health related quality of life. The RAND SF-36 has been extensively used in the general population and patients with chronic illness to describe health related quality of life and as an outcome measures in clinical trials (Hays & Morales, 2001). The wide utility of the measure offers the benefit that scores can be compared between different populations. Indeed, several studies have revealed that people with FMS have poorer health related quality of life outcomes across the eight outcome domains than healthy controls (Martinez et al., 2001), those with arthritis and

heart disease (Epstein et al., 1999; Salaffi, Sarzi-Puttini, Girolimetti et al., 2009). Evidence has supported the unidimensionality of the eight subscales, with each scale revealing a Cronbach's alpha score above 0.7 (Kosinski, Keller, Hatoum, Kong, & Ware, 1999; Moorer, Suurmeije, Foets, & Molenaar, 2001) and inter item correlations above 0.4 (Leung et al., 2010). Some ceiling and floor effects have been found in the utilisation of the SF36 in clinical populations (McHorney, Ware, Lu, & Sherbourne, 1994) and the measurement characteristics of the role limitations due to emotional and physical functioning scales have come under question in patients with arthritis (Ruta, Hurst, Kind, Hunter, & Stubbings, 1998). Despite these limitations the SF-36 has been recommended for use as an assessment measure in studies with people with FMS (Salaffi, Sarzi-Puttini, Ciapetti et al., 2009). In addition, the SF-36 was also chosen for use in this study as it includes scales focusing specifically on levels of pain and fatigue (the two main symptoms in FMS), in addition to factors exploring general health quality of life.

Age, length of illness, negative affect, coping and sleep quality sub-scales were considered to be independent variables and constructs (subscales) of health related quality of life, the dependent variables.

Data Analysis

Data was entered into SPSS Version 16.0 (SPSS for Windows, 2006) and the questionnaire measures were scored according to their instructions. The median and inter-quartile range were calculated to describe the distribution of the ordinal data for the questionnaire variables (Howitt & Cramer, 2005). Underlying the analysis of the data, presented in this thesis, is the principle that data from the questionnaire scales used in this thesis was ordinal, there being no evidence that there are equal intervals between the points on the given scales. Rasch analysis can be a useful tool to explore the intervals between points on a scale to determine if they are equal and providing evidence for treating the data as ratio level data. However, due to its complexity, Rasch analysis has not always been conducted on every standardized measure, and within every population under investigation (particularly this has not been applied to the measures used within this thesis in the FMS population).

It is recognised that there is currently wide debate as to whether standardized scales should be analysed using non-parametric statistical tests or if there is justification for using parametric statistical tests. Some professions (such as psychology) consider that if data meet the other requirements for parametric tests (such as a normal distribution), then there is justification for using parametric tests. This is supported by the argument that applying numbers to complex multidimensional constructs (such as psychological variables) is an arbitry approach anyway. Many published authors in the field of chronic pain and fibromyalgia (Ashworth et al., 2010; Ellis et al., 2007; Martin et al., 1996; Nicassio et al., 1995) have applied parametric tests, such as multiple regression, to what could be considered ordinal level data. This approach is recognised and accepted within the field. Therefore parametric tests were used in the published paper based on this dataset in line with this common practice. However, on review of the literature on the use of parametric tests for this thesis and to ensure rigour, it was decided that there was greater justification for treating all data, for which there is no evidence of equal intervals between the points on a scale, as ordinal level data. As the data was considered to be at the ordinal level, the data was not deemed to meet the assumptions required to use parametric statistical tests and therefore non-parametric statistical tests were applied throughout this thesis.

It should be highlighted, that if true relationships do exist, then these relationships should be evident whether the data was analysed using non-parametric or parametric statistical tests. Indeed comparing the analysis from the published paper where the data was analysed using parametric tests (see Appendix E) in comparison to the non-parametric analysis described in Chapter Four, it is evident that the same findings were revealed in both sets of analysis.

As described in Chapter Two, the more stringent PSQI global score of >6 has been found to reliably indicate the existence of significant sleep disturbances in need of treatment (Sayar et al., 2002). The number (%) of participants in the sample receiving a PSQI global score of >6 was calculated to establish the extent of sleep disturbance in this population. The exact nature of the sleep difficulties experienced was explored by scores on the seven sub-scales of the PSQI: subjective sleep quality, sleep onset latency (time taken to fall asleep), sleep duration (total hours of sleep), sleep efficiency (% time asleep/time awake) night-time awakenings, use of hypnotic medication and daytime dysfunction.

In order to explore the links between negative affect and coping and health outcomes in FMS, Spearman's r correlation coefficients were calculated between sleep, coping and health related quality of life variables. The inter-item consistency of the questionnaires used in this study was explored using Cronbach's alpha. Scores of more than 0.7 were considered to be indicative of acceptable reliability (Wood & Haber, 2006).

Results

Participant Characteristics

Of the 200 questionnaires that were distributed, 111 (56%) were returned. Eight questionnaires were omitted from the analysis as the responder did not meet the inclusion criteria for the following reasons: one participant reported a diagnosis of sleep apnoea and four participants had not been diagnosed with FMS by a GP or clinician. As highlighted in previous studies using questionnaires, if >20% of the questionnaire data is missing, this is highly problematic for interpretation of the results (Field, 2009; Valentine, Lavallee, Liu, Bensel, & Murray, 2003). Tabachnick and Fiddell (2007, p. 62) state that "missing data is one of the most pervasive problems in data analysis". The data was screened for missing values and as a check to ensure that there was no pattern in the missing data that could be important to note for participants for whom >20% of the data was missing, the distribution of missing values was explored. Missing values were randomly distributed across variables indicating that excluding the participants who omitted to complete 20% of the questionnaire should not affect the generalisability of the findings (Field, 2009). Consequently, the three participants who returned questionnaires where more than 20% of their questionnaire contained missing data were also excluded from the analysis as planned.

Missing values were distributed randomly across the variables in the dataset and it was observed that <10% of the data were missing on each individual variable. Although specific guidance as to the number of missing values that are acceptable for a given sample size is not available, several authors state that up to 10% of missing data should not have a large impact on the usefulness of a questionnaire in the analysis (Cohen,

2001; Revicki, 2002). Tabachnick and Fiddell (2007) suggested that a small number of randomly missing values are less of a concern and that different ways of dealing with missing data leads to similar results. This perspective is supported by Hawthorne and Elliot (2005) who revealed in a study exploring the comparison of different methods of dealing with missing data, that person mean substitution is the 'method of choice' when at least 50% of data are available for the remainder of a scale. In addition, deleting cases with any missing values would have significantly reduced the sample size for this study and may have biased the sample (De Vaus, 2002). Therefore as the data was considered missing at random and less than 10% of the values were missing, person mean substitution was conducted based on the other items available for each case on the given scale before the analysis (Hawthorne & Elliott, 2005; Scheffer, 2002). The drawback of the person mean substitution method is that this approach can reduce the correlations between variables as the variance is reduced (Scheffer, 2002; Tabachnick & Fidell, 2007). Therefore to check the effect of this procedure for dealing with missing data, data analysis was completed before (excluding the cases with missing values) and after the mean substitution as suggested by Tabachnick and Fiddell (2007). The procedure had little effect on the results.

The questionnaire data was scored according to the individual questionnaire instructions and the resulting variables were checked for skewness and kurtosis using the explore function within SPSS 16.0. Skewness and kurtosis scores of below 0.3 were used to indicate if the data in each variable was normally distributed (Field, 2009). All subscales of the RAND SF-36, the COPE Scale, the PSQI and the negative affect scale of the PANAS revealed skewed distributions; the medians were reported as the measure of central tendency. Mean scores were calculated for the age, length of illness and the PSQI Global score variables which met the assumptions of ratio level data and revealed a normal distribution.

Of the 101 participants included in the analysis, 94 were female (93%) and 7 were male (7%). This translates into a female to male ratio of 14:1, which is slightly higher than reflected in pervious prevalence studies. Thirty five participants (34.7%) were employed at the time of completing the questionnaire and of these; three participants (3%) were required to work shifts, which is known to affect sleeping patterns. Excluding the data from these three participants did not greatly alter the overall pattern of results and therefore their data was included in the analysis. At the time of completing the

questionnaire 78 (77.2%) of the participants were taking prescribed medication to help them manage their FMS symptoms. The average length of illness was nine years (SD 10.0).

Table 1, presents the scores of the questionnaire measures incorporated in the study. Means and standard deviations are presented to enable comparison with published data and medians and interquartile ranges are included as the data are considered to be at the ordinal level in this thesis and are considered to be the most appropriate measure of central tendency for non-normal distributions.

Table 1. Participant characteristics and assessment measure scores

	Median (IQR)	**Mean (SD)**	**95% Confidence Intervals**	**Cronbach's α**
Age	56.00 (16.0)	54.8 (11.8)	52.5-57.1	-
PSQI Global score (0-21)	13.0 (5.0)	13.6 (13.8)	12.8-14.2	0.61
PANAS Negative affect (10-50)	26.0 (10.5)	25.4 (8.4)	23.7-27.1	0.87
PANAS Positive affect (10-50)	28.0 (9.5)	27.2 (7.5)	25.8-28.7	0.87
COPE Positive reinterpretation(1-16)	12.0 (5.0)	11.4 (3.1)	10.8-12.1	0.83
COPE Mental disengagement(1-16)	9.0 (3.0)	9.4 (2.1)	8.9-9.8	0.14
COPE Venting emotions(1-16)	9.0 (6.0)	9.2 (3.2)	8.5-9.9	0.85
COPE Instrumental social support (1-16)	10.0 (5.0)	10.1 (3.4)	9.4-10.8	0.83
COPE Active coping(1-16)	11.0 (4.0)	11.0 (3.0)	10.4-11.6	0.76
COPE Denial(1-16)	5.0 (3.0)	6.0 (2.2)	5.6-6.4	0.56
COPE Turning to religion(1-16)	5.0 (5.0)	7.2 (4.1)	6.4-8.0	0.95
COPE Use of humour(1-16)	8.0 (6.0)	8.5 (3.5)	7.8-9.2	0.90
COPE Behavioural disengagement(1-16)	7.0 (3.0)	6.9 (2.1)	6.5-7.4	0.50
COPE Restraint(1-16)	10.0 (4.0)	9.9 (2.7)	9.0-10.4	0.73
COPE Seeking emotional support(1-16)	10.0 (5.0)	9.7 (3.5)	9.0-10.4	0.87
COPE Substance use(1-16)	4.0 (2.0)	5.3 (2.4)	4.8-6.0	0.87
COPE Acceptance(1-16)	12.0 (4.0)	11.8 (2.6)	11.3-12.4	0.70
COPE Suppression of activities(1-16)	10.0 (4.0)	9.9 (2.3)	9.5-10.4	0.42
COPE Planning(1-16)	12.0 (5.0)	11.5 (2.9)	10.9-12.0	0.79
Sleep onset latency (in minutes)	62.6 (1.17)	63.8 (51.5)	53.4-74.2	-
Sleep efficiency as a % (0-100)	68.0 (25.4)	68.2 (20.0)	64.2-72.2	-
PSQI Sleep quality subscale (0-3)	2.0 (1.0)	2.1 (0.8)	1.9-2.2	-
PSQI Sleep onset latency subscale (0-3)	2.0 (1.5)	2.1 (0.9)	2.0-2.3	-
PSQI Sleep duration subscale (0-3)	1.0 (2.0)	1.3 (1.1)	1.0-1.5	-
PSQI Sleep efficiency subscale (0-3)	2.0 (2.0)	1.8 (1.2)	1.5-2.0	-
PSQI Sleep disturbances subscale (0-3)	2.0 (2.0)	2.4 (0.6)	2.2-2.5	-
PSQI Use of medication subscale (0-3)	2.0 (3.0)	1.6 (1.4)	1.3-1.9	-
PSQI Daytime dysfunction subscale (0-3)	2.0 (1.0)	2.2 (0.7)	2.1-2.4	-
SF36Physical functioning(0-100)	30.0 (40.0)	33.0 (24.9)	28.0-38.0	0.90
SF36Role limitations physical (0-100)	0.0 (0.0)	8.2 (17.6)	4.7-11.8	0.57
SF36Role limitations emotional (0-100)	33.3 (67.0)	32.6 (38.2)	25.0-40.3	0.75
SF36Fatigue (0-100)	20.0 (25.0)	23.6 (17.6)	20.1-27.2	0.66
SF36Well-being (0-100)	60.0 (28.0)	57.2 (20.8)	53.0-61.4	0.85
SF36Social functioning (0-100)	50.0 (38.0)	43.6 (27.2)	38.1-49.0	0.87
SF36Pain (0-100)	32.5 (22.0)	30.9 (18.8)	27.1-34.6	0.77
SF36General health (0-100)	30.0 (25.0)	34.0 (17.7)	30.4-37.5	0.67

The range of possible scores for each measure are given in brackets

Table 1, highlights that people with FMS most frequently used positive reinterpretation, acceptance, planning and active coping approaches as coping strategies, rarely relied on substance use and did not turn to religion to help them to cope. Participants reported very poor sleep quality with a high median PSQI global score and very low ratings of enjoyment of sleep and feeling refreshed in the morning. Low levels of health related quality of life for the sample were revealed by the SF-36 scale scores particularly with reference to role limitations due to physical problems, pain and fatigue where >85% of the sample scoring <50 on the SF-36. These findings support the findings of previous research, highlighting that people with FMS have poorer health related quality of life than the general population and people with other chronic pain conditions such as arthritis (Epstein et al., 1999; Martinez et al., 2001).

Descriptive Statistics

Ninety-seven participants (97%) revealed a global score of >6 on the PSQI, which is indicative of clinically significant sleep disturbance requiring intervention. This reveals that sleep problems are highly prevalent in this sample. The mean PSQI global score for this sample (as shown in Table 1, p. 62) is comparable to the mean PSQI global score of 13.6 (SD = 3.70) found in patients with other chronic pain conditions (Currie et al, 2000). Participants slept for between 1 and 10 hours each night (mean time asleep 5.95 hours, SD 1.83). This compares to a mean of 6.52 hours in men (+/- 55 minutes) and 7.11 hours (+/- 57 minutes) in women, as revealed in a European general population study (Jansson & Linton, 2005).

The sleep parameters used to assess clinically significant poor sleep quality (Morin et al., 1999) suggest that normal sleep onset latency (time taken to fall asleep) should be 30 minutes or less. Sixty one participants (60.40%) in this sample reported taking more than 30 minutes to fall asleep. It became apparent that participants were experiencing a high number of awakenings during the night with 73 participants (72.28%) experiencing more than three awakenings each night. For just under half of the participants (N= 52, 51.49%), these awakenings lasted over 20 minutes. The recommended sleep parameters also suggest that sleep efficiency should be 80% or over (Jansson & Linton, 2005; Morin et al., 1999). In this sample only 26/101 (25.74%) met this criteria for sleep

efficiency, suggesting that participants were spending large periods of time in bed while not asleep.

Fifty participants (49.50%) reported using medication (prescribed or over the counter) to improve their sleep at least three times per week, although 41 participants (40.60%) had not used any hypnotic medication in the past month. The levels of reported daytime dysfunction as a result of poor sleep were high, with over half the sample (N=59, 58.4%) reporting that they experienced a problem in maintaining enthusiasm to get things done at least three or more times a week.

To ensure the questionnaire measures contained items that were measuring the same underlying construct within this specific population, the inter-item consistency of the scales was analysed based on the criterion outlined in the introduction to this thesis (p. 18), and mean inter-item coefficients of between 0.2 and 0.4, which are indicative that the items within the scale are exploring similar constructs (Piedmont & Hyland, 1993). To check the internal reliability of the scales used within this study, Cronbach's alpha and inter-item coefficients were calculated for each scale in the analysis. The suppression of competing activities, denial and mental and behavioural disengagement scales of the COPE, and role limitations due to physical problems subscale of the SF36, yielded Cronbach's alpha scores below 0.6 or had inter-item correlation coefficients below 0.2 or above 0.5 (Field, 2009; Piedmont & Hyland, 1993) and were therefore excluded from further analysis. The role limitations due to physical problems scale of the SF-36 also revealed ceiling effects (with the majority of the sample scoring 0, indicating highly reduced quality of life) which limited its use for this sample. Median values, interquartile ranges and Cronbach's alpha scores for the assessment measures are outlined in Table 1 (p. 62).

Correlation Analysis

Spearman's r correlation coefficients were calculated between sleep, coping and health related quality of life variables. Spearman's correlation coefficient was used as the data were considered to be ordinal level data and to account for the non-normal distribution of the study variables.

As analysis of all possible relationships between these variables would require multiple comparisons, there was an increased risk of finding a relationship that occurred by chance (not a true relationship, a type one error) (Bland & Altman, 1995; Tabachnick & Fidell, 2007). At the $P<0.05$ level, this would mean a 1 in 20 chance of revealing a significant difference by chance. This risk was considered to be too high (considering the number of multiple comparisons needed within this exploratory study) and therefore the significance level needed to be adjusted. There is currently no standard recommended approach for adjusting to multiple comparisons (Feise, 2002). Procedures for correcting for multiple comparisons have been proposed, such as the Bonferroni correction (Bland & Altman, 1995). The Bonferroni correction approach recommends that the significance level of 0.05 is divided by the number of comparisons to reduce the risk of finding significant relationships by chance. However, the focus of Bonferroni adjustments is on the null hypotheses, rather than testing the main study hypotheses and increases the risk of type two errors (that true relationships that do exist are not revealed). Type two errors are no less problematic than type one errors (Perneger, 1998). Consequently the Bonferroni correction method has been proposed to be more appropriate for studies confirming pre-established relationships or for studies where less than five comparisons are being made (Bender & Lange, 2001; Perneger, 1998) . Other available tests (such as the Tukey or Scheffe tests) did not fit the level of data, the planned analyses or account for the non-normal distribution of the variables (Tabachnick & Fidell, 2007). Rothman (1990) proposed that there is no need to make adjustments for multiple comparisons, as it is better to identify possible relationships for further testing rather than to be cautious and miss potentially important findings. As this was an exploratory study that aimed to identify relationships to inform further investigation, it was important not to set a significance level too high and risk a type two error (Bender & Lange, 2001). The approach of making adjustments for multiple comparisons would risk being too conservative for this study. To that end, in order to find a balance between avoiding both type one and type two errors, the significance level was set at the more stringent level of $p<0.01$ for the data analysis (Field, 2009).

A post hoc power calculation based on a two-tailed bivariate normal model correlation using G*power 3.1.0, sample size of 101, and using a more stringent significance level of 0.01, revealed that this study had a reasonable level of power of 0.7 to detect a medium correlation of 0.3 found in this study (Faul et al., 2007; Field, 2009).

Older age and longer length of illness were significantly associated with better general health, suggesting that participants may learn to manage their symptoms more effectively over time or it may be that the symptom experience changes over time. The overall PSQI global score was not significantly associated with mood or use of coping strategies in this sample. However, the PSQI global sleep quality score was significantly associated with poorer physical functioning, role limitations due to emotional difficulties, fatigue, well-being, social functioning and pain. As components of the PSQI have been found to have different effects on outcomes, for example sleep quality has been found to be more related to health and well-being than sleep quantity (Pilcher, Ginter, & Sadowsky, 1997), the components of sleep quality were used in the analysis to see if they were significantly associated with health outcomes in FMS. Looking at the associations between the individual components of sleep quality and illness outcomes (Table 2, p. 68), it was revealed that the sleep quality subscale was significantly associated with higher levels of pain. The sleep disturbances subscale was significantly associated with poorer physical functioning, higher role limitations due to emotional problems, higher levels of pain, poorer general health and higher negative affect. Sleep onset latency, sleep duration and sleep efficiency were not significantly associated with health outcomes in FMS.

As expected, higher negative affect was significantly associated with poorer health outcomes on all variables including physical functioning, role limitations due to emotional health, fatigue, pain, well-being, social functioning, pain and general health. Higher positive affect was associated with lower role limitations due to emotional problems and fatigue and better emotional well-being and general health. Mood and coping style were also significantly correlated with venting emotions and acceptance associated with higher negative affect, and with positive reinterpretation, active coping, seeking instrumental social support and planning significantly associated with higher positive affect.

The use of problem focused coping strategies (including positive reinterpretation, active coping) and acceptance, were significantly associated with better emotional well-being. The use of positive reinterpretation as a coping strategy was also significantly associated with lower role limitations due to emotional problems, although problem focused strategies were not associated with other health outcome variables. Use of venting emotions was associated with poorer emotional well-being and general health.

Restraint coping was significantly associated with lower physical functioning. However, coping was not significantly associated with sleep quality.

As the data was considered to be ordinal level data and because there was an insufficient sample size to explore the large number of variables that would need to be investigated in multivariate stepwise regression, regression analysis was not completed (Field, 2009; Tabachnick & Fidell, 2007).

Table 2. Correlations between demographic and health outcome variables

	Gen	Age	Len	PR	VE	ISS	AC	Rel	Hum	Res	ESS	SU	ACC	PL	PF	RE	FA	WB	SF	PAI	GH	NA	PA	GL	SQ	SOL	SD	SE	DI	MD
Age	.18	1.00																												
Len	-.06	.10	1.0																											
PR	-.02	-.00	.05	1.00																										
VE	.25*	**-.30****	-.13	-.07	1.00																									
ISS	.02	-.21*	-.07	**.30****	.15	1.00																								
AC	-.02	.18	-.03	**.61****	-.12	**.42****	1.00																							
Rel	.16	.17	.08	.13	-.04	-.04	.06	1.00																						
Hum	.02	.01	-.00	**.49****	-.06	.14	**.36****	-.15	1.00																					
Res	.07	.07	-.02	**.39****	.02	.16	**.45****	-.15	.25*	1.00																				
ESS	.15	-.14	-.03	.24*	**.35****	**.76****	**.31****	.07	.06	.07	1.00																			
SU	-.02	.02	-.01	-.25*	-.16	-.14	-.14	-.08	-.19	-.07	-.10	1.00																		
Acc	.03	-.03	-.05	**.46****	**-.28****	.17	**.37****	.00	**.33****	**.33****	.03	-.22*	1.00																	
PL	-.02	-.01	.09	**.61****	-.07	**.36****	**.74****	.06	**.39****	**.42****	.16	-.12	**.38****	1.00																
PF	-.22*	-.06	.07	-.03	-.02	.03	-.04	.12	-.10	**-.27****	.11	-.17	.00	-.04	1.00															
RE	.11	.13	.04	**.27****	.03	.24*	.19	.01	.07	.09	.25*	**-.26****	.14	.14	**.27****	1.00														
FA	-.10	.23*	.05	.11	-.17	.17	.17	-.01	-.06	.03	.20*	-.16	-.11	.04	**.29****	**.44****	1.000													
WB	-.14	.25*	.08	**.42****	**-.35****	.24*	**.41****	.01	.16	.06	.22*	**-.33****	**.31****	.23*	.22*	**.47****	**.46****	1.00												
SF	.08	.18	-.02	.01	-.05	.10	.00	.08	-.09	-.11	.22*	-.15	-.03	-.14	**.41****	**.55****	**.50****	**.34****	1.00											
PAI	-.07	.06	-.00	.13	.03	.10	.06	.07	-.06	-.16	.22*	-.20*	-.05	-.03	**.60****	**.50****	**.49****	**.33****	**.65****	1.00										
GH	-.11	**.40****	**.28****	.08	**-.29****	-.05	.20*	.21*	-.01	-.05	-.00	-.05	.01	.07	**.37****	**.38****	**.41****	**.44****	**.37****	**.39****	1.00									
NA	.18	-.23*	-.15	**-.39****	**.48****	-.15	**-.26****	-.03	-.17	-.17	-.07	.25*	**-.27****	-.22*	**-.27****	**-.40****	**-.38****	**-.70****	**-.33****	**-.28****	**-.36****	1.00								
PA	-.19	.21*	.08	**.48****	-.12	**.28****	**.45****	-.07	.10	.24*	.23*	-.18	.20*	**.38****	.13	**.35****	**.46****	**.64****	.17	.24*	**.32****	**-.45****	1.00							
GL	-.00	-.02	.15	-.00	.11	-.16	-.08	.02	.13	-.09	-.12	.12	-.05	-.01	**-.28****	**-.28***	**-.28****	**-.26****	**-.35****	**-.30****	-.21*	.25*	-.15	1.00						
SQ	-.02	-.19	.11	-.08	.01	-.07	-.16	.02	-.01	-.12	-.16	.03	-.03	-.11	-.16	-.19	-.16	-.25*	-.23*	**-.28****	-.10	.19	**-.27****	**.43****	1.00					
SOL	.03	-.08	-.01	.15	.20*	-.00	.05	-.07	.23*	.11	-.05	.01	-.01	.07	-.15	-.11	-.07	-.14	-.19	-.02	-.22*	.23*	-.01	**.61****	.17	1.00				
SD	-.03	.10	.13	.03	-.03	-.18	-.12	.13	.09	-.09	-.19	.06	-.09	-.01	-.07	-.11	-.15	-.10	-.15	-.13	.03	-.01	.02	**.72****	.25*	**.40****	1.00			
SE	-.01	.02	.07	.06	.08	-.12	-.11	.03	.15	-.09	-.09	.16	-.11	-.07	-.16	-.15	-.11	-.12	-.20*	-.11	-.02	.09	.02	**.75****	**.26****	**.47****	**.80****	1.00		
DI	.16	.07	.08	-.13	.17	-.23*	-.08	.05	-.04	-.21*	-.09	.10	-.10	-.10	**-.33****	**-.36****	-.23*	-.25*	-.21*	**-.26****	**-.27****	**.40****	-.19	**.52****	**.26****	**.28****	**.23***	**.32****	1.00	
MD	-.10	-.11	.18	.01	.04	.08	.10	-.07	.10	.03	.10	.06	-.03	.17	-.18	-.04	-.07	-.03	-.10	-.15	-.16	.05	.00	.38**	.00	.09	-.03	.02	.06	1.00
DD	.22*	.09	-.15	-.02	**.35****	-.04	.00	.10	.00	-.07	.03	.18	-.04	-.08	-.19	-.16	**-.29****	**-.29****	**-.26****	-.20*	-.17	**.35****	-.20*	**.26****	.09	.12	.11	.10	.28**	-.18

** = P<0.01

Gen = Gender
Age = Age in years
Len = Length of illness in years
PR = COPE Positive reinterpretation
VE = COPE Venting emotions
ISS = COPE Instrumental social support
AC = COPE Active coping
Rel = COPE Turning to religion
Hum = COPE Use of humour
Res = COPE Use of restraint coping
ESS = COPE Emotional social support
Acc = COPE Acceptance
PL = COPE Planning
PF = SF36 Physical functioning
SU = Substance use
DD = PSQI Daytime dysfunction subscale
RE = SF36 Role limitations due to emotional difficulties
FA = SF36 Fatigue
WB = SF36 Emotional wellbeing
SF = SF36 Social functioning
PAI = SF36 Pain
GH = SF36 General health
NA = PANAS Negative affect
PA = PANAS Positive affect
GL = PSQI Global score
SQ = PSQI Sleep quality subscale
SOL = PSQI Sleep onset latency subscale
SD = PSQI Sleep duration subscale
SE = PSQI Sleep efficiency subscale
DI = PSQI Sleep disturbances subscale
MD = PSQI Use of medical subscale

Logistic Regression

As 97% of the sample revealed a PSQI score of >6 (the cut-off score) used by the PSQI, the sample was split into two groups based on the median score to indicate those experiencing milder (those scoring 0-13, N= 56) and more severe levels of sleep difficulties (those scoring 14 or above) to enable an exploration of the factors associated with more severe forms of sleep disturbance. A logistic regression was conducted entering in the variables; age, gender, positive affect, negative affect, and the eight subscale scores of the RAND SF-36 using the forward log likelihood method. This method compares each variable in the model in the absence and presence of other variables to explore its contribution to the model. Variables not significantly contributing to the model are excluded. The final model with significant predictors is shown in Table 3, revealing that only the lower quality of life in the RAND SF-36 subscale relating to role difficulties due to emotional problems is significantly associated with more severe global sleep disturbances.

Table 3. Final model of variables associated with global sleep quality in the logistic regression

	B	Standard Error	P value	Odds ratio	95% Confidence Intervals
Constant	-0.41	.28			
Role difficulties due to emotional problems	-0.2	.01	0.00	0.98	0.97-0.99

As the distribution of health outcomes was negatively skewed on the SF36, participants could not be classified into those with poor or good health outcomes within this study consequently, logistic regression was deemed not to be appropriate. Structural equation modelling offered an analytic approach that would assist in exploring the complex relationships between variables that emerged in the correlation analysis. This approach offers the ability to explore how the variables interact, the validity of the data and enables the investigation of moderating and mediating variables. However, according to Tabachnick and Fidell (2007) prior knowledge of the potential relationships between variables is needed to apply structured equation modelling. Because this was an exploratory analysis (due to the fact that the nature of the relationships between variables is unknown in this population) and considering the number of variables that would need to be entered into the structural equation model, the sample size of this study was considered to be too small to apply structural equation modelling to the data

(Tabachnick & Fidell, 2007). Therefore further analysis of the data set was not completed.

Discussion

This exploratory study aimed to investigate the extent and nature of sleep difficulties in FMS and to explore the effects of self-reported sleep and coping on health outcomes. A high percentage of the sample (97%) were found to have sleep quality above the level indicative of significant sleep disturbance in need of treatment, a level higher than indicated in previous research. This suggests that sleep difficulties are an important issue for people with FMS (Osorio et al., 2006; Rao & Bennett, 2003). This study found that global sleep quality was significantly associated with physical functioning, role limitations due to emotional difficulties, fatigue, well-being, social functioning, and levels of pain. The most prominent sleep difficulties related to overall poor sleep quality and frequent night-time awakenings, which were significantly correlated with poorer health outcomes in FMS.

The Nature of Sleep Difficulties in FMS

As discussed in Chapter Two, identifying the specific sleep difficulties that people experience is crucial to inform suitable treatment interventions. In this study, the main difficulties people with FMS experienced were perceptions of overall poor sleep quality, frequent awakenings during the night and difficulties being able to return to sleep afterwards. This contrasts with previous research findings for people with chronic pain who reported that their main difficulties related to initial sleep onset, total time spent asleep and sleep efficiency as described in Chapter Three (Wittig et al., 1982). These findings did not support the hypothesis for this study.

The frequent experience of night-time awakenings in FMS may be due to cognitive factors such as worrying about sleep or feeling stressed. These cognitive factors may also have an important influence on sleep quality in FMS. In the general population difficulties returning to sleep after awakening are often increased by worrying or ruminating about daily events (Sadeh et al., 2004). As a high proportion of FMS participants in this study reported low enjoyment of sleep, while spending a lot of time

in bed, participants may have developed negative associations with going to bed, dysfunctional beliefs about their sleep or started to engage in sleep catastrophising (Morin, Stone, Trinkle, Mercer, & Remsberg, 1993). The wide variability in the duration of night-time awakenings found in this study, suggests that this may be an important distinction in our understanding of the role of night-time awakenings in FMS. Objective measures of sleep have shown higher frequencies of night-time awakenings than subjective reports which may occur as people could experience brief awakenings that they may not be fully conscious of at night (Lockley, Skene, & Arendt, 1999). Consequently, it may be the case that nocturnal awakenings of several minutes may have less of an impact on FMS symptoms, than awakenings of several hours and this was not explored within this study. Physiological factors such as increased pain due to a period of inactivity may prevent sleep onset after awakening or awakenings may be due to abnormal levels hormones and neurotransmitter activity as described in Chapter One. Therefore, further investigation of the causes of night-time awakenings in FMS is necessary.

The Effect of Sleep on Health Outcomes in FMS

The results of this study support previous findings that components of poor sleep quality are significantly associated with pain, poorer physical functioning and higher levels of negative affect in FMS (Affleck et al., 1996; Agargun et al., 1999; Nicassio et al., 2002). Previous studies of sleep in FMS have explored self-reported sleep using global measures of sleep quality such as single VAS scales. However, in line with the proposals of Pilcher et al (1997), the role of sleep on health outcomes became clearer when the individual components of the PSQI were used in the analysis. For example, in this study it appeared that the number of night-time awakenings and overall sleep quality were more related to health outcomes in FMS than sleep quantity, sleep onset latency or sleep efficiency, and it was interesting to note that the global PSQI score was not significantly correlated with general health. As only night-time awakenings and perceived sleep quality were the components of sleep quality that were significantly correlated with health outcomes, in this study, this would suggest that reducing night-time awakenings and perceived sleep quality should be the focus of interventions to improve health related quality of life in FMS.

Looking at the relationships between sleep and fatigue, it was also interesting that the only component of sleep quality that significantly correlated with fatigue was daytime dysfunction. These items focused on difficulties staying awake and low enthusiasm to get things done, rather than nocturnal sleep itself. This suggested that sleep has a more significant link to pain than to fatigue. However, these findings may be due to the way fatigue was assessed. The fatigue subscale of the SF36 only includes four items asking about perceived energy levels and sleepiness. There is considerable debate in the literature as to whether fatigue is a unidimensional (Fisk & Doble, 2002) or multi-dimensional concept, encompassing mental and physical fatigue, reduced motivation and lower engagement in activities (Kos, Kerckhofs, Nagels, D'Hooghe M, & Ilsbroukx, 2008). This outcome measure may therefore have focused more on 'sleepiness' than 'fatigue'. Further work using a more comprehensive assessment of fatigue is needed to confidently refute any link between nocturnal sleep quality and fatigue in FMS.

The Relationships between Demographic Variables, Sleep and Health Outcomes in FMS

In support of the unexpected findings revealed by Reisine et al (2008) that older age was associated with lower levels of pain, fatigue and depression in FMS, this study found that older age and a longer duration of illness were also positively associated with better general health. These findings suggested that people may adjust and learn to manage living with a chronic condition more effectively or that the symptom profile may change over time.

In the study by Mellinger, Balter and Uhlenhuth (1985), it was revealed that 25% of people aged 60 or over reported experiencing sleep difficulties. In addition, older adults have been found to be more likely to experience difficulties initialising sleep than younger adults (McCrae et al., 2003). The mean age of participants in this study was 55 years of age and therefore older age may have contributed to the higher prevalence of sleep difficulties reported in this study. However, age was not significantly associated with the PSQI global score or the components of sleep quality in this population, and the most common difficulties were related to night-time awakenings rather than sleep onset difficulties. Therefore age may not play such an important role in this population, although comparisons to an age and sex matched control group would help to confirm this proposal.

Relationship between Negative Affect, Sleep and Health Outcomes in FMS

As expected, higher negative affect was associated with higher levels of pain and poorer sleep quality, supporting previous research findings (Nicassio et al., 2002; Staud, Price, Robinson, & Vierck, 2004). It was found that the relationship between negative affect and poor sleep quality was strongest between the frequency of night-time awakenings and daytime dysfunction outcomes. Due to the cross-sectional nature of this study, it remains unclear whether negative affect leads to, or is the result of, poor sleep and poor health outcomes. On further analysis of negative affect, it became evident that the most frequent negative feelings were being ashamed, afraid and hostile. This contrasts with the findings from a previous study in chronic pain patients conducted by Sofaer and Walker (1994), who revealed that the most frequent negative feelings were tension, worry and irritability. This may be due to the different demands placed on people with FMS (in contrast to other chronic illnesses) such as difficulties in receiving a diagnosis, high unpredictability of symptoms and the low recognition of the condition in the medical field, as described in Chapter Three.

The Influence of Coping on Health Outcomes in FMS

As suggested by the Self Regulatory Model (Leventhal et al., 1980; Leventhal et al., 1984), the use of problem and emotion focused coping strategies were significantly associated with health related quality of life outcomes including well-being, role limitations due to emotional problems and lower negative affect. However, none of the coping strategies in this study were related to physical health outcomes such as pain and fatigue, as proposed by the Self Regulatory Model. This supports the findings by Martin et al (1996) who revealed that coping attempts were not significantly associated with poorer disability outcomes, but were associated with improved psychosocial outcomes. Although active coping strategies may not relieve the physical symptoms of FMS, they may help the person to feel more in control of their illness. Therefore these findings suggest that problem-solving coping strategies are related to better psychological well-being, but that other factors may have a more important influence than coping on physical health outcomes and sleep quality in FMS.

However, it may be the case that current measures are not eliciting the strategies that affect physical health outcomes in FMS. For example, the previous study described by Nicassio et al (1995) which found negative effects of active coping strategies on health outcomes, used the Coping Strategies Questionnaire instead of the COPE, which may have been measuring different aspects of coping. The COPE was used as a trait measure of coping and is based on the assumption that people use the same coping strategies in response to different situations and stressors. In contrast, the CSQ focuses specifically on coping in response to pain which may explain the different results between this study and the study conducted by Nicassio et al (1995).

The results from this study provide partial support for current models of sleep and pain, as proposed by Currie et al (2000) and Call-Schmidt and Richardson (2003). However, it appears that these current models need to incorporate additional variables, such as negative affect and to ensure relevance to people with FMS.

Strengths and Limitations

The findings of this study are limited by the low response rate of 56%. It may be the case that there were significant differences between responders and non-responders threatening the generalisability of the results and incurring selection bias. For example, people are more likely to respond to postal questionnaires that are of interest to them and it is possible that despite asking people to complete the questionnaire whether they were experiencing sleep difficulties or not, people experiencing sleep difficulties were more likely to return the completed questionnaire (Edwards et al., 2002; Scott & Edwards, 2006). Based on the findings of a systematic review of approaches to increase participant response rates, the low response rate could have been improved by making the questionnaires more visually appealing by the use of colour or by personalising questionnaires (Edwards et al., 2002). Follow up contact or sending a second copy of the questionnaire to people who did not respond initially may also have been useful strategies to increase the response rate (Edwards et al., 2002; Scott & Edwards, 2006).

A further limitation of the study is that only 7% of the sample were male, which is less than the prevalence estimates of 6-10:1 (Wolfe et al., 1990; Yunus, 2001). This may suggest that although the sampling strategy enabled us to access people with a range of disease severity, this may not have been an optimum strategy for recruiting male

participants, who may be less likely to attend support groups than women (Taylor, Falke, Shoptaw, & Lichtman, 1986). Consequently it is difficult to generalise these findings to males with FMS.

The cross-sectional nature of this study meant that only a 'typical' or 'average' nights sleep was explored over the previous month and it is possible that participants' sleep patterns may vary over time. It also remains inconclusive as to whether poor sleep leads to poorer health outcome or vice versa, or if there is a bi-directional relationship between sleep and pain. A further limitation of the cross-sectional design of the study is that coping may have a more significant effect over time, which would not have been accounted for in this research design. Indeed, Nicassio et al (1995) found that coping explained more variance on levels of pain in the longitudinal analysis of their data than during cross-sectional analysis. Therefore longitudinal research is needed to help clarify the relationships and interactions between components of sleep and coping on health outcomes. Future research may be enhanced by the use of sleep diaries which are commonly used in research into insomnia and allow people to record sleep quality, quantity and behaviour each day over several days or weeks (Affleck et al., 1998; Moldofsky, 2009).

Fatigue was assessed as a single construct within this study which may be considered to be another weakness of this study. As fatigue has been proposed to be a multidimensional construct, the lack of a relationship between fatigue and sleep may have been due to issues of measurement. Consequently, future studies need to investigate the different dimensions of fatigue including mental fatigue (impairment in concentration and thinking as a result of demanding or sustained activities) and physical fatigue (a sense of physical exhaustion or depletion of energy as result of direct physical effort) (Moldofsky, 2009).

Despite the limitations of this research, this study has revealed the important links between sleep quality and a range of quality of life outcomes in FMS. This work builds on previous research findings by exploring the components of sleep quality and highlighting the most prevalent sleep difficulties in order to inform clinical treatment. The results highlight the need for careful comparison of results from studies which use assessments of coping and also the need to assess a range of health outcomes in research into the complex condition of FMS.

Future Directions

This study only explored the effect of mood, coping and sleep on health outcomes in FMS. As both sleep and FMS are complex phenomena, other factors that were not accounted for in this study may also affect sleep quality and health outcomes in FMS. It is well documented that people with high levels of sleep related dysfunctional thinking, have heightened levels of arousal that can exacerbate sleep disturbances (Espie, Inglis, Harvey, & Tessier, 2000; Harvey, 2002; Morin et al., 1993). In addition, Masi et al (2002) highlighted that dysfunctional beliefs can lead to increased attention to pain. This perspective is supported by Smith et al (2001) who found that participants with chronic pain conditions reported thinking about their levels of pain before sleep onset. Therefore dysfunctional beliefs may have an effect on both sleep and health outcomes in FMS. Further research is needed to explore the role of beliefs and dysfunctional thinking about sleep, sleep quality and health outcome in FMS.

Implications

The high prevalence of sleep difficulties in this population clearly highlights that sleep disturbance was a profound challenge faced by people with FMS. Henriksson (1994) outlined in a longitudinal study, that 80% of patients with FMS reported an increase or no change in sleep difficulties and levels of pain over a five year period, therefore interventions to improve sleep quality are needed. The finding that the most common sleep difficulties reported by participants are night-time awakening and poor perceived sleep quality, which were found to have a significant effect on physical functioning, role limitations due to emotional factors, pain and general health, suggests that interventions focusing on improving the maintenance of sleep may help to improve health outcomes for people with FMS.

Summary

The high prevalence of night-time awakenings and poor sleep quality presents a significant challenge to people with FMS. Sleep disturbances are significantly associated with reduced physical functioning, increased role limitations due to

emotional problems, increased pain and poor general health. A greater understanding of the factors that may be causing the night-time awakenings and perceptions of poor sleep quality, therefore requires further investigation to inform possible treatment interventions. Case-control studies provide stronger evidence of cause-effect associations compared to cross-sectional studies and also enable comparison with controls to be made, thus indentifying significant differences that may affect the outcome under investigation. A case-control study examining the potential factors that may influence sleep quality in patients with FMS was therefore selected for Study Two of this thesis.

Chapter Five. Investigation of the Factors that may Influence Sleep Quality in FMS

The previous chapter revealed that sleep disturbance is a common difficulty experienced by people with FMS, with up to 97% of patients reporting poor sleep quality. As discussed in Chapter Two, the literature on insomnia has revealed that psychological factors have been found to be central to the maintenance of sleep disturbance. To extend the findings from Study One on the nature and frequency of sleep disturbances in this population, this study aimed to explore if any psychological factors may influence poor sleep quality specifically for people with FMS.

Dysfunctional Beliefs about Sleep

As discussed in Chapter Two, models of insomnia and the development of sleep difficulties in chronic pain, suggest that cognitive factors are likely to have a significant impact on insomnia (Call-Schmidt & Richardson, 2003; Currie et al., 2000; Lundh & Broman, 2000) and sleep quality in people with chronic pain (Call-Schmidt & Richardson, 2003; Currie et al., 2000). Elaborating on the role of cognitive factors within poor sleep quality, Harvey (2002) developed the Cognitive Model of Insomnia and proposes that some people become anxious and worry excessively about their sleep quality and the consequences of not getting enough sleep. These worries stem from the establishment of dysfunctional beliefs about sleep (people's inaccurate expectations of the amount and quality of sleep that they need, and the consequences that poor sleep will have on their daily functioning). Worrying about sleep may increase attention to the problem and sensitivity to symptoms (Masi et al., 2002). This increased cognitive activity may lead to an increase in brain activity, basal and central nervous system metabolic rate and body temperature, which have all been associated with increased arousal thereby delaying sleep onset and increasing the risk of people experiencing sleeping difficulties (Harvey, 2002; Lichstein & Rosenthal, 1980; Ohayon, Caulet, & Guilleminault, 1997).

Research evidence has provided support for links between beliefs and expectations about sleep and sleep quality. For example, people experiencing insomnia describe high levels of worry, planning, thinking about daily events and difficulties calming their mind before sleep onset (Lichstein & Rosenthal, 1980; Ohayon et al., 1997). Exploring these cognitions in more detail, it has been revealed that thoughts eliciting emotional

reactions are most likely to be detrimental to sleep quality (Morin et al., 1993). High levels of pre-sleep cognitive arousal have been found to be associated with delayed sleep onset latency and the total amount of time spent asleep in people with insomnia (Broman & Hetta, 1994; Gross & Borkovec, 1982). This suggests that cognitions may influence the experience of sleep, although research exploring the role of cognitions on sleep quality in FMS is lacking.

Beliefs and expectations about sleep are most commonly assessed using the Dysfunctional Beliefs and Attitudes Scale (DBAS) (Morin, 1993). The DBAS was initially developed as a 30 item scale, however the DBAS is also available in shorter 16 item and 10 item versions, which have revealed more robust psychometric properties. Research utilising the DBAS has revealed that although both good and poor sleepers may hold dysfunctional beliefs about sleep to some extent (as not all dysfunctional beliefs discriminate between insomniacs and normal sleepers) (Carney & Edinger, 2006; Ellis, Hampson, & Cropley, 2007), poor sleepers have stronger and more rigid dysfunctional beliefs and attitudes towards sleep. Ellis et al (2007) identified that 8 of the 10 items from the DBAS-10 discriminated between good and poor sleepers. The two items that did not discriminate were: 'When I don't get the proper amount of sleep on a given night, I need to catch up on the next day by napping or on the next night by sleeping longer' and 'When I have trouble getting to sleep, I should stay in bed and try harder' (Ellis et al., 2007). As highlighted by Morin (1993), it is important to identify the beliefs that discriminate between good and poor sleepers to inform treatment. Indeed, cognitive behavioural therapy has been found to significantly reduce dysfunctional beliefs about sleep resulting in improved sleep efficiency for people with insomnia (Carney & Edinger, 2006; Sato, Yamadera, Matsushima, Itoh, & Nakayama, 2010).

Despite the evidence suggesting that cognitive factors have a key role on sleep quality, little research has explored the role of beliefs about sleep on sleep quality in chronic pain. One recent study using the DBAS-16 in a sample of patients with chronic benign pain (pain which has persisted despite medical intervention), revealed that high dysfunctional beliefs about sleep, depression and night-time levels of pain, significantly contributed to the model of pain, explaining 51% of the variance in poor sleep quality (Ashworth, Davidson, & Espie, 2009). However, this study did not explore which beliefs discriminated between good and poor sleepers in people with chronic pain.

These people may be different to people with primary insomnia due to the different demands their medical condition places on their lives. As poor sleep quality is a significant problem for people with FMS, the role of cognitive factors on sleep quality in this population needs further exploration, particularly as treatments addressing dysfunctional beliefs has been found to significantly improve sleep quality (Ellis et al., 2007).

Stress

Many studies have revealed that stress is also linked to poor sleep quality. High levels of stress have been associated with increased physiological and psychological arousal preventing sleep onset. Even minor daily stresses have been found to have a negative impact on subsequent sleep quality in people with insomnia (Rubman et al., 1990). It is likely that appraisals of potential stressors are affected by a number of factors such as past experience, mood, perceived coping ability and the effect of other stressful circumstances coinciding at the same time. Assessments exploring perceptions of overall stress have been found to be more highly correlated with mood and physical symptoms, than an assessment of the experience of life events (Pbert, Doerfler, & DeCosimo, 1992). Healey et al (1981) revealed that the most frequent stressful events reported by people with poor sleep were related to illness, and loss. It may be that ruminating about daily stressors or symptoms of pain may delay sleep onset or lead to disrupted sleep. This concept was supported by Smith et al (2001) who revealed that ruminating about pain was significantly predictive of longer sleep onset latency and total duration of night-time awakenings in chronic pain patients. This may also be the case in people with FMS. Studies have found that stress responses appear to be elevated in FMS in comparison to healthy controls, and evidence suggests that patients with FMS have difficulty adapting to stress. Evidence has also revealed that symptoms of FMS are exacerbated by stress (Crofford & Demitrack, 1996), therefore stress may have an important role to play in the sleep quality of patients with FMS (Thieme et al., 2006). In addition, poor sleep may also have a direct negative impact on a person's ability to utilise adaptive coping strategies in response to stressful situation, therefore preventing recovery from stress, due to excessive daytime sleepiness and creating a vicious cycle (Moldofsky, 2010).

It has been suggested that the autonomic nervous system (part of the body's stress response system) may not be working effectively in people with FMS. Several researchers (Martinez-Lavin, 2007; Zurowski & Shapiro, 2004) have also suggested that living with FMS and sleep difficulties may cause increased stress as a result of dealing with the increased demands of managing a chronic pain condition. In addition, polysomnographic evidence has revealed increased frontal cognitive activity during sleep in people with FMS in comparison to controls (Horne & Shackell, 1991). Indeed, participants with FMS have described finding it difficult to calm their mind before sleep, suggesting that cognitive factors may have an affect on sleep quality in people with FMS. Therefore stress is likely to influence sleep quality in FMS.

Given the evidence that stress and beliefs about sleep may affect sleep quality, there is a need to investigate the role of these factors on sleep quality in FMS and to identify the factors that may influence the onset and maintenance of sleep disturbances. The present study aimed to explore whether levels of perceived stress and dysfunctional beliefs about sleep are different between people with FMS and healthy controls, and to explore the relationships between stress, dysfunctional beliefs about sleep, sleep quality and health related quality of life in FMS. Based on the research literature it is hypothesised that people with FMS will have significantly higher dysfunctional beliefs about sleep and greater levels of stress than healthy controls. Moreover, it is expected, that high dysfunctional beliefs about sleep and levels of stress will be significantly associated with poorer sleep quality and health related quality of life.

Methods

In order to identify whether perceived levels of stress and dysfunctional beliefs about sleep are important to perceived sleep quality in FMS, this study employed a case-control design. Case-control studies provide stronger evidence of cause-effect associations compared with studies only exploring the population of interest, as they can be used to identify factors that may contribute to a medical condition by comparing people who have a certain condition (cases), with patients who are similar but do not have the condition (controls) (Bland, 2000).

Based on the current research evidence, it was hypothesised that:

1) People with FMS would have significantly higher perceived levels of stress than healthy controls;
2) People with FMS would have significantly higher dysfunctional beliefs about sleep than healthy controls;
3) People with FMS would have higher levels of poor sleep quality than healthy controls;
4) Higher levels of perceived stress and dysfunctional beliefs about sleep would be associated with poorer sleep quality;
5) Poor sleep quality is a predictive factor in being diagnosed with FMS.

Power Calculations

A priori power calculation using G*power 3.1.0 based on a two-tailed, Mann Whitney test, with a medium effect size of 0.5, alpha 0.05 and power 0.8 revealed that a minimum of 128 participants (64 per group) would be needed for this study to have power to detect significant differences between the two groups.

Participant Recruitment

As the recruitment procedure worked effectively in recruiting sufficient numbers of participants with a range of symptom severity in the previous study, an identical recruitment procedure was applied for this study. This involved advertising for volunteers through patient support groups (see Chapter Four for details). To be included in this study as ‘cases’, participants were required to have received a diagnosis of FMS by a GP or consultant. Due to financial limitations we were unable to confirm the diagnosis of FMS. To elicit a comparative sample of ‘control’ participants of a similar age range, people without a diagnosis of FMS were recruited through community groups run by the University of the Third Age (U3A) organisation. This organisation runs community based activity and socialisation groups within the same regions of the UK as FMS support groups. This approach also aimed to control for any factors relating to being a member of a community group, such as increased social support.

For both groups, participants were required to be aged >18 years. Participant's data was excluded if: 1) they had been diagnosed with a sleep disorder caused by an identified physical cause such as sleep apnoea or restless legs syndrome; 2) if more than 20% of a measure within the questionnaire was incomplete. Healthy control group participants were excluded if they revealed that they had been diagnosed with FMS.

Outcome Measures

Three hundred information sheets, consent forms and questionnaires were distributed to potentially eligible participants (150 to 'cases' and 150 to 'controls') via the post and through community group meetings. Participants were asked to complete the questionnaire in their own time. They were informed that the questions would be asking about their thoughts on sleep, perceived stress, sleep quality and levels of pain and fatigue. Information on demographic and clinical variables including age, medication use and employment status including shift work) was requested. In addition the questionnaire included the following standardised assessment measures:

Dysfunctional Beliefs about Sleep

The Dysfunctional Beliefs and Attitudes About Sleep Scale (DBAS-10) (Espie et al., 2000) consists of 10 statements exploring patient beliefs and attitudes about sleep. The participant indicates their level of agreement to each statement on a visual analogue scale, scoring between 1 'strongly disagree' to 10 'strongly agree'. Items are summed to yield a total score (maximum possible score of 100). High scores on the DBAS-10 are indicative of high dysfunctional beliefs about sleep. The DBAS-10 was chosen specifically, as these 10 items were found to be the most sensitive to change in a clinical trial and were found to have improved internal consistency in comparison to the more comprehensive DBAS-30 measure (Espie et al., 2000). The DBAS-10 has been found to be highly correlated with the full DBAS scale (Edinger & Wohlgemuth, 2001; Espie et al., 2000; Morin et al., 1993), indicating that the two scales are measuring similar constructs (Edinger & Wohlgemuth, 2001). The DBAS-10 has also independently revealed respectable internal consistency (a = 0.7 in good sleepers and 0.68 in people with insomnia) (Edinger & Wohlgemuth, 2001) and has been shown to be sensitive to recovery (Edinger, Wohlgemuth, Radtke, Marsh, & Quillian, 2001). The DBAS-16 version of the scales has revealed a test-retest correlation of r=0.83 (Morin, Vallieres, & Ivers, 2007). The measure has been widely used in a clinical context to identify specific

dysfunctional beliefs that need to be addressed in treatment (Morin, 1993). Factor analysis completed in people with insomnia revealed three underlying factors of the DBAS-10 relating to: 1) immediate consequences of insomnia; 2) beliefs about the long-term consequences of insomnia; and 3) beliefs about the need to control insomnia (Espie et al., 2000). As this measure has not been previously used in people with FMS, the underlying factor structure of this measure will be explored in people with FMS.

Perceived Levels of Stress

The Perceived Stress Scale (PSS-10, Cohen, Kamarck, & Mermelstein, 1983) includes 10 items which focus on the overall perceived stress, perceived control and ability to cope in response to stressful events over the previous month. This measure assesses people's appraisals of stressful events, rather than just describing the nature of the event itself. Scores are summed to yield a total score, with high scores reflecting a greater level of perceived stress. The scale has demonstrated acceptable internal consistency of between 0.78 (Cohen & Williamson, 1988) and 0.86 (Cohen et al., 1983) and test retest correlation of 0.85 (Cohen et al., 1983) and it has been widely used in clinical populations (Cohen et al., 1983). Previous factor analysis has only been completed on the PSS-14 version of the scale which revealed two underlying factors: 1) perceived distress; and 2) perceived coping (Hewitt, Flett, & Mosher, 1992). Similar to the DBAS-10, this measure has not previously been used in people with FMS and therefore the underlying structure will be explored in this study.

Self-reported Sleep Quality

Sleep quality was assessed using the PSQI (Buysse et al., 1989). As described in Chapter Two, this measure was chosen to enable the assessment of the various components of sleep quality, with higher scores reflecting poorer sleep quality.

Pain

The pain subscale from the Short Form Medical Outcomes Questionnaire (SF-36) (Ware & Sherbourne, 1992) was used to assess levels of pain and interference of pain on daily activities, over the previous month. This scale consists of two items which have demonstrated high internal consistency (Cronbach's alpha = 0.85) (Jenkinson, Stewart-Brown, Petersen, & Paice, 1999) and good test retest reliability of 0.86 (Gummesson, Atroshi, & Ekdahl, 2003). This scale was chosen as it has been widely applied to people

with and without chronic medical conditions. High scores on this measure are indicative of lower levels of pain.

Fatigue

The Fatigue Assessment Scale (FAS, Michielsen, De Vries, & Van Heck, 2003) contains 10 items. This scale was chosen as it explores both the physical and mental components of fatigue (with five items exploring physical fatigue and five items exploring mental fatigue). Participants are asked to respond to each statement on a five point scale ranging from 1 (never) to 5 (always), in order to represent how they have been feeling over the past month. A total score is calculated from the sum of the individual items. The FAS has demonstrated good internal consistency (Cronbach's alpha = 0.90) shown correlations over 0.7 with other measures of fatigue (Michielsen et al., 2003) and has a test retest reliability of 0.88 (De Vries, Van der Steeg, & Roukema, 2010) and was chosen in response to the limitations of the fatigue scale of the SF-36 which does not explore the different dimensions of fatigue as outlined in Chapter Four. Although the FAS measures different components of fatigue, it was revealed that in comparison to four other measures of fatigue, the FAS revealed a clear one factor structure through factor analysis. This suggested that although it is important to explore both mental and physical fatigue, the components combine into an overall assessment of 'fatigue' revealing good internal consistency (Michielsen et al., 2003). High scores on this measure indicate higher levels of fatigue.

Piloting of the Full Questionnaire

The complete questionnaire, including the scales described above, was piloted with five people with FMS and five healthy controls before submission to the ethics committee. People piloting the questionnaire reported that full questionnaire took approximately 13 minutes to complete. On completion of the questionnaire, participants were asked to return the questionnaire and signed consent form in the pre-paid envelope provided.

Data Analysis

The same procedures for data entry, screening and scoring were utilised as described in the study outlined in Chapter Four.

The questionnaire data were analysed using t-tests (if the data met parametric assumptions), chi-square tests for nominal data or Mann Whitney U tests, (if the data did not meet parametric assumptions), to explore if there were differences between patients with FMS and healthy controls.

Correlation analysis was used to explore the associations between perceived stress, dysfunctional beliefs about sleep, sleep quality, pain and fatigue. Conditional logistic regression was used to explore if these psychological factors were significant risk factors for FMS.

Results

Of the 300 questionnaires that were distributed, 112 (74.67%) were returned by participants diagnosed with FMS and 92 (61.33%) were received from healthy controls. On receipt, the questionnaires were screened to ensure that the participants met the inclusion criteria. The screening process resulted in four participants being excluded, of these, three participants were excluded as more than 20% of the questionnaire data was missing and one FMS participant was omitted as they had not been diagnosed by a GP or consultant, as stated in the inclusion criteria. Frequency matching was used to 'match' cases with controls (Sturmer & Brenner, 2001). The age and gender of the recruited cases were identified and listed and controls continued to be recruited until matches were found for over 80 cases (based on the sample size calculation that only 64 cases and controls were needed). The remaining questionnaires (those unmatched) were excluded to form two equally matched participant groups (N=83 FMS participants and N= 83 age and sex matched healthy controls), with N=7 males (8.4%) in each group and N=42 (50.6%) <55 years of age in each group. The age of 55 years was chosen to ensure that half of the sample were young-middle aged adults and half were older adults to account for any possible age related sleep difficulties. Missing values were treated with person mean substitution as discussed on pages 60-61.

As previously described on page 61, the questionnaire data was scored according to the individual questionnaire instructions and the resulting variables were checked for skewness and kurtosis. Transformation of skewed variables aims to normalise the distribution of the data in order to meet the assumptions of parametric statistics (Norris & Aroian, 2004). There are several different approaches for transforming data, dependent on the degree and direction of the skew. Due to the need to use different transformation approaches for different distributions of data, this can cause difficulties in applying transformations, as all items on a given scale need to be transformed using the same approach to enable the comparison of like with like, and one approach may not be suitable for all items within a scale. Consequently, transformation of skewed data is not always recommended (Norris & Aroian, 2004). As the data were considered to be ordinal in this thesis (as discussed in Chapter Four) non-parametric statistics were used to analyse the data in this study. Non-parametric tests do not require data to be normally distributed and therefore the skewness of the study variables were not corrected.

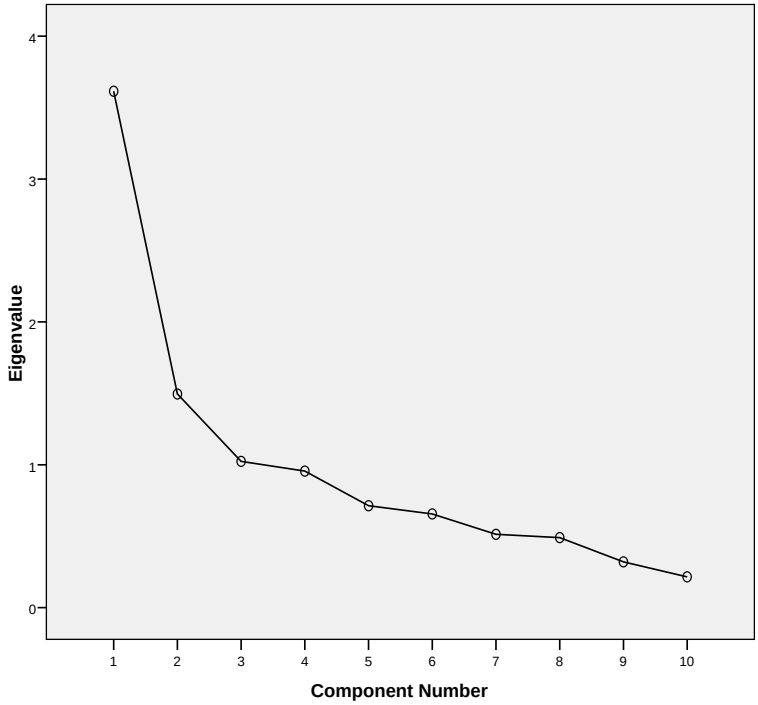
To account for multiple comparisons, findings were only considered to be significant at the $p<0.01$ level (see Chapter Four, p. 65 for a discussion of this approach). A post hoc power analysis was conducted to ensure the study had sufficient power to detect differences at the more stringent significance level (see the differences between FMS participants and controls section p. 92).

As both the DBAS-10 and the PSS measures have not been previously used in the FMS population, principal components factor analysis was conducted on these measures for the FMS participants based on the component matrix (see Tables 4, p. 89 and 5, p. 91; and Figures 7, p. 90 and 8, p. 92).

Table 4. Factor structure of the DBAS-10 for FMS participants

	Consequences of poor sleep	Sleep Need	Rumination
I am concerned that chronic insomnia may have serious consequences on my physical health	**.67**	-.05	-.37
I am worried that I may lose control over my abilities to sleep	**.60**	-.07	.37
After a poor nights sleep, I know that it will interfere with my activities the next day	**.74**	-.24	-.07
When I feel irritable, depressed or anxious during the day, it is mostly because I did not sleep well the night before	**.79**	-.33	-.07
When I sleep poorly on one night, I know it will disturb my sleep schedule for the whole week	**.69**	.12	-.18
When I feel tired, have no energy, or just seem not to function well during the day, it is generally because I did not sleep well the night before	**.77**	-.28	-.12
I need 8 hours of sleep to feel refreshed and function the next day	**.49**	**.66**	.03
When I don't get the proper amount of sleep on a given night, I need to catch up on the next day by napping or on the next night sleeping longer	.34	**.71**	.14
When I have trouble getting to sleep, I should stay in bed and try harder	.35	**.48**	.09
I get overwhelmed by my thoughts at night and often feel I have no control over this racing mind	.32	-.25	**.81**

Figure 7. Scree plot for the exploratory factor analysis of the DBAS-10



Factors were extracted if they had an eigen value of >1 as recommended by Field (2009). This was because low eigen values (<1) suggest that the factor is contributing little to the explanation of variance in the variables. The individual questionnaire items were loaded onto a factor on the basis of the highest scores, with values over 0.4 indicating that the item was significantly loaded onto that factor as suggested by Field (2009) (See Tables 4, p. 89 and 5, p. 91).

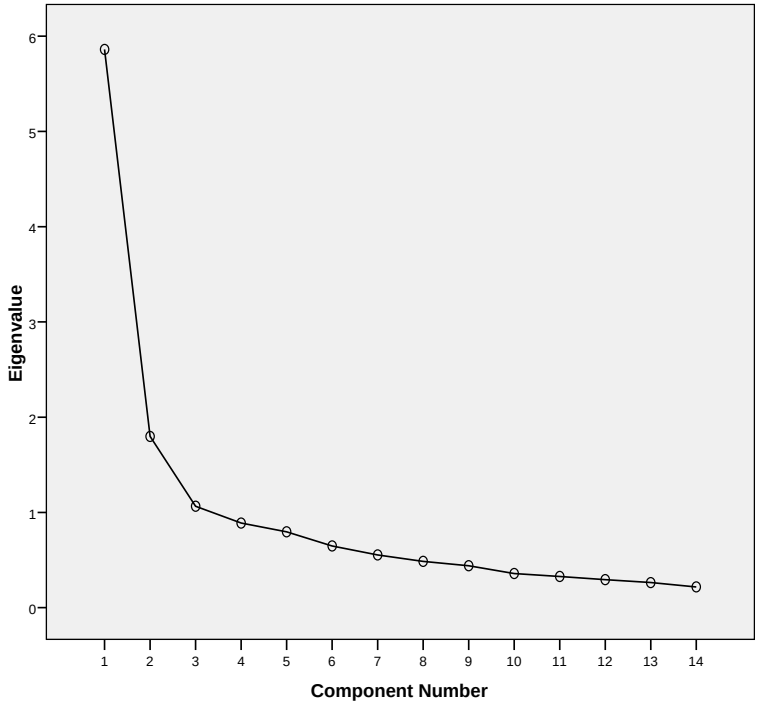
Similar to the findings revealed by Edinger and Wohlgemuth (2001) and Espie et al. (2000) the DBAS-10 yielded a three factor structure, based on a varimax rotation. The eigen value for a one factor structure was 3.62 (explaining 36.15% of the variance). For two factors the eigen value was 1.50 (explaining 51.10% of the variance) and with a three factor structure the eigen value was 1.02 (explaining 61.34% of the variance). With four factors or more, the eigen values were <1). The varimax rotation method was used as it has been found to be useful for exploring how groupings or items measure the same concept. The first two factors related to the consequences of poor sleep and sleep need. The consequence of poor sleep sub-scale, revealed in this study, mirrors that of the consequences of insomnia scale highlighted by Edinger and Wohlgemuth (2001) and Espie et al (2000). However, there was some inconsistency between the items loaded onto this factor in comparison to previous findings. The third factor (rumination)

only contained one item, and was therefore not included in the analysis. Only one item loaded onto more than one factor in this factor analysis (at the 0.4 level) indicating that the item 'I need 8 hours of sleep to feel refreshed and function the next day' loads onto both factors and could indicate a sleep need with or without consequences of poor sleep. All the scales revealed Cronbach's alphas of more than 0.6 (to account for diversity in psychological constructs) and were therefore included in subsequent analysis (Kline, 1999; Loewenthal, 2001).

Table 5. Factor structure of the PSS-10 for FMS participants

	Personal Coping Ability	Distress
1. How often have you been upset because of something that happened unexpectedly?	**.56**	**.49**
6. How often have you felt confident about your ability to handle your personal life?	**.77**	.32
7. How often have you felt things were going your way?	**.73**	.38
9. How often have you been able to control irritations in your life?	**.70**	.15
10. How often have you felt that you were on top of things?	**.83**	.05
2. How often have you felt that you were unable to control the important things in your life?	**.43**	**.70**
3. How often have you felt nervous and 'stressed'?	**.43**	**.65**
11. How often have you been angered because of things that happened that were outside of your control?	.21	**.56**
14. How often have you felt difficulties were piling up so high that you could not overcome them?	**.42**	**.74**
8. How you often have you found that you could not cope with all the things that you had to do?	.10	**.73**

Figure 8. Scree plot for the exploratory factor analysis of the PSS



The two factor structure of the PSS-14, identified by Hewitt et al (1992), perceived distress and perceived coping was supported by this study. The eigen value for a one factor structure was 5.86 (explaining 41.87% of the variance) with two factors the eigen value was 1.80 (explaining 54.71% of the variance). With three factors and higher, the eigen values were <1). Four items loaded onto both factors so the highest loadings are highlighted in Table 5 (p. 91). The high cross loadings suggest that the two underlying factors are not distinctive, therefore the one total scale was used in the analysis.

Differences between FMS Participants and Controls

The two groups were different in terms of employment status, with a higher number of FMS patients no longer working compared to the healthy controls. As highlighted in Chapter One, this may be expected, with many patients having to give up work or reduce their hours as a result of their condition (Burckhardt et al., 1992).

Exploring the differences on the assessment measures between the two groups, participants with FMS had significantly higher levels of perceived stress, dysfunctional beliefs about sleep, pain, fatigue and poorer sleep quality (including all components of sleep quality) as shown in Table 6 (p. 94). Eighty three (100%) of FMS participants

received a PSQI global score ≥6 compared to 38 (45.78%) healthy controls. However, using the more conservative cut-off criteria of ≥10, as used by Osorio et al (2006), 70 (84.34%) participants with FMS and 11 (13.25%) controls were identified as meeting the threshold for sleep disturbance (Osorio et al., 2006). Using a 2x2 contingency table, to explore the number of cases and control participants with clinically significant poor sleep quality (as defined by the more stringent PSQI global score of ≥10) (Osorio et al., 2006), an odds ratio was calculated (dividing the odds in the cases by the odds in the controls). It was found that people with FMS were 32 times more likely to have a clinically significant sleep difficulty than healthy controls (95% CI = 14.80 - 83.94). As shown in Table 6, participants with FMS reported significantly poorer sleep quality than controls across all components of sleep quality.

The effect size for the differences in the key variables of interest in the study between the two groups; dysfunctional beliefs about sleep and perceived stress, were calculated using the equation proposed by Rosenthal (1991).

$$r = \frac{z}{\sqrt{N}}$$

With z representing the z score from the Mann Whitney U test and N representing the number of participants (N=166). Based on a z score of z=-4.86, there was a small effect size for dysfunctional beliefs about sleep, r = -0.38. With a z score of z=-7.07, there was a medium effect size for perceived stress, r = -0.55. The effect size for sleep quality between the two groups was much larger (based on a z score of z=-9.88) at r = -0.77.

A post hoc power analysis was calculated using G*power 3.1.0 to check the power of the study to detect true differences between the two groups at the more stringent level of significance ($p<0.01$). Based on two-tailed Mann Whitney test using the mean effect size found in this study (a medium effect size) of 0.6, alpha 0.01 and N=166. This study was revealed to have a high power of 0.9 to detect a significant difference between the two groups.

Table 6. Participant characteristics and outcome measure scores

	FMS participants (*n* = 83)	Healthy controls (*n* = 83)	Significance test	Cronbach's (*α*)
	Mean (SD)	**Mean (SD)**	-	-
Age	52.59 (11.42)	51.67 (15.47)	$t = -0.43$	-
	Median (IQR)	**Median (IQR)**	-	-
Women	91.60%	91.60%	$\chi^2 = 0.00$, df = 2	-
Percentage in employment (% shift work)	33.73% (4.82%)	55.42% (7.23%)	$\chi^2 = 9.66$, df = 2	-
Pain‡	29.58 (18.10)	82.53 (22.13)	$U = 388.00^{**}$	0.93
Fatigue	31.00 (8.00)	21.00 (4.00)	$U = 341.00^{**}$	0.73
Dysfunctional beliefs total (10-100)	62.50 (26.25)	46.00 (21.00)	$U = 1941.00^{**}$	0.81
DBAS Consequences (6-60)	6.58 (3.21)	4.33 (2.33)	U = 1833.00**	0.78
DBAS Sleep need (3-30)	6.33 (3.08)	5.33 (2.33)	U = 2904.50	0.61
Perceived stress total (0-40)	23.00 (7.25)	14.00 (7.00)	$U = 1178.00^{**}$	0.88
PSQI Sleep quality	2.00 (1.00)	1.00 (1.00)	$U = 1016.50^{**}$	-
PSQI Sleep latency	2.00 (2.00)	1.00 (2.00)	$U = 1381.00^{**}$	-
PSQI Sleep duration	1.00 (2.00)	0.00 (1.00)	$U = 2005.50^{**}$	-
PSQI Sleep efficiency	2.00 (2.00)	0.00 (1.00)	$U = 1510.50^{**}$	-
PSQI Sleep disturbances	2.00 (1.00)	1.00 (2.00)	$U = 876.00^{**}$	-
PSQI Sleep medication	3.00 (3.00)	0.00 (0.00)	$U = 1608.00^{**}$	-
PSQI Daytime dysfunction	2.00 (1.00)	1.00 (1.00)	$U = 886.50^{**}$	-
PSQI Global sleep score	14.00 (6.00)	5.00 (4.25)	$U = 378.50^{**}$	0.84

** $p < 0.01$

‡ High scores = better outcomes

As the specific nature of the dysfunctional beliefs is important to inform clinical treatment and to build on the work conducted by Carney and Edinger (2006) and Ellis et al (2007), the differences between the individual items of the DBAS-10 were explored to see if some items were better discriminators between patients with FMS and normal controls. Eight of the 10 DBAS-10 items were significantly higher in patients with FMS in comparison to healthy controls (see Table 7, p. 96). The dysfunctional beliefs that discriminated between the two groups included the consequences of poor sleep scale items, the rumination item and the need to catch up on poor sleep by napping. The two items that were not significantly different between the two groups, included two of the three items that loaded onto the sleep need scale, 'I need 8 hours of sleep to feel refreshed and function the next day' and 'When I have trouble getting to sleep, I should stay in bed and try harder'.

Table 7. Measures of central tendency and variability for the individual DBAS-10 items

Dysfunctional Belief	FMS participants	Healthy controls	Significance test
	Median (IQR)		
1. I need eight hours of sleep to feel refreshed and function the next day	8.00 (5.00)	8.00 (4.00)	U=3154.00
2. When I don't get the proper amount of sleep on a given night, I need to catch up on the next day by napping or on the next night sleeping longer	8.00 (6.00)	4.00 (5.00)	U=2461.00**
3. I am concerned that chronic insomnia may have serious consequences on my physical health	7.00 (4.00)	5.00 (6.00)	U=2249.00**
4. When I have trouble getting to sleep, I should stay in bed and try harder	3.00 (4.00)	4.00 (4.00)	U=3155.50
5. I am worried that I may lose control over my abilities to sleep	5.00 (5.00)	3.00 (3.00)	U=2461.00**
6. After a poor nights sleep, I know that it will interfere with my activities the next day	9.00 (4.00)	6.00 (5.00)	U=1892.50**
7. When I feel irritable, depressed or anxious during the day, it is mostly because I did not sleep well the night before	7.00 (4.00)	5.00 (5.00)	U=2387.50**
8. When I sleep poorly on one night, I know it will disturb my sleep schedule for the whole week	5.00 (6.00)	2.00 (2.00)	U=2061.50**
9. When I feel tired, have no energy, or just seem not to function well during the day, it is generally because I did not sleep well the night before	7.00 (4.00)	5.00 (5.00)	U=2641.50**
10. I get overwhelmed by my thoughts at night and often feel I have no control over this racing mind	7.00 (5.00)	5.00 (5.00)	U=2614.00**

df, 164, ** = $p < 0.01$

Correlation Analysis

Spearman correlation analysis was used to explore the associations between perceived stress, dysfunctional beliefs about sleep quality, pain, fatigue and sleep for the two groups. In order to account for the multiple correlation analyses, the significance level was set at $p<0.01$. The correlation analyses (shown in Tables 8, p. 97 and 9, p. 98) revealed very different patterns between the two groups. For healthy control participants, overall high levels of stress and perceived distress were both significantly associated with increased levels of fatigue, sleep quality, daytime dysfunction and global sleep quality. High perceptions of the consequences of poor sleep were also significantly associated with distress, overall stress levels and daytime dysfunction; whereas, dysfunctional beliefs about sleep were not related to other outcome variables. In contrast, for people with FMS, perceived consequences of poor sleep were not significantly associated with any of the other variables in the analysis, although higher dysfunctional beliefs about sleep need were significantly associated with poorer sleep quality. High perceived distress and overall levels of distress were significantly associated with higher levels of fatigue, pain, daytime dysfunction and overall stress and high perceived stress was significantly associated with night-time awakenings.

Table 8. Correlations between psychological factors and sleep quality in healthy control participants

	CON	SN	PSS	FAS	PAIN	SQ	SOL	DUR	SE	DIS	MED	DD
SN	**.53****	1.00										
PSS	**.39****	.19	1.00									
FAS	.18	.15	**.32****	1.00								
PAIN	.00	.04	-.13	-.24*	1.00							
SQ	.25*	.04	**.36****	**.29****	-.11	1.00						
SOL	.19	.05	.19	.08	-.17	**.45****	1.00					
DUR	-.20	-.17	.03	-.01	-.07	.24*	.05	1.00				
SE	-.19	-.16	-.04	.21	-.20	.27*	.24*	**.60****	1.00			
DIS	.19	.14	.12	.20	**-.37****	**.33****	.26*	.19	.24*	1.00		
MED	.08	-.06	.22*	.23*	-.28*	**.29****	.22*	.19	.18	**.40****	1.00	
DD	**.38****	.14	**.36****	**.45****	-.06	**.60****	.26*	.05	.06	.21	.26*	1.00
PSQIG	.14	.02	**.31****	**.29****	-.22	**.77****	**.67****	**.51****	**.55****	**.50****	**.44****	**.54****

CON = DBAS-10 Dysfunctional beliefs about consequences of poor sleep
SN = DBAS-10 Dysfunctional beliefs about sleep need
PSS = PSS-10 Total score
FAS = Levels of fatigue
PAIN = Levels of pain
SQ = PSQI Sleep quality
SOL = PSQI Sleep onset latency
DUR = PSQI Sleep duration
SE = PSQI Sleep efficiency
DIS = PSQI Sleep disturbances
MED = PSQI Use of medication to improve sleep
DD = Daytime dysfunction
PSQIG = PSQI Global sleep score

Table 9. Correlations between psychological factors and sleep quality in FMS participants

	CON	SN	PSS	FAS	PAIN	SQ	SOL	DUR	SE	DIS	MED	DD
SN	**.35****	1.00										
PSS	.09	.03	1.00									
FAS	.20	.23*	**.44****	1.00								
PAIN	-.02	-.06	**-.33****	-.26*	1.00							
SQ	.23*	.18	.13	.28*	-.18	1.00						
SOL	.19	-.02	.02	.18	-.05	.25*	1.00					
DUR	.01	**-.34****	-.04	-.03	-.08	**.30****	**.37****	1.00				
SE	.01	-.25*	-.02	.03	-.13	**.35****	**.47****	**.80****	1.00			
DIS	-.02	.00	**.29****	.21	-.23*	.27*	.26*	.18	**.33****	1.00		
MED	.09	-.01	-.09	-.17	-.03	-.06	.05	-.00	.02	.00	1.00	
DD	-.06	-.04	**.29****	**.35****	-.19	.07	.15	.13	.07	.26*	-.16	1.00
PSQIG	.10	-.17	.06	.15	-.16	**.44****	**.70****	**.75****	**.81****	**.45****	**.33****	**.26***

CON = DBAS-10 Dysfunctional beliefs about consequences of poor sleep
SN = DBAS-10 Dysfunctional beliefs about sleep need
PSS = PSS-10 Total score
FAS = Levels of fatigue
PAIN = Levels of pain
SQ = PSQI Sleep quality
SOL = PSQI Sleep onset latency
DUR = PSQI Sleep duration
SE = PSQI Sleep efficiency
DIS = PSQI Sleep disturbances
MED = PSQI Use of medication to improve sleep
DD = Daytime dysfunction
PSQIG = PSQI Global sleep score

Logistic Regression

A logistic regression analysis was conducted to explore if pain, fatigue, sleep, beliefs about sleep, stress and negative affect variables, could accurately predict whether people were diagnosed with FMS or were healthy controls. The categorical outcome group variable was whether people were diagnosed with FMS or were healthy controls (group membership). Logistic regression does not require variables to have a normal distribution, linear relationship or equal variance, and requires that the dependent variable is categorical rather than continuous and was therefore used to explore the variables in this study. As the subscales of the DBAS-10 were highly correlated with each other (as illustrated in Tables 8, p. 97 and 9, p. 98), the total scale score of this measure and the overall score for sleep quality, which were not highly correlated with each other, were used in the regression analysis (Field, 2009). Because cases and controls have been matched for age and gender, variables were entered into the model using the forward conditional method (Field, 2009). This method was used to allow for identification of which single predictor contributed most to the model and variables not significantly contributing to the model were excluded.

A test of the model, including predictors against the constant only model, was statistically significant X^2 (3) = 174.55, $p<0.01$, indicating that the predictors of pain, fatigue and overall sleep quality reliably distinguished between cases and controls. Stress (score = 0.29, p=0.59), beliefs about sleep (score = 0.63, p=0.43) and negative affect (score = 0.14, p=0.71) variables, were not found to contribute significantly to the model on entry and were therefore excluded from the final model (presented in Table 10, p. 100). The Nagelkerke R square of 0.87 indicated a strong relationship between the predictors and group membership and the overall success rate of the model to classify participants was 95%. The Hosmer-Lemeshow Goodness of Fit test revealed that the model estimated the data at an acceptable level X^2(8) 12.41, $p>0.05$. The Wald Criterion demonstrated that pain, overall sleep quality (PSQI global score), and fatigue variables made a significant contribution to prediction of group membership (Table 10, p. 100), Wald statistic = 10.61, 5.83 and 9.38, $p<0.05$ respectively, indicating that the best single predictor was pain. Beliefs about sleep, levels of stress and negative affect did not significantly contribute to the model of group membership.

The Exp (B) values revealed that higher levels of pain and fatigue and poorer overall sleep quality lead to increased risk of being diagnosed with FMS. To check the model against the order of entry of variables from effecting the results, the log likelihood backward method of regression was also used and the same model was revealed verifying the findings.

Table 10. Logistic regression analysis

	B	Standard Error	P value	Odds ratio	95% Confidence Intervals
Constant	-8.68	3.01			
Pain	-0.05	0.02	0.00	0.95	0.93-0.98
Fatigue‡	0.36	0.12	0.00	1.43	1.14-1.80
Overall sleep quality‡	0.23	0.09	0.02	1.26	1.04-1.51

‡ = high scores are indicative of poorer outcomes

Discussion

This study explored differences in dysfunctional beliefs and attitudes about sleep and stress on perceived sleep quality between people with FMS and healthy controls. The results revealed that in comparison to healthy controls, participants with FMS have significantly poorer sleep quality, higher levels of dysfunctional beliefs and attitudes about sleep and higher levels of perceived stress. High overall levels of perceived stress were significantly related to pain and fatigue, and high levels of perceived stress were significantly related to night-time awakenings in people with FMS. Dysfunctional beliefs and attitudes about sleep were also significantly related to sleep duration in the FMS group. These relationships suggest that psychological factors have an important role in sleep quality in FMS.

The significantly higher levels of perceived stress in participants with FMS in comparison to health controls, may reflect the additional pressures of living with a chronic illness (Zurowski & Shapiro, 2004). Stressful life events and altered stress responses are often thought to be involved in the development of FMS symptoms, and

the high levels of perceived stress in the FMS sample may reflect this underlying theory. The finding that high levels of perceived stress were significantly related to increased fatigue in both healthy controls and participants with FMS, suggested that stress management approaches may help to improve fatigue. Exploring the relationship between stress and health outcomes in FMS, specifically stress was significantly linked to more frequent night-time awakenings (a key sleep difficulty experienced by people with FMS). This suggests that interventions incorporating strategies to manage stress, increase perceptions of self control and address dysfunctional beliefs about sleep may help to improve sleep quality and health outcomes for people with FMS.

The factor analyses conducted on the DBAS-10 revealed that the scales had three underlying factors in the FMS population. These underlying factors were used as separate scales in the analysis for this study. Further investigation into the factor structure of the DBAS in clinical populations is needed to explore if this factor structure holds for other populations as well as those with FMS. It is acknowledged that one item loaded onto two factors at the 0.4 level used in this thesis and 7/10 items indicated a possible loading onto other factors (at the 0.3 level). This may indicate that the population was too homogenous, that there was a response within the dataset or that the items are too similar giving the impression of a substantive factor (Boyle, 2010). However, the factor structure found in this thesis is comparable to that found in previous studies in other populations, suggesting the stability of the underlying factor structure in this measure (Edinger & Wohlgemuth, 2001; Espie et al., 2000)

As highlighted by Morin (1993), the specific nature of dysfunctional beliefs held by particular groups is important to clinical treatment and therefore the differences in the level of agreement on the individual items of the DBAS-10 were explored between the two groups. The dysfunctional beliefs identified as being significantly different in FMS participants in comparison to healthy controls were similar to those found to discriminate between good and poor sleepers in previous research (Carney & Edinger, 2006; Ellis et al., 2007). However, one additional item: ‘When I don’t get the proper amount of sleep on a given night, I need to catch up on the next day by napping or on the next night sleeping longer’ was also found to highly discriminate between patients with FMS and healthy controls in this study. This suggests that this item may have particular importance for people with FMS and may reflect the demands of living with FMS and the effect of poor sleep on symptoms such as pain and fatigue. Little research

has explored the use of napping on symptom management in FMS, and requires further investigation to explore whether it is beneficial or not. In addition, it may be argued that item six, 'after a poor nights sleep I know that it will interfere with my activities the next day' may not necessarily be a 'dysfunctional belief' in FMS, as poor sleep quality has previously been associated with poor physical functioning the following day. However, if people begin to expect negative consequences after a poor nights sleep, it may become a self fulfilling prophecy and is therefore important to explore in clinical treatment. Overall, the findings of this study reveal that participants with FMS may be more concerned about the consequences of poor sleep on symptoms and functioning the following day rather than the sleep difficulties themselves. However, it became evident in the correlation analysis that it was beliefs about sleep need that were most significantly related to sleep quality in FMS and should form the focus of clinical treatment.

There were two items of the DBAS-10 that did not discriminate between patients with FMS and healthy controls. One of these items, item four, 'When I have trouble getting to sleep I should stay in bed and try harder' also did not discriminate between good and poor sleepers in a previous study (Carney & Edinger, 2006; Ellis et al., 2007), which raises questions about the importance of this item in the DBAS-10. The second item that did not significantly discriminate between the two groups was item one, 'I need 8 hours of sleep to feel refreshed and function the next day'. Both groups reported strong agreement with this item which may reflect a common misconception held by the general population that people need eight hours of sleep per night and demonstrating low public awareness that people have a natural sleep need which may be shorter or longer than eight hours (as discussed in Chapter Two). Indeed, Ellis et al (2007), revealed that this belief was actually significantly higher in good sleepers than poor sleepers. The exploration of the role of specific beliefs in this study may have been limited by the use of the short version of the DBAS-10 measure and therefore other beliefs that may have an important influence on sleep quality were not explored. These findings do however clearly demonstrate that cognitive factors, such as beliefs about sleep, have an important role in the experience of sleep quality in FMS.

The term 'dysfunctional beliefs' has been used within this thesis as defined by the authors of the DBAS-10 (Espie et al., 2000), however the usefulness of the term 'dysfunctional' should be considered. For example, as highlighted in Chapter Four, poor

sleep is linked to poor pain fatigue and social functioning the following day and therefore items one, 'I need 8 hours of sleep to feel refreshed and function the next day'; three, 'I am concerned that chronic insomnia may have serious consequences on my physical health'; six, 'After a poor nights sleep, I know that it will interfere with my activities the next day'; and nine, 'When I feel tired, have no energy, or just seem not to function well during the day, it is generally because I did not sleep well the night before'; may actually reflect 'accurate' rather than 'dysfunctional' beliefs and the term may therefore not be a true reflection of the nature of these beliefs in this or potentially other clinical populations. Never-the-less, even if they are 'accurate' beliefs, they may still need to be addressed in clinical intervention to prevent self fulfilling prophecies emerging and maintaining sleep disturbance.

The logistic regression analysis highlighted that increased pain and fatigue and poor overall sleep quality were significant predictors of being diagnosed with FMS. Dysfunctional beliefs about sleep, stress and negative affect did not significantly contribute to the model, suggesting that although these factors may be important to the experience of sleep quality and health outcomes in FMS, they were not significant risk factors in the diagnosis of FMS.

Strengths and Limitations

To date, this is the first study that has highlighted the role of beliefs and stress on sleep quality in participants with FMS. The findings revealed that psychological factors such as dysfunctional beliefs about sleep and stress were significantly related to sleep quality, pain and fatigue. However, due to limitations of a cross-sectional questionnaire based design, it is unclear if dysfunctional beliefs and attitudes about sleep and stress lead to, or are the result of, chronic sleep problems in FMS and whether they are directly related to pain, sleep quality and fatigue, or if all these factors interrelate. The finding that beliefs about sleep and stress appear to influence different aspects of sleep quality (e.g. dysfunctional beliefs about sleep need were significantly associated with reduced sleep duration and high levels of stress were associated with increased night-time awakenings), further highlights the importance of exploring the separate components of sleep quality when establishing the effect of psychosocial factors on sleep.

It became clear, through the analysis of the data, that there were significant differences in the levels of dysfunctional beliefs about sleep and stress between people with FMS and healthy controls, suggesting that these psychological factors may have a role in the FMS experience and symptom severity. However, this study may not have accounted for all possible influential factors on these relationships. For example, previous research has found that social support is a protective factor of the effects of stress and this study was limited as it did not control for the effects of social support on the relationships explored.

Although dysfunctional beliefs about sleep need, overall levels of stress and distress were significantly associated with health outcomes such as pain, fatigue and components of sleep quality, the relationship between these psychological factors may have been affected by the more stringent significance level utilised to reduce the risk of type one errors. As can be seen in Tables 8 (p. 97) and 9 (p. 98), a number of relationships were significant at the $p<0.05$ level and therefore there is a risk that a type two error may have occurred. Further exploration of these relationships for people with FMS is warranted.

It should also be noted that although factor analysis was conducted to explore the underlying factor structure of the PSS-10 and DBAS-10 measures, because these measures had not previously been used within this population, this study was powered to detect significant differences between the groups and there may be insufficient numbers within this study to be confident in the outcome of the factor analysis. As stated by Field (2009), 10 participants per item is the recommended sample size to conduct a factor analysis. With 83 participants in each group, this study fell just short of the recommended ratio and therefore the findings of the factor analysis should be interpreted with caution. Despite this, the findings revealed that the measures may explore different concepts in people with FMS, and disease specific measures designed specifically for a given population may have greater utility in studies of this nature and require development.

The response rate for people with FMS (almost 75%) is well within the accepted response rate for case-control studies. It should also be highlighted that the response rate for the healthy control group was about 10% lower than for people with FMS. This may reflect the lower level of interest in people without FMS in this study. Indeed

research has revealed that belief by the respondent concerning the relevance of the project and interest to a person, significantly affects their response rate (Edwards et al., 2002). This relatively lower response rate in the healthy control group may have resulted in a selection bias and the group may not be entirely representative of the general population, as participants who did respond may have a greater interest in sleep. This relatively low response rate in the control group may have been increased by sending repeated invitations to potential participants, but due to financial constraints this was not possible in this study. In addition, we were interested in recruiting controls free from the condition of interest (FMS) and the relatively low response rate is unlikely to influence the validity of the findings. In comparison to the FMS population estimates described in Chapter One, females were overrepresented in this sample and therefore the extent to which these findings can be generalised to males with FMS is unclear. Despite these limitations the study clearly highlights that dysfunctional beliefs about sleep and perceived levels of stress are significantly higher in people with FMS.

Implications

The high prevalence of sleep difficulties in FMS participants and the significant role of psychosocial factors such as stress and beliefs about sleep on the maintenance of poor sleep revealed in this study, highlights the need to address these factors in the treatment of sleep difficulties and management of symptoms in patients with FMS.

Summary

The study consisted of two groups of participants, 83 FMS participants and 83 healthy controls (matched for age and gender). Participants with FMS were 32 times more likely to have sleep disturbance and revealed significantly higher levels of dysfunctional beliefs about sleep and stress in comparison to healthy controls. High dysfunctional beliefs about sleep and perceived stress were associated with higher levels of pain and fatigue and poorer sleep quality, and may be important to target as part of an intervention to improve sleep quality and quality of life for patients with FMS. However, further understanding of the links between psychological factors, such as stress, sleep and health outcomes in FMS is needed to inform future treatment

interventions. With this in mind, the next chapter reports a qualitative study that explores the sleep experience for patients with FMS in more detail.

Chapter Six. Exploring the Sleep Experience for Patients with FMS

The previous two studies, which used quantitative research methods, provided an overview of the scope and nature of sleep difficulties in people with FMS. However, the use of questionnaires limited the range of answers participants could provide about their experience of sleep quality in FMS. As sleep quality is primarily a subjective experience, understanding what poor sleep means to people with FMS and how it affects their daily lives, is essential to inform how rehabilitation can address patients' needs. Qualitative approaches enable the exploration of factors that are important to patients, rather than those identified by the researcher. In order to increase our understanding of the sleep difficulties people with FMS experience, and the impact they have on peoples' daily living, a qualitative approach was therefore needed to explore the phenomena in more detail.

Previous qualitative studies in patients with FMS have explored the illness experience, focusing on the difficulties in managing an illness with a complex range of fluctuating symptoms, no distinctive visible signs and the impact the condition has on quality of life (Arnold et al., 2008; Cunningham & Jillings, 2006; Madden & Sim, 2006; Sim & Madden, 2008). To expand on the findings from the previous two studies within this thesis, this study aimed to increase our understanding of the meaning that sleep has for patients with FMS, the development of sleep difficulties and the impact of poor sleep on patient's everyday lives. As the aim of this study was to explore how participants understand their illness and the meaning that their symptoms have for them (including their sleep difficulties), interpretative phenomenology was deemed to be the most appropriate approach for this study.

Methodology

As the study did not aim to explore relationships in order to develop a theory (which would arguably require a grounded theory approach), or to explore the use of language in describing a phenomena (such as the discourse analysis approach), it was felt that a phenomenological methodology would be the most suitable approach to gain insights into how people with FMS perceive their sleep quality and make sense of the symptoms they experience.

The philosophy of phenomenology was developed through the work of Edmund Husserl (Husserl, 1931). Husserl believed that people do not experience life in its actual state, but that people are naturally driven to find meaning in what happens to them. Therefore people's life experiences are influenced by how they interpret daily events. These interpretations will have been shaped by personal values, attitudes and prior experiences. Phenomenologists therefore aim to describe the essence of people's experiences, and what an experience means for a specific group of people (Spinelli, 2005). Several strands of phenomenology have emerged over time, with Husserl's approach seen within the context of what has become known as the 'transcendental phenomenological approach'. This approach aims to describe people's conscious experiences and their meaning, with an open mind that is not influenced by pre-understanding (Moustakas, 1994). The hermeneutic phenomenology strand has also emerged, with the key distinctions being that hermeneutic phenomenologists aim to interpret (rather than just describe), people's experiences and their meaning, by uncovering hidden assumptions (that the person may not be conscious of) and linking different aspects of experience that may be influenced by the experienced and viewpoint of the researcher (Gupta, 2000).

Out of the hermeneutic phenomenological strand (based within the interpretivist paradigm), Interpretative Phenomenological Analysis (IPA) has emerged. This approach, developed within the field of health psychology, aims to explore the lived experience of receiving health care. It was felt to be the most appropriate approach for this study, as it aims to explore how participants make sense of their world and is "ideally suited to exploring topics in health, social and clinical psychology where there is a need to discern how people perceive and understand events in their lives" (Smith & Eatough, 2007, p. 36).

IPA differs from 'traditional' hermeneutic pheneomenology, as it incorporates both hermeneutic and transcendental phenomenological ideals. For example, the IPA approach assumes that there is a link between what people say and what they are thinking, and aims to both describe and interpret people's experiences to provide a detailed exploration of the phenomenon. IPA also draws on social interactionism, a sociological perspective that emphasises the importance of social interactions on how people derive meanings from their life experiences. The social interactionism perspective was initially proposed by Blumer (1969) who highlighted three core

fundamental aspects of the perspective" 1) people respond to life experiences on the basis of the meaning(s) of that experience to them; 2) the meaning of life experiences arise out of the social interaction that someone has with others and society; and 3) that meanings may change over time as a person continually interprets and re-interprets daily events. Therefore how an individual interprets an experience may be influenced by their past and future, and the interpretations of others gained through social interaction. Consequently, this approach lends itself to the focus of health psychology research and has the additional advantage in that it advocates the use of an empathic and flexible questioning approach, which are important components of psychological enquiry.

In accordance with hermeneutic phenomenology, IPA acknowledges that the researcher plays an active part in the data analysis, as their prior knowledge and professional background will influence how they interpret people's experiences, particularly playing a key role in identifying the underlying concepts that the participant may articulate but may not be consciously aware of (Smith & Eatough, 2007). It should therefore be noted that the transcripts were analysed by two registered health psychologists (Alice Theadom and Mark Cropley) who were involved in the previous two quantitative studies of this thesis and who had experience of working with people with FMS. Psychology is a 'scientific study of people, the mind and behaviour', with the specialised branch of health psychology focusing on the prevention and management of illness; the identification of psychological factors contributing to physical illness; the improvement of the health care system, and the formulation of health policy. The conduct of this study using IPA methods, and the interpretation of the data, was therefore based on the health psychology perspective and consequently the researchers' previous experience and knowledge will have influenced their interpretations of the findings. However, an advantage of the IPA approach is that when coding the transcripts, the researcher is constantly brought back to the raw data to ensure that the interpretations are valid (Smith, 2003).

The IPA approach has not previously been used in FMS and therefore had potential to provide a unique contribution to the evidence base by exploring in more detail people's experiences of sleep and how poor sleep quality affects them.

Methods

Participants were given a written information sheet and were offered verbal information about the study through presentations at support group meetings for people with FMS. Participants interested in the study were asked to contact the researcher. Participants were advised that they did not have to be experiencing sleep disturbance to take part in the study, thus enabling the exploration of the effect of both good and poor sleep quality in FMS. Participants were included if: 1) they had received a diagnosis of FMS by a clinician and; 2) were aged over 18 years. Participants were excluded if they were unable to speak or understand English or if they had been diagnosed with an organic sleep disorder with an identified underlying physical cause (such as sleep apnoea or restless legs syndrome). After confirming that the participants had received and read the information sheet, and had been given the opportunity to ask any questions they had about the study, a mutually convenient time was arranged to conduct the interview.

Participant Recruitment

The IPA approach aims to identify the commonalities of people experiencing a specific phenomenon and therefore participants are sampled to ensure that they can offer a meaningful perspective on the phenomenon being investigated (Smith & Eatough, 2007). For this study, participants were recruited through FMS support groups in the South-East of England in an attempt to achieve a relatively homogenous sample. The IPA approach advocates that small homogenous samples should be used in order to obtain a detailed understanding of individuals' personal experiences and to ensure that in-depth analysis is feasible (Reid, Flowers, & Larkin, 2005). The interview process was explained to participants, providing them with the opportunity to ask further questions before they were asked for their permission to record the interview using a digital voice recorder and to sign the consent form.

Data Collection

To provide a context for the data, background information was collected from the participants, including their date of birth, details of their diagnosis, employment status

and medication use. A sound check was completed before commencing the interview to ensure the sounds quality was sufficient to enable accurate transcription. A brief semi-structured interview schedule (Table 11, p. 112) was developed to guide the interview, asking broad questions about the participant's illness, symptom experience and daytime functioning. The interview schedule enabled the researcher to explore areas relating to the research question, while providing the flexibility for the participant to talk about the issues that were important to them and for the researcher to explore interesting concepts emerging during the interview. In accordance with the IPA approach the questions remained broad, to enable the participant to express openly what the experience meant to them. Prompts were only used if they were required to facilitate the interview and to encourage the participant to talk about their experiences. All interviews were conducted at participants' home to enable participants to feel comfortable in their surroundings during the interview. Interviews were conducted with only the researcher and participant present, although it should be noted that for two participants, other people were present in other areas of the house which may have influenced how participants responded. The interviews were recorded using a digital voice recorder and were later transcribed verbatim and checked by an independent researcher for accuracy of transcription. All 16 participants who met the study criteria and expressed an interest in the study completed the interview.

Table 11. Interview schedule for the qualitative interviews

How would you describe your quality of life with fibromyalgia? Prompts (to be used only if additional guidance is required); • How did you receive your diagnosis? • What are your main fibromyalgia symptoms? • What do you believe to be the cause of your fibromyalgia? • What effect does having fibromyalgia have on your life? • Could you describe a typical day living with fibromyalgia?
How would you describe the quality of your sleep? Prompts (to be used only if additional guidance is required); • Can you tell me about your typical sleeping pattern? • When would you usually go to bed? • Could you describe a typical evening when you are preparing to go to bed? • What effects your sleep quality? • How does your sleep quality affect you?
How do you cope with your fibromyalgia symptoms? Prompts (to be used only if additional guidance is required); • Is there anything that helps you to manage your fibromyalgia? • What support have you received?

Data Analysis

The data was analysed and coded by two researchers, independently using the recommended IPA approach (Smith, 2003).

The interview transcripts were read several times to increase familiarity with the data and a layered analysis approach was used. All transcripts were typed into a table format with an empty column to the left and right of the transcript. Initial comments and preliminary interpretations of the data were noted in the right hand columns with key words and phrases highlighted within the transcript itself. These initial comments and preliminary interpretations were then used as a basis for analysis of subsequent

transcripts, with any inconsistencies or revisions to the emerging themes noted in the left hand margin. This approach helped to refine the emerging themes upon completion of the transcript analysis. The emerging themes were discussed between the two independent researchers. Although participants talked about a wide range of issues related to living with FMS, as the aim of the study was to explore the experience of sleep in FMS, the analysis focused primarily on the data focusing on sleep related issues and the additional information was used to provide a context and greater understanding of the sleep related data.

Themes were clustered together and reapplied to the interview transcripts, noting any inconsistencies between participants and exploring negative cases to form themes (Mays & Pope, 2000). Although this technique emerged from other qualitative approaches, as the aim of this study was to explore interpretations and meanings for participants, it was felt to be equally applicable to this IPA study. Extracts from the interview transcripts were then related to each theme manually. This was completed by writing each theme on a piece of paper and then placing the interview extracts (labelled by participant number and page number) that related to each theme underneath the respective heading. This process ensued that the interpretations were linked to the raw data. Each extract could be used to demonstrate more than one theme if relevant, although this process often highlighted that two themes could be clustered together. The themes were then refined to ensure the name of the theme reflected the relevant extracts and their interpreted meaning. Each theme was then examined in detail to explore if it included different components.

The participant sample was described in terms of mean age, duration of symptoms and percentage of participants in employment and those taking hypnotic and/or pain relieving medication, so that the interpretations could be related to the sample from which they were taken. Direct quotations from participants were used to illustrate each theme and each quote was identified using the study participant number to ensure confidentiality. Information on the participant's age and gender is provided for context.

Rigour

The interview transcripts were transcribed by the researcher conducting the interview to ensure that the context of the interview was reflected and to integrate field notes and observations into the transcripts. For example, describing the nature of any interruptions or noting changes in participants behaviour (such as becoming tearful) in brackets within the transcript (Smith & Osborn, 2008). The text of the interview within the transcript was checked against the audio recording to ensure accuracy of the transcription (Dean, Smith, & Payne, 2006).

The independent analysis supported the verification of the identified themes, as there was high consistency between the two researchers; any inconsistencies that became evident were discussed and the themes refined to reflect the consensus decision. Using extracts direct from the participant transcripts ensured that the interpretations and themes reflected the raw data (Smith & Osborn, 2008). If there was not a good fit between the extracts and the name of the themes, then the name of the theme was further refined to reflect the raw data. The two researchers discussed which extracts were then most representative of each theme and its components to be used in the writing up the results.

Results

A sample of 16 participants took part in the interviews (14 females and 2 males), which lasted between 20 and 65 minutes, with the average duration of the interviews being 40.37 (SD 13.54) minutes. Participants were aged between 21 and 61 years (mean age = 50.95 years, SD 11.94) and all spoke English as their first language. All participants had completed secondary education, with 31.25% of them attending college or university. Only one participant was in full time employment, five were working part-time, five were retired and five were no longer working due to ill-health. The mean duration of FMS symptoms was 17.25 years (SD 14.77) with an average length of time since diagnosis of 4.13 years (SD 4.37). Most participants were using some form of pain relieving medication on a regular basis (62.5%) and just over half of participants were prescribed medication to aid sleep (56.3%). The age and gender sample characteristics

compare favourably with prevalence estimates of the FMS population (described in Chapter One).

The interviews with participants revealed four themes: (1) the experience of sleep disturbances; (2) inter-relationship between symptoms; (3) coping with disturbed sleep; and (4) impact on daily living and relationships with others. Each theme encompassed several components (sometimes referred to as categories or sub-themes in other qualitative approaches) which are outlined below and illustrated by direct quotations from the interview transcripts. Each theme is identified by a sub-title and its components highlighted in bold. The participant reference number, gender and age are indicated in brackets at the end of each quote used to illustrate the components of each theme.

Theme One. The experience of sleep disturbance

Many participants discussed their experience of sleep during the first few questions about their quality of life with FMS before they were prompted by the questions focusing on their sleep, highlighting the importance of sleep disturbance to participants with FMS. Participants described their sleep difficulties in terms of comparisons to how they used to sleep before experiencing FMS symptoms, what they observed about their sleep quality and the nature of their difficulties and how it affected them.

Onset of poor sleep

There was considerable individual variability in the onset of sleep difficulties with some participants reporting that they could not identify when their difficulties started; whereas other participants perceived that they experienced sleep difficulties for most of their life.

> *"I've never been a terrific sleeper, even before this, I was never the sort of person who can sleep all night and never wake up sort of thing and find it difficult to wake up, I've always been a light sleeper, like I'll be sleeping and I'll hear things and be instantly awake, immediately alert." [010 F56]*

However, other participants reported that their sleep difficulties occurred before or around the time of onset of other FMS symptoms:

"The main symptom is this overwhelming fatigue, like even now I'm struggling because I've been awake most of the night um, and I used to sleep soundly, I could sleep on a washing line, um I'd got to bed at night and wake up in the morning full of the joys of spring… then things just started changing with my sleep, I found I had no problems getting to sleep as always, but that I couldn't stay asleep and that's, I was wide awake and there was nothing I could do, I tried all the sleep hygiene that was recommended to me and that made it even worse." [010 F56]

Existence of possible sleep disorder

Three participants described experiences that were indicative of a sleep disorder that had not been diagnosed, such as bruxism (teeth grinding), sleep walking and periodic limb movement disorder. One participant described the sensations he felt in his legs during the night:

"You toss and turn, you can't keep still, I'm not being funny but my legs have spasms, they just jump around like someone's putting an electric shock through you every five seconds, your limbs jump and twitch." [009 M53]

Another participant described her experience of waking up in different areas of the house at night:

"I can wake up screaming or um I talk a lot, I do walk because I'm always waking up in different places, generally in the kitchen because I've been eating, or in here (sitting room), but at the moment I seem to be, I can't describe it, I'm sort of semi.., I know I'm, I feel that I'm awake, but I'm not awake, do you know what I mean? The other night I was sitting on the sofa and I can remember doing it, thinking, I'm awake but then the next thing I fell and I just saved myself before I hit the floor so I can't be awake, for me to, it's like I'm semi conscious and then I completely go and that's how a few times I've ended up with bruises." [011 F59]

'Sleeping in blocks'

It became apparent that the main difficulties participants experienced with their sleep were waking up during the night and feeling un-refreshed the following day. Fifteen of the 16 participants described waking up several times a night on a regular basis which caused a considerable degree of frustration:

"A typical night if you can describe the sleep as typical, is I go to bed around 10, 10:30, I fall asleep straight away (clicks fingers) drop of a hat, head on the pillow and I'm away, I'll sleep for two or three hours, then I'm up for between two or three hours, then I'll sleep for two hours and then I'm up." [013 F51]

Another participant added:

> *"I can sleep, I can go off to sleep but if I don't take anything (referring to medication) I do lie awake, just lie awake or I get woken up this constant being woken up is the worse thing.'' [006 F61]*

Participants described that when they woke up during the night, they would wake-up suddenly, feeling very alert, and this made it difficult to try and go back to sleep.

> *"I go to bed about 10, I'm always tired and I invariably 90% of the time go straight to sleep and I will wake one to two hours later feeling as if it is time to get up." [004 F55]*

Un-refreshing sleep

In the morning several participants also described feeling un-refreshed which may be a result of the disturbed sleep throughout the night;

> *"I've quite often woke up feeling more tired than when I went to bed." [003 F48]*

Negative thoughts and worry about sleep

For several participants, going to bed had become a negative experience due to their sleeping difficulties, and some participants reported developing negative thoughts and expectations about sleep. Many had simply resigned themselves to the belief that their sleep quality would be poor.

> *"If there's something on my mind, that makes me a bit worried about sleeping, I don't know what it is but I sort of need to try and get to the bottom of it, but I sort of have this fear of going to bed." [015 F21]*

Four participants also reported that they often worried about daily events and concerns while lying in bed, which may prevent sleep onset:

> *"If you're worried about one of the children or there's something particular you're worried about.., you tend to sort of go over that in your mind." [002 F48]*

Other triggers of disturbed sleep were identified as drinking alcohol, stress, worry, and the need to urinate during the night.

Theme Two. Inter-relationship between symptoms

When describing how their sleep quality affected them, all participants described the effects of poor sleep quality on their other FMS symptoms, such as a pain, fatigue and their ability to manage to those symptoms. Complex interactions between sleep and symptoms became evident, with participants reporting both direct and indirect effects of sleep quality on their other symptoms, and a bi-directional effect between sleep and pain.

Effect of sleep on pain

Eleven participants felt that a poor nights sleep was directly associated with reduced overall functioning the following day. When asked to describe a typical day living with FMS one participant described;;

> *"Today I'm just exhausted, but I didn't sleep, I hardly slept last night so erm yeah, they (symptoms) completely vary, erm the pain's worse today, but that's because I'm tired, it's always worse when I'm tired." [011 F59]*

Waking up due to the pain

Participants also described that pain affected their sleep quality. Sitting or lying for long periods of time was perceived to lead to increased pain during the night and participants often highlighted that they needed to keep changing positions in order to remain comfortable in bed, or they were restless at night as they were unable to feel comfortable in one position. Many participants stated that being in pain woke them up during the night.

> *"Lack of sleep affects your pain and er, and if you're in a lot of pain and you roll over, the pain will wake you up." [014 F53]*

Reduced ability to manage symptoms

The majority of participants felt that the quality of their sleep was related to feelings of fatigue and pain. Three participants elaborated that they believed that feeling tired after a poor nights sleep made it harder to cope the following day, affecting their perceptions of pain.

"*In some ways it's more difficult because I'm so tired I don't have the energy to cope with things, so I think they get me down a bit more." [007 F53]*

Expecting a 'bad night'

All of the participants interviewed had experienced disturbed sleep for a number of years and almost expected to sleep poorly, especially if they were experiencing high levels of pain and fatigue.

"You almost know, that's psychological again, you almost know you've had a fairly bad period you're not going to sleep well either or is it a fact?" [002 F61]

Another participant elaborated:

"I do all my strategies and they wouldn't work so going and making a mug of weak tea and coming back to bed and listening to the radio, something to warm myself for an hour or two and then eventually I might drop off again, but I might have been awake for two or three hours before I'm ready to sleep again and then I'd wake at the normal time anyway or I might wake u about half past five, so they'd be like two blocks of sleep separated by a very long period of mental hyperactivity um, and this has been happening pretty much all the time, so it was getting to the point where I was actually getting quite anxious about going to sleep." [008 F60]

Theme Three. Coping with disturbed sleep

In addition to coping with their symptoms of pain and fatigue, as outlined in previous qualitative studies in FMS (Lempp et al., 2009; Madden & Sim, 2006; Sim & Madden, 2008; Undeland & Malterud, 2007), participants talked specifically about how they managed their sleep difficulties during the night and the effects of poor sleep the following day.

Searching for answers

Little information had been given to participants from health professionals on how to manage their FMS or sleep difficulties effectively. As a result, participants appeared desperate to seek answers and described trying a whole range of strategies to improve their sleep quality:

"I put ear plugs in and I find when I put ear plugs in I seem to sleep different... although I don't like things in my ears, if it means I'm going to sleep a bit better, so whether that's about noise, although it's very quiet

where I live, so I don't know, I think I'm just looking for answers." [001 F59]

'A juggling act'

In order to manage their symptoms and engage in everyday activities, participants described the need to plan and pace their activities, including rest periods or taking a daytime nap throughout the day:

"Some days when I walk the dog, I'll come home and I'll go to bed for anything up to two hours, I will get up, I will get up for an hour or two and go back to bed and sleep for two or three hours. It all depends on the day, and also if you said to me, oh you're going out tonight i.e. my wife's going to the theatre tonight and if I was going, I'd probably be going to bed now to make sure I'm rested to cope. Life evolves around the fact that if I'm not properly rested I won't enjoy it." [005 M60]

Participants reported that extended periods of inactivity increased levels of pain and muscle stiffness. Participants described the need to balance rest periods with the need to keep moving around.

"That's the thing about fibromyalgia, you need to rest but at the same time you need to move… you kind of just want to stay in bed or whatever but you, you it's hard but you need to keep moving but at the same time you need to rest as well." [016 F32]

Although two participants avoided napping during the day, the other participants found that daytime naps helped to re-energise them; particularly if they were feeling fatigued in the afternoons, enabling them to carry on with daily activities.

"I might have to go to bed for a couple of hours and then I'll be alright for the evening, because I know they advise you not to go to bed don't they, but I can't physically not and I find it makes me feel better actually if I do, so for me it works better, so you, I've learnt to do what suits me, rather than what I'm told to do you know, they say you muck up your body clock up if you sleep in the day but for me it doesn't work that way." [014 F53]

Interestingly, participants did not report that their sleep quality at night was affected by taking a daytime nap.

"I'd get home from work after having done only four hours, I'd get home and I've slept in this chair for three hours, absolutely wiped out and then I'd go to bed in the evening and fall asleep no problem and again it's just the staying asleep." [013 F 51]

Nocturnal coping strategies

On awakening at night, participants described utilising a range of approaches to help them return to sleep. Many participants reported keeping the light low and trying to relax in order to return to sleep when they wake up too early.

> *"Sometimes I think I can get back to sleep, so I wait to see if I can and I think come on and I just lie there and hopefully I can get back to sleep easily again, um, but more often than not, I can't, so after I try for about 15 to 20 minutes and if I can't get back to sleep after that time then as I say I put the television on and it'll refocus me and if I fall back to sleep, good." [013 F51]*

However many participants reported being awake for up to several hours during the night and being unable to get back to sleep:

> *Oh I just get up, it's just ridiculous trying to sleep and you can't sleep, you know you get to hate your bed after a while because you get fed up tossing around and trying to get to sleep the whole time." [006 F61]*

Change to routine

Participants demonstrated a high level of awareness of the principles of sleep hygiene to aid sleep quality and many described avoiding large meals and stimulants such as caffeine in the evening:

> *"I tend not to watch TV too late unless there's something really good on but I try and make an effort, like I used to really like watching DVDs late at night and now I don't do that as much or I'll listen to the radio, it's a bit more chilled really, yeah drink herb tea, just sort of wind down." [016 F32]*

Medication as a last resort

Ten participants had been prescribed medication to aid sleep although it was reported that the effects were limited in reducing night-time awakenings.

> *"I take sleeping tablets but I have to take double the dose that's 14mg of sleeping pills , and I take the sleeping pill… it knocks me out, even then when I take those I'm still awake at four o'clock, so they only get me to sleep, they don't keep me asleep (I see) they're designed to get you going, they get you away to sleep but then the drug gets out of your body in three or four hours and bing, you're wide awake." [P005 M60]*

Participants also described how the lack of evidence to inform clinical treatments for FMS made it difficult for them and their clinicians to make informed choices about possible interventions to improve sleep quality in FMS:

> "*Well um Professor XXX who I have been seeing, bless him he is an absolute sweetheart but you know, even he is scrabbling around because of the lack of knowledge of it um and he gave me um some sleeping tablets, I can't remember which ones they were, but I looked at them and I thought oh, er they're addictive which is, and I don't like taking tablets at the best of times anyway but I thought ok I'll give it a try, so I took them for about two or three nights… and to be quite honest my sleep didn't improve and maybe I should have tried for longer but my sleep didn't improve and I just felt dreadful during the day, I was making really stupid mistakes because I was groggy." [013 F51]*

Another participant elaborated on her reluctance to take her prescribed hypnotic medication:

> *"I normally wake up about one o'clock, um could be two o'clock, I could be lying there for half an hour trying to sleep, I could be there for three hours before going back to sleep and um, because my doctor put the fear of death into me about taking these very mild sonata sleeping tablets, I think I've got that embedded now in my brain (laughing) and even if I'm laying there for three hours for some reasons my brain doesn't go, right XXXX (name of participant) why don't you take one of those sleeping tablets cause that'll help, so I've got a bit of an issue with the pills." [001 F59]*

Theme Four. Impact on daily living and relationships with others

In addition to the effects of poor sleep on their FMS symptoms and ability to cope with their health, participants described the effects of poor sleep as being more wide ranging including affecting their performance at work, social relationships and planning for their future.

Consequences of poor sleep

The concern about trying to ensure a good nights sleep before going to work or an organised activity caused anxiety amongst participants.

> *"The not sleeping and then not being able to function the next day when you need to perform at work… when you're being paid and you're meant to work and you can't function, it's horrible, it's really horrible because you feel like a failure." [014 F53]*

Another participant described:

> *"I find it quite restricting, because I'm scared to arrange things because I know I'm going to be too tired, and if um, if I'm going anywhere where I know I'll be late back here then I think that I'm going to need to book the next day off work because I'm going to be too tired to work." [007 F53]*

The extended burden

Participants were concerned about the impact of a poor nights sleep on their bed partners and the pressure this placed on their relationship.

> *"I think it was half the trouble with my husband, I think it caused the problem there, as I can remember him saying oh you kept me awake by tossing and turning." [006 F61]*

The effect of a poor nights sleep also impacted on families and friends through the need to cancel or reschedule activities, rest and nap during the day if their sleep had been disturbed.

> *"It does concern me a lot, but they've (children) adjusted and they know that if I'm bad, that they're fine with me laying down, whereas before it would have been, they wouldn't handle it at all, you know, but now they just know it's part of life really and that I need to have a sleep." [011 F33]*

Coping with poor sleep at night was also affected by the presence of a bed partner.

Reduced spontaneity

Participants described the need to plan and pace their activities in order to manage their pain and fatigue. The need to schedule in times to rest and sleep caused some frustration and resentment.

> *"All I know is, is that I never used to need a lot of sleep, never, and I now really resent that fact that I need so much, I'm not saying my life is so exciting but when it's, just now I think oh, I have to plan it round, oh can I have a lay in this weekend, can I do this, can I do that, I find that very hard to cope with. [007 F53]*

When planning for activities, participants also described the need to rest before, as well as needing to allow time to rest and recover following activities:

> *"XXXX (name of person) planned a surprise weekend in XXX (name of place) for me and the plan went, travel, day's rest, surprise day, day's rest, does that… (mm)... now we're in a fortunate position we can do that, now in reality it didn't work out like that, but there are time when yes we kind of think, yes we're going to do this because we knew those two weeks away, full of activity and yes I was sleeping during the day and yes we knew I was going to come back feeling bad and you kind of go, yes let's think this through what we are going to do, how are we going to do it and we said to our friends in XXX (name of place) don't be surprised if XXX (name of participant) needs to go to bed in the afternoon and the only thing they were surprised about was the amount of time I was sleeping." [005 M60]*

The perceived impact of poor sleep on physical functioning also caused additional apprehension regarding life decisions, such as starting a new job with early starting hours or having a baby.

> *"We're wanting to start a family, so that's kind of an issue regarding sleep, actually; yes that's a massive issue, because we've been wanting to start a family for ages, we're not even doing that because I don't think I could have that sort of sleep deprivation. [016 F32]*

Discussion

This is the first study to explore FMS participants' experience of sleep using qualitative methodology. Four themes emerged from the interviews: 1) experience of sleep disturbance; 2) interrelationship between symptoms; 3) coping with disturbed sleep; and 4) impact on daily living and relationships with others. Poor sleep was revealed to be a core part of the symptom experience in FMS, as coping with the sleep disturbance and striving to achieve a good night's sleep dominated participants' lives.

Participants' descriptions of experiencing night-time awakenings and restless sleep are consistent with previous research using objective measures of sleep (Korszun et al., 2002; Perlis, Giles, Bootzin et al., 1997). Many participants described a pattern of sleep consisting of several blocks of sleep lasting two to three hours, with periods of wakefulness in between. Participants found it difficult to find and maintain a comfortable position at night and that they were often woken by pain. The need to keep changing position to prevent pain, and stiffness also disrupted their sleep. The

perception of feeling un-refreshed after sleep appeared to result from the disrupted sleep pattern and caused them the greatest concern.

In contrast to previous research, into other chronic pain conditions, the majority of participants in this study did not report difficulties with initial sleep onset when they first went to bed (Abad et al., 2008). However, participants stated that it was hard to go back to sleep when they woke-up during the night and described feeling very alert upon awakening. This sleep pattern may be supportive of a hyperarousal model of insomnia as described in Chapter Five (Perlis, Giles, Mendelson, Bootzin, & Wyatt, 1997). This model proposed that people with insomnia are more alert than would be expected after having experienced poor sleep. This may be due to an increase in brain activity, basal and central nervous system metabolic rate and body temperature. Additionally, compensatory strategies that people engage in when they experience poor sleep, such as going to bed before the natural decline in body temperature, worrying about sleep or ruminating about daily events may also have an adverse effect on their sleep quality. Although a number of participants reported avoiding stimulating activities before sleep onset to improve their sleep quality.

There was some disparity between participants about the most effective way to manage night-time awakenings. Participants described adopting a wide range of strategies from using instrumental supports (such as special mattresses and pillows), cognitive coping approaches and engaging in passive activities, such as listening to relaxing music. Many participants had actively sought information and had often spent large sums of money trying to improve their sleep quality, even if there was little clinical evidence of effectiveness. It became evident that all participants felt a loss of personal control over their sleep and were desperate for answers. This may have been a result of a shortage of information and support available on how to specifically manage FMS and sleep difficulties. Evidence from people experiencing primary insomnia has revealed that non-pharmacological, group based, interventions including the provision of information about sleep and application of cognitive and behavioural strategies, can effectively improve sleep quality with benefits lasting several years (Backhaus et al., 2001). The findings from this study augments the increasing evidence that cognitive and behavioural interventions may be beneficial to improve sleep quality for people with FMS, and more methodologically robust clinical trials are required to explore the efficacy of these interventions within this population.

A strong theme that emerged in this study was the impact of napping during the day on symptoms and sleep quality. Many participants described that when they felt severely fatigued during the day (usually mid afternoon) napping was beneficial in relieving pain and fatigue, enabling them to continue their daily activities. Napping was often actively incorporated into a daily schedule if participants were planning on going out in the evening or seeing friends and family to enable them to cope with these activities. Interestingly in this study, many participants reported that they had been advised to avoid napping during the day, by health professionals, because of the negative effect daytime napping may have on subsequent sleep quality. The limited use of napping by participants revealed in this study supports previous findings that patients with chronic pain report limited use of daytime napping (Call-Schmidt & Richardson, 2003; McCracken & Iverson, 2002; Scheuermann, 2008). However, in the general population, daytime naps of <30 minutes duration have been found to have beneficial effects on excessive daytime sleepiness, mood and cognitive performance (Dhand & Sohal, 2006; Takahashi, 2003; Tietzel & Lack, 2002). Clinical guidelines do not currently provide any specific guidance on managing sleep disturbance in FMS (Carville et al., 2008) and clinical recommendations regarding the use of daytime napping appear to be highly diverse. Previous research on the effects of daytime napping have only been conducted in people without an underlying medical condition and it is currently unclear as to whether these findings can be effectively applied to people with FMS or other chronic pain and fatigue conditions. Further research exploring the use of daytime napping in patients with chronic pain and fatigue conditions, including FMS, is therefore needed to inform clinical guidelines.

Although over half of the participants had been prescribed hypnotic medication, all participants who had been prescribed medication to improve their sleep were reluctant to use it. This was due to being discouraged by their clinicians, concerns that their prescription may not be renewed if they used too much medication, and perceptions that the medication had a limited effect. Participants also stated that because their sleep was often unpredictable, it was difficult for them to know when they would need to take the medication (as they are usually required to take the medication an hour before going to bed). Participants described that they mainly felt the need to use the medication in the early hours of the morning to help them get back to sleep after awakening. The use of Pregabalin and Gabapentin have been found to significantly improve pain and sleep

quality in FMS (Crofford et al., 2005; Hauser, Bernardy et al., 2009; Russell et al., 2009); however, this study revealed that participants taking these medications still experienced significant sleep disturbance that disrupted their daily lives, supporting the need for a multifaceted treatment approach.

Strength and Limitations

The findings of this study strengthen the increasing body of evidence that sleep quality plays an important role in the exacerbation of symptoms in FMS (Korszun et al., 2002). This qualitative study expanded on a number of areas highlighted in previous quantitative studies. For example, participant's descriptions of the effects of poor sleep provide further evidence that the links between pain and sleep in FMS are bi-directional. In addition, it also became evident that in support of the quantitative findings, night-time awakenings appeared to be a significant difficulty for people with FMS. However, it also emerged from the interviews, that people described waking up suddenly during the night and feeling very alert which may help in our understanding of the causes of these disturbances. The anxiety surrounding sleep and the expectations of a bad night elicited in this study supports the exploration of stress and beliefs about sleep discussed in Study Two, and highlights the need to address the reported mental alertness at night as part of a sleep intervention to improve sleep quality for this population.

This study has also aided the explanation of the unexpected finding in the first study which revealed low correlations between coping and health outcomes in FMS. It became apparent in this qualitative study that coping in FMS is a complex process, and that the high symptom variability affected the strategies people employed to cope with their symptoms. For example in this study, poor sleep was found to reduce people's ability to utilise problem focused coping strategies, and many participants reported using relaxation based approaches to improve their sleep. Increases in the use of relaxation and physical activity were found to be significantly related to improvements in outcome, in a clinical trial of a multifaceted cognitive behavioural intervention in people with FMS (Nielson & Jensen, 2004). The use of relaxation and increasing physical activity were not specifically explored as coping strategies within the generic coping measure (The COPE scale) used in the study, described in Chapter Four. This suggests that further studies using a more specific measure of coping in FMS,

conducted at several time points, would provide further clarity on the role of coping on FMS outcomes.

In addition to talking about their sleep experience, participants also raised a number of issues unrelated to sleep as part of the interview. Some of these issues such as the demands of living with an 'invisible illness', the impact of diagnosis, their relationship with their health care provider and their daily lives have been described in previous research (Arnold et al., 2008; Cunningham & Jillings, 2006; Madden & Sim, 2006; Sim & Madden, 2008), and were therefore not incorporated in this analysis. However, it is important to acknowledge these issues in the interpretation of the findings from this study.

The ability to generalise the findings from this study may be reduced as the sample may not be representative of the population of people with FMS. Variations in sleep quality may exist between patients with different degrees of disease severity or due to other aspects of the patient's history. However, one of the aims of IPA is to identify a relevant homogenous sample for the research question in order to conduct a detailed exploration of the research question and the individual experience.

A further limitation of the study was that the sleep experience was only explored at one point in time and it is likely that the quality of sleep changes over the course of time and over the course of the illness. Qualitative interviews conducted across several time-points would provide a greater understanding of these changes and the adaptations people make to adjust to living with FMS and poor sleep.

One of the key strengths of qualitative research is that it can elicit new information to inform future research. The findings also highlighted that a number of studies are needed to increase our understanding of the role of sleep in FMS, including the effect and use of daytime napping as a coping strategy, existence of possible sleep disorders and further exploration of the use of hypnotic medication within this population.

Implications

It is of concern that three participants described experiences that were indicative of a sleep disorder that had been undiagnosed, and it became evident that these participants had not undergone any screening or investigation. Some sleep disorders with an underlying physical cause, such as sleep apnoea, can be effectively managed using specific medical treatments once diagnosed (McDaid et al., 2009). The findings of this study therefore strongly support the European League Against Rheumatism (EULAR) recommendations, suggesting that patients should be screened for sleep disorders as part of clinical evaluation. In addition, the recommendations by EULAR suggest that due to the complexity of FMS, comprehensive evaluations including analysis of sleep quality are needed to identify individual needs. Optimal treatment of FMS should then be based on a multidisciplinary approach (including both non-pharmacological and pharmacological interventions tailored to the identified needs (Perlis, Giles, Bootzin et al., 1997).

Summary

Sleep difficulties are one of the most challenging symptoms to cope with for patients with FMS, and poor sleep can exacerbate levels of pain, fatigue, and cognitive difficulties. This study augmented the findings of the previous two studies in this thesis, and highlights that people with FMS find awakening in the night in a high state of arousal, after a short block of sleep, is the most disruptive aspect of their sleep. Participants expressed a feeling of a lack of control and knowledge of how to manage their sleep quality and use their medication appropriately. Current information provision from services appears to be highly diverse. Although half of the participants had been prescribed hypnotic medication pro re nata (to be taken as and when needed), many were reluctant to use it due to fears of dependence or side effects the following day. The majority of participants found the only way to cope with poor sleep was to take naps during the daytime. Screening for sleep disorders and recommendations on how to manage sleep disturbance in FMS needs to be included into clinical management guidelines.

Chapter Seven. Investigating the Effects of Mindfulness on Sleep Quality in FMS

The first three studies within this thesis revealed that people with FMS experience high levels of cognitive arousal and difficulties maintaining sleep throughout the night. In addition, psychological factors such as stress and beliefs about sleep were also found to be associated with poor sleep quality. Due to the limitations of current treatment approaches there is an urgent need to explore the applicability and potential effectiveness of non-pharmacological interventions to improve sleep quality in patients with FMS. Based on the models of sleep and pain, described in Chapter Two, improving sleep quality may also lead to improvements in other symptoms such as pain and fatigue. To address the difficulties experienced by people with FMS, an intervention that aims to reduce the impact of stress, beliefs about sleep and cognitive arousal may help to improve sleep quality in people with FMS.

There are currently contrasting opinions about whether sleep difficulties in patient populations should be treated as part of the illness or as a separate entity (Harvey, 2001; Mahowald & Mahowald, 2000; Watts, Coyle, & East, 1994). However, as the evidence suggests that sleep has a significant influence on health outcomes in FMS, interventions that improve sleep quality are likely to lead to improvements in the overall symptom experience and therefore sleep problems should be specifically addressed. After an initial search of the literature and as part of a systematic review (completed in addition to this thesis), it became evident that there were few completed, fully powered, randomised controlled trials exploring the efficacy of non-pharmacological interventions to improve sleep quality in FMS (Theadom, Cropley, Hankins, & Smith, 2009).

There is emerging evidence from pilot studies, that non-pharmacological interventions addressing dysfunctional beliefs, incongruent sleep behaviours and lifestyle factors that may exacerbate sleep difficulties, can reduce the experience of FMS symptoms and the amount of time spent awake during the night, in comparison to patients receiving usual care or using sleep hygiene principles alone (Edinger et al., 2005; Singh, Berman, Hadhazy, & Creamer, 1998). These studies have employed intensive group therapy approaches, delivered by a trained specialist lasting for one hour, for at least six weeks. A full scale trial is now underway to explore the efficacy of a group therapy

intervention for people with FMS in the USA. These intensive interventions may be difficult to implement in clinical practice however, due to the high costs of delivery and the difficulties of being able to travel long distances to attend the group sessions faced by FMS participants. These feasibility issues are of particular importance in countries such as New Zealand and the UK where many people live in remote areas and are unable to access such specialist professionals and group based programmes. Therefore an intervention that could be delivered within the community or at a person's home is likely to have greater clinical utility for FMS patients.

The Mindfulness Approach

The mindfulness approach, which focuses on increasing acceptance of thoughts and focusing attention on the present moment in a non-judgemental way (Kabat-Zinn, 1982, 1990), may provide one such approach to address the high cognitive arousal, perceived levels of stress, dysfunctional beliefs and poor sleep quality in people with FMS.

The practice of mindfulness emerged from eastern Buddhist traditions where it was recognised that mindfulness can improve well-being and self awareness. Mindfulness approaches are now being increasingly used in medical settings, with structured mindfulness programmes being developed, which specifically focus on application to patient groups. The Mindfulness Based Stress Reduction (MBSR) programme was developed by Kabat-Zinn (1982, 1990) for patients with chronic pain and stress related medical conditions. The programme involves eight weekly group sessions, lasting two and a half hours (often including a whole day session towards the end of the programme). Components of the programme include meditation, (sitting quietly and focusing attention on a specific stimulus for prolonged periods); a body scan, (directing attention to different parts of the body); and hatha yoga, (directing attention to the body through a series of postures and movements). In addition to the group training sessions, patients are encouraged to practice the techniques at home. An important principle of mindfulness is that it does not aim to reduce physical symptoms, but intends only to increase patient's awareness and acceptance of their thoughts and physical sensations, without trying to interpret or challenge them. Developing acceptance of symptoms has been associated with lower perceived pain and enables patients to continue to engage in

activities because they no longer feel controlled by their thoughts and feelings (McCracken & Zhao-O'Brien, 2010).

Mindfulness has been found to improve both mental and physical health in clinical populations (Grossman, Niemann, Schmidt, & Walach, 2004). The results from pilot studies in people with FMS have also been promising (Astin et al., 2003; Grossman, Tiefenthaler-Gilmer, Raysz, & Kesper, 2007; Kaplan, Goldenberg, & Galvin-Nadeau, 1993; Lush et al., 2009). For example, Grossman et al (2007) found that people with FMS who completed an eight week MBSR programme, demonstrated sustained benefit on mental and physical health at three years, when compared to education and relaxation control group; although the findings were limited by the small sample size of N=58. In another trial with women with FMS, MBSR was found to improve women's sense of coherence (perception that life is meaningful and manageable), in comparison to a control group (Weissbecker et al., 2002). Interventions combining the mindfulness approach with additional interventions have not been so encouraging; for example, Astin et al (2003) found no significant improvements in patients with FMS receiving mindfulness plus a Qi-Gong intervention, in comparison to an education support group. Sephton et al (2007) explored the effect of an MBSR programme on depression and sleep quality in patients with FMS and found that although improvements in depression were found and sustained at two months, there was no significant change in sleep quality. However, Sephton et al (2007) questioned the feasibility of implementing the intervention as part of a daily schedule; therefore suggesting the need for an alternative mode of delivery of the mindfulness approach for people with FMS.

To explore whether MBSR may work by reducing the physiological reaction (basal sympathetic activation) that occurs in response to stress, Lush et al (2009) measured skin conductance levels, heart rate and peripheral temperature (all associated with basal sympathetic activation), before and after an eight week MBSR programme. Their study revealed that skin conductance levels did significantly decrease after the MBSR programme in patients with FMS, indicative of reduced basal sympathetic activation. However, there was no significant difference in heart rate or peripheral temperature. The authors highlighted that just under half (44%) of participants dropped out of the intervention due to other commitments such as work and child care or difficulties accessing the intervention due to physical impairment (Lush et al., 2009). This high attrition rate has also been found in other FMS intervention studies (Goldenberg et al.,

1994; Kaplan et al., 1993) with participants reporting that due to symptom variability, they often find it difficult to attend appointments if they have an unexpected flare-up, and many found that travelling to health care centres lead to an increase in fatigue. Such difficulties may prevent people with FMS from fully engaging in rehabilitation interventions, therefore introducing a self-selection bias into these studies (Lush et al., 2009). Participants with FMS may also find some of the techniques difficult, for example, sitting in one position for a long period of time may increase levels of pain. Consequently, in order to overcome some of these feasibility issues, mindfulness interventions may need to be delivered in an alternative format which will increase accessibility for patients with FMS.

The Mindfulness Body Scan

Although commonly taught in intensive group sessions, the mindfulness approach also lends itself to the use of particular 'mindfulness based' techniques at home. One such technique is the mindfulness body scan, which is an introductory exercise used at the beginning of the MBSR programme to help patients learn the skills of mindfulness and to increase self awareness through directing their attention to their breathing and different parts of the body. Participants are asked to scan different parts of their body to notice if they are experiencing any physical sensations in that part of the body, to explore what they feel like and to accept these sensations whether they are pleasant or unpleasant. The mindfulness body scan can be delivered by audiotape (Ditto, Eclache, & Goldman, 2006) which can increase accessibility of mindfulness interventions for patients unable to access the full MBSR programme. This study aims to explore if a brief audio body scan intervention, delivered within a community setting, is feasible and associated with improvements in sleep quality and health related quality of life for people with FMS.

Previous studies have highlighted feasibility difficulties in implementing mindfulness with people with FMS. However, the aim of this study was to explore the feasibility of a modified mindfulness intervention for this population. The study also aimed to explore trends in health outcomes to determine if the modified intervention warrants further investigation in studies powered to explore the size and direction of any effects.

Therefore as this was a feasibility study rather than a study aiming to determine the size of an effect, a priori power calculation was not conducted.

It was hypothesised that:

1. There would be improvements in objective sleep quality in people receiving the brief mindfulness body scan intervention in comparison to people receiving a control group intervention;
2. There would be improvements in subjective sleep quality in people receiving the brief mindfulness body scan intervention in comparison to people receiving a progressive muscle relaxation intervention (control group).

Method

Participant Recruitment

Thirty six participants were recruited though patient support groups in the South East of England. To be eligible to participate in the study participants were required to: 1) have a diagnosis of FMS by their GP or consultant; and 2) be >18 years of age. Participants were excluded if they had: 1) a diagnosed organic sleep disorder (such as sleep apnoea; or 2) if they had experienced a change in their medical treatment within the last three months, to prevent these factors from affecting the findings of the study.

Participants were recruited via advertisements disseminated through patient support groups of the Fibromyalgia Association UK. Participants expressing an interest in the study gave permission to the support group coordinators to pass their contact details on to the research team. Potentially eligible participants were contacted by the research team, by telephone, to explain the study and what would be involved in more detail, to check their eligibility, and to offer participants the opportunity to ask any questions about the study. Eligible participants were then sent an information sheet and consent form via the post, and were contacted a week later to ask if they would like to take part. They were also given an opportunity to ask any further questions over the telephone and those wishing to participate returned a signed consent form.

Outcome Measures:

Participants were engaged in the study for a three week period. In week one (the baseline week) participants were asked to complete standardised questionnaires and questions regarding their age, gender, symptom duration, co-morbid conditions, employment status, hours of paid work, and if they were required to undertake any shift work.

Mood was assessed using the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983). This scale has been widely used for assessing levels of anxiety and depression in patients with medical problems (Herrmann, 1997). The scale consists of 14 questions that ask participants how they have been feeling over the past week. There are two subscales (anxiety and depression) and subscale scores range between 0-21 (0-7 normal, 8-10 mild, 11-14 moderate and 15-21 representing a severe level of anxiety/depression). The HADS has been found to have high reasonable internal consistency of between 0.68 to.093 (mean.83) for the anxiety subscale and between 0.67 to 0.90 (mean 0.82) for the depression subscales (Bjelland, Dahl, Haug, & Neckelmann, 2002); and is sensitive to treatment related change with test retest correlations at six weeks of 0.70 (Herrmann, 1997). As high levels of depression and anxiety have been found in people with FMS (Epstein et al., 1999) this measure was utilised to assess levels of anxiety or depression between the two groups, and to reveal if there if there were any differences that would need to be accounted for in the analysis.

Primary outcome measures

Actigraphy

As highlighted in Chapter Two, actigraphy can be used as an objective measure of movement (where periods of inactivity are indicative of sleep or rest) and can also providing a measure of activity levels during the day and over night in a naturalistic setting (Smith & Haythornthwaite, 2004). This study utilised actigraphs developed by Cambridge Neurotechnology Ltd., which measured changes in acceleration created by movement of the arm and summed over one minute epoch intervals. In order to account for the variability in sleep quality over time, participants were asked to wear the actigraph throughout the day and night for the three week duration of the study.

Self-reported sleep quality was assessed using the PSQI (Buysse et al., 1989). As described in Chapter Two, this measure was utilised to explore the effect of the interventions on different components of sleep quality.

Secondary outcome measures

As pain and fatigue were found to be to be highly correlated with sleep quality in the previous studies, completed as part of this thesis, the effects of an intervention on pain and fatigue should also be explored. Pain and fatigue were therefore assessed using the respective subscales of the RAND 36-Item Health Survey 1.0 (SF-36) (Hays et al., 1993b; Ware & Sherbourne, 1992), as described in Chapter Four.

Procedure

Participants were randomised by computer using block randomisation, to receive either the mindfulness body scan intervention or a Progressive Muscle Relaxation (PMR) intervention (further details and rationale of the interventions are described in the intervention section of this chapter). Participants were randomised in blocks of six, (three randomised to the mindfulness group and three randomised to the PMR in each block) using the website Randomization.com (http://www.randomization.com). This approach ensured that the number of participants allocated to each group were within (N=3) at all times so that should the study need to be stopped early, or if recruitment proved to be difficult, (which may have occurred as the feasibility of the study was unclear), there would be comparable numbers of participants between the two groups to enable analysis of the data collected. This approach also served to reduce any order effects in participant recruitment, i.e. participants responding first may have been more motivated to participate in the study, than participants responding several weeks later.

Participants were sent an information pack which was relevant to the group into which they had been randomised. The pack contained: an instruction manual, a questionnaire booklet, an actigraph and an MP3 player programmed with the respective intervention. All participants were contacted by telephone to ensure they had received all the necessary resources, to check their understanding of what was required of them and to ask if they had any questions or concerns. Participants were able to contact a member of the research team if they had any questions at any time throughout the study.

In week one (baseline week), participants were asked to complete a questionnaire booklet that included measures of self-reported sleep quality (PSQI), mood (HADS) and health related quality of life (SF-36). In week two (intervention week), participants completed an audio delivered intervention for 10 minutes every day for seven days. In week three (follow up week), participants were asked to stop the intervention and to complete the same booklet of questionnaires as completed at week one. Participants were asked to wear the actigraph throughout the day and night for the three weeks of the study.

On completion of the questionnaires, in week three, participants were asked to return all materials to the study team in a pre-paid envelope. If the documents were not received within the following two weeks, a reminder call was made. Actigraphy data was available for weeks one, two and three and the questionnaire data was available for weeks one and three.

The Interventions

The mindfulness body scan is usually conducted for a period of 45 minutes, however as the person is required to be inactive during the completion of the body scan, this length of time may prove problematic for FMS patients who often report that levels of pain increase after long periods of inactivity (as described in the results section of Chapter Six). Therefore a 10 minute audio guided body scan and PMR intervention were developed specifically for this study and were delivered via an MP3 player.

The mindfulness body scan

Participants were guided to focus on their breathing and to observe the air moving in and out of their body. The audio programme then guided participants to observe any sensations in their body and to become aware of any thoughts they were experiencing without interpreting them. If no sensations were present, participants were asked to acknowledge this.

The progressive muscle relaxation (PMR) intervention

In order to assess whether any potential benefits may just be due to a relaxation response of taking time out and listening to an audio tape, the control group of participants were offered a PMR intervention (Jacobson, 1938). Participants were asked to tense a given muscle for several seconds and then to release the tension and relax the muscle. Participants were guided around different muscle groups over the body, starting with the feet and working up to the head.

Both audio interventions were pre-recorded by the same person (a member of the research team) and started and finished in the same way, to control for any effects of the mode of intervention delivery. As this was a feasibility study, the interventions were only administered for a period of one week, as it was unclear how participants would respond to the intervention and tolerate the actigraphy recording.

Statistical Analysis:

To explore if there were any significant differences between the groups, t-tests for data meeting parametric assumptions and chi square tests and Mann Whitney U tests for non-parametric data were used. Repeated measures ANOVA analysis was conducted for outcome data meeting parametric assumptions to explore the interaction effect by group (mindfulness vs relaxation) and over time (weeks one, two and three). Mann Whitney U tests were used to explore any differences in data that did not meet parametric assumptions.

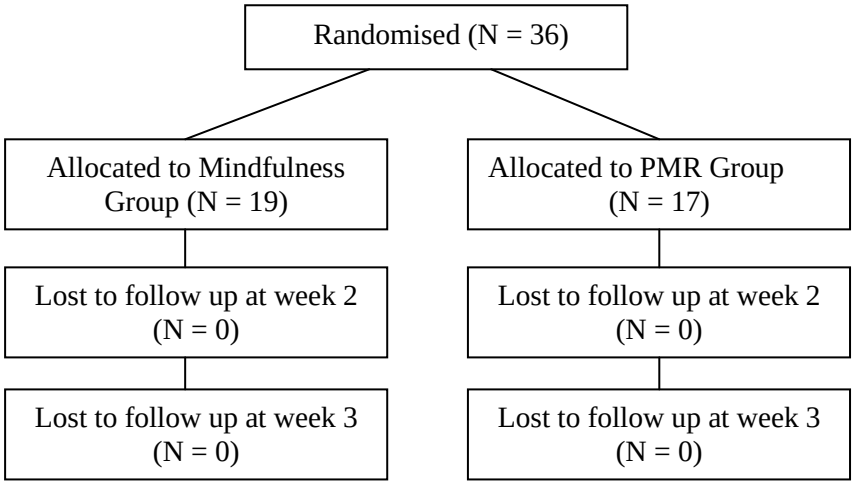
Results

The data collected for this study was screened to check for the normality of data distribution for each variable, and to identify the occurrence of outliers. A descriptive analysis exploring the sample characteristics for each treatment group was conducted. To explore if there were any significant differences between the groups at baseline, t-tests for data meeting parametric assumptions and chi square tests for non-parametric data were used. Means for each variable in the diary and actigraphy data were calculated for each week (to account for variability in sleep patterns). The questionnaire measures (HADS, PSQI and SF-36) were scored as per the manual instructions and the

resulting variables re-checked for obscure values and missing data. Missing data was treated with person mean substitution as described on p. 60-61.

The mindfulness based body scan audio intervention was found to be feasible and well tolerated within this population. This was demonstrated as no participants were lost to follow up during the course of the three week study (as illustrated in Figure 9). However, feasibility issues did arise for the actigraphy outcome measures as no actigraph data was available for six participants (N=2 in the mindfulness group and N = 4 in the PMR group) for the three week duration of the study. This was due to the participants reporting that it was too uncomfortable to wear the actigraph as a result of skin irritation. Participants who were unable to wear the actigraph were not included in the analysis of the actigraphy data, although they were included in the analysis of the subjective questionnaire measures.

Figure 9. Flow chart of the study population



For all other variables, the pattern of missing data appeared to be random (e.g. there were no more than two missing data points per variable, and missing data points occurred across participants). To minimise bias and to prevent data from being discarded from the analysis on these variables, the group median was imputed for missing values to account for repeated measures effects. As highlighted by Scheffer (2002) imputation for missing values can be effective if <10% of data is missing (as was the case in this study), although the impact that imputation may have on the variance for each variable needs to be considered in the data analysis.

Exploring the baseline data, there were no significant differences between the two groups on any of the demographic, mood or medical details data (see Table 12).

Table 12. Participant characteristics

	Mindfulness N=19	**PMR N=17**	Test of significance	
Gender	2 males 17 females	2 males 15 females	X^2=0.14	n.s
Age (Mean and SD) Age range 26-78yrs	52.94 (13.34)	52.71 (11.71)	t=0.06	n.s
Symptom duration in years (Mean and SD)	16.88 (13.60)	10.60 (8.07)	U=113.00	n.s
Other medical conditions	Y=15 N=4	Y=14 N=3	X^2=1.01	n.s
Employment				
Yes	2	3	X^2=0.69	n.s
No	9	6		
No longer working	2	2		
Retired	6	6		
Taking pain relieving medication	Y = 15 N = 4	Y = 12 N= 5	X^2 = 0.33	n.s
HADS depression (Mean and SD)	18.78 (2.02)	19.41 (1.97)	U = 128.00	n.s
HADS anxiety (Mean and SD)	17.44 (2.66)	17.53 (2.18)	U = 152.00	n.s.

n.s = non significant at P<0.05 level

Analysis of primary outcome variables

There were trends of improvements in sleep efficiency and the sleep fragmentation index for people in the mindfulness group and reduced sleep quality on these variables for those in the PMR group (as shown in Table 13, p. 141).

Table 13. Measures of central tendency and variability for the actigraphy data

	Mindfulness Group Mean (SD)			PMR Group Mean (SD)		
Variable	Week 1	Week 2	Week 3	Week 1	Week 2	Week 3
*Sleep efficiency (0-100%)	80.35 (13.71)	80.57 (11.61)	83.06 (14.91)	83.96 (12.33)	79.64 (20.44)	79.83 (19.33)
*Total sleep time (hh:mm)	7.53 (2.06)	8.08 (1.45)	7.51 (2.10)	6.31 (1.23)	6.27 (1.26)	6.11 (0.47)
Sleep fragmentation index (AG (activity counts)	33.54 (24.24)	32.29 (19.68)	30.81 (17.33)	27.07 (22.82)	32.95 (25.80)	30.95 (27.75)
	Median (IQR)			**Median (IQR)**		
	Week 1	Week 2	Week 3	Week 1	Week 2	Week 3
Sleep onset latency (hh:mm)	0.12 (0.11)	0.08 (0.12)	0.11 (0.14)	0.11 (0.18)	0.12 (0.14)	0.12 (0.12)
Number of awakenings	2.28 (1.75)	2.24 (0.98)	2.18 (1.70)	2.25 (0.46)	2.35 (1.31)	2.20 (0.79)

* high scores = better sleep quality

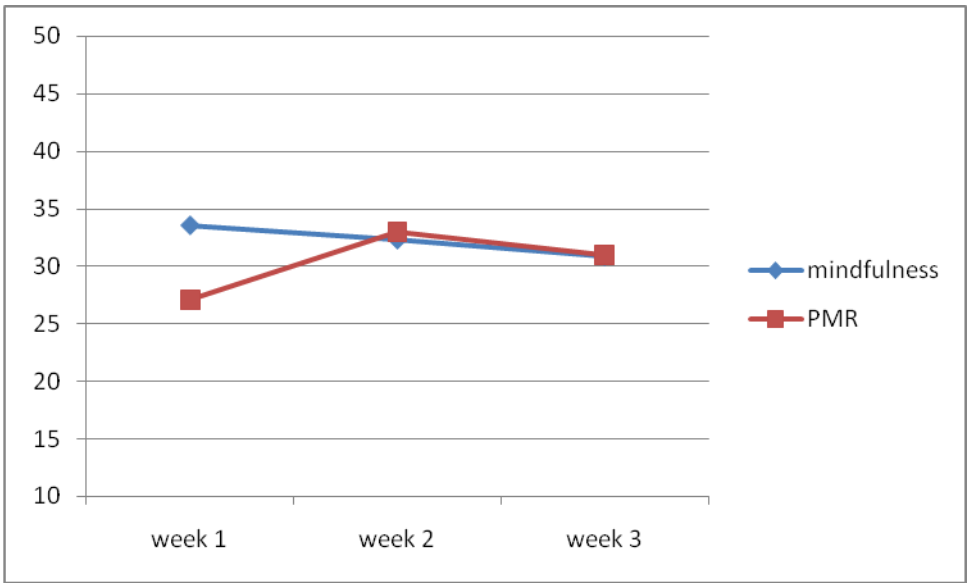
Repeated Measures ANOVA analysis

ANOVA analysis was completed for the variables measured by the actigraphy, which displayed a normal distribution and homogeneity of variance assumptions, (as assessed by a non-significant Levene's test). Repeated measures ANOVA analysis was chosen to explore the interaction between each group and time as the same measurements were conducted on three occasions for each participant. Post hoc tests were not completed as there were less than three groups in the analysis (SPSS, 1999). As there were no significant differences in demographic, mood or medical variables at baseline between the two groups, these variables were not entered as covariates.

To check that the variables in the repeated measures ANOVA analysis met the assumptions for a multivariate approach, Box's test of equality of covariance matrices and Mauchley's test of sphericity were explored. The actigraphy variables: sleep efficiency, total sleep time and sleep fragmentation index were significant $p<0.05$ for the Mauchley's test of sphericity, suggesting that the variance co-variance assumption was not satisfied. As highlighted by Boik (1981) even a small divergence from the assumption of spheircity can result in a large bias in the multivariate analysis.

Consequently, univariate analysis was used to explore the interaction effect as recommended by SPSS (1999). Using the most conservative measure (lower bound) of the interaction effect, there was no significant interaction between group and time for sleep efficiency $F = 3.06$, $p>0.05$ and total sleep time $F = 0.36$ $p>0.05$. There was a significant interaction effect for the sleep fragmentation index $F = 4.33$ $P<0.05$. As can be seen in Figure 10, the interaction effect appears to be the result of an increase in fragmented sleep in the PMR group during week two (during completion of the intervention), although there was a gradual improvement in the sleep fragmentation index in the mindfulness group.

Figure 10. Sleep fragmentation index as measured by actigraphy for the two groups



As the perceived sleep quality variables did not meet the assumption of a normal distribution, Mann Whitney U tests were used to explore if there were any differences between the two groups at each time-point as displayed in Table 14. No significant differences were found between the two groups at baseline or follow up. However, as this was a feasibility study the trends in the data were explored. As can be seen from Table 14, improvements in sleep efficiency were observed in both groups at week 3 follow up in comparison to baseline. There also appeared to an improvement in perceived sleep quality in the mindfulness group at week three.

Table 14. Measures of central tendency and variability for perceptions of sleep quality

	Median (IQR) Week 1			**Median (IQR) Week 3**		
	Mindfulness group	**PMR group**	**Mann Whitney U test**	**Mindfulness group**	**PMR group**	**Mann Whitney U test**
*Sleep efficiency (0-100%)	60.00 (39.94)	68.49 (32.65)	U=136.50 n.s	70.00 (24.67)	78.00 (22.56)	U=148.50 n.s
*Total sleep time (hh:mm)	6.00 (2.25)	6.00 (2.05)	U=149.50 n.s	7.00 (1.45)	6.50 (1.35)	U=160.50 n.s
Sleep onset latency (hh:mm)	0.22 (0.21)	0.30 (0.5)	U=135.50 n.s	0.30 (0.28)	0.25 (0.18)	U=138.00 n.s
Global Score	15.00 (5.75)	13.00 (8.50)	U=148.50 n.s	13.00 (4.50)	13.00 (5.25)	U=148.50 n.s
Number of awakenings	3.00 (2.04)	2.92 (1.36)	U=78.00 n.s	2.50 (1.79)	2.29 (1.75)	U=84.00 n.s

* high scores = better sleep quality
n.s = non significant at P=0.01 level

There was no significant correlation between objective and subjective measures of sleep quality at baseline (see Table 15).

Table 15. Correlation between subjective and objective measures of sleep quality

	%PSE	PSOL	PTST	AG%SE	AGSOL
%PSE	1				
PSOL	-.29	1			
PTST	.89**	-.39*	1		
AG%SE	-.09	-.10	-.03	1	
AGSOL	-.01	.05	-.01	-.51**	1
AGTST	-.27	.08	-.11	-.56*	-.22

Analysis of secondary outcome variables

Mann Whitney U tests were used to explore any differences between the two groups as they did not meet parametric assumptions. The analysis of other health outcomes as part of the study revealed that there were no significant differences between the two groups at baseline or follow up. However, positive trends were observed in perceived levels of pain and fatigue in both groups at follow up with larger improvements observed in the mindfulness group, as shown in Table 16.

Table 16. Measures of central tendency and variability for the measures of health related quality of life

	Week 1 Median (IQR)			**Week 3 Median (IQR)**		
	Mindfulness	**PMR**	**Mann Whitney U Test**	**Mindfulness**	**PMR**	**Mann Whitney U Test**
*SF-36 Pain Scale	22.50 (17.50)	32.50 (17.50)	U = 136.50 n.s	33.75 (39.38)	38.75 (20.00)	U = 123.00 n.s
*SF 36 Fatigue Scale	15.00 (27.50)	30.00 (27.50)	U = 158.50 n.s	22.50 (23.75)	30.00 (22.50)	U = 135.00 n.s

*High scores indicate better outcomes

n.s. = non significant

Discussion

This study explored the effects of a brief mindfulness body scan intervention on sleep quality in people with FMS in comparison to a PMR control group. There was a significant interaction effect on the sleep fragmentation index as measured by actigraphy for group and time. There were no other significant differences between the groups at baseline or follow up, although positive trends were observed in the mindfulness groups for overall perceived sleep quality (PSQI global score). Positive improvements were also observed in both groups in perceived sleep efficiency, pain, fatigue, although the magnitude of the improvements appeared to be larger in the mindfulness group.

The significant intervention between group and time for sleep fragmentation appeared to be due to increased sleep fragmentation in the PMR group, rather than improvements in the mindfulness group, suggesting that the PMR intervention may have been disruptive to sleep quality while participants were completing the intervention. Indeed, three participants who completed the PMR intervention provided informal feedback to the team that the intervention had aggravated their symptoms. As a result participants reported that they had discontinued the intervention for the remainder of the week or did not carry it out every day.

Previous research has revealed that PMR has been shown to be particularly effective for those experiencing chronic pain with high levels of arousal (Friedberg & Jason, 2001). However, Friedberg (2001) noted that this type of relaxation may lead to an initial increase in fatigue or pain (Friedberg & Jason, 2001). This study has highlighted that PMR may also lead to an increase in fragmented sleep. It appears that the increase in sleep fragmentation, decreased after discontinuation of the intervention (in week three), although as the intervention was only completed for the period of one week, it is unclear if this increase would have decreased over time naturally as the previous findings suggest.

This study revealed that participants underestimated their total sleep time and sleep efficiency, and overestimated the amount of time it took for them to fall asleep (sleep onset latency) when compared to the objective actigraphy findings. This supports the findings of previous research using subjective and objective measures of sleep quality in

people with FMS (Perlis, Giles, Mendelson et al., 1997). This highlights the importance of the role of beliefs and expectations about sleep and people's perceptions of sleep quality (Morin & Espie, 2003). It also suggests that these perceptions need to be addressed in interventions to improve sleep quality in this population. However, there was objective evidence of the poor sleep quality experienced by people with FMS in the actigraphy findings suggesting that the sleep disturbance experienced is unlikely to be a sleep state misperception disorder. There is emerging evidence that non-pharmacological interventions focusing on addressing dysfunctional beliefs, re-establishing a consistent sleep pattern and improving coping may improve sleep difficulties and other health outcomes in FMS (Edinger et al., 2005).

Although the observed positive trends in perceived sleep efficiency, pain and fatigue did not reach significance, the findings do suggest that further investigation of the effects of a brief mindfulness intervention is warranted. The magnitude of the findings may have been reduced as measures were not taken in week two when the greatest impact of the intervention was likely to be observed (rather than taken on week three after participants had been asked to stop completing the intervention). Therefore any benefits of the intervention may have been weakened. Questionnaire assessments at week two would have also enabled better comparison with the actigraphy measures taken across the three weeks. It has also been suggested that a three point difference in SF-36 scores may be a clinically significant change (although this may not reach statistical significance) (Samsa et al., 1999). Previous research has also revealed positive trends in mindfulness based interventions that have not reached significance, due to comparable improvements in the control group who were offered an education intervention (Astin et al., 2003). This suggests that people with FMS may benefit from increased education about their condition, time with a supportive therapist or the observed improvements may be due to an expectancy effect and therefore a usual care control would strengthen studies exploring mindfulness in FMS.

Strengths and Limitations

The effect of the mindfulness intervention on health outcomes in FMS may have been limited, as improvements were observed in sleep efficiency, pain and fatigue in both groups. Although the PMR intervention was used to control for the effects of relaxation

and time away from daily life to complete the intervention, PMR in itself may have therapeutic benefits. It would have been useful to have included a third group of participants who received usual care in this study, to enable the exploration of effects of the mindfulness and PMR in comparison to a group receiving no intervention and thus to increase understanding of the therapeutic benefits of the interventions. The findings of this study may also have been limited, as the compliance with completion of the intervention could not be reliably explored in this study, and it unclear if participants completed the full intervention on all occasions. Indeed as previously described, some participants in the PMR group provided informal feedback that they discontinued the intervention due to an increase in their FMS symptoms, and some mindfulness group participants reported continuing the intervention in week three (when they had been asked to discontinue the intervention) because they had found it to be of benefit. This informal feedback was useful when interpreting the results of a feasibility study, and the study would have been strengthened by recording this feedback in a more standardised format, such as through a qualitative interview on completion of the study. An interview would have enabled further exploration of participants' experiences of the two interventions to inform interpretation of the findings and further research.

A key strength of this study is that no participants were lost to follow up or withdrew from the study after randomisation (although the attrition rates may have been due partly to the short intervention duration and follow up). Previous studies have highlighted high attrition rates, with between 21- 39% of participants failing to complete the full intervention program due to scheduling conflicts, difficulties arranging childcare, work commitments, lack of interest and older age (Astin et al., 2003; Kaplan et al., 1993; Lush et al., 2009). This intervention was designed to address these accessibiliy issues and revealed that these issues can be overcome by tailoring the interventions to the needs of the specific population. However, a limitation of this study was that six (16%) participants were unable to tolerate wearing the actiwatch due to skin sensitivity and this will have reduced the ability of the study to detect and change between the two groups on the objective measures. Participants experiencing discomfort were advised to wash their actigraph strap several times to loosen the material and to ease discomfort as advised by the manufacturing company, although this did not appear to resolve the problem for these participants. Modifications to the straps of the actigraphs may therefore be required for future research studies with this population.

The aim of this study was to explore the effect of a brief mindfulness intervention on sleep and key health outcomes such as levels of pain and fatigue in people with FMS. However, as revealed throughout this thesis, the sleep experience in FMS is a complex phenomenon and many other factors are likely to have influenced the effects of the intervention that were not explored in this feasibility study. For example, the mindfulness intervention was chosen as it is based on principles of acceptance and has been found to be beneficial in reducing the effects of stress and cognitive arousal which were found to significantly influence sleep quality in FMS (as described in Chapter Five). However, changes in mindfulness state, sense of coherence, perceived stress and dysfunctional thoughts were not explored within this study, so it remains unclear if the trends in improved sleep quality are indeed a result of these mechanisms. Levels of physical activity during the day are also likely to affect sleep quality and it would have been useful to control for this as part of this study, particularly as daytime napping was found to be coping strategy for people with FMS. As highlighted in Chapter Six, reduced activity may have had a negative impact on subsequent sleep quality. In addition, many of the participants (74%) had a co-morbid condition (such as arthritis, irritable bowel syndrome, diabetes) which may have also affected the results. Given there is such a high co-morbidity in FMS, it may be argued that excluding these participants would have reduced the representativeness of the FMS population. The influence of these factors on outcomes from mindfulness interventions to improve sleep would need to be explored as part of a full randomised clinical trial.

As the assessments were completed by participants on their own at home (and were not administered by a researcher), the data was collated by one researcher who was not blind to the treatment allocation of participants. This may have resulted in a researcher bias in the scoring of the assessments, although assessments were scored according to their specific instructions. The participant scores on the assessment measures may also have been affected by the time of day that people completed the assessments measures or the intervention. For example, if the assessments were completed first thing in the morning, the pain ratings were likely to be higher (as this is when pain likely to be at its worst, Moldofsky & MacFarlane, 2005) and are likely to change over the course of the day. This may have affected the scoring if participants completed the assessments at different time for each week of the three week study. A full randomised controlled trial would need to control for these factors by asking participants to complete the assessment measures and the intervention at the same time each day or through the use

of diary to assess levels of pain at several different times over the course of a 24 hour period (Affleck et al., 1998). It may also be the case that the intervention may have different affects on weekdays and weekends, and between those who are employed and those not working, as people are more likely to have a consistent sleep pattern during the week if they are employed. Further exploration of these factors needs to be considered in future research.

As the focus of this feasibility study was to explore the effect on sleep quality, the measures of pain and fatigue were kept short and concise and therefore did not provide a comprehensive assessment of the different aspects (physical and mental) of fatigue (Moldofsky & MacFarlane, 2005; Shaver et al., 1997). A more comprehensive assessment of these outcomes would have been beneficial to explore the effects of the intervention within this population and whether certain types of people or illness characteristics are more likely to benefit from the intervention than others (Nielson & Jensen, 2004). As highlighted by Mace (2008) some people find it easier than others to experience mindfulness. Indeed, one study revealed that 12.5% of participants were classed as 'marked responders' (participants showing an improvement of 75% or more on the outcome measures), suggesting that they benefitted from the intervention far more than those classed as responders (participants showing an improvement of 25% or more on the outcome measures) (Kaplan et al., 1993).

Subsequent to the onset of this study further recommendations on the outcome measures that should be employed in clinical trials in people FMS were published. Although this study had already included many of the recommended outcome measures, such as measures of pain, fatigue, sleep disturbance and depression, the trial did not include a measure of patient global satisfaction. A measure of global satisfaction should be employed within future clinical trials to ensure that comprehensive outcomes found both to be important to people with FMS and utilised in other clinical trials are included to enable comparisons to be made (Mease et al., 2009).

Implications

This study revealed that a brief mindfulness body scan intervention may improve subjective and objective sleep quality for people with FMS, as positive trends were

observed in perceived overall sleep quality, sleep efficiency, pain and fatigue. Previous research has utilised intensive mindfulness interventions that are delivered by a trained professional and are carried out for a minimum of 30 minutes for eight to 10 weeks alongside home practice for approximately 45 minutes each day (Grossman et al., 2007; Lush et al., 2009). Accessing these interventions can be challenging for people with FMS, as they often experience difficulties travelling long distances and maintaining concentration for long periods of time, and these factors may have influenced the high attrition rates reported in previous studies (Astin et al., 2003; Kaplan et al., 1993; Lush et al., 2009). Therefore this brief intervention (which can be self-delivered at home), offers increased accessibility and feasibility for people with FMS. As the mindfulness experience is likely to become more effective with practice, the improvements in perceived overall sleep quality, sleep efficiency, pain and fatigue as observed in this study after completing the intervention for only one week, are likely to continue to increase over the longer term. Therefore, studies employing a longer intervention period and follow up are warranted.

Many studies exploring the effectiveness of interventions to improve sleep quality, also explore the clinical significance of the findings. For example, observing how many people fall within the parameters defining a 'good sleeper' (e.g. sleep onset latency <30 minutes and sleep efficiency of 80% or more), before and after the intervention (Jansson & Linton, 2005). As the interventions were only implemented for a one week period to explore the feasibility and trends in health outcomes in people with FMS, the observed results were not expected to be of clinical significance as defined by Jansson and Linton (2005). However, these measures would be worthy of exploration in a full scale trial to explore if improvements in sleep quality were clinically significant.

Summary

This feasibility study explored the effects of a brief mindfulness body scan intervention delivered in a community setting on sleep quality in people with FMS in comparison to a relaxation control group. The intervention was feasible to administer and attrition rates were low. Positive trends in overall sleep quality, sleep efficiency, pain and fatigue were observed in the mindfulness group but did not reach statistical significance. A mindfulness based audio body scan intervention may be beneficial to improve sleep quality and other health outcomes for people with FMS.

Chapter Eight. Integrated Discussion

The overarching aim of this thesis was to extend the current knowledge of the nature of sleep disturbance in people with FMS. The first three chapters reviewed the available literature on sleep and FMS, and the findings were used to inform the design of four inter-linked studies which aimed to address the gaps in the literature. A mixed methods (quantitative and qualitative) approach was used to explore the sleep experience in order to elicit a more comprehensive understanding of the role of sleep in FMS.

Overall this thesis highlighted that disturbed sleep is one of the most disabling difficulties for people with FMS, that psychological factors have an integral role in people's perceived sleep experience and that interventions to improve sleep quality need to be tailored to the needs of the population, and include a component addressing the psychological factors. The four objectives of this thesis were addressed by several of the embedded studies, highlighting the cohesiveness of the thesis as a combined whole.

Objective One. The Nature and Extent of Sleep Difficulties in FMS

The first objective of this thesis was to describe the nature and extent of self-reported sleep difficulties in FMS. The first study (Chapter Four) highlighted that participants reported a short sleep duration total sleep (mean of six hours) and poor sleep efficiency. It was also revealed that a high percentage (97%) of participants experienced significant sleep difficulties in need of further intervention in support of previous findings in FMS (Osorio et al., 2006). The high frequency of sleep disturbances in this population was further supported in the following case-control study (Chapter Five) which revealed that people with FMS were (32 times) more likely to have severe sleep difficulties than healthy controls.

Participants also reported that the most common sleep difficulty was waking up several times throughout the course of the night, a finding that was supported in the study described in Chapter Seven, and in a previous study conducted by Korszun et al (2002) using sleep actigraphy. The experience of night-time awakenings was

elaborated on in Chapter Six, which revealed that participants described waking up suddenly during the night, feeling very alert and that it was difficult for them to return to sleep after awakening due to a high level of mental alertness, even if they felt physically tired. Participants described their nocturnal sleep quality as blocks of several hours sleep with awakenings in between. This contrasts with previous evidence for people with other chronic pain conditions which revealed that the most significant difficulties experienced by people with chronic pain were related to initial sleep onset and reduced sleep time (Ohayon, 2005; Wittig et al., 1982). It is, therefore, likely that the sleep experience is different in FMS to other chronic pain conditions.

This study also extended the knowledge base into the nature of sleep difficulties experienced by people with FMS, by revealing that for many people, their sleep difficulties had preceded or started around the same time as their other FMS symptoms (such as pain and fatigue), rather than being a result of experiencing chronic pain and fatigue. This suggests that sleep difficulties are not just a consequence of pain and fatigue. Poor sleep quality was found to be a significant predictor of being diagnosed with FMS in the case control study (Chapter Five) emphasising the importance of sleep quality in the symptom profile of FMS.

It should be acknowledged that across the four integrated studies over half of the participants were prescribed medication to relieve their FMS symptoms which may have affected the results. Analysis of the types of medications taken by participants, revealed a wide range of medication types including opiod analgesics and hypnotic medications (such as co-codamol, codydamol, ibuprofen, paracetamol, amitriptyline, diclofenac, seroxat, temazepam, prednizolone, and gabapentin). Due to the wide variety of medications taken for symptoms of FMS, sub-analysis of participants taking medication versus those who were not was not appropriate. Never-the-less, it is likely that different medication types have different effects on symptoms (see Chapter Two). In addition, sub-analysis was unable to be undertaken by medication type as the sample sizes would have become too small for the analysis to be meaningful. Therefore these findings are likely to underestimate the relationships between sleep and health outcomes in FMS due to the symptom reduction effects of medications taken.

Although perceptions of sleep quality were not found to be significantly associated with objective measures of sleep quality (as revealed in Chapter Eight), as participants

overestimated the time it took them to fall asleep and their sleep efficiency, there was agreement observed between the two measures for total sleep duration in hours and the number of night-time awakenings. This strengthens the evidence that people with FMS experience difficulties maintaining sleep quality through the night. Interventions to improve sleep quality need to focus on reducing night-time awakenings in order to improve sleep quality for people with FMS. The findings in Chapter Six also highlight the possible existence of undiagnosed sleep disorders within this population. This supports the results of previous research in FMS where sleep disorders have been found to be prevalent (Mease et al., 2009); screening for sleep disorders in people with FMS is therefore advisable.

Objective Two. The Psychological Factors Affecting Sleep Quality in FMS

The second aim of the thesis was to explore the psychological factors that may contribute to poor sleep quality in patients with FMS. The first study (Chapter Four) highlighted that coping did not have a significant direct effect on sleep quality, however higher levels of negative affect and lower social functioning were associated with poorer sleep quality. These findings were extended in the second study (Chapter Five) in which people with FMS were found to have higher dysfunctional beliefs about sleep need and higher perceived levels of stress than healthy controls, and that these factors were significantly associated with poorer sleep quality. The findings from Chapter Five were supported and expanded in the qualitative exploration, (Chapter Six) as participants with FMS were very aware of the role of psychological factors on their sleep quality and described how high cognitive arousal, worrying about daily stressors and expectations about their sleep, all affected the sleep quality they experienced at night. The influence of these psychological factors needs to be considered in future research and interventions focusing on improving sleep in people with FMS.

Objective Three. The Effect of Sleep Quality on Symptoms and Daily Life for People with FMS

In addition to describing the experience of sleep in FMS, this thesis aimed to explore how sleep quality affects patients' symptoms and daily lives. The first study (Chapter

Four) revealed that global sleep quality was significantly associated with poorer health outcomes including physical functioning, role limitations due to emotional difficulties, fatigue, well-being, social functioning and pain. Higher levels of perceived pain and poorer physical functioning were significantly associated with more frequent night-time awakenings. This supports previous research findings which found that poor sleep quality is associated with higher levels of pain (Nicassio et al., 2002) and that fatigue was only associated with worse daytime dysfunction. In the qualitative study, (Chapter Six), participants described a strong interrelationship between their sleep quality and other symptoms relating to their condition (such as pain and fatigue), with a poor nights sleep leading to higher levels of pain and fatigue the following day and high levels of pain interfering with their sleep at night. Participants also described feeling more fatigued and less able to participate in daytime activities after a poor nights sleep, supporting the quantitative findings (Chapters Four and Five). As sleep quality, pain and fatigue fluctuated over time, this caused participants with FMS significant difficulties in being able to plan activities and they often had to cancel arrangements due to a poor nights sleep. As a way of coping with their poor sleep and symptoms, participants described planning rest periods and using daytime naps, to help them to increase their energy levels over the course of the day. It was also observed that most people with FMS perceived that the onset of their sleep difficulties occurred prior to, or at the same time as, the onset of their other FMS symptoms; suggesting that sleep difficulties are not just a consequence of pain and fatigue. As shown in Chapter Five, sleep disturbance is a significant risk factor for diagnosis of FMS, and sleep appears to be a significant cause of disability and reduced social functioning in people with FMS. This supports the recent recommendations on outcome measures for clinical trials in FMS which state that sleep should be considered to be key outcome for interventional studies within this population (Mease et al., 2009).

Objective Four. An Intervention to Improve Sleep Quality

Lastly this study aimed to trial an intervention with the aim to improve sleep quality for patients with FMS. Drawing on the findings from the first three studies, this feasibility study explored the effect of a brief mindfulness intervention, based on the principles of acceptance of physical sensations and thoughts and thereby reducing stress and arousal on sleep quality in FMS. Although the intervention was only piloted

for a period of one week, the study showed that the mindfulness body scan intervention was feasible to implement in a community setting and participants receiving the mindfulness body scan intervention displayed greater improvements in sleep quality and levels of pain in comparison to the PMR control group. This contrasts with a previous study using sleep quality as an outcome measure, which found that mindfulness had no effect on sleep quality in people with FMS (Sephton et al., 2007). The discrepancy in the findings may be explained as the study, completed as part of this thesis, employed a unique approach, which was feasible for people with FMS to implement in their own homes, rather than an intensive interventions delivered by a trained specialist (as applied by Sephton et al., 2007), which may be difficult for people with FMS to access. The low attrition rates and positive trends in this feasibility study suggest that a brief mindfulness body scan is a promising intervention for improving sleep quality and symptoms of pain and fatigue for people with FMS.

Added Value of the Thesis to the Research Literature

This thesis has helped to clarify the nature of the sleep disturbance experienced in FMS and has explored some of the factors that may be influencing sleep quality in this population. By exploring the separate components of sleep quality, these studies have highlighted the complex nature of the sleep process and how psychological factors may be involved in the sleep process. For example, some factors such as perceived levels of stress were found to affect night-time awakenings but not sleep duration in FMS.

The findings of this thesis revealed that the influence of psychological factors on sleep quality provides support for the integrative model of sleep-interfering and sleep-interpreting processes proposed for insomnia (Lundh & Broman, 2000). However, looking specifically at the models proposed for people with chronic pain conditions, the findings of this thesis suggest that the maintenance of sleep disturbances in FMS is far more complex than current models suggest. Previous models of sleep and pain have highlighted the cyclical relationships between fatigue, poor sleep and pain which are supported by the findings of this thesis for people with FMS. However the links between coping, sleep and pain remain unclear in people with FMS.

Modifications to the Call-Schmidt and Richardson (2003) model (re-illustrated in Figure 11) are proposed in Figure 12 (p. 157), to ensure the model fits with the research evidence for people with FMS. The variables of stress, dysfunctional beliefs about sleep and negative affect have been added into the model as a result of the findings from this thesis. The box in the bottom right hand corner has also been amended to describe the effect of poor sleep quality (rather than good sleep quality as specified in the original model). This box has been further integrated with the other variables in the model to reflect how poor sleep is part of a cycle in which people with FMS seem to find themselves, as suggested by the findings of this thesis. As the direction of the associations cannot be determined by the cross-sectional nature of the completed studies, links between the included variables have been considered as bi-directional.

Figure 11. Original Conceptual Framework of Pain and Sleep adapted from Call-Schmidt and Richardson (2003)

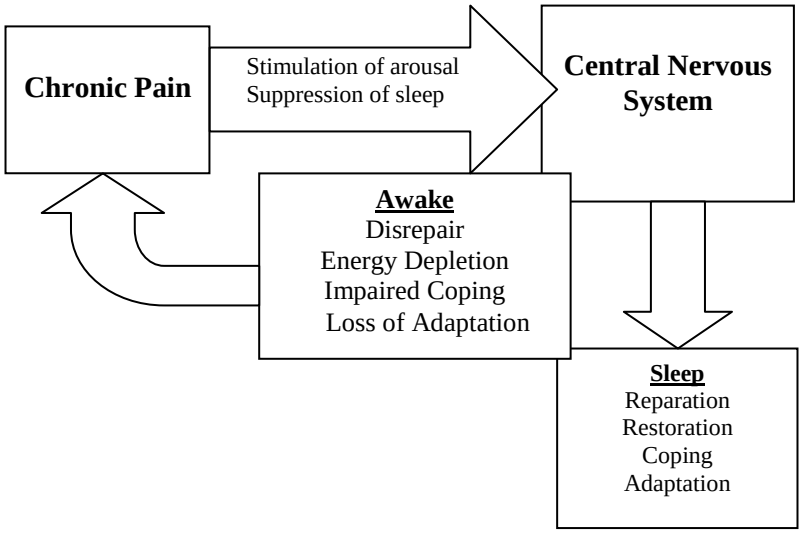
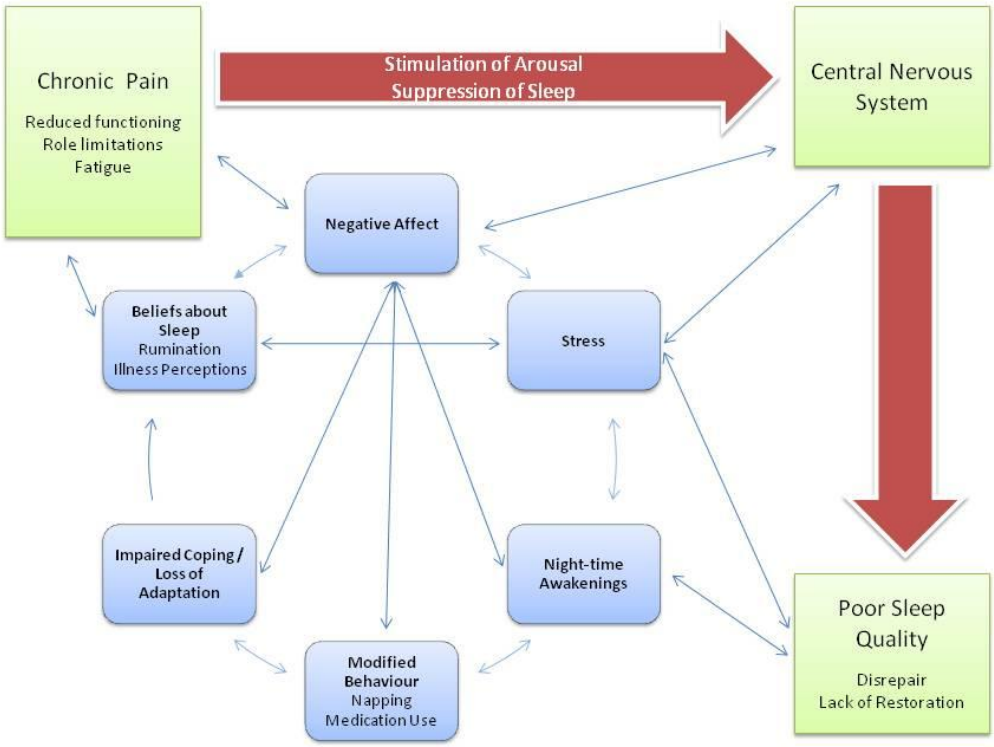


Figure 12. Revised Conceptual Framework of Pain and Sleep adapted from Call-Schmidt and Richardson (2003)



Regarding the use of napping for people with FMS, the thesis has raised some additional questions that need further exploration, such as how often do people take a nap and what is the optimum nap time for this population. Previous studies have indicated that in the general population daytime naps of <30 minutes duration have been found to have beneficial effects on excessive daytime sleepiness, mood and cognitive performance (Dhand & Sohal, 2006; Takahashi, 2003; Tietzel & Lack, 2002). It is unclear however, if these findings can be generalised to people with FMS and further work is needed to examine if napping is effective in relieving symptoms of pain and fatigue, and to explore the impact of daytime naps on subsequent sleep quality and night-time awakenings in this population (Scheuermann, 2008).

As a result of this work, it has become apparent that there is a need for a systematic review of non-pharmacological interventions for FMS, with sleep quality included as an outcome measure. A review of the general literature in FMS (in Chapters Two and Three) and specifically the literature evaluating the effectiveness of the eight-week

MBSR programme in people with FMS (Chapter Seven) revealed that a number of clinical trials of non-pharmacological studies have been completed; although the effectiveness of the intervention remains unclear, due to small sample sizes and consequent low statistical power to detect any effect. A meta-analysis of these studies, (and other non-pharmacological) interventions, may help to clarify the effectiveness of these findings by combining studies of comparable interventions. Due to the influential role of psychological factors identified within this thesis, non-pharmacological interventions may be ideally placed to address these factors in clinical treatment and an analysis of their effectiveness would therefore provide important information to inform treatment of the condition. A Cochrane review of non-pharmacological interventions is currently underway (Theadom et al., 2009).

Thesis Limitations and Recommendations for Future Research

Limitations relating specifically to each study of this thesis were discussed within the relevant chapters. However, there were some general limitations across the four interlinked studies completed as part of this thesis that will be considered here.

Another factor related to sleep that was not explored within this thesis was the role of chronotype on sleep disturbance. As described in Chapter Two, people have underlying natural circadian rhythms, and a natural sleep chronotype (patterns of when they feel more alert and when they feel more tired) (Randler, 2008). For example, people are often referred to as 'larks' if they prefer to go to sleep earlier and wake up earlier in the morning, or 'owls' if they prefer to stay up later in the evening and wake up later in the morning (Cavallera & Giudici, 2007). It is currently unclear if people with FMS are affected by their underlying sleep chronotype. Understanding if chronotype does play a role in the sleep experience may help to inform the treatment of sleep disturbances for people with FMS. If chronotype is associated with sleep disturbance, then clinicians could help to support people with FMS to manage their sleep disturbance through identifying times of the day when they may be more alert, within which to schedule daily activities, and periods when the person may be feeling more fatigued, within which to schedule in rest or more passive activities, to be in harmony with their underlying circadian rhythm. A further study is currently being planned to explore the

effect of chronotype of sleep disturbance in FMS utilising a cross-sectional internet survey.

Although the studies within this thesis explored the effect of sleep on a number of outcome variables in people with FMS, not all outcomes that are likely to be affected by sleep disturbance were explored. For example, cognitive difficulties have been proposed as a key symptom of FMS, and one study has shown that memory impairments, mental confusion and speech difficulties are associated with sleep disturbance in people with FMS (Katz, Heard, Mills, & Leavitt, 2004). Although this study has drawn attention to the role of sleep on cognitive factors in FMS, the findings were limited as cognitive disturbance was only measured by self-report. Research exploring the effects of sleep disturbance using more objective measures of cognitive functioning (such as through the use of standardised computer administered neuropsychological tests), may reveal more accurately the links between sleep and cognitive functioning in people with FMS. This would enable the exploration of the effect of sleep on different components of cognitive ability (such as memory, attention and executive functioning) and further exploration is warranted.

Some researchers in the field of sleep have suggested that measures of daytime sleepiness are a useful tool (in addition to measures of nocturnal sleep quality), and it has been proposed that measures of daytime sleepiness may even be a more reliable indicator of poor sleep quality (Lundh & Broman, 2000). For example, nocturnal sleep quality measures (such as the PSQI used within this thesis) consider a sleep duration of <7 hours as indicative of poor sleep quality. However, as described in Chapter Two, five to six hours of sleep may be sufficient sleep for some people. Consequently measures of daytime sleepiness such as the Epworth Sleepiness Scale may have been beneficial to include within some of the studies included in this thesis.

Verification of the sleep patterns described using subjective measures within this thesis using polysomnographic measures would strengthen the research findings and increase the evidence base for whether the sleep disturbances are related more to a sleep state misperception or psychophysiological insomnia. The use of polsyomnography would also confirm if participants, descriptions of their sleeping pattern and night-time experiences which appear to indicate a potential organic sleep disorder meet the

diagnostic criteria for these sleep disorders (such as periodic limb movement disorder, bruxism, sleep apnea or restless legs syndrome).

The findings of this thesis should be interpreted with some caution as the analyses did not account for possible measurement and sampling error. As little research has been completed in the field of FMS using the measures incorporated within this thesis, little is known about the psychometric properties of these measurement tools with the FMS population. Consideration of the most evidence based measures for use within this thesis (as described in Chapter Four) and procedures for reducing systematic error were applied (such as double entering data, the measures being administered by one trained researcher). However, despite these efforts there remains a risk of measurement error; (that the assessment tools do not measure what they state they are measuring or due to human consistency) which may bias the results. There may be a particular risk of possible misclassification of participants into outcome groups for the logistic regression, (as conducted in Chapter 5) due to measurement error and therefore caution needs to be applied in the interpretation of these findings.

There is a need for further studies to explore the psychometric properties of these assessment tools in more detail to ensure the accuracy of research findings. It has been found that measurement error can reduce the power of a study by over 25% (Cheng, Branscum, & Stamey, 2010). Therefore, in future studies it is recommended that adjustments for possible sampling error be made in sample size calculations for studies utilising these tools, particularly when exploring constructs that are known to frequently occur within a given population. As the high frequency of sleep difficulties was unknown at the time of study completion, this was not accounted for within this thesis; but on reflection accounting for this risk of error would have increased confidence in the research findings.

Participants were recruited through community based support groups and although this approach was chosen to ensure the capture of people with varying degrees of severity of FMS (rather than only those requiring support from hospital services or specialist clinics), this may limit the generalisability of the results to people who do not attend support groups. People attending support groups may differ from people with FMS who do not, such as an increased need for social support or seeking information (Davison, Pennebaker, & Dickerson, 2000). For example, it was found in a study in HIV patients

that people who attended support groups had higher levels of education and a longer duration of the illness than non-attenders (Walch, Roetzer, & Minnett, 2006). This has not yet been specifically explored in the FMS population.

A further limitation of the overall thesis is that there were minimal eligibility criteria for inclusion as an 'FMS participant'. Participants were required to have received a formal diagnosis of FMS from a GP or a consultant, however as discussed in Chapter One, many patients are not diagnosed based specifically on the ACR (1990) criteria in clinical practice, or in some cases the criteria were applied incorrectly. Therefore we cannot be completely confident that all participants would have met the ACR criteria and this may affect the reliability of the findings. However, it could be argued that as some researchers believe the ACR criteria only diagnose people with more severe symptoms of the condition (Bidari et al., 2009), the fact that this study included participants who did not have a diagnosis based specifically on the ACR criteria, meant this thesis was more inclusive of the FMS clinical population. In response to the criticisms of the ACR criteria, proposals are underway to review the criteria and to reduce the reliance on the tender point examination which is most commonly misapplied. The proposed new criteria aims to focus more on the other symptoms of FMS, such as sleep disturbance, fatigue and cognitive difficulties in order to provide a more comprehensive measure of symptoms experienced. This new approach will provide a method of verifying the diagnosis of FMS in research studies and enable an exploration of different severities of FMS, without the need for a tender point examination by a trained clinician (Wolfe et al., 2010).

Recent recommendations on the use of outcome measures that were published after the design of the studies included in this thesis, suggest that a FMS disease-specific measure such as the Fibromyalgia Impact Questionnaire should be employed in clinical trials for this population. This scale lists items relating to specific symptoms of FMS including fatigue, sleep and pain. As these concepts needed to be explored in detail for this thesis (for example, to explore the effect of sleep on the different components of fatigue) more comprehensive measures of these specific constructs were used within this thesis. However, such an approach prevented this research from being directly compared to other research findings for people with FMS. This should be considered in future research to facilitate comparability of the findings, in addition to more

comprehensive measures to look at the constructs under investigation in more detail (Scheuermann, 2008).

Implications for Practice

Due to the extremely high prevalence of sleep difficulties in FMS and the identified links between sleep and pain and fatigue, interventions designed to improve sleep may lead to improvements in not only sleep quality, but also quality of life and reduction in medication use for participants with FMS.

This thesis has extended the current knowledge base by exploring the components of sleep quality and highlighting that sleep maintenance, rather than sleep onset difficulties, are most problematic for people with FMS. In addition, a number of factors were shown to be influential to sleep quality (including negative affect, beliefs about sleep, stress, worry and high levels of cognitive arousal) and these need to be addressed in targeted interventions to facilitate sleep quality. There is currently contrasting opinions about whether sleep difficulties in patient populations should be treated as part of the illness or as a separate entity (Mahowald & Mahowald, 2000; Watts et al., 1994). As sleep and other symptoms of the condition were found to be highly interlinked within this thesis, this supports the notion that sleep interventions should be an integral component of interventions for people with FMS.

Conclusion

Poor sleep quality can affect all aspects of a person's daily functioning, and for people with FMS the effects are even more profound. The key contributions to knowledge reflected in this thesis are that sleep disturbance was more highly prevalent in FMS than previously described, and that poor sleep was linked to the exacerbation of symptoms of pain, fatigue and reduced social functioning. In particular, frequent night-time awakenings, while feeling mentally alert at night, was found to be the most common difficulty, with people experiencing sleep in blocks of two to three hours throughout the night. This contrasts to people with other chronic pain conditions, who have been found to experience greater difficulties with initial sleep onset and reduced total sleep time. Undiagnosed sleep disorders may also be particularly problematic for people with FMS and routine screening should be recommended. This thesis also highlighted that psychological factors such as high negative affect, stress and dysfunctional beliefs about sleep were found to be associated with greater sleep disturbance.

While there are important advances still to be made (such as exploring if daytime napping is a beneficial management strategy for this population), the findings from this thesis have important implications for treatment. Interventions that identify sleep difficulties and manage the psychological aspects, in addition to the environmental and physiological aspects of sleep disturbance, should form an integral part of treatment to improve quality of life for people with FMS. Findings indicate that a brief mindfulness body scan intervention may provide one component of an intervention to address the psychological aspects of sleep disturbance. While some continue to trivialise sleep problems and the consequences of disturbed sleep, the studies incorporated within this thesis have identified the importance of sleep disturbance on health, and has contributed to potential ways forward in managing poor sleep for people with FMS.

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Glossary

ACR = American College of Rheumatology
ANOVA = Analysis of variance
CFS = Chronic fatigue syndrome
CSQ = Pain Coping Strategies Questionnaire
DBAS = Dysfunctional Beliefs about Sleep Scale
df = Degrees of freedom
ESS = Epworth Sleepiness Scale
EULAR = European League Against Rheumatism
FAS = Fatigue Assessment Scale
FMA–UK = Fibromyalgia Association UK
fMRI = Functional Magnetic Resonance Imaging
FMS = Fibromyalgia syndrome
GP = General Practitioner
HADS = Hospital Anxiety and Depression Scale
ICD-10 = International Classification of Disease – Version 10
IPA = Interpretative Phenomenological Analysis
IQR = Interquartile range
MBSR = Mindfulness Based Stress Relaxation
MOS-SS = Medical Outcomes Study Sleep Scale
NREM = Non-Rapid Eye Movement sleep
N = Number of participants
OMERACT = Outcome Measures in Rheumatology Clinical Trials Working Group
PANAS = Positive and Negative Affect Scale
PMR = Progressive muscle relaxation
Pro re nata = To be taken as and when needed
PSQI = Pittsburgh Sleep Quality Index
PSS = Perceived Stress Scale
REM = Rapid Eye Movement sleep
SD = Standard deviation
SF-36 = Short Form Medical Outcomes Survey
Sleep efficiency = Number of hours spent asleep/Total time spent in bed x100
Sleep onset latency = Time taken in minutes to fall asleep
UK = United Kingdom
US = United States of America
X^2 = Chi Square

Appendices

Appendix A: Search Strategy for Literature Review

1. Exp fibromyalgia
2. Fibromyalg$
3. Fibrositis
4. Or/ 1-3
5. Exp fatigue
6. Tired$
7. Letharg$
8. Exp pain
9. Quality of life
10. Exp sleep
11. 4 AND 5-10
12. Polysomnography
13. Actigraphy
14. 4 AND 12-13
15. Outcome assessment
16. Outcome measure
17. 4 AND 15-16
18. 5 AND 15-16
19. 8 AND 15-16
20. 10 AND 15-16

Additionally reference lists of relevant articles were searched and additional searches were completed for specific aspect arising in the four component research studies.

Sleep, Coping and Quality of Life

Information Sheet

Thank you for your interest in this study on sleep, coping and quality of life.
Please read the following information carefully and feel free to ask me if anything is unclear or if there is anything else you would like to know about the study. Please take time to decide if you would like to participate, although you may withdraw from this study at any time.

The study
This study is investigating the beliefs people with have about their sleep, their sleep patterns and quality of life. The study will be conducted by myself (Alice Theadom), a Chartered Health Psychologist and Dr Mark Cropley at the University of Surrey.

Instructions
If you wish to participate please complete the attached questionnaire , returning this to us in the envelope provided. Please complete the questionnaire in your own time and at your own pace. It is 9 pages long and takes approximately 15-20 minutes to complete. There will be detailed instructions on how to complete each section of the questionnaire. There are no right or wrong answers to these questions and you may choose not to respond to any questions you do not wish to answer.

Benefits and Risks
Participating in this study will contribute to the understanding of sleep, coping and quality of life in Fibromyalgia syndrome by comparing responses between patients with and without this condition. It is hoped that the findings of the study will help to provide information for practitioners in the field, with the aim to improve the quality of life for individuals with this health condition.

You may find answering some of the questions upsetting or distressing for you. You are under no pressure to participate in the study and you may choose not to answer specific questions or to withdraw from the study at any time.

All information will be completely anonymous and confidential. Please return all questionnaires in the stamped addressed envelope provided. This study has received ethical approval from the University of Surrey ethics committee.

Contact Details

Alice Theadom **alice.theadom@thh.nhs.uk** **01895 279021**

Mark Cropley **Mark.Cropley@surrey.ac.uk** **01483 686928**

Sleep and Fibromyalgia Syndrome

Consent Form

I agree to take part in the study on sleep and Fibromyalgia syndrome. I have read and understood the information sheet provided. I have been given the opportunity to ask questions on all aspects of the study and I have understood the advice and information given.

I understand that any information I provide will be anonymous and treated as confidential.

I understand that I may withdraw from the study at any time without reason or needing to justify my decision.

I confirm that I have read and understood the above and freely consent to participate in the study. I have been given adequate time to consider my participation and I agree to follow the instructions and restrictions of the study.

Name of volunteer_____
(Block Capitals)

Signature of volunteer_____

Date_____

Appendix C: Letter of Ethical Approval for Study One (Chapter Four)

UniS
Ethics Committee

03 June 2005

Ms Kirsty Humphrey
10 Wheelers Orchard
Chalfont St Peter
Bucks
SL9 0HL

Dear Ms Humphrey

An investigation into the relationship between sleep, pain, fatigue and quality of life in Fibromyalgia patients (EC/2005/24/PSYCH)

On behalf of the Ethics Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the submitted protocol and supporting documentation.

Date of confirmation of ethical opinion: **03 June 2005**

The list of documents reviewed and approved by the Committee is as follows:-

Document Type: Application
Dated: 15/02/05
Received: 09/03/05

Document Type: Research Proposal
Received: 09/03/05

Document Type: Questionnaire
Received: 09/03/05

Document Type: Information Sheet
Received: 09/03/05

Document Type: Consent Form
Received: 09/03/05

Document Type: Your First Response to the Committee' Comments
Dated: 18/04/05
Received: 21/04/05

Document Type: Your Second Response to the Committee's Comments
Dated: 03/05/05
Received: 05/05/05

Document Type: Your Third Response to the Committee's Comments
Dated: 24/05/05
Received: 31/05/05

This opinion is given on the understanding that you will comply with the University's Ethical Guidelines for Teaching and Research.

The Committee should be notified of any amendments to the protocol, any adverse reactions suffered by research participants, and if the study is terminated earlier than expected, with reasons.

You are asked to note that a further submission to the Ethics Committee will be required in the event that the study is not completed within five years of the above date.

Please inform me when the research has been completed.

Yours sincerely

Catherine Ashbee

Catherine Ashbee (Mrs)
Secretary, University Ethics Committee
Registry

cc: Professor T Desombre, Chairman, Ethics Committee
Dr M Cropley, Supervisor, Department of Psychology
Alice Theadom, Camden Primary Care Trust

Appendix D: Participant questionnaire for Study One (Chapter Four)

Individuals' Experiences of Sleep. Coping and Quality of Life

Age:_____ **Gender:** Male/Female (please circle)

1. Do you have any diagnosed medical conditions?

If yes, what is your diagnosis?_____

2. Do you regularly take any medication for sleep, pain or fatigue related complaints?

Yes / No (please circle)

If yes which medication(s) are you taking?_____

3. If you are working does your work involve shift work? Please circle the most appropriate answer for you

Yes / No / I am not currently working (please circle)

The following questions relate to your usual sleep habits. Please describe the pattern of your sleep on a typical night during the past month.

1. What time do you usually go to bed? _____pm/am (please delete as appropriate)

2. How long has it taken you to fall asleep each night?

_____ hours_____ minutes

3. Approximately how many times do you wake up during the night? _____

4. Approximately how long are you awake during each awakening?

____hours _____minutes

5. What time do you usually get up in the morning? _____ am

6. How many hours of actual sleep do you usually get?

_____ hours _____ minutes (This may be different to the number of hours you spent in bed)

7. How refreshed do you feel in the morning?

Very Refreshed Very Un-refreshed
1 2 3 4 5 6 7 8 9 10

8. How enjoyable would you rate your sleep?

Very Enjoyable Very Un-enjoyable
1 2 3 4 5 6 7 8 9 10

The following questions relate to your usual sleeping habits. Please indicate, how often have you have experienced the situations listed below by ticking the box that represents how often this has occurred in the past month.

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
1. Cannot get to sleep within 30 minutes	0	1	2	3
2. Wake up in the middle of the night or early morning	0	1	2	3
3. Have to get up to use the bathroom	0	1	2	3
4. Cannot breathe comfortably	0	1	2	3
5. Cough or snore loudly	0	1	2	3
6. Feel too cold	0	1	2	3
7. Feel too hot	0	1	2	3
8. Have bad dreams	0	1	2	3
9. Have pain	0	1	2	3
10. Other reason(s) please describe including how often you have had trouble sleeping because of this reason:	0	1	2	3
11. During the past month how often have you taken medicine (prescribed or over the counter) to help you sleep?	0	1	2	3
12. During the past month how often have you had trouble staying awake while driving, eating meals or engaging in social activity	0	1	2	3
13. During the past month how much of a problem has it been for you to keep up enthusiasm to get things done	0	1	2	3
	Very Good	Fairly good	Fairly bad	Very bad
14. During the past month how would you rate your sleep quality overall	0	1	2	3

The scale below consists of a number of words that describe different feelings and emotions. Please tick the box next to the word indicating the extent to which you have felt this way during the past month.

		Very slightly or not at all	A little	Moderately	Quite a bit	Extremely
1.	**Interested**	1	2	3	4	5
2.	**Distressed**	1	2	3	4	5
3.	**Excited**	1	2	3	4	5
4.	**Upset**	1	2	3	4	5
5.	**Strong**	1	2	3	4	5
6.	**Guilty**	1	2	3	4	5
7.	**Scared**	1	2	3	4	5
8.	**Hostile**	1	2	3	4	5
9.	**Enthusiastic**	1	2	3	4	5
10.	**Proud**	1	2	3	4	5
11.	**Irritable**	1	2	3	4	5
12.	**Alert**	1	2	3	4	5
13.	**Ashamed**	1	2	3	4	5
14.	**Inspired**	1	2	3	4	5
15.	**Nervous**	1	2	3	4	5
16.	**Determined**	1	2	3	4	5
17.	**Attentive**	1	2	3	4	5
18.	**Jittery**	1	2	3	4	5
19.	**Active**	1	2	3	4	5
20.	**Afraid**	1	2	3	4	5

There are lots of ways to try to deal with stress. This questionnaire asks you to indicate what you generally do and feel when you experience stressful events. Obviously, different events bring out somewhat different responses, please tick the box that indicates **what you usually do** when you are under a lot of stress. Please try to respond to each item separately from each other item.

	I usually don't do this at all	I usually do this a little bit	I usually do this a medium amount	I usually do this a lot
1. I try to grow as a person as a result of the experience	1	2	3	4
2. I turn to work or other substitute activities to take my mind off things	1	2	3	4
3. I get upset and let my emotions out	1	2	3	4
4. I try to get advice from someone about what to do	1	2	3	4
5. I concentrate my efforts on doing something about it	1	2	3	4
6. I say to myself "this isn't real"	1	2	3	4
7. I put my trust in God	1	2	3	4
8. I laugh about the situation	1	2	3	4
9. I admit to myself that I can't deal with it, and quit trying	1	2	3	4
10. I restrain myself from doing anything too quickly	1	2	3	4
11. I discuss my feelings with someone	1	2	3	4
12. I use alcohol or drugs to make myself feel better	1	2	3	4
13. I get used to the idea that it happened	1	2	3	4
14. I talk to someone to find out more about the situation	1	2	3	4
15. I keep myself from getting distracted by other thoughts or activities	1	2	3	4
16. I daydream about things other than this	1	2	3	4
17. I get upset, and am really aware of it	1	2	3	4
18. I seek God's help	1	2	3	4
19. I make a plan of action	1	2	3	4
20. I make jokes about it	1	2	3	4

	I usually don't do this at all	I usually do this a little bit	I usually do this a medium amount	I usually do this a lot
21. I accept that this has happened and that it can't be changed	1	2	3	4
22. I hold off doing anything about it until the situation permits	1	2	3	4
23. I try to get emotional support from friends or relatives	1	2	3	4
24. I just give up trying to reach my goal	1	2	3	4
25. I take additional action to try to get rid of the problem	1	2	3	4
26. I try to lose myself for a while by drinking alcohol or taking drugs	1	2	3	4
27. I refuse to believe that it has happened	1	2	3	4
28. I let my feelings out	1	2	3	4
29. I try to see it in a different light, to make it seem more positive	1	2	3	4
30. I talk to someone who could do something concrete about the problem	1	2	3	4
31. I sleep more than usual	1	2	3	4
32. I try to come up with a strategy about what to do	1	2	3	4
33. I focus on dealing with this problem, and if necessary let other things slide a little	1	2	3	4
34. I get sympathy and understanding from someone	1	2	3	4
35. I drink alcohol or take drugs , in order to think about it less	1	2	3	4
36. I kid around about it	1	2	3	4
37. I give up the attempt to get what I want	1	2	3	4
38. I look for something good in what is happening	1	2	3	4
39. I think about how I might best handle the problem	1	2	3	4
40. I pretend that it hasn't really happened	1	2	3	4
41. I make sure not to make matters worse by acting too soon	1	2	3	4

	I usually don't do this at all	I usually do this a little bit	I usually do this a medium amount	I usually do this a lot
42. I try hard to prevent other things from interfering with my efforts at dealing with this.	1	2	3	4
43. I go to the movies or watch TV, to think about it less	1	2	3	4
44. I accept the reality of the fact that it happened	1	2	3	4
45. I ask people who have had similar experiences what they did	1	2	3	4
46. I feel a lot of emotional distress and I find myself expressing those feelings a lot	1	2	3	4
47. I take direct action to get around the problem	1	2	3	4
48. I try to find comfort in my religion	1	2	3	4
49. I force myself to wait for the right time to do something	1	2	3	4
50. I make fun of the situation	1	2	3	4
51. I reduce the amount of effort I'm putting into solving he problem	1	2	3	4
52. I talk to someone about how I feel	1	2	3	4
53. I use alcohol or drugs to help me get through it	1	2	3	4
54. I learn to live with it	1	2	3	4
55. I put aside other activities in order to concentrate on this	1	2	3	4
56. I think about what steps to take	1	2	3	4
57. I act as though it hasn't even happened	1	2	3	4
58. I do what has to be done, one step at a time	1	2	3	4
59. I learn something from the experience	1	2	3	4
60. I pray more than usual	1	2	3	4

This set of questions asks your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Please tick the box that represents how you feel. If you are unsure about how to answer questions please give the best answer you can.

	Excellent	Very Good	Good	Fair	Poor
1. In general would you say your health is:					
	Much better	Somewhat better	About the same	Somewhat worse	Much worse
2. Compared to one year ago how would you rate your health in general now					

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so how much? Please tick the box that indicates how you feel.

	Limited a lot	Limited a little	Not limited at all
3. Vigorous activities such as running, lifting heavy objects, participating in strenuous sports	1	2	3
4. Moderate activities such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
1. Lifting or carrying groceries	1	2	3
2. Climbing several flights of stairs	1	2	3
3. Climbing one flight of stairs	1	2	3
4. Bending, kneeling or stooping	1	2	3
5. Walking more than a mile	1	2	3
6. Walking several blocks	1	2	3
7. Walking one block	1	2	3
8. Bathing or dressing yourself	1	2	3

During the past month have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Please tick the appropriate box.

	Yes	No
13. Cut down on the amount of time you spent on work or other activities	1	2
14. Accomplished less than you would like	1	2
15. Were limited in the kind of work or other activities?	1	2
16. Had difficulty performing the work or other activities for example it took extra effort	1	2

During the past month have you had any of the following problems with your work to other regular activities as a result of any emotional problems e.g. feeling depressed or anxious? Please tick the appropriate box.

	Yes	No
17. Cut down on the amount of time you spent on work or other activities	1	2
18. Accomplished less than you would like	1	2
19. Didn't do work or other activities as carefully as usual	1	2

	Not at all	Slightly	Moderately	quite a bit	Extremely
20. During the past month to what extent has your physical health or emotional problems interfere with your normal social activities with family, friends, neighbours or groups					

	None	Very mild	Mild	Moderate	Severe	Very Severe
21. How much physical pain have you had in the past month						

	Not at all	A little bit	Moderately	Quite a bit	Extremely
22. During the past month how much did pain interfere with your normal work (both paid and/or housework)					

These questions are about how you feel and how things have been with you during the past month. Please tick the box that indicates how you have been feeling.

Please circle one number for each line	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
23. Did you feel full of life?	1	2	3	4	5	6
24. Have you been a very nervous person?	1	2	3	4	5	6
25. Have you felt so down in the dumps that nothing cheers you up?	1	2	3	4	5	6
26. Have you felt calm and peaceful?	1	2	3	4	5	6
27. Did you have a lot of energy?	1	2	3	4	5	6
28. Have you felt downhearted and blue?	1	2	3	4	5	6
29. Did you feel worn out?	1	2	3	4	5	6
30. Have you been a happy person?	1	2	3	4	5	6
31. Did you feel tired?	1	2	3	4	5	6

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
32. During the past 4 weeks how much of the time has your physical health interfered with your social activities (visiting your friends etc..)					

How true or false is each of the following statements for you?

Please circle one number on each line	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
33. I seem to get sick a little easier than other people	1	2	3	4	5
34. I am as healthy as anybody I know	1	2	3	4	5
35. I expect my health to get worse	1	2	3	4	5
36. My health is excellent	1	2	3	4	5

Thank you so much for your time

Appendix E: Published paper of Study One (Chapter Four)

ELSEVIER

Journal of Psychosomatic Research 62 (2007) 145–151

Journal of Psychosomatic Research

Exploring the role of sleep and coping in quality of life in fibromyalgia☆

Alice Theadom, Mark Cropley*, Kirsty-Louise Humphrey

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Received 4 May 2006; received in revised form 19 September 2006; accepted 21 September 2006

Abstract

Objective: The objective of this study was to explore the effect of sleep and coping on health-related quality of life in fibromyalgia syndrome (FMS). **Methods:** Patients diagnosed with FMS (N=101) completed the Positive and Negative Affect Schedule, the Pittsburgh Sleep Quality Index, the COPE, and the Medical Outcomes Study—Short-Form Health Survey for the previous month. **Results:** Poor sleep quality was reported by 99% of participants. Sleep quality was significantly predictive of pain, fatigue, and social functioning in patients with FMS. Active coping, planning, acceptance, and seeking instrumental and emotional social support were not predictive of health outcomes in FMS. However, the use of restraint coping was predictive of poorer physical functioning. **Conclusion:** Sleep quality has significant implications for health-related quality of life in FMS. The use of coping strategies contributed little to the models' ability to predict health outcomes in FMS. Interventions designed to improve sleep quality may help to improve health-related quality of life for patients with FMS.

Keywords: Coping; Cross-sectional; Fibromyalgia; Pain; Quality of life; Sleep

Introduction

Fibromyalgia syndrome (FMS) has been estimated to occur in 3.5–5% of the population. It is characterized by chronic widespread pain, tender points, and fatigue [1]. There is currently no recognized effective treatment for FMS patients [2], which has large implications for quality of life, well-being, ability to work, physical functioning, and health care utilization. Poor sleep quality is a prominent feature of FMS, with 70–90% of patients experiencing some form of sleep disturbance [2,3]. Poor sleep has also been found to take on primary significance in the course of FMS [4], with strong links between sleep and the experience of pain [5–8]. These links appear to be bidirectional, with poor sleep linked to increased pain and with pain linked to poor sleep [6], although little is known about the effect of sleep on other health outcomes such as fatigue, emotional well-being, and physical functioning in FMS.

There is emerging evidence of abnormalities in the sleep architecture in patients with FMS. For example, patients with FMS have been found to have increased Stage 1 nonrapid eye movement (NREM) sleep [9,10] and less slow-wave sleep [11,12]. Higher α-wave intrusions during NREM sleep have also been found in patients with FMS in comparison to healthy controls [13]. These high α-wave intrusions have been associated with higher levels of pain and tender points [14], although findings have not been consistent [15,16].

In order to establish a comprehensive understanding of the role of sleep and its effect on quality of life in FMS, it is important to fully explore patients' perceptions and experiences of sleep quality. Previous studies of sleep and FMS have revealed a high prevalence of sleep disturbances and the effect of poor sleep on pain in patients with this condition. However, perceptions of sleep quality have not been based on standardized assessment measures. For

☆ There were no competing interests.

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example, Nicassio et al. [8] measured subjective sleep quality based on a rating of 1–10 on a visual analogue scale. There are several components of sleep that can affect sleep quality, such as sleep latency, sleep efficiency, and frequency of disturbances during the night, which need to be taken into account in measures of sleep quality [17]. One study used the Pittsburgh Sleep Quality Index (PSQI) as a measure of subjective sleep quality, although the findings of this study were limited by its small sample size [7].

Coping strategies can be effective in helping patients manage chronic conditions and other difficulties experienced, such as poor sleep quality. Coping strategies are often classified as either problem-focused (the person confronts the problem directly, such as coming up with a strategy to resolve the problem) or emotion-focused (the person focuses on controlling their emotional reactions, such as talking to family and friends) [18]. Some researchers in the chronic pain literature classify coping in terms of active coping (such as planning and pacing activities) and passive coping (such as resting and taking medications) strategies. Research on coping and chronic pain has revealed that active coping strategies are associated with improved health outcomes. In contrast, research focusing on coping and FMS, specifically, has revealed that active coping is associated with increased disability, pain, and poor physical functioning [19,20]. However, these studies only explored the use of coping strategies specifically in response to pain [19,20]. As FMS is a complex syndrome, it may be necessary to explore the use of more generic coping strategies on a range of outcomes in addition to pain to understand the effect of coping on FMS.

Sleep may also be associated with coping, as poor sleep may reduce patients' ability to successfully use cognitive coping strategies in response to pain [21]. It is likely that mechanisms regulating attention to pain may be disrupted by poor sleep [6]. Sadeh and Grober [22] suggest that a passive coping approach, such as using disengagement, may be related to increased sleep as a way of escaping the stressor. They also suggest that some strategies (such as cognitive rumination) may lead to increased arousal, preventing sleep onset; therefore, poor sleep may be indicative of the use of less effective coping strategies [23]. For example, although information seeking may be a useful strategy to reduce stress, its use has also been associated with insomnia [24]. In addition, compared to good sleepers, patients with insomnia have been found to perceive minor stressors as having a higher negative impact [25].

Sleep and mood are highly correlated [26,27], and mood has been related to a wide range of physical and psychological problems in FMS [28,29]. Negative affect is thought to influence the relationship between self-reports of stressors and strain [30–32], and one study revealed that patients with FMS found it more difficult to sustain positive affect in response to stressful situations [33] and, therefore, both positive affect and negative affect need to be controlled for when exploring coping in patients with FMS. The present study aims to explore the links between sleep and coping in health-related quality of life in FMS.

Method

Participants

Participants were recruited through community-based FMS support groups in southeast England. This was performed to ensure that patients managed by their general practitioners (GPs) in primary care (who may not attend a rheumatology clinic) were not excluded. General inclusion criteria were as follows: (a) diagnosis of FMS by a GP or a consultant, based on the 1990 American College of Rheumatology criteria [34]; (b) FMS as the primary medical diagnosis; and (c) age of ≥18 years. Participants were excluded from the study if they had been diagnosed with a sleep disorder.

Participants were asked to complete a questionnaire about their sleep patterns and fibromyalgia symptoms over the past month. Participants were informed that they did not need to be experiencing difficulties sleeping in order to participate. The volunteers participating in the study were given an information sheet about the study, a consent form, a copy of the questionnaire, and a prepaid return envelope. Participants were given the opportunity to complete the questionnaire in their own time. The study received ethical approval from the University of Surrey Ethics Committee.

Measures

Sleep quality was assessed using the PSQI [17]. This measure contains 19 items measuring the quality and the pattern of sleep over the past month. The PSQI has seven components: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. Each component score of the PSQI ranges from 0=*no impairment* to 3=*maximum impairment*. These component scores can be summed to yield a global PSQI score ranging between 0 and 21 as a measure of overall sleep quality. Higher scores indicate poorer sleep quality. Some researchers set the cutoff score for sleep disturbance at >5 [17], although other researchers use a more conservative global score of >6 to indicate sleep disturbance [35], which will be used in the present study. The PSQI has been used effectively in both clinical [36] and nonclinical samples [37].

The COPE scale [38] is theoretically derived. The subscales exploring problem-focused and emotion-focused coping were included to explore the types of coping used by the participants over the past month. The scales exploring problem-focused coping included: active coping, planning, suppression of competing activities, restraint coping, and seeking instrumental social support. The scales exploring emotion-focused coping included: seeking emotional social

Table 1
Means and standard deviations of sleep quality, coping, and quality of life

	Mean	S.D.	α
PANAS			
Negative affect	25.41	8.41	.87
Positive affect	27.04	7.47	.87
PSQI Global	13.49	3.67	.68
COPE			
Active	10.90	2.92	.76
Planning	11.33	2.86	.79
Instrumental social support	10.08	3.42	.83
Restraint	9.76	2.79	.73
Emotional–social support	9.61	3.49	.87
Positive reinterpretation	11.27	3.11	.83
Acceptance	11.73	2.65	.72
SF-36			
Physical functioning	33.02	24.74	.90
Social functioning	42.95	27.12	.87
Bodily pain	30.77	18.56	.78
Energy/fatigue	23.66	17.32	.66
Emotional well-being	57.11	20.51	.85
General health	33.17	17.33	.66

support, positive reinterpretation, acceptance, denial, and turning to religion. On a scale ranging from 1=*I usually do not do this at all* to 4=*I usually do this a lot*, participants were asked to indicate how often they use different types of coping. Higher scores were indicative of higher use of coping strategy. The COPE scale has been widely used to explore coping behavior, revealing good reliability and validity [38].

Health-related quality of life was assessed using the Medical Outcomes Study—Short-Form Health Survey (SF-36) [39]. Participants were asked to describe how they felt and how able they were to carry out their usual activities over the past month. Scores for individual items were recoded and summed to create eight component scales. Scores ranged from 0 to 100, with a higher score indicating a higher health-related quality of life. Since the aim of the study was to explore the effect of sleep and coping on health outcomes, only the health outcome scales from the SF-36 were used; these consisted of physical functioning, pain, general health, fatigue, and well-being. The SF-36 has been effectively used in the general population and in patients with chronic illness conditions and has demonstrated good reliability and validity [40,41]. The SF-36 was used in this study as it included scales focusing specifically on levels of pain and fatigue (the two main symptoms in FMS), in addition to factors exploring general health quality of life.

The Positive and Negative Affect Schedule (PANAS) [42] was used to control for levels of positive and negative affect in the sample. The two scales of the PANAS consist of 10 negative or 10 positive adjectives describing feelings and emotions. On a scale from 1=*very slightly or not at all* to 5=*extremely*, participants were asked to rate the extent to which they had felt the way described in the past month. Scores are summed to give a total score, with high scores being indicative of a higher level of positive and negative affect. Both subscales of the PANAS have revealed good validity and test–retest reliability [42].

Participants also provided information about their age, length of illness, employment status (including shift work), and drug, alcohol, and medication use, and specified any comorbid conditions.

Data analysis

First bivariate correlations between sleep, coping, and quality-of-life variables were calculated. A series of multiple regression analyses was then used to identify those sleeping or coping variables that were predictive of quality of life in FMS. SPSS Version 14.0 was used to analyze the data.

Results

Participant characteristics

Of the 200 questionnaires that were distributed, 111 (56%) were returned. Ten questionnaires were omitted from the analysis as they did not meet the inclusion criteria (e.g., one participant reported a diagnosis of sleep apnea that had not been previously identified, or more than 20% of a questionnaire was missing). Of the 101 participants included in the analysis, 94 were female (93%) and 7 were male (7%). All participants were aged between 26 and 80 years, with a mean age of 55 years (S.D.=11.76). Illness duration ranged between 1 and 30 years, with a mean duration of 10.14 years (S.D.=7.30).

Descriptive statistics

Ninety-nine percent of participants revealed a global score of >6 on the PSQI, which was indicative of poor sleep. Participants slept, on average, 6 h 37 min (S.D.=1.82) per night, ranging from 1 to 10 h. Participants reported waking up, on average, three to five times during the night, with each nighttime awakening lasting approximately 31–40 min.

Participants reported feeling unrefreshed after sleep, with a mean rating of 7.97 (S.D.=1.89) on a scale of 1=*very refreshed* to 10=*very unrefreshed*, and reported low enjoyment of sleep with a mean score of 6.88 (S.D.=2.33) on a scale of 1=*very enjoyable* to 10=*very unenjoyable*.

As 44.9% of participants did not turn to religion as a coping strategy, this variable was omitted from further analysis. The PSQI, PANAS, and SF-36 scales all revealed Cronbach's α scores of >.7, indicative of acceptable reliability. However, the suppression of competing activities and denial scales of the COPE yielded Cronbach's α scores of <.7 (α=.42 and α=.58, respectively), which were therefore excluded from further analysis. The means, standard deviations, and Cronbach's α scores for assessment measures are outlined in Table 1.

Table 2
Correlations between variables

	AG	LE	OT	NA	PA	PG	A	PL	IS	RE	ES	PR	AC	PA	PF	GH	SF	WB	VI
AG	1																		
LE	.08	1																	
OT	−.20	.02	1																
NA	−.21	−.12	.19	1															
PA	.22	.09	−.09	−.50*	1														
PG	.04	.08	−.06	.30*	−.16	1													
A	.18	.01	−.13	−.32*	.49*	−.13	1												
PL	−.02	.12	−.09	−.25	.40*	−.08	.74*	1											
IS	−.21	−.05	.08	−.21	.34*	−.17	.44*	.37*	1										
RE	.08	−.03	−.14	−.20	.22	−.07	.46*	.43*	.18	1									
ES	−.16	−.03	−.02	−.12	.27*	−.15	.34*	.21	.77*	.07	1								
PR	.03	.07	.17	−.43*	.46*	.02	.61*	.59*	.32*	.41*	.27*	1							
AC	−.01	−.02	−.33*	−.34*	.25	−.06	.40*	.42*	.17	.34*	.04	.51*	1						
PA	.07	−.03	.05	−.29*	.24	−.33*	.03	−.07	.03	−.15	.14	.12	−.01	1					
PF	−.08	.05	.15	−.27*	.13	−.27*	−.06	−.07	.01	−.32*	.12	−.03	.00	.63*	1				
GH	.35*	.31*	.02	−.42*	.35*	−.20	.20	.11	.01	−.02	.01	.12	.11	.40*	.36*	1			
SF	.16	.01	−.02	−.34*	.20	−.38*	.02	−.11	.09	−.12	.20	.05	−.01	.68*	.44*	.39*	1		
WB	.23	.09	−.23	−.73*	.67*	−.28*	.44*	.25	.27*	.06	.26	.44*	.35*	.35*	.22	.46*	.36*	1	
VI	.17	.10	−.08	−.40*	.49*	−.30*	.18	.07	.16	.02	.18	.14	−.07	.48*	.33*	.43*	.52*	.46*	1

AG=age in years; LE=length of illness; OT=comorbid condition; NA=negative affect; PA=positive affect; PG=PSQI sleep global score; A=COPE active coping; PL=COPE planning; IS=COPE seeking instrumental social support; RE=COPE use of restraint; ES=COPE seeking emotional social support; PR=COPE positive reinterpretation; AC=COPE acceptance; PA=SF-36 bodily pain; PF=SF-36 physical functioning; GH=SF-36 general health; SF=SF-36 social functioning; WB=SF-36 emotional well-being; VI=SF-36 vitality/fatigue.

* $P<.01$.

Correlational analysis

To account for multiple comparisons, the significance level was set at $P<.01$. Older age and longer length of illness were significantly associated with better general health. As expected, negative affect significantly correlated with poor sleep quality, low use of both problem-focused and emotion-focused coping strategies, and poorer quality-

Table 3
Hierarchical regression analysis for predictors of quality of life

Dependent variables	Block	Independent variables	R	R^2	ΔR^2	F	df	ΔF	β	Tolerance
Emotional well-being	1	Demographic variables	.41	.16	.16	3.07**	6,94	3.07**	−.19	.96
	2	Negative affect	.74	.54	.38	15.79**	1,93	77.18**	−.69	.81
	3	Positive affect	.82	.66	.12	22.68**	1,92	32.95**	.41	.71
	4	Sleep quality	.82	.67	.01	20.41**	1,91	1.44	−.08	.86
	5	Coping strategies	.82	.68	.01	14.03**	4,87	0.56	.04	.63
Energy/fatigue	1	Demographic variables	.36	.13	.13	2.25*	6,94	2.25*	−.05	.96
	2	Negative affect	.46	.21	.08	3.50**	7,93	9.72**	−.32	.81
	3	Positive affect	.56	.31	.10	5.15**	8,92	13.41**	.38	.71
	4	Sleep quality	.59	.34	.03	5.25**	9,91	4.52*	−.20	.86
General health		Demographic variables	.51	.26	.26	5.42**	6,94	5.42**	−.05	.97
	1	Negative affect	.59	.35	.09	7.16**	1,93	13.36**	−.34	.81
	2	Positive affect	.60	.36	.01	6.54**	8,92	1.78	.13	.71
	3	Sleep quality	.61	.37	.01	6.03**	9,91	1.59	−.11	.86
Physical functioning	1	Demographic variables	.39	.15	.15	2.85*	6,94	2.85*	.13	.96
	2	Negative affect	.46	.21	.06	3.62**	7,93	7.07**	−.27	.81
	3	Sleep quality	.48	.24	.02	3.53**	8,92	2.49	−.16	.86
	4	Coping strategies	.58	.33	.10	5.07**	9,91	13.56**	−.33	.89
Social functioning	1	Demographic variables	.26	.07	.07	1.10	6,94	1.10	.02	.96
	2	Negative affect	.41	.17	.10	2.71*	1,93	11.62**	−.36	.81
		Positive affect	.41	.17	.00	2.37*	1,92	0.15	.04	.71
		Sleep quality	.50	.25	.08	3.32**	1,91	9.24**	−.30	.86
Bodily pain	1	Demographic variables	.24	.06	.06	0.97	6,94	0.97	.07	.96
	2	Negative affect	.36	.13	.07	1.96	7,93	7.48**	−.30	.81
	3	Positive affect	.38	.14	.01	1.88	8,92	1.30	.13	.71
	4	Sleep quality	.44	.19	.05	2.67*	9,91	5.53*	−.24	.86

* $P<.05$.
** $P<.01$.

of-life outcomes. Positive affect was associated with increased use of problem-focused and emotion-focused coping strategies and high health-related quality of life, although it was not associated with better sleep quality. There were no significant correlations between sleep quality and coping variables.

Both problem-focused (active coping and seeking instrumental social support) and emotion-focused (positive reinterpretation and acceptance) coping strategies were associated with better emotional well-being. However, the use of restraint coping was related to poorer physical functioning (see Table 2).

Multiple regression analysis

Hierarchical multiple regression analyses were performed to explore whether sleep and coping strategies were predictive of quality of life in FMS, after controlling for age, sex, length of illness, comorbid conditions, and drug, alcohol, and medication use (see Table 3). Variables that significantly correlated with health-related quality-of-life dependent variables were entered into regression analyses by the following process:

Step 1: Demographic and clinical variables
Step 2: Negative affect
Step 3: Positive affect
Step 4: Sleep quality
Step 5: Coping strategies.

As coping variables were not associated with fatigue, general health, social functioning, and pain, the final step (Step 4) of the regression process was omitted for these variables.

Negative affect significantly contributed to the model for all quality-of-life outcomes. Sleep quality significantly contributed to the models' ability to predict levels of fatigue (β=−.20, t=−2.13, P<.05), social functioning (β=−.30, t=−3.04, P<.01), and pain (β=−.24, t=−2.35, P<.05). The use of restraint coping was the only coping strategy that significantly predicted physical functioning (β=.33, t=−3.68, P<.05). No other coping variables significantly contributed to the models for other quality-of-life variables.

Discussion

This exploratory study aimed to investigate the effect of self-reported sleep and coping in participants with FMS. A high percentage of the sample (99%) experienced some form of sleep difficulties [2,3], with poor sleep quality being significantly predictive of pain, fatigue, and social functioning. In support of previous findings, negative affect was significantly predictive of poorer health outcomes, and positive affect was significantly associated with better health outcomes, excluding physical functioning [43].

These results support previous findings that poor sleep is strongly associated with pain, fatigue, and other health outcomes in FMS [5–8]. The mean scores on the subscales of the sleep quality measure indicate that participants reported having difficulty falling asleep initially and also reported having difficulty falling back to sleep after waking up during the night. Sleep onset is often prevented by worrying or ruminating [23]; with a high proportion of participants reporting low enjoyment of sleep while spending a lot of time in bed, participants may have developed dysfunctional beliefs about sleep or may have engaged in sleep catastrophizing [44], although causal inferences cannot be drawn on the links between sleep and health outcomes in FMS due to the cross-sectional nature of this study.

These findings reveal that the use of problem-focused and emotion-focused coping strategies was not significantly associated with health-related quality-of-life outcomes such as pain, fatigue, and general health in FMS. High use of restraint was significantly predictive of poorer physical functioning. The items of the COPE that were used to assess the use of restraint focused on delaying coping with a situation until the right time. This may suggest that, although problem-focused coping strategies do not directly improve physical health, delaying coping or not managing a stressful situation in some way is detrimental to physical functioning in FMS. These findings suggest that, although problem-focused and emotion-focused strategies do not improve quality of life, they are not predictive of poorer health outcomes either. Due to the complex nature of FMS, these findings may reflect the importance of exploring the effect of coping on a range of outcomes in FMS rather than physical pain alone. It may be that current measures are not tapping into strategies that affect physical health, or it may be that other factors, such as affect and sleep, are more important to the management of FMS. However, measures exploring coping specifically in response to sleep difficulties, such as sleep hygiene behaviors (e.g., caffeine intake and presleep routine), may be a useful addition to research on sleep and health outcomes in FMS.

The mean age of participants in this study was 55 years. As more than 25% of people aged ≥60 years report experiencing sleep difficulties [45], this may have influenced the high prevalence of sleep difficulties, although age did not correlate with sleep in this sample. Older age and length of illness were significantly associated with better general health, which may suggest that self-management of FMS improves with age and time as patients adapt to living with the condition.

Further limitations of the study included minimal eligibility criteria for inclusion. Many of the participants (82%) had a comorbid condition, and the diagnostic criteria only required diagnosis from a GP or a consultant. Therefore, misdiagnosis or comorbidity may have affected the results. However, as there is such a high rate of comorbid conditions in FMS, it may be argued that excluding these

participants may reduce the representativeness of the sample. There may be limitations to the generalization of the findings of this study, as participants were recruited through community-based support groups. It may be that patients attending support groups may differ from patients with FMS who do not, such as in terms of an increased need for social support or of information seeking.

The cross-sectional nature of this study meant that only a "typical" or an "average" night's sleep was explored over the previous month, and it is possible that participants' sleep patterns varied over time. Further research is needed to explore the frequency and the nature of sleep disturbances in FMS symptoms over a longitudinal period to be able to draw causal inferences since the effects of coping may not be observed immediately. Indeed, Nicassio et al. [20] found that coping explained more variance on levels of pain in the longitudinal analysis of the data than during cross-sectional analysis. Research may be enhanced by the use of sleep diaries commonly used in research on insomnia, which record sleep quality, quantity, and behavior for each day over several days or weeks [46], and by the use of sleep actigraphy or objective measures of sleep to validate self-reports of sleep quality [47,48].

There are currently contrasting opinions about whether sleep difficulties in patient populations should be treated as part of the illness or as a separate entity [49–51]. However, if there is a bidirectional relationship between sleep and the experience of symptoms in FMS, interventions focusing on improving sleep in FMS may be needed to successfully manage the condition. There is emerging evidence from pilot studies that nonpharmacological interventions focusing on dysfunctional beliefs, sleep behavior, and lifestyle factors that may maintain sleep difficulties can reduce the experience of FMS symptoms [52,53]. Since there is currently no recognized effective treatment for this condition, further research on the role of sleep in FMS and on effective interventions to improve patient quality of life is urgently needed. Despite the limitations of this research, this study has revealed the important links between sleep quality and a range of quality-of-life outcomes in FMS. It highlights the need for a careful comparison of results on the use of coping assessments and the need to assess a range of health outcomes in research on the complex condition of FMS.

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Sleep and Fibromyalgia Syndrome

Information Sheet

Thank you for your interest in this study on sleep and Fibromyalgia Syndrome.

Please read the following information carefully and feel free to ask me if anything is unclear or if there is anything else you would like to know about the study. Please take time to decide if you would like to participate, although you may withdraw from this study at any time.

The study

This study is investigating the beliefs people with Fibromyalgia have about their sleep, their sleep patterns, and their experience of Fibromyalgia Symptoms.

The study will be conducted by myself (Alice Theadom), a Health Psychologist working, under the supervision of Mark Cropley at the University of Surrey and Kirsty-Louise Humphrey, a postgraduate student at the University of Surrey.

Instructions

If you wish to participate please complete both copies of the consent form attached, returning one copy to us with your questionnaire and retaining one copy for your yourself. You will be given a questionnaire to complete at your own pace. It is 10 pages long and takes approximately 15-20 minutes to complete. There will be detailed instructions on how to complete each section of the questionnaire. There are no right or wrong answers to these questions and you may choose not to respond to any questions you do not wish to answer.

Benefits and Risks

Participating in this study will contribute to the understanding of Fibromyalgia. It is hoped that the findings of the study will help to provide information for practitioners in the field, with the aim to improve the quality of life for individuals with this health condition.

You may find answering questions about your illness or some specific questions are upsetting or distressing for you. You are under no pressure to participate in the study and you may choose not to answer specific questions or to withdraw from the study at any time.

This study has received ethical approval from by the departmental ethics committee. All information will be completely anonymous and confidential. Please return all questionnaires by April 25th 2005.

Many Thanks.

Contact Details

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Sleep and Fibromyalgia Syndrome

Consent Form

I agree to take part in the study on sleep and Fibromyalgia syndrome. I have read and understood the information sheet provided. I have been given the opportunity to ask questions on all aspects of the study and I have understood the advice and information given.

I understand that any information I provide will be anonymous and treated as confidential.

I understand that I may withdraw from the study at any time without reason or needing to justify my decision.

I confirm that I have read and understood the above and freely consent to participate in the study. I have been given adequate time to consider my participation and I agree to follow the instructions and restrictions of the study.

Name of volunteer_____
(Block Capitals)

Signature of volunteer_____

Date_____

Appendix G: Letter of Ethical Approval for Study Two (Chapter Five)

Mark Cropley
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Chartered Health Psychologist

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Department of Psychology

In confidence

Alice Theadom
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Hillingdon Hospital
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10 Oct 2005

Dear Ms Theadom

Research Ethics

I am writing to you regarding your recent correspondence about your study entitled:

'An investigation into the relationship between sleep, pain, fatigue and quality of life in fibromyalgia patients (EC/2005/24/PSYCH)

I understand that you would like to continue with this study by extending recruitment to include a sample of healthy controls and you requested further ethical approval. As ethics has been initially granted on the 3rd June 2005, for 3 years and you are not changing the design, I can confirm that further ethical approval is not needed.

Please keep me informed of the progress of the project.

Yours sincerely

Mark Cropley
MSc Health Psychology, Senior Lecturer and Course Director

Appendix H: Participant Questionnaire for Study Two (Chapter Five)

Individuals' Experiences of Sleep. Coping and Quality of Life

Age:_____ **Gender:** Male/Female (please circle)

1. Do you have any diagnosed medical conditions?

If yes, what is your diagnosis?_____

2. Do you regularly take any medication for sleep, pain or fatigue related complaints?

Yes / No (please circle)

If yes which medication(s) are you taking?_____

3. If you are working does your work involve shift work? Please circle the most appropriate answer for you

Yes / No / I am not currently working (please circle)

The following questions relate to your usual sleep habits. Please describe the pattern of your sleep on a typical night during the past month.

1. What time do you usually go to bed? _____pm/am (please delete as appropriate)

2. How long has it taken you to fall asleep each night?

_____ hours_____ minutes

3. Approximately how many times do you wake up during the night? _____

4. Approximately how long are you awake during each awakening?

_____hours _____minutes

5. What time do you usually get up in the morning? _____ am

6. How many hours of actual sleep do you usually get?

_____ hours _____ minutes (This may be different to the number of hours you spent in bed)

7. How refreshed do you feel in the morning?

Very Refreshed Very Un-refreshed
1 2 3 4 5 6 7 8 9 10

8. How enjoyable would you rate your sleep?

Very Enjoyable Very Un-enjoyable
1 2 3 4 5 6 7 8 9 10

The following questions relate to your usual sleeping habits. Please indicate, how often have you have experienced the situations listed below by ticking the box that represents how often this has occurred in the past month.

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
1. Cannot get to sleep within 30 minutes	0	1	2	3
2. Wake up in the middle of the night or early morning	0	1	2	3
3. Have to get up to use the bathroom	0	1	2	3
4. Cannot breathe comfortably	0	1	2	3
5. Cough or snore loudly	0	1	2	3
6. Feel too cold	0	1	2	3
7. Feel too hot	0	1	2	3
8. Have bad dreams	0	1	2	3
9. Have pain	0	1	2	3
10. Other reason(s) please describe including how often you have had trouble sleeping because of this reason:	0	1	2	3
11. During the past month how often have you taken medicine (prescribed or over the counter) to help you sleep?	0	1	2	3
12. During the past month how often have you had trouble staying awake while driving, eating meals or engaging in social activity	0	1	2	3
13. During the past month how much of a problem has it been for you to keep up enthusiasm to get things done	0	1	2	3
	Very Good	Fairly good	Fairly bad	Very bad
14. During the past month how would you rate your sleep quality overall	0	1	2	3

Below are 10 statements reflecting attitudes and beliefs about sleep. Please circle the number that best represents your level of agreement to each statement.

1. **I need 8 hours of sleep to feel refreshed and function the next day**

Strongly Agree Strongly Disagree
1 2 3 4 5 6 7 8 9 10

2. **When I don't get the proper amount of sleep on a given night, I need to catch up on the next day by napping or on the next night sleeping longer**

Strongly Agree Strongly Disagree
1 2 3 4 5 6 7 8 9 10

3. **I am concerned that chronic insomnia may have serious consequences on my physical health**

Strongly Agree Strongly Disagree
1 2 3 4 5 6 7 8 9 10

4**. When I have trouble getting to sleep, I should stay in bed and try harder**

Strongly Agree Strongly Disagree
1 2 3 4 5 6 7 8 9 10

5. I am worried that I may lose control over my abilities to sleep

Strongly Agree Strongly Disagree
1 2 3 4 5 6 7 8 9 10

6. After a poor nights sleep, I know that it will interfere with my activities the next day

Strongly Agree Strongly Disagree
1 2 3 4 5 6 7 8 9 10

7. When I feel irritable, depressed or anxious during the day, it is mostly because I did not sleep well the night before

Strongly Agree Strongly Disagree
1 2 3 4 5 6 7 8 9 10

8. When I sleep poorly on one night, I know it will disturb my sleep schedule for the whole week

Strongly Agree Strongly Disagree
1 2 3 4 5 6 7 8 9 10

9. When I feel tired, have no energy, or just seem not to function well during the day, it is generally because I did not sleep well the night before

Strongly Agree Strongly Disagree
1 2 3 4 5 6 7 8 9 10

10. I get overwhelmed by my thoughts at night and often feel I have no control over this racing mind

Strongly Agree Strongly Disagree
1 2 3 4 5 6 7 8 9 10

The following ten statements refer to how you usually feel. For each statement please tick the box that best represents how you have felt over the past month.

	Never	Sometimes	Regularly	Often	Always
1. I am bothered by fatigue	1	2	3	4	5
2. I get tired very quickly	1	2	3	4	5
3. I don't do much during the day	1	2	3	4	5
4. 4. I have enough energy for everyday life	1	2	3	4	5
5. Physically, I feel exhausted	1	2	3	4	5
6. I have problems starting things	1	2	3	4	5
7. I have problems thinking clearly	1	2	3	4	5
8. I feel no desire to do anything	1	2	3	4	5
9. Mentally, I feel exhausted	1	2	3	4	5
10. When I am doing something I can concentrate quite well	1	2	3	4	5

The questions in this scale ask you about your feelings and thoughts during the last month. In each case, please indicate with a check how often you feel or thought a certain way.

In the past month…..	Not at all	Almost Never	Sometimes	Fairly Often	Very Often
1. How often have you been upset because of something that happened unexpectedly?	0	1	2	3	4
2. How often have you felt that you were unable to control the important things in your life?	0	1	2	3	4
3. How often have you felt nervous and 'stressed'?	0	1	2	3	4
4. How often have you dealt successfully with irritating life hassles?	0	1	2	3	4
5. How often have you felt that you were effectively coping with important changes that were occurring in your life?	0	1	2	3	4
6. How often have you felt confident about your ability to handle your personal life?	0	1	2	3	4
7. How often have you felt things were going your way?	0	1	2	3	4
8. How you often have you found that you could not cope with all the things that you had to do?	0	1	2	3	4
9. How often have you been able to control irritations in your life?	0	1	2	3	4
10. How often have you felt that you were on top of things?	0	1	2	3	4
11. How often have you been angered because of things that happened that were outside of your control?	0	1	2	3	4
12. How often have you found yourself thinking about things that you have to accomplish?	0	1	2	3	4
13. How often have you been able to control the way you spend your time?	0	1	2	3	4
14. How often have you felt difficulties were piling up so high that you could not overcome them?	0	1	2	3	4

Pain items of the RAND 36 items Short Form Health Survey (SF-36)

	None	Very mild	Mild	Moderate	Severe	Very Severe
1. How much physical pain have you had in the past month						

	Not at all	A little bit	Moderately	Quite a bit	Extremely
2. During the past month how much did pain interfere with your normal work (both paid and/or housework)					

Thank you for participating in this research project

Please return the completed questionnaire in the freepost envelope provided

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Original article

Dysfunctional beliefs, stress and sleep disturbance in fibromyalgia

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Abstract

Objective: To explore sleep-related dysfunctional beliefs, stress levels and sleep quality in patients with fibromyalgia in comparison to healthy controls.
Methods: One hundred sixty-six participants (83 patients with fibromyalgia and 83 healthy controls) completed self-report measures exploring beliefs and attitudes about sleep, perceived stress, sleep quality and levels of pain and fatigue.
Results: Relative to healthy controls, patients with fibromyalgia revealed significantly higher levels of dysfunctional beliefs and attitudes about sleep and perceived stress. High dysfunctional beliefs were significantly associated with poorer sleep quality and high perceived stress was significantly related to higher sleep disturbances and daytime dysfunction.
Conclusions: Beliefs about sleep and perceived stress play a significant role in the sleep quality of patients with fibromyalgia. Interventions to improve sleep quality for people with fibromyalgia need to identify and address dysfunctional beliefs about sleep and incorporate stress management approaches.

Keywords: Beliefs about sleep; Stress; Sleep; Fibromyalgia; Sleep disturbance

1. Introduction

Fibromyalgia syndrome (FMS) is a chronic musculoskeletal condition of unconfirmed aetiology. The American College of Rheumatology (ACR) [1] criteria classifies FMS by the experience of chronic, widespread pain for a minimum of 3 months, with pain in 11 out of 18 tender point sites. FMS occurs predominantly in women, affecting approximately 2–5% of the general population [2]. It is a debilitating condition, associated with significant individual, societal and financial costs. For example, patients have been found to make frequent visits to health care services and have high prescription rates [3]. In addition, many patients have to leave employment or reduce their working hours due to high levels of pain and fatigue [4]. Prognosis remains unclear and there is currently no standardised, effective treatment for the condition [5].

There is a high prevalence of sleep difficulties in patients with FMS, with up to 99% of patients reporting poor sleep quality [6]. It has been revealed that patients with FMS sleep for an average of 5 h per night, which is comparable to patients with insomnia [7]. Poor sleep is associated with higher levels of pain and fatigue and reduced physical functioning [8] and therefore sleep quality appears to have an important role in the experience of symptoms in FMS. The sleep difficulties that are most commonly reported by FMS patients include delayed sleep latency, high sleep disturbances and high daytime dysfunction [6,9]. These findings have been moderately supported by objective measures of sleep quality, which have revealed that patients with FMS

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are more easily aroused during sleep [10] and have higher levels of physical activity at night [11].

Stress has been found to be associated with increased arousal and poor sleep, with even minor daily stresses related to sleep quality the following night [12]. Healey et al. [13] revealed that the most frequent stressful events reported by people with poor sleep are related to illness and loss and it may be that ruminating about daily stressors or FMS symptoms may delay sleep onset or lead to disrupted sleep. Indeed, Smith et al. [14] revealed that ruminating about pain was significantly predictive of longer sleep onset latency and total duration of night-time awakenings in chronic pain patients. Stress responses appear to be elevated in FMS in comparison to healthy controls and, therefore, stress may have an important role to play in the sleep quality of patients with FMS [15].

The Cognitive Model of Insomnia proposes that dysfunctional beliefs about sleep (inaccurate expectations of the amount and quality of sleep that are needed and the consequences that poor sleep will have on daily functioning) may lead to increased arousal and attention toward sleep-related threats, preventing sleep onset and exacerbating sleep difficulties [16]. It is likely that many people have dysfunctional beliefs about sleep to some extent, as not all dysfunctional beliefs discriminate between insomniacs and normal sleepers [17]. However, poor sleepers may have stronger and more rigid dysfunctional beliefs and attitudes towards sleep. Dysfunctional beliefs and attitudes are frequently assessed using the Dysfunctional Beliefs and Attitudes Scale (DBAS). Ellis et al. [18] identified 8 of the 10 items from the DBAS-10 that discriminated between good and poor sleepers. This has also been supported by Carney and Edinger [17] who identified eight items included in the DBAS-10 (identified from the 30-item version of the DBAS), that discriminated between good and poor sleepers. These beliefs related to consequences of poor sleep and loss of control. A recent study exploring dysfunctional beliefs in disorders characterized by sleep disturbance revealed that patients with FMS have high dysfunctional beliefs about sleep that were not accounted for by depression [19]. However, the exact nature of discriminating beliefs and their impact on sleep quality has yet to be explored in this population. Cognitive behavioural therapy has been found to significantly reduce dysfunctional beliefs about sleep, resulting in improved sleep efficiency and insomnia symptoms [17]. Therefore, identifying the presence and type of dysfunctional beliefs in poor sleepers such as fibromyalgia patients has important clinical implications for the management of chronic sleep difficulties [18]. In the present study, we aimed to explore the role of dysfunctional beliefs and stress on sleep quality in patients with fibromyalgia in comparison to healthy controls.

2. Methods

2.1. Participants

The study consisted of two groups of participants, 83 fibromyalgia participants and 83 age- and sex-matched healthy controls. For inclusion in the study, participants with fibromyalgia were required to have been diagnosed with FMS by a general practitioner or consultant, based on the American College of Rheumatology classification criteria [1]. For both groups, participants were excluded if (a) they were under 18 years of age, (b) they had been diagnosed with a sleep disorder, or (c) more than 20% of their questionnaire was incomplete. Participants with FMS were recruited through community-based support groups to incorporate patients managed in both primary and secondary care. Control group participants were recruited from the general population and community-based social groups from within the same geographical areas. The study received ethical approval from the University of Surrey Ethics Committee.

2.2. Measures

Participants were asked to complete a battery of measures on their own time to explore their beliefs and attitudes about sleep, perceived stress, sleep quality and levels of pain and fatigue. Questionnaires were returned in a pre-paid envelope. In addition, information on demographic and clinical variables including age, medication use and employment status (including shift work) was collected.

The Dysfunctional Beliefs and Attitudes About Sleep Scale (DBAS-10) [20] consists of 10 statements exploring patient beliefs and attitudes about sleep. The participant indicates his or her level of agreement to each statement on a visual analogue scale, scoring between 1 ('strongly disagree') and 10 ('strongly agree'). Items are summed to yield a total score (maximum possible score of 100). High scores on the DBAS-10 are indicative of high dysfunctional beliefs about sleep. The DBAS-10 has revealed respectable internal consistency and good discriminative ability [21].

Perceived stress was measured using the Perceived Stress Scale (PSS) [22], which includes 10 items focusing on the frequency of stressful events, perceived control and ability to cope in response to stressful events for the past month. High scores reflect a high level of perceived stress. The scale has demonstrated moderate validity and inter-item consistency and has been used in clinical populations [22].

Sleep quality was assessed using the Pittsburgh Sleep Quality Index (PSQI) [23]. This measure contains 19 items measuring the quality and pattern of sleep over the past month. The PSQI has seven components: subjective sleep quality, sleep latency, sleep duration, habit-

ual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. Each component score of the PSQI ranges from 0 (no impairment) to 3 (maximum impairment). These component scores can be summed to yield a global PSQI score ranging between 0 and 21 as a measure of overall sleep quality, with higher scores indicative of poor sleep quality. The PSQI has demonstrated acceptable reliability and the ability to discriminate between good and poor sleepers [23].

The Fatigue Assessment Scale (FAS) [24] contains 10 items (five items exploring physical and five items exploring mental fatigue). Participants respond to each statement on a five-point rating scale ranging from 1 (never) to 5 (always) to represent how they have been feeling over the past month. A total score is calculated from the sum of the individual items. The FAS has demonstrated good reliability and validity [24].

The pain subscale from the Short-Form Medical Outcomes Questionnaire (SF-36) [25] was used to assess levels of pain and interference of pain in normal work/daily activities over the previous month. This scale consists of two items which have demonstrated high internal consistency and good reliability [26].

2.3. Statistical analysis

A priori power calculation with a medium effect size of 0.5, α 0.05 and power 0.8 revealed that a minimum of 128 participants (64 per group) would be needed for this study to have sufficient power to detect significant differences between the two groups.

The questionnaire data were analysed using *t*-tests (if the data met parametric assumptions) or Mann–Whitney *U*-tests (if the data did not meet parametric assumptions) to explore if there were differences between patients with FMS and healthy controls. Correlational analysis was used to explore the associations between perceived stress, sleep quality and health outcomes. SPSS version 14.0 was used to analyse the data and, due to the number of comparisons being made, *p* values were considered to be significant at the $p < 0.01$ level.

3. Results

Of the 300 questionnaires that were distributed, 112 (74.67%) were returned by participants with fibromyalgia and 92 (61.33%) were received from healthy controls. Four questionnaires were excluded, as more than 20% of the questionnaire data was missing, and one questionnaire was omitted, as the patient had not been diagnosed by a general practitioner or consultant as stated in the inclusion criteria. The questionnaire took approximately 13 min to complete. Control group participants were matched for age and gender by group and the remaining questionnaires were excluded to form two equally matched participant groups. Participants were predominantly female (91.6%), which is representative of the male–female ratio of people diagnosed with FMS.

There were no significant differences between the two groups for age or gender. Although a significantly higher number of fibromyalgia patients were no longer working in comparison to healthy controls, this is to be expected because many patients must give up work or reduce their work hours due to reduced physical functioning [4].

Participants with FMS had significantly higher levels of perceived stress and dysfunctional beliefs about sleep, pain, fatigue and poorer sleep quality (including all components of sleep quality) as shown in Table 1. Seventy

Table 1
Participant characteristics

	Fibromyalgia patients ($n = 83$)	Healthy controls ($n = 83$)	Significance test	Cronbach's alpha (α)
Age[§]	52.59 (11.42)	51.67 (15.47)	$t = -0.43$	
Women[‡]	91.60%	91.60%	$\chi^2 = 0.0$, df = 2	
Employment status working (% shift work)[‡]	38.6% (4.8%)	62.7% (7.2%)	$\chi^2 = 9.66$, df = 2	
Negative affect[‡]	25.76 (8.25)	17.16 (5.71)	$U = 1.337.50^{**}$	0.89
Positive affect[§]	26.55 (7.15)	34.92 (6.55)	$t = 7.85^{**}$	0.90
Pain[‡]	29.58 (18.10)	82.53 (22.13)	$U = 388.00^{**}$	0.93
Fatigue[§]	30.87 (5.17)	21.04 (3.44)	$t = -14.42^{**}$	0.73
Dysfunctional beliefs[§]	61.51 (16.42)	48.59 (15.55)	$t = -5.09^{**}$	0.81
Perceived stress[§]	30.60 (8.53)	20.78 (6.74)	$t = -8.2^{**}$	0.90
Sleep quality[‡]	2.06 (0.76)	0.89 (0.70)	$U = 1016.50^{**}$	
Sleep latency[‡]	3.25 (1.57)	1.48 (1.32)	$U = 1422.00^{**}$	
Sleep duration[‡]	1.27 (1.17)	0.40 (0.68)	$U = 2005.50^{**}$	
Sleep efficiency[‡]	1.86 (1.22)	0.57 (0.84)	$U = 1510.50^{**}$	
Sleep disturbances[‡]	2.39 (0.62)	1.33 (0.50)	$U = 876.00^{**}$	
Sleep medication[‡]	1.70 (1.40)	0.23 (0.72)	$U = 1608.00^{**}$	
Daytime dysfunction[‡]	2.19 (0.80)	0.82 (0.77)	$U = 886.50^{**}$	
Global sleep score[‡]	14.71 (4.29)	5.72 (3.39)	$U = 378.50^{**}$	0.84

[§] Mean (SD).
[‡] Median and interquartile range.
** $p < 0.01$.

(84.34%) participants with fibromyalgia and 11 (13.25%) healthy controls had a PSQI global score ⩾10 (the cut-off score indicative of poor sleep quality), which has been used to identify the frequency of poor sleepers in previous research into fibromyalgia [9]. It was found that people with fibromyalgia are 32 times more likely to have sleep difficulty than healthy controls (95% confidence interval [CI] = 14.80–83.94). Difficulty falling asleep, disturbed sleep and daytime dysfunction were the most frequently reported sleep difficulties in participants with FMS.

Differences between the components of dysfunctional beliefs (DBAS-10) were explored to see if some components were better discriminators between patients with FMS and normal controls. Eight of the 10 DBAS-10 items were significantly higher in patients with FMS in comparison to healthy controls (see Table 2). These dysfunctional beliefs related to the consequences of a poor night's sleep and loss of control. One item that related to sleep behaviour focused on the 'need to catch up on poor sleep by napping'.

The two items that were not significantly different between the two groups related to sleep need ('I need 8 hours of sleep to feel refreshed and function the next day') and sleep behaviour ('When I have trouble getting to sleep, I should stay in bed and try harder'; as shown in Table 2). The most commonly rated dysfunctional beliefs in participants with FMS were Item 1 ('I need 8 hours of sleep to feel refreshed and function the next day'; 55.42%), Item 2 ('When I don't get the proper amount of sleep on a given night, I need to catch up on the next day by napping or on the next night sleeping longer'; 51.60%) and Item 6 ('After a poor night's sleep, I know that it will interfere with my activities the next day'; 63.86%).

Correlation analysis revealed that higher dysfunctional beliefs and attitudes about sleep were significantly associated with higher levels of pain ($\rho = 0.28$, $p < 0.05$), fatigue ($\rho = 0.25$, $p < 0.05$) and poorer sleep quality ($\rho = 0.23$, $p < 0.05$). High perceived stress was associated with higher levels of fatigue ($\rho = 0.39$, $p < 0.01$), pain ($\rho = 0.32$, $p < 0.01$), more frequent sleep disturbances ($\rho = 0.26$, $p < 0.05$) and higher daytime dysfunction ($\rho = 0.27$, $p < 0.05$).

4. Discussion

This study explored the role of dysfunctional beliefs and attitudes about sleep and stress on perceived sleep quality in fibromyalgia. The results revealed that, in comparison to healthy controls, participants with fibromyalgia have significantly poorer sleep quality, higher levels of dysfunctional beliefs and attitudes about sleep and higher levels of perceived stress. Higher dysfunctional beliefs and attitudes about sleep were significantly associated with poorer sleep quality. High perceived stress was significantly associated with more frequent sleep disturbances and higher daytime dysfunction, pain and fatigue.

In support of the findings by Osorio et al. [9] the most frequent sleep difficulties experienced by participants with FMS included sleep latency, sleep disturbances and daytime dysfunction. The mean PSQI global score was comparable to previous findings from previous research into sleep and FMS [9].

Table 2
Means, medians and measures of variability for the individual DBAS-10 items

Dysfunctional belief	Fibromyalgia patients	Healthy controls	Significance test
1. I need 8 hours of sleep to feel refreshed and function the next day[‡]	8.00 (5.00)	8.00 (4.00)	$U = 3154.00$
2. When I don't get the proper amount of sleep on a given night, I need to catch up on the next day by napping or on the next night sleeping longer[‡]	8.00 (6.00)	4.00 (5.00)	$U = 2461.00^{**}$
3. I am concerned that chronic insomnia may have serious consequences on my physical health[‡]	7.00 (4.00)	5.00 (6.00)	$U = 2249.00^{**}$
4. When I have trouble getting to sleep, I should stay in bed and try harder[‡]	3.00 (4.00)	4.00 (4.00)	$U = 3155.50$
5. I am worried that I may lose control over my abilities to sleep[‡]	5.00 (5.00)	3.00 (3.00)	$U = 2461.00^{**}$
6. After a poor night's sleep, I know that it will interfere with my activities the next day[§]	7.23 (2.67)	5.61 (2.72)	$t = -5.05^{\dagger,**}$
7. When I feel irritable, depressed or anxious during the day, it is mostly because I did not sleep well the night before[§]	6.80 (2.60)	5.40 (2.58)	$t = -3.47^{\S,**}$
8. When I sleep poorly on one night, I know it will disturb my sleep schedule for the whole week[‡]	5.00 (6.00)	2.00 (2.00)	$U = 2061.50^{**}$
9. When I feel tired, have no energy, or just seem not to function well during the day, it is generally because I did not sleep well the night before[§]	6.51 (2.76)	5.39 (2.76)	$t = -2.62^{\dagger,**}$
10. I get overwhelmed by my thoughts at night and often feel I have no control over this racing mind[§]	6.24 (3.00)	5.0 (2.76)	$t = -2.77^{\S,**}$

[§] Mean (SD).
[‡] Median and interquartile range.
[†] df = 164.
[**] $p < 0.01$.

The significantly higher levels of perceived stress in participants with FMS may reflect the additional pressures of living with a chronic illness. Stressful life events and altered stress responses are often thought to be involved in the development of FMS symptoms and the high levels of perceived stress in the FMS sample may reflect this underlying theory. However, findings exploring the role of stress in FMS have not been consistent and comparisons of stress responses to people with other chronic pain conditions may be needed. The finding that high stress was significantly related to increased fatigue in both healthy controls and participants with FMS suggests that stress management approaches may help to improve fatigue.

The dysfunctional beliefs identified as significantly different in FMS participants in comparison to healthy controls were similar to those found to discriminate between good and poor sleepers in previous research [17,18]. However, one additional item ('When I don't get the proper amount of sleep on a given night, I need to catch up on the next day by napping or on the next night sleeping longer') was found to discriminate between patients with FMS and healthy controls in this study. This distinction may specifically relate to the demands of living with FMS and the effect of poor sleep on symptoms such as pain and fatigue. In addition, it may be argued that Item 6 ('interference with activities the next day') may not actually be a 'dysfunctional belief' in FMS, as poor sleep quality has been associated with poor physical functioning the following day and this belief may have become established through experience. Indeed, the most frequent and strong dysfunctional beliefs identified suggest that participants with FMS may be more concerned about the consequences of poor sleep on symptoms and functioning the following day rather than the sleep difficulties themselves.

Two items of the DBAS-10 did not discriminate between patients with FMS and healthy controls. Both groups reported strong agreement with Item 1, which may reflect a common misconception that people need 8 h of sleep to feel refreshed and function the next day. Indeed, Ellis et al. [18] revealed that this belief was actually significantly higher in good sleepers. There was also no significant difference between participants with FMS and healthy controls for Item 4 ('When I have trouble getting to sleep, I should stay in bed and try harder'), which has also not been found to discriminate between good and poor sleepers in previous research [17,18].

To our knowledge, this is the first study that has highlighted the role of beliefs and stress on sleep quality in participants with fibromyalgia. The findings also revealed that both dysfunctional beliefs about sleep were related to pain and fatigue.

Due to limitations of a cross-sectional questionnaire-based design, it is unclear whether dysfunctional beliefs and attitudes about sleep and stress lead to or are the result of chronic sleep problems, whether they are related to pain and fatigue as a result of poor sleep, or if all these factors interrelate. The finding that beliefs about sleep and stress appear to influence different aspects of sleep quality also highlights the importance of exploring the separate components of sleep quality when establishing the effect of psychosocial factors on sleep.

The high prevalence of sleep difficulties in FMS and the significant role of psychosocial factors on the maintenance of poor sleep revealed in this study highlight the urgent need for further research and treatment of sleep difficulties in patients with FMS. There have been promising results from a pilot study exploring the effectiveness of behavioural strategies on sleep quality in FMS [27]. However, the results from the present study suggest that there is also a need to address patients' cognitions and to incorporate stress management strategies into sleep interventions in order to improve their effectiveness for people with FMS.

References

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References

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brighton and sussex medical school

UNIVERSITY OF SURREY

Exploring the role of sleep in Fibromyalgia Syndrome

People with fibromyalgia syndrome often describe that they experience difficulties sleeping. Research has shown that there is a link between poor sleep quality and higher levels of pain and fatigue in people with this condition.

We would like to talk to people diagnosed with fibromyalgia syndrome to explore their experience of sleep, how they feel sleep quality affects their health and quality of life and how they cope with any sleep difficulties that they have.

We are interested in talking to people with who experience difficulties sleeping as well as people who feel that they sleep well.

Are you intrigued?

If you:

- have been diagnosed with fibromyalgia syndrome
- and are aged over 18 years

you may be able to take part in this study.

Interviews will be held at a time and place convenient to you and any travel expenses will be reimbursed.

If you're interested, please contact:

Alice Theadom
Tel: 01273 642186
Email: a.theadom@bsms.ac.uk

or Mark Cropley
Tel: 01483 686928
Email: Mark.Cropley@surrey.ac.uk

We will send you further information about the study to help you decide whether you would like to take part.

INFORMATION SHEET

Sleep in Fibromyalgia Syndrome

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?
People with Fibromyalgia commonly experience sleep difficulties. This study aims to explore your sleeping patterns, any difficulties you have sleeping and how you feel sleep affects your symptoms and quality of life. This research study will be run over 6 months in total. Your participation in this study will last for up to 1 and a half hours.

Why have I been chosen?
You have been chosen to take part as you have been identified as having Fibromyalgia syndrome. There will be approximately 14 other participants taking part.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form. If you do decide to take part you are still free to withdraw at any time, without giving a reason. A decision to withdraw at any time, or not to take part in the study, will not affect your current care.

What will happen to me if I take part?
If you would like to take part in this study you will be asked to meet with a researcher to discuss your experiences. At the start of the interview you will have the opportunity to ask any further questions you have about the study and if you would like to take part you will be asked to sign a consent form. The meeting will be at a time and location that is convenient for you and will last for up to 1 and half hours, or shorter if you wish. The researcher will ask you talk about the quality of your sleep and how you feel sleep affects your symptoms and quality of life. This discussion will be tape recorded. This is so that the interviewer can focus their attention on what you have to say rather than taking notes.

What do I have to do?
You will be asked to talk about your sleeping pattern, the quality of your sleep and about your fibromyalgia symptoms. This will help us to understand the links between sleep and fibromyalgia better.

What are the side effects of any treatment received or possible risks when taking part?
You may find that you become upset talking about your experiences. You will be able to contact a member of the research team at any time during the study if you are at all concerned. The researcher will be a Chartered Health Psychologist.

What are the possible benefits of taking part?
Some people find talking about their condition to others helpful and talking about your experiences may help you to understand your condition better. The information we get from this study may help us to treat future patients with Fibromyalgia better.

What happens when the research study stops?
You will be able to contact a researcher at any point during the research study. You will be sent a summary of the study findings for your interest, unless you ask us not to receive this.

Will my taking part in this study be kept confidential?
All information which is collected about you during the course of the research will be kept strictly confidential. Your name and contact details will be kept in a locked filing cabinet. Information will only be disclosed if it indicates a serious threat to either yourself or others. Any information about you which leaves the university will have your name and address removed so that you cannot be recognised from it.

The interview tape will not have your name on it. It will be coded with a research identification number and so you will be anonymous to the secretary who will transcribe the taped interview. The taped interviews will be kept in a locked filing cabinet separate from your contact details and will be destroyed at the end of the study. Two researchers will read and analyse the typed transcripts for common themes.

Your GP will be informed of your participation in this study only with your permission. Any other information about you that leaves the university will have your name and address removed so you cannot be recognised from it.

What will happen to the results of the research study?
The results of the research will be presented at medical and psychology conferences and will be published in a research journal. You will not be identified in any report or publication.

Who has reviewed the study?
This study was given a favourable ethical opinion from the University of Surrey Ethics Committee.

Complaints
Any complaint or concerns about any aspects of the way you have been dealt with during the course of the study will be addressed. Please contact;
Dr Mark Cropley, Principal Investigator on (01483 686928).

Contact for Further Information
If you would like any further information please contact:

Alice Theadom
01273 642186
alice.theadom@bsms.ac.uk

Mark Cropley
01483 686928
Mark.Cropley@surrey.ac.uk

Thank you for your time and interest in this study.

Sleep in Fibromyalgia Syndrome

Consent Form

- I the undersigned voluntarily agree to take part in the study on sleep in fibromyalgia syndrome.

- I have read and understood the Information Sheet provided. I have been given a full explanation by the investigators of the nature, purpose, location and likely duration of the study, and of what I will be expected to do. I have been advised about any discomfort and possible ill-effects on my health and well-being which may result. I have been given the opportunity to ask questions on all aspects of the study and have understood the advice and information given as a result.

- I agree to comply with any instruction given to me during the study and to co-operate fully with the investigators. I shall inform them immediately if I suffer any deterioration of any kind in my health or well-being, or experience any unexpected or unusual symptoms.

- I agree to the investigators contacting my general practitioner about my participation in the study.

- I understand that all personal data relating to volunteers is held and processed in the strictest confidence, and in accordance with the Data Protection Act (1998). I agree that I will not seek to restrict the use of the results of the study on the understanding that my anonymity is preserved.

- I understand that I am free to withdraw from the study at any time without needing to justify my decision and without prejudice.

- I understand that in the event of my suffering a significant and enduring injury (including illness or disease) as a direct result of my participation in the study, compensation will be paid to me by the University subject to certain provisos and limitations. The amount of compensation will be appropriate to the nature, severity and persistence of the injury and will, in general terms, be consistent with the amount of damages commonly awarded for similar injury by an English court in cases where the liability has been admitted

- I confirm that I have read and understood the above and freely consent to participating in this study. I have been given adequate time to consider my participation and agree to comply with the instructions and restrictions of the study.

Name of volunteer (BLOCK CAPITALS) .....

Signed .....

Date .....

Name of researcher/person taking consent (BLOCK CAPITALS) .....

Signed.....

Date .....

Appendix L: Letter of Ethical Approval for Study Three (Chapter Six)

UNIVERSITY OF SURREY

Ethics Committee

21 June 2007

Dr Mark Cropley
Department of Psychology
School of Human Sciences

Dear Dr Cropley

Exploring the role of sleep in Fibromyalgia Syndrome (EC/2007/48/Psych)

On behalf of the Ethics Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the submitted protocol and supporting documentation.

Date of confirmation of ethical opinion: 28 June 2007

The final list of documents reviewed by the Committee is as follows:

Document	Date
Application	25/05/2007
Research Proposal	07/01/2007
Information Sheet and Consent Form	30/05/2007
Letter to Participants' GPs	26/02/2007
Interview Schedule	26/02/2007
Insurance Proforma	25/05/2007
Your Response to Committee's Comments with Amended Documents	22/06/2007

This opinion is given on the understanding that you will comply with the University's Ethical Guidelines for Teaching and Research.

The Committee should be notified of any amendments to the protocol, any adverse reactions suffered by research participants, and if the study is terminated earlier than expected with reasons.

You are asked to note that a further submission to the Ethics Committee will be required in the event that the study is not completed within five years of the above date.

Please inform me when the research has been completed.

Yours sincerely

Catherine Ashbee (Mrs)
Secretary, University Ethics Committee
Registry

cc: Professor T Desombre, Chairman, Ethics Committee
Ms A Theadom, University of Brighton

[GP Contact Address]

Exploring the role of sleep in fibromyalgia syndrome

Participant identification Number for this study: _____

Dear Dr …..[GP Name]……,

Re: …[Participant's name and address]…

This patient has agreed to take part in a research study looking at the role of sleep in fibromyalgia syndrome in collaboration with the University of Surrey. This is a qualitative study exploring patients experience of sleep and how the perceive sleep impacts on their symptoms and quality of life.

I enclose a copy of the information sheet about the study which has also been given to your patient. If your patient develops symptoms that concern us we will ask that they contact your surgery for an appointment to see you.

If you would like to see the study protocol, please contact me at the above address. If you have any reservations about your patient being involved in this study, please let me know as soon as possible.

Thank you for your co-operation in this important research.

Yours sincerely

Alice Theadom
Research Fellow
Brighton and Sussex Medical School
Tel: 01273 642186
Email: alice.theadom@bsms.ac.uk

INFORMATION SHEET

Relaxation in Fibromyalgia Syndrome

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?
People with Fibromyalgia commonly experience sleep difficulties. This study aims to explore the effects of two types of relaxation technique on sleeping and quality of life. This research study will be run over 6 months in total. Your participation in this study will last for 3 weeks.

Why have I been chosen?
You have been chosen to take part as you have been identified as having Fibromyalgia syndrome. There will be approximately 39 other participants taking part.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form. You are still free to withdraw at any time, without giving a reason. A decision to withdraw at any time, or not to take part in the study, will not affect your current care.

What will happen to me if I take part?
If you would like to take part in this study you will be invited to attend an initial assessment meeting with a researcher. The assessment meeting will be at a time and location that is convenient for you, if it is easier the assessments may be completed over the telephone. At the start of the assessment you will have the opportunity to ask any further questions you have about the study. You will then be asked to complete some questionnaires about your sleep patterns and quality of life, you will also be given instructions on how to use the relaxation audio and daily sleep diary.

What do I have to do?
The sleep diary will be completed for three weeks; the first week is to establish a baseline measure of your sleep patterns. The second week you will be randomly assigned to doing one of two types of relaxation exercise, either a 'body scan' exercise or an 'isometric exercise'. You will need to practice the relevant relaxation technique on a daily basis for one week whilst keeping your sleep diary. The third week will be a post-relaxation exercise week where again you will need to complete a sleep diary. This will help us to understand the effects of relaxation on sleep and Fibromyalgia better.

What are the side effects of any treatment received or possible risks when taking part?
You may find that you do not like the relaxation exercises or find them uncomfortable to do. You will be able to contact a member of the research team at any time during the study if you are at all concerned. The researcher will be a Chartered Health Psychologist.

What are the possible benefits of taking part?
Some people find that practising relaxation exercises can be beneficial. The information we get from this study may help us to treat future patients with Fibromyalgia better.

What happens when the research study stops?
You will be able to contact a researcher at any point during the research study. You will be sent a summary of the study findings for your interest, unless you ask us not to receive this.

Will my taking part in this study be kept confidential?
All information which is collected about you during the course of the research will be kept strictly confidential. Your name and contact details will be kept in a locked filing cabinet. Information will only be disclosed if it indicates a serious threat to either yourself or others. Any information about you which leaves the university will have your name and address removed so that you cannot be recognised from it.

The questionnaires and daily sleep diaries will not have your name on them. They will be coded with a research identification number so you will be anonymous to the researcher analysing the data. The questionnaires will be kept in a locked filing cabinet separate from your contact details and will be destroyed at the end of the study.

Your GP will be informed of your participation in this study only with your permission. Any other information about you that leaves the university will have your name and address removed so you cannot be recognised from it.

What will happen to the results of the research study?
The results of the research will be presented at medical and psychology conferences and will be published in a research journal. You will not be identified in any report or publication.

Who has reviewed the study?
This study was given approval from the University of Surrey Ethics Committee.

Contact for Further Information
If you would like any further information please contact:

Alice Theadom
01273 642186
alice.theadom@bsms.ac.uk

Mark Cropley
01483 686928
Mark.Cropley@surrey.ac.uk

Joanna Rodriguez
jr00008@surrey.ac.uk

Thank you for your time and interest in this study

Consent Form

- I the undersigned voluntarily agree to take part in the study on the effects of relaxation in people with Fibromyalgia Syndrome.

- I have read and understood the Information Sheet provided. I have been given a full explanation by the investigators of the nature, purpose, location and likely duration of the study, and of what I will be expected to do. I have been given the opportunity to ask questions on all aspects of the study and have understood the advice and information given as a result.

- I agree to comply with any instruction given to me during the study and to co-operate fully with the investigators. I shall inform them immediately if I suffer any deterioration of any kind in my health or well-being, or experience any unexpected or unusual symptoms.

- I agree to the investigators contacting my general practitioner about my participation in the study, and I authorise my GP to disclose details of my relevant medical or drug history, in confidence.

- I understand that all personal data relating to volunteers is held and processed in the strictest confidence, and in accordance with the Data Protection Act (1998). I agree that I will not seek to restrict the use of the results of the study on the understanding that my anonymity is preserved.

- I understand that I am free to withdraw from the study at any time without needing to justify my decision and without prejudice.

- I confirm that I have read and understood the above and freely consent to participating in this study. I have been given adequate time to consider my participation and agree to comply with the instructions and restrictions of the study.

Name of volunteer (BLOCK CAPITALS) .....

Signed .....

Date .....

Name of researcher/person taking consent
(BLOCK CAPITALS .....

Signed .....

Date . ……...

UNIVERSITY OF SURREY

brighton and sussex medical school

Does mindfulness improve sleep quality and quality of life in patients with fibromyalgia?

People with fibromyalgia syndrome often find that they experience difficulties sleeping. Research has shown that poor sleep quality is linked to higher levels of pain and fatigue in people with this condition. A recent research study has found that an approach called mindfulness can improve sleep quality for people with insomnia.

We are running a study to see if a mindfulness relaxation approach can help to improve sleep quality and quality of life for patients with fibromyalgia.

Are you intrigued?

If you:

- have been diagnosed with fibromyalgia syndrome
- and are aged over 18 years

you may be able to take part in this pilot study.

No travel will be required and all equipment will be provided.

If you're interested, please contact:

Joanna Rodriguez at the University of Surrey

Tel: 07747823645 **Email: jr00008@surrey.ac.uk**

or Alice Theadom
Brighton and Sussex Medical School
01273 642186
a.theadom@bsms.ac.uk

Mark Cropley
University of Surrey
01483 686928
Mark.Cropley@surrey.ac.uk

We will send you further information about the study to help you decide whether you would like to take part.

Appendix P: Letter of Ethical Approval for Study Four (Chapter Seven)

Dr Kate Davidson
Chair: SHS Ethics Committee
University of Surrey

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University of Surrey
Guildford
Surrey GU2 7XH UK
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School of Human Sciences

Joanna Rodriguez
Department of Psychology
University of Surrey

6 June 2007

Dear Joanna

Reference: 133-PSY-07
Effects of a guided relaxation routine on sleep and quality of life in people with Fibromyalgia Syndrome

Thank you for your submission of the above proposal.

The School of Human Sciences Ethics Committee has given a favourable ethical opinion.

If there are any significant changes to this proposal you may need to consider requesting scrutiny by the School Ethics Committee.

Yours sincerely

Dr Kate Davidson

Appendix Q: Participant Questionnaire for Study Four (Chapter Seven)

Patient No:____
Pre/Post

Name:_____

Date:_____

Research Study

The Effectiveness of a brief Audio Intervention for Patients with Fibromyalgia Syndrome

Questionnaire Booklet

1. **Gender:** Male / Female (please circle)

2. **Age**:_____

3. **Approximate length of time you have experienced symptoms of Fibromyalgia.**

   ____ years ____ months

4. **Do you have any other medical condition?**

   Yes / No (please circle)

If yes, what is your diagnosis_____

5. **Are you currently employed?**

   Yes / No / I am not currently working / Retired (please circle)

If yes;

Approximately how many hours do you work each week?_____

Does your work involve shift work?

Yes / No / I am not currently working (please circle)

HAD Scale

Read each item and place a tick (√) in the box opposite the reply that comes closest to how you have been feeling in the past few weeks. Don't take too long over your replies; your immediate reaction to each item will probably be more accurate than a long thought-out response

1. I feel tense/wound up:

Most of the time	
A lot of the time	
Occasionally	
Not at all	

2. I still enjoy the things I used to enjoy:

Definitely as much	
Not quite as much	
Only a little	
Hardly at all	

3. I get a sort of frightened feeling as if something awful is about happen:

Very definitely and quite badly	
Yes, but not too badly	
A little, but it doesn't worry me	
Not at all	

4. I can laugh and see the funny side of things

As much as I always could	
Not quite so much now	
Definitely not so much now	
Not at all	

5. Worrying thoughts go through my mind

A great deal of the time	
A lot of the time	
From time to time	
Only occasionally	

6. I feel cheerful:

Not at all	
Not often	
Sometimes	
Most of the time	

7. I can sit at ease and feel relaxed:

Definitely	
Usually	
Not often	
Not at all	

8. I feel as if I am slowed down:

Nearly all the time	
Very often	
Sometimes	
Not at all	

9. I get a sort of frightened feeling like: butterflies in the stomach:

Not at all	
Occasionally	
Quite Often	
Very Often	

10. I have lost interest in my appearance

Definitely	
I don't take as much care as I should	
I may not take quite as much care	
I take just as much care as ever	

11. I feel restless as if I have to be on the move

Very much indeed	
Quite a lot	
Not very much	
Not at all	

12. I look forward with enjoyment to things

As much as ever I did	
Rather less than I used to	
Definitely less than I used to	
Hardly at all	

13. I get sudden feelings of panic programme:

Very often indeed	
Quite often	
Not very often	
Not at all	

14. I can enjoy a good book, radio or TV

Often	
Sometimes	
Not often	
Very seldom	

This set of questions asks your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Please tick the box that represents how you feel. If you are unsure about how to answer questions please give the best answer you can.

	Excellent	Very Good	Good	Fair	Poor
1. In general would you say your health is:					
	Much better	Somewhat better	About the same	Somewhat worse	Much worse
2. Compared to one year ago how would you rate your health in general now					

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so how much? Please tick the box that indicates how you feel.

	Limited a lot	Limited a little	Not limited at all
3. Vigorous activities such as running, lifting heavy objects, participating in strenuous sports	1	2	3
4. Moderate activities such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
11. Lifting or carrying groceries	1	2	3
12. Climbing several flights of stairs	1	2	3
13. Climbing one flight of stairs	1	2	3
14. Bending, kneeling or stooping	1	2	3
15. Walking more than a mile	1	2	3
16. Walking several blocks	1	2	3
17. Walking one block	1	2	3
18. Bathing or dressing yourself	1	2	3

During the past month have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Please tick the appropriate box.

	Yes	No
13. Cut down on the amount of time you spent on work or other activities	1	2
16. Accomplished less than you would like	1	2
17. Were limited in the kind of work or other activities?	1	2
16. Had difficulty performing the work or other activities for example it took extra effort	1	2

During the past month have you had any of the following problems with your work to other regular activities as a result of any emotional problems e.g. feeling depressed or anxious? Please tick the appropriate box.

	Yes	No
17. Cut down on the amount of time you spent on work or other activities	1	2
18. Accomplished less than you would like	1	2
19. Didn't do work or other activities as carefully as usual	1	2

	Not at all	Slightly	Moderately	quite a bit	Extremely
20. During the past month to what extent has your physical health or emotional problems interfere with your normal social activities with family, friends, neighbours or groups					

	None	Very mild	Mild	Moderate	Severe	Very Severe
21. How much physical pain have you had in the past month						

	Not at all	A little bit	Moderately	Quite a bit	Extremely
22. During the past month how much did pain interfere with your normal work (both paid and/or housework)					

These questions are about how you feel and how things have been with you during the past month. Please tick the box that indicates how you have been feeling.

Please circle one number for each line	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
23. Did you feel full of life?	1	2	3	4	5	6
24. Have you been a very nervous person?	1	2	3	4	5	6
25. Have you felt so down in the dumps that nothing cheers you up?	1	2	3	4	5	6
26. Have you felt calm and peaceful?	1	2	3	4	5	6
27. Did you have a lot of energy?	1	2	3	4	5	6
28. Have you felt downhearted and blue?	1	2	3	4	5	6
29. Did you feel worn out?	1	2	3	4	5	6
30. Have you been a happy person?	1	2	3	4	5	6
31. Did you feel tired?	1	2	3	4	5	6

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
32. During the past 4 weeks how much of the time has your physical health interfered with your social activities (visiting your friends etc..)					

How true or false is each of the following statements for you?

Please circle one number on each line	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
33. I seem to get sick a little easier than other people	1	2	3	4	5
34. I am as healthy as anybody I know	1	2	3	4	5
35. I expect my health to get worse	1	2	3	4	5
36. My health is excellent	1	2	3	4	5

Please check that you have answered all the questions

Thank you for your time

Appendix R. Letter from Dr Mark Cropley Verifying Own Contribution to the Works Included in this Thesis

Dr Mark Cropley
Reader in Health Psychology

Department of Psychology
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Guildford, Surrey GU2 7XH, UK
Tel: +44 (0)1483 686928
Email: Mark.cropley@surrey.ac.uk

28 Jun. 10

Dear Whom it may concern

Alice Theadom

This letter is to outline the support Alice Theadom received for her PhD from myself and MSc students at the University of Surrey.

For the two projects that involved MSc students, Alice was responsible for generating the initial idea and for drafting the design, and conducting the data analysis. She also took the lead in writing-up the research for publication and addressing issues arising from the reviewers. Alice is the first author in all the publications that have resulted from work presented in her thesis. The student's role was comparable to that of a research assistant, and they helped in data collection, data input, and they conducted some preliminary data screening. The two students used some parts of the data to present in their research dissertations. Alice also provided support and guidance to the students while they completed their Master's dissertations.

Alice drafted all ethical submission letters and dealt with any ethical issues raised by the ethics board.

My input to the work was in accordance with what is expected as the supervisor of a doctorial thesis. I have given guidance on methodological design, and have provided feedback on various chapters within her thesis.

Yours truly,

Dr Mark Cropley

Appendix S: Curriculum Vitae

Alice Theadom
BSc, MSc, MNZPsS, MIHP

QUALIFICATIONS

2005-Present PhD Candidate Auckland University of Technology, NZ

2005 Stage 2 Qualification in Health Psychology British Psychological Society, UK

2003 MSc Health Psychology, Distinction, University of Surrey, UK

1999 BSc Psychology (Hons) 2:1, University of Essex, UK

PROFESSIONAL AFFILIATIONS

New Zealand Psychologists Board, Registered Psychologist
Full Member of the New Zealand Psychological Society
British Psychological Society, Chartered Psychologist
Full Member of the Division of Health Psychology, British Psychological Society, UK
Visiting Research Fellow, Brighton and Sussex Medical School, UK
Member of the Medical Advisory Board to the Fibromyalgia Association UK

PREVIOUS EMPLOYMENT

Cavit ABI Senior Research Fellow 18/05/2009- Present
National Research Centre for Stroke, Applied Neurosciences and Neurorehabilitation, AUT University, NZ
Postdoctoral Research Fellow 04/09/2006-03/09/2008
Department of Primary Care and Public Health, Brighton and Sussex Medical School, UK
Research Psychologist, 14/09/2005 - 04/09/2006
Department of Research and Development, Hillingdon Hospital, Central and North West London Mental Health Trust, UK
Health Psychologist 19/01/2004 – 11/09/2005
Camden Stop Smoking Service, Camden Primary Care Trust, St Pancras Hospital, UK
Research Assistant 11/07/2003 – 16/01/2004
Department of Community Health Sciences, St George's Hospital Medical School, UK
Assistant Psychologist 18/09/2000 – 26/07/2002
Hollyrood Autism Service, The Disabilities Trust, UK
Auxiliary Nurse 06/01/2001 – 30/10/2001
Princess Royal Hospital NHS Trust, UK

PUBLICATIONS

Peer Reviewed Journal Articles

1) **Theadom, A.**, Cropley, M., Hankins, M., Smith, H.E. (2009). Mind and body interventions for fibromyalgia. Published Protocol. Cochrane Database of Systematic Reviews, Issue 4. DOI: 10.1002/14651858.CD001980.pub2
2) **Theadom, A.,** Smith, H.E., Horne, R., Bowskill, R., Apfelbacher, C.J. & Frew, A.J. (2009). Participant experience of a written emotional disclosure intervention in asthma. Stress and Health, 26(1), 45-50. DOI: 10.1002/smi.1255
3) **Theadom, A.**, Smith, H.E., Yorke, J., Hankins, M., Apfelbacher, C.J., Horne, R., Bowskill, R. & Frew, A.J. (2009). Written emotional disclosure for asthma. Published Protocol. Cochrane database of Systematic Reviews, Issue 2. DOI: 10.1002/14651858.
4) Cropley, M., **Theadom, A.,** Pravettoni, G., Webb, G. (2008). The effectiveness of smoking cessation interventions prior to surgery: A systematic review. Nicotine & Tobacco Research, 10(3), 407-412.
5) **Theadom, A**. & Cropley, M. (2008). Dysfunctional beliefs, stress and sleep disturbance in fibromyalgia syndrome. Sleep Medicine, 9(4), 376-381.
6) **Theadom, A.,** Cropley, M. & Humphrey, K.L. (2007). Exploring the role of sleep and coping on quality of life in fibromyalgia. Journal of Psychosomatic Research, 62(2), 145-151.
7) Mead, K., **Theadom, A**., Byron, K. & Dupont, S. (2007). Pilot study of a 4-week pain coping strategies (PCS) programme for the chronic pain patient. Disability and Rehabilitation, 29(3), 199-203.
8) De Lusignan, S., Chan, T., **Theadom, A**., Dhoul, N. (2007). The roles of policy and professionalism in the protection of processed clinical data: A literature review. International Journal of Medical Informatics, 76(4), 261-268.
9) **Theadom, A**., Dupont, S. & Byron, K. (2006). Functional somatic symptoms in accident and emergency – an exploratory study. Journal of Accident and Emergency Nursing, 14(3), 171-177.
10) **Theadom, A**. & Cropley, M. (2006). Does preoperative smoking cessation reduce postoperative complications? A systematic review. Tobacco Control, 15(5), 352-358.
11) De Lusignan, S., Wilson, E., Dyble, A., Grant, T., **Theadom, A.** & Chan, T. (2003). The feasibility of using pattern recognition software to measure the influence of computer use on the consultation. BMC – Medical Informatics and Decision Making, 3(12) 1-10.
12) **Theadom, A.**, de Lusignan, S., Wilson, E. & Chan, T. (2003). Using three-channel video to evaluate the impact of the use of the computer on the patient-centredness of the general practice consultation. Informatics in Primary Care, 11(3), 149-156.

Professional and Commissioned Journal Articles

1) Feigin, V., Barker-Collo S., Krishnamurthi, R., **Theadom, A.,** Starkey, N., (In press). Epidemiology of ischaemic stroke and traumatic brain injury. Best Practice and Research Clinical Anaesthesiology.
2) Cropley, M. & **Theadom, A.** (2008). Sleep Disturbance in Fibromyalgia Syndrome. Evaluation of: Bigatti, S.M. et al. Sleep disturbances in fibromyalgia syndrome: relationship to pain and depression. Arthritis and Rheumatology, 59(7), 961-967.
3) **Theadom, A.** & Buckley, E. (2006). Achieving the Stage 2 Qualification. Health Psychology Update, 15(3), 13-16.
4) **Theadom, A**. (2006). Research and Development in the NHS – An emerging role for health psychology? Health Psychology Update, 15(1), 11-13.
5) **Theadom, A**. & Webb, Z. (2003) Using the AAPEP with adults with autism spectrum disorders; strengths, weaknesses and modifications. Good Autism Practice, 4(2), 66-70.

Conference papers and published abstracts

1) Starkey, N.J., Feigin, V., Barker-Collo, S., **Theadom, A.,** on behalf of the BIONIC research team. (2010). Examining the incidence and outcome of paediatric traumatic brain injury in New Zealand. Australasian Winter Conference on Brain Research, Wanaka, NZ
2) Starkey, N.J., Barker-Collo, S., Feigin, V., **Theadom, A.,** on behalf of the BIONIC research team. (2010). Traumatic brain injury burden in New Zealand: a population-based incidence and outcomes study. New Zealand Psychological Society Annual Conference, Rotorua, NZ
3) Smith, H.E., Jones, C.J., **Theadom, A**., Horne, R., Bowskill, R., Hankins, M., Frew, A.J. (2009) Writing about emotional experiences reduces B-agonist use in patients with asthma - 3 month follow up of a randomised controlled trial. Journal of Allergy and Clinical Immunology 123(2), Suppl 1, S273-S330.
4) **Theadom, A.,** Smith, H.E., Horne, R., Bowskill, R., Hankins, M., Jones, C. & Frew, A.J. (2008). Writing about emotional experiences to improve lung function in patients with asthma - a randomised controlled trial. Research in Progress Poster Presentation, NAPCRG Annual Meeting, Rio Grande, Puerto Rico.
5) Jones, C., **Theadom, A.,** Smith,H.E., Hankins, M., Bowskill, R., Horne, R. & Frew, A,J. (2008). Writing about emotional experiences to improve lung function and quality of life in patients with asthma – 3-month follow up of a randomised controlled trial. British Thoracic Society Winter Meeting, London, UK.
6) **Theadom, A.,** Smith, H.E., Miarkowska, D. & Frew, A.J. (2008). The readability of Allergy UK's information factsheets for patients with allergy, intolerance and sensitivity. Poster Presentation, British Society for Allergy and Clinical Immunology Conference, Loughborough, UK.
7) Howard, C., Wray, J., **Theadom, A**. & Carby, M. (2008). Being at the centre of a balance'. Living with respiratory disease and panic-like episodes. Health Psychology Annual Conference, Bath, UK.
8) Howard, C., Hallas, C. & **Theadom, A.** (2007). Being at the centre of a balance'. Living with respiratory disease and experiences of breathlessness

and panic-like episodes, Faculty of Clinical Health Psychology Annual Conference, Sheffield, UK.
9) **Theadom, A**., Cropley, M. & Humphrey, K.L. (2007). Beliefs about sleep and sleep quality in fibromyalgia. Division of Health Psychology Annual Conference, University of Nottingham, UK.
10) **Theadom, A.,** Smith, H.E., Horne, R., Bowskill, R. & Frew, A.J. (2007). Participant experiences of an expressive writing intervention for patients with asthma in primary care. Poster Presentation, Society for Academic Primary Care, London, UK.
11) **Theadom, A**., Cropley, M. & Humphrey, K.L. (2006). Sleep, coping and quality of life in fibromyalgia. Division of Health Psychology Annual Conference, University of Essex, UK.
12) Leinonen, R., **Theadom, A.** & Cain, S. (2006). Increasing the use of written materials in NHS community based stop smoking interventions. The impact of providing a comprehensive resource pack. Postgraduate Health Psychology Conference, University of Derby, UK.
13) Leinonen, R., **Theadom, A.** & Cain, S. (2006). Increasing the use of written materials in NHS community based stop smoking interventions. The impact of providing a comprehensive resource pack. Poster Presentation, National Smoking Cessation Conference, Gateshead, UK.
14) **Theadom, A**, (2006). Invited speaker at the Postgraduate Health Psychology Conference, 'Completing the Stage 2 Qualification in Health Psychology; the BPS Route' University of Derby, UK.
15) **Theadom, A**. & Hampson, S.E. (2005). Unravelling the mystery, illness perceptions, coping and pain in fibromyalgia syndrome. Poster presentation, European Conference of Health Psychology, Galway. Ireland.

RESEARCH GRANTS

1) McPherson, K., **Theadom, A**., Levack, W., Fadyl, J., Harwood, M., Kayes, N., Starkey, N., Christey, H., Feigin, V., (2010). Experiences of recovery and adaptation after disabling traumatic injury. Health Research Council, NZ.
2) **Theadom, A.,** Feigin, V., Cropley, M. (2009). Applying the structured clinical interview schedule to patients with fibromyalgia syndrome. Summer studentship award, TEC/AUT, NZ.
3) Feigin, V.F, Barker-Collo S., **Theadom, A.** McPherson, K., (2009). The effect of Enzogenol Supplementation on memory after mild traumatic brain injury. ENZO Nutraceuticals.
4) Fisher, J., **Theadom, A.** & Dunn, E. (2008). Efficacy of cognitive stimulation therapy for adults with fibromyalgia syndrome. Big Lottery Fund Development Grant.
5) Cropley, M. & **Theadom, A.** (2007). Effects of guided relaxation on sleep and quality of life in people with fibromyalgia. University of Surrey Pump-priming Fund.
6) **Theadom, A.** (2006). Sleep, coping and quality of life in fibromyalgia. Oral Presentation, Division of Health Psychology Annual Conference, University of Essex. Arthritis Research Council Educational Travel / Training Bursary.