

The Efficacy of a Combined Cognitive-Behavioural and Interpersonal Therapy Approach
to the Treatment of Fibromyalgia Syndrome: A Randomized Controlled Trial

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Abstract

The purpose of the current study was to develop a manualized treatment for fibromyalgia syndrome (FM) and to examine the efficacy of the treatment in a randomized controlled clinical trial. FM is a chronic musculoskeletal pain disorder characterized by tender points and generalized pain. Depression, chronic fatigue, and sleep disturbance are common. A biopsychosocial model served as a framework for understanding FM by integrating psychological, social, and physical factors. Cognitive-behavioural therapy (CBT), an empirically validated treatment for arthritis, has also been used with FM patients in an attempt to improve pain control, reduce disability, and increase self-efficacy. Overall, the attention/placebo controlled studies employing CBT as a treatment for FM show that it is not superior to a credible attention placebo. The current study attempted to combine the necessary components of CBT with interpersonal therapy to address relational patterns and personality characteristics that can affect ability to cope with chronic pain. One hundred and five women diagnosed with FM by a rheumatologist were randomly assigned to the CBT-interpersonal treatment condition or an attention-control condition. There were 8 treatment groups with a mean of 6-7 participants in each. The treatment consisted of weekly 2-hour sessions over 8 consecutive weeks. Outcome measures included: FM impact, pain, health care utilization, depression, coping, and self-efficacy. An intention-to-treat analysis was conducted. Results showed that the impact of FM symptoms was reduced following treatment compared to the control group and this was statistically and clinically significant, but was not maintained at 3-month follow-up. Significant improvements were also observed in coping strategies, some of which were maintained at follow-up. Importantly, self-efficacy improved significantly following treatment compared to the control group. Self-efficacy beliefs have been related to pain, coping efforts, disability, and psychological functioning. Directions for future research may include a focus on long-term maintenance of treatment gains that may be mediated by improvements in self-efficacy. There is strong evidence that changes in self-efficacy are enduring and affect changes in health behaviours and health status.

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Introduction

Fibromyalgia syndrome is a chronic pain disorder characterized by physical symptoms such as tender points and generalized pain (Okifuji & Turk, 1999). In addition, patients report psychological dysfunction and functional limitations including depression, anxiety, chronic fatigue, sleep disturbance, stiffness, and headaches (Okifuji & Turk). Friedberg and Jason (2001) have argued that psychological interventions have much to contribute to the treatment of fibromyalgia beyond existing medical interventions. Furthermore, preliminary studies suggest that psychological interventions hold much promise for the treatment of fibromyalgia (Rossy et al., 1999).

The current study begins by describing fibromyalgia in terms of the criteria for its classification as well as its medical and psychological symptoms. This is followed by a summary of the etiological theories of fibromyalgia. Next, the literature surrounding psychotherapeutic approaches to the treatment of fibromyalgia will be reviewed, with an emphasis on the literature related to cognitive-behavioural treatments. The limitations of previous psychotherapeutic interventions will be discussed and a line of research will be proposed. This will include discussion of the manualized treatment and the methodology for the combined cognitive-behavioural and interpersonal group treatment for fibromyalgia. Finally, the results of the clinical trial will be discussed and contributions, limitations, and clinical implications of the current study are reviewed followed by recommendations for future research.

Fibromyalgia Syndrome

Fibromyalgia is a chronic musculoskeletal pain disorder. It is a rheumatologic condition, which means that the muscles and connective tissues can be painful. In arthritis, also a rheumatologic condition, the joints are also affected. Fibromyalgia, however, is a nonarticular condition; therefore the joints are not affected. Fibromyalgia is not degenerative or deforming and has no known excess mortality (Goldenberg, 1987; Okifuji & Turk, 1999). Long-term studies indicate that most fibromyalgia patients will experience chronic pain for more than 5 years after their diagnosis (Forseth, Forre, & Gran, 1999; Norregaard, Bulow, Prescott, Jacobsen, & Danneskiold-Samsoe, 1993; Wigers, 1996). Fibromyalgia is estimated to affect 3 to 6 million individuals in the United States (Okifuji & Turk) and approximately 3 in 100, or 900,000 individuals in Canada (Arthritis Society, 2008). The prevalence in the general population is

approximately 2% and the female to male ratio is 9:1 when the presence of more than 11 tender points is used for the diagnosis (Wolfe et al., 1995).

Since the early 1900's the terms fibrositis, fibromyositis, and psychogenic rheumatism have been applied to that which is currently called fibromyalgia, a term first suggested by Hensch in 1976 (Okifuji & Turk, 1999; Wolfe et al., 1990). The terms primary and secondary fibromyalgia have also been used in the diagnostic literature. Primary fibromyalgia referred to the presence of fibromyalgia in the absence of other rheumatic illness, whereas secondary fibromyalgia referred to the presence of fibromyalgia and another condition such as rheumatoid arthritis. Wolfe et al., however, suggest that the distinction between primary and secondary fibromyalgia should be abolished at the diagnostic level and the term 'fibromyalgia' used instead. When a person has another illness the term 'concomitant' should be used, or fibromyalgia and the other condition are said to be associated.

The existence of fibromyalgia syndrome and the utility of the diagnosis have been challenged by some. For example, authors argue that the diagnostic label, 'fibromyalgia syndrome,' drives the illness-disease paradigm, promoting sickness behaviour and somatization in people with normal aches and pains (Bohr, 1995; Hadler, 1996). Goldenberg (1999), however, argues that the diagnostic label itself does not promote sickness behaviour unless it is used as a substitute for patient information and education. The diagnosis can be reassuring for many people, enabling them to stop worrying that they have a degenerative disease and to begin focusing on improving symptoms.

The American College of Rheumatology (1990) criteria for the classification of fibromyalgia are: 1) history of widespread pain for at least 3 months (pain in the left and right side of the body, pain above and below the waist, and axial skeletal pain), in combination with, 2) pain in 11 or more of the 18 specific tender point sites on digital palpation (Wolfe et al., 1990). Tender points are examined by palpating with the thumb or the first 2 or 3 fingers at a pressure of approximately 4 kg/cm squared or less, or by using a dolorimeter or algometer. This amount of mechanical force can easily be approximated by applying enough manual pressure to blanch the thumbnail bed (Ang & Wilke, 1990). The tender points are located bilaterally at the occipital and lower cervical area, trapezius and supraspinatus muscle, second costosternal junction, both lateral epicondyles, gluteus muscle, greater trochanteric area, and the medial fat pads of the knees (see Appendix A; Wolfe et al., 1990). Principal symptoms include sleep

disturbance, fatigue, and morning stiffness, with at least one of these symptoms present in 75% of fibromyalgia patients (Wolfe et al., 1990). Fibromyalgia symptoms are strongly correlated with decreased mechanical pain thresholds. That is, individuals with fibromyalgia have a low pain threshold when pressure is applied. This is referred to as mechanical hyperalgesia (Wolfe et al., 1995). Staud and Domingo (2001) stated that mechanical hyperalgesia is always detectable in fibromyalgia patients, and it seems to represent a very important aspect of the syndrome's underlying pathophysiology. Other symptoms of fibromyalgia can include anxiety, depression, and irritable bowel syndrome (Ahles, Yunus, Riley, Bradley, & Masi, 1984; Burckhardt, Clark, & Bennett, 1992; Sivri, Cinda, Dincer, & Sivri, 1996). High levels of disability, poor quality of life, and extensive use of medical care are often reported (Hadhazy, Ezzo, Creamer, & Berman, 2000; Turk, Okifuji, Starz, & Sinclair, 1996).

The relation between the physical symptoms, such as pain, and the psychological symptoms, such as depression, is complex, leading many authors to argue that a biopsychosocial model is the best model with which to conceptualize fibromyalgia and its treatment (Friedberg & Jason, 2001; Okifuji & Turk, 1999; Terrell White, Parr Lemkau, & Clasen, 2001; White & Nielson, 1995). A number of etiological theories, however, have been proposed and will be reviewed.

Etiological Theories of Fibromyalgia

There are a number of theories postulating the underlying mechanisms of fibromyalgia; however, there does not appear to be conclusive evidence for any one particular etiological model. A number of theories are briefly described below, and then the biopsychosocial model will be discussed in greater detail.

Psychogenic Model

Some authors have proposed a psychogenic model of fibromyalgia, suggesting that depression is the primary mechanism underlying the disorder (Alfieri, Sigal, & Landau, 1989). According to this model, the organic condition does not explain the pain reported by the patient. Rather, psychological features such as depression and abnormal illness behaviour are seen to play a critical role in the etiology of fibromyalgia (Ercolani et al., 1994). Since the earliest studies, researchers observed that a high percentage of patients with fibromyalgia displayed various psychological symptoms (Ellman, Savage, Wittkower, & Rodger, 1945). For example, Hench and Bolland (1946) found that fibromyalgia patients display psychological symptoms

including depression and hostility, while Stolze related this to an “inner conflict arising from strong unexpressed aggressive feelings” (Ercolani et al.). Fibromyalgia was viewed as having a psychological cause, in the form of unexpressed anger and hostility. More recent studies suggest that the diagnosis of fibromyalgia is, in fact, major depression in 29% to 71% of cases (Ferraccioli, Cavalieri, & Salaffi, 1990; Hudson & Pope, 1989). In the current climate, depression may be seen as a more favorable explanation for the etiology of fibromyalgia than “inner conflict” and “unexpressed aggression.”

Other studies, however, report no difference between fibromyalgia patients and controls on psychological variables. For example, Kirmayer, Robbins, and Kapusta (1988) found that fibromyalgia patients were not significantly more likely to report depressive symptoms or to receive a diagnosis of major depression compared to rheumatoid arthritis patients. In addition, there were no significant differences between the groups in the number of times each patient spoke with a physician about nerves or emotional worries in the preceding 12 months. These findings demonstrate that major depression was not a common correlate of fibromyalgia syndrome, thus, failing to support the psychogenic model.

Aaron and Bradley et al. (1996) examined the lifetime prevalence of psychiatric disorders in patients with fibromyalgia in tertiary care, in a community sample of people diagnosed with fibromyalgia (non-patients), and in healthy controls. There were a significantly higher number of lifetime psychiatric diagnoses in the fibromyalgia patients in tertiary care compared to the fibromyalgia non-patients and healthy controls. However, there was not a significant difference in psychiatric diagnoses between fibromyalgia non-patients and healthy controls. The authors concluded that psychiatric disorders are not intrinsically related to fibromyalgia. Instead, they argue that multiple lifetime psychiatric diagnoses may contribute to the decision to seek medical care for fibromyalgia in tertiary settings.

Yunus, Ahles, Aldag, and Masi (1991) demonstrated that fibromyalgia symptoms such as tender points, fatigue, and paresthesia are independent of the psychological status of the patient, although the degree of pain may be influenced by psychological factors. In other words, a person can be diagnosed as having fibromyalgia based on the clinical symptom presentation. Whether or not psychological symptoms are present does not preclude the fact that the clinical symptoms of fibromyalgia are real. Certainly, the notion that psychological factors can affect the pain experience is not unfamiliar. This notion is consistent with the gate control theory of pain

proposed by Melzack and Wall (1965). The fact that psychological factors can alter the pain experience does not necessitate that the psychological factors caused the pain. The gate control theory of pain incorporates facts about the nervous system, plausible explanations for clinical pain, and stimulates experiments to test the theory. Melzack and Wall (1965) explain that there are powerful influences descending from the brain, which modulate spinal reflexes. The descending influence on inhibitory neurons, in addition to ascending messages to the brain that can influence descending controls, complete a loop from the spinal cord to the brain and back to the spinal cord (Melzack & Wall, 1965).

In general, results from empirical studies fail to support the psychogenic model of fibromyalgia (Okifuji & Turk, 1999). Although depression is a frequently found symptom in people with fibromyalgia, the model cannot explain the presence of large individual differences in the degree of depression and other types of psychological distress among people with fibromyalgia. Also, depression is not specific to fibromyalgia, nor do all people with fibromyalgia report elevated levels of depression (Okifuji & Turk).

Affective Spectrum Disorder Model (ASDM)

Unlike the psychogenic model, the ASDM of fibromyalgia does not suggest a causal relationship between psychological disorders, such as depression, and fibromyalgia. Instead, the ASDM proposes that there is a group of medical and psychiatric disorders that share a common pathophysiology. Hudson and Pope (1989) proposed this model based on the observation that major depression was common in fibromyalgia patients and their first-degree relatives. They suggest that the co-occurrence of disorders such as fibromyalgia, irritable bowel syndrome, migraine, and major depression is due to a common abnormality. Positive responses to antidepressants in some cases have been proposed as evidence for this model, such that the medication is acting on the pathophysiology that is shared by the fibromyalgia and depressive symptoms. Okifuji and Turk (1999) stated that the empirical evidence for the ASDM is inconsistent. For example, greater prevalence of depression is not always observed in fibromyalgia compared to other chronic pain conditions. Also, the effectiveness of antidepressant medication on fibromyalgia seems to be overestimated in this model. Furthermore, the underlying assumption that if one medication improves multiple symptoms, then all of those symptoms share a common pathology is not warranted. For example, analgesics can relieve pain that is caused by many different mechanisms.

Cognitive Factors

Although research has demonstrated that cognitive factors affect one's ability to adapt to his or her symptoms, cognitive factors are generally not considered to be etiological (Turk & Rudy, 1986). A number of chronic pain disorders may be initiated by physical pathology, but over time the physical pathology plays a diminished role, while maladaptive cognitions play a larger role and may maintain and aggravate symptoms. One difficulty with this approach is determining whether cognitive factors alter the physical symptoms or whether cognitive factors alter the 'perception' of the symptoms.

Research in the area of cognition and fibromyalgia is limited compared to other chronic pain disorders. Results, however, indicate that maladaptive thinking is commonly observed in people with fibromyalgia, and is associated with functional limitations and affective distress. Perceived lack of control and self-efficacy beliefs have been related to increased pain, disability, and depressed mood (Buckelew, Murray, Hewett, Johnson, & Huyser, 1995; Turk & Okifuji, 1997). It is important to note, though, that not all people with fibromyalgia have maladaptive cognitions. Turk, Okifuji, Starz, and Sinclair (1996) reported that the level and nature of maladaptive thoughts vary greatly, with approximately one-third of people with fibromyalgia adapting well to their conditions (Burckhardt & Bjelle, 1996; Pastor et al., 1993).

Hypervigilance Model and Central Modulation Model

Although the hypervigilance and central modulation models have produced separate lines of research, they both define fibromyalgia as a disorder primarily characterized by maladaptive information processing. The models focus on the interaction of neuroendocrine factors and the central nervous system. Although research in this area is increasing, a limited number of studies have examined hypotheses stemming from these models, and results thus far have been inconsistent and confusing (Okifuji & Turk, 1999). A number of hypotheses will be presented within the areas of neuroendocrine abnormalities, followed by neurologic abnormalities.

Neuroendocrine Abnormalities

The autonomic nervous system and the hypothalamic pituitary axis (HPA) are partly responsible for physiological pain modulation. Corticotropin-releasing hormone (CRH) and adrenocorticotropin hormone (ACTH) function as part of the HPA. Stress and pain activate neurons that release CRH, and subsequently ACTH is released and painful symptoms are decreased (Staud & Domingo, 2001). Several studies have shown a hyperactivity of the HPA in

patients with fibromyalgia (Clauw & Chrousos, 1997; Demitrack & Crofford, 1998; Pillemer, Bradley, Crofford, Moldofsky, & Chrousos, 1997). That is, patients responded with a significant increase in ACTH release when stimulated with CRH. In contrast, patients with chronic fatigue syndrome, which shares some features with fibromyalgia, show a hypoactivity of the HPA. Because of the comorbidity of fibromyalgia and depression, the effects of major depression on neuroendocrine functioning have also been examined. Crofford, Jacobson, and Young (1999) found that in contrast to fibromyalgia patients, depressed individuals show a blunted ACTH response to CRH. Therefore, concomitant psychiatric symptoms do not seem to be responsible for the neuroendocrine abnormalities observed in fibromyalgia patients. Although fibromyalgia, chronic fatigue syndrome, and depression have overlapping features, they are distinct syndromes with different neuroendocrine abnormalities (Staud & Domingo, 2001).

Abnormalities in growth hormone (GH) secretion have been examined in fibromyalgia patients. Prominent GH secretion occurs during stages III and IV of sleep. These stages of sleep are frequently abnormal in fibromyalgia patients; therefore, abnormalities in GH secretion have been postulated as a possible etiology for fibromyalgia (Moldofsky, Scarisbrick, England, & Smythe, 1975). Low levels of GH have been reported in some fibromyalgia patients (Bennett, 1998), whereas elevated levels have been found in patients with chronic fatigue syndrome. Replacement of GH was reported to be beneficial only for those fibromyalgia patients deficient of GH (Bennett, Clark, & Walczyk, 1998). Elevated levels of prolactin have also been observed in fibromyalgia patients and these elevated levels seem to correlate with symptom severity. Sperber et al. (1999) found that 71% of subjects with hyperprolactinemia could also be diagnosed with fibromyalgia, in contrast to only 4.5% of normoprolactinemic control subjects.

Although a number of neuroendocrine abnormalities are present, it is unclear to what extent these neuroendocrine responses are adaptive CNS responses to chronic pain and stress. Researchers continue to pursue this line of investigation.

Neurological Abnormalities

Abnormal central processing has been proposed as a possible etiology for the increased pain sensations experienced by fibromyalgia patients. Staud and Domingo (2001) examined the psychophysical evidence for the possibility that input to central nociceptive pathways is abnormally processed in individuals with fibromyalgia. In particular, they examined temporal summation of pain. Compared to control participants, fibromyalgia patients show differences in

response to repetitive thermal stimuli. Levels of temporal summation from repetitive stimulation consistently exceeded those of control participants over a range of stimulus frequencies. In addition, after-sensations lasted longer and were more frequently painful in fibromyalgia participants (Staud & Domingo).

Bennett (2004) stated that there is an impressive body of research that has established that pain in fibromyalgia results from abnormal sensory processing within the central nervous system, referred to as central sensitization. Central sensitization acts as an amplifier, resulting in sensations that formerly were non-painful becoming painful. Bennett stated that this is not a psychological amplification, but rather a physiological amplification that occurs mainly at the level of the spinal cord. Hyperalgesia and allodynia are important clinical features of central sensitization (Staud & Domingo, 2001). Hyperalgesia and allodynia may be responsible for the increased excitability of spinal and supraspinal neurons. Hours after noxious stimuli are presented, there are increases in spontaneous activity, enhanced responsiveness to stimuli, and enlarged receptive fields of dorsal horn neurons (Staud & Domingo). Hyperalgesia is defined as “the exaggerated response to noxious stimuli (e.g. painful heat), whereas allodynia describes the painful response to a non-noxious stimulus like light touch, mild warmth, or cold. Both features of central sensitization are frequently present in fibromyalgia patients” (Staud & Domingo, p. 211).

Substance P levels in the cerebrospinal fluid of fibromyalgia patients have been found to be elevated more than two to three times that of normal control subjects (Russell et al., 1994). Substance P is a polypeptide that functions as a neurotransmitter and a neuromodulator. In the central nervous system, Substance P has been associated with pain and nociception. Nociception is unconscious activity induced by a harmful stimulus in sense receptors, peripheral nerves, the spinal column and the brain (Russell et al.). Substance P is also activated following tissue injury; despite no evidence of tissue injury, fibromyalgia patients have elevated levels of substance P. Several studies of fibromyalgia patients report lower cerebrospinal fluid concentration of analgesic neurotransmitters compared with normal individuals. These neurotransmitters provide pain inhibitory and facilitatory signals to the dorsal horn, thus decreasing or increasing hyperalgesia (Urban & Gebhart, 1999).

Staud and Domingo (2001) stated that there is convincing evidence that there are distinct biological abnormalities present in almost all people with fibromyalgia. Bennett (2004) provides

a review of the research supporting such abnormalities, including: elevated cerebrospinal fluid levels of Substance P, dynorphin, and nerve growth factor, enhanced temporal summation, enhanced somatosensory potentials, a lower threshold for elicitation of the nociceptive flexion reflex, and decreased thalamic activity on functional brain scans. Bennett (2004) suggests a contemporary paradigm for understanding fibromyalgia, which “envisages fibromyalgia as a disorder in which the central nervous system amplifies pain sensations (‘central sensitization’) due to a complex interplay between genetic predisposition, the cumulative burden of painful insults (‘peripheral pain generators’), and a dysregulation of the normal response to stressors (‘dys-stress’)” (p. 23).

Biopsychosocial Model

Certainly, a number of the above mentioned etiological models for fibromyalgia contribute much to the conceptualization of the disorder, particularly the multi-faceted paradigm suggested by Bennett (2004). Some of the models, however, fail to explain important aspects of the disorder. For example, a substantial number of people suffer from persistent pain that is unmanaged by available medical and surgical treatments. In addition, functional disability often appears to be in excess of what might be expected on the basis of physical pathology alone (Turk, 1996). These models have been criticized for the failure to account for psychological and psychosocial variables in health and disease and for the dynamic interaction of these variables with pathophysiological factors (Engel, 1977).

Indeed, research indicates that psychological and social variables modulate nociception and moderate the pain experience and related disability. Turk and Okifuji (2002) stated that “there has been a growing recognition that pain is a complex perceptual experience influenced by a wide range of psychosocial factors, including emotions, social and environmental context, sociocultural background, the meaning of pain to the person, and beliefs, attitudes, and expectations” (p.679). The biopsychosocial model serves as a framework for understanding chronic pain and disability by integrating psychological and social factors with physical factors. Numerous authors suggest a biopsychosocial model of fibromyalgia (Friedberg & Jason, 2001; Hadhazy et al., 2000; Terrell White et al., 2001; Turk & Okifuji, 2002). Okifuji and Turk (1999) proposed a diathesis-stress model specifically for fibromyalgia, called the dynamic process model. The model is designed to be a heuristic, serving as a guide for a comprehensive conceptualization of fibromyalgia that incorporates the authors’ understanding of the current

literature. Turk and Okifuji (2002) stated that the biopsychosocial model presumes some form of physical pathology in the muscles, joints, or nerves that generate nociceptive input to the brain. Perception involves the interpretation of nociceptive input and identifies the type of pain (i.e., sharp, burning, punishing). Appraisal involves the meaning that is attributed to the pain and influences subsequent behaviors. These appraisals will be influenced by the beliefs each person develops over his or her lifetime. On the basis of these beliefs and the appraisal process, the person may choose to ignore the pain and continue working, walking, socializing, and engaging in previous levels of activity or may choose to leave work, refrain from all activity, and assume the sick role. In turn, this interpersonal role is shaped by responses from significant others that may promote either the healthy and active response or the sick role (Turk & Okifuji, 2002).

There is significant evidence for the biopsychosocial model of chronic pain. Among psychological factors, the importance of patients' beliefs has been studied widely. Beliefs about the meaning of symptoms and self-efficacy in pain control play a central role in chronic pain. Such beliefs are associated with psychological functioning (Jensen, Romano, Turner, Good, & Wald, 1999; Stroud, Thorn, Jensen, & Boothby, 2000), physical functioning (Stroud et al., 2000; Turner, Jensen, & Romano, 2000), coping efforts (Anderson, Dowds, Pelletz, Edwards, & Peeters-Asdourian, 1995), behavioral responses (Jensen et al., 1999), and response to treatment (Tota-Faucette, Gil, Williams, Keefe, & Goli, 1993). Social factors are also associated with pain and distress. For example, significant others play an important role in influencing pain reports and communications of distress and suffering. Significant others' reinforcement of pain behaviour, solicitousness, criticism, and support, and marital conflict are among the social factors that play a role in chronic pain. These social factors are associated with surgery results (Epker & Block, 2001; Graham, 2000; Schade, Semmer, Main, Hora, & Boos, 1999), display of pain behaviors (Schwartz, Slater, & Birchler, 1996), physical disability, and nonverbal pain behavior (Romano, Turner, Jensen, Friedman, et al., 1995).

In summary, neuroendocrine dysfunction, maladaptive psychological responses, and maladaptive behaviors are associated with fibromyalgia. The biopsychosocial model integrates premorbid, precipitating, and psychological factors with stress responses in an attempt to understand the development and maintenance of fibromyalgia. For example, a stressor may trigger physiological and psychological responses in an individual, mediated by biological and experiential predispositions. At this point, the individual may become aware of symptoms but

predispositional factors, such as central nervous system reactivity, maladaptive cognitions, psychological factors such as depression, or neuroendocrine factors may inhibit the initiation of adaptive responses to the symptoms.

Based on the biopsychosocial model of fibromyalgia and the belief that psychological factors can contribute to the maintenance and aggravation of symptoms, psychological interventions have been used in the treatment of fibromyalgia.

Psychotherapeutic Approaches to the Treatment of Fibromyalgia

Cognitive-Behavioral Approaches

Given the chronic nature of fibromyalgia, and the fact that the etiology and cure are not completely known, people with fibromyalgia may develop the belief that their pain and level of disability are uncontrollable. This belief may result in negative affect, pain, sleep disturbance, and reduced attempts to engage in daily activities and to develop effective coping strategies (Okifuji & Turk, 1999). Cognitive-behavioral psychotherapy is a model of therapy based on the assumption that a person's perceptions and evaluations of his or her life events influence his or her emotional and behavioral reactions to events (Bradley, 1989). Perceived lack of control is present among fibromyalgia patients, contributing to difficulties with self-esteem, depression, pain, functional disability, compliance, and coping. Targeting these perceptions with cognitive-behavioral techniques has been suggested as an intervention for fibromyalgia (Bradley, 1989). Cognitive-behavioral therapy (CBT) has focused on teaching fibromyalgia patients the skills necessary to control pain and disability and to believe that they can employ these skills. By doing so, patients learn to diminish negative cognitions and perceptions surrounding lack of control.

In a meta-analysis of 49 fibromyalgia treatment outcome studies, Rossy et al. (1999) suggested that nonpharmacological treatments, specifically CBT and exercise, are more helpful in managing self-reported fibromyalgia symptoms (i.e. pain, fatigue, and morning stiffness) than pharmacological treatment alone. However, the positive effect sizes reported in the review are associated with studies that compare active treatment to no treatment, such as a wait-list control condition, or they are single group uncontrolled studies (Bradley, 2002). The effects are much smaller when active treatment is compared to adequate placebo conditions. In a review conducted by Bradley and Alberts (1999), three studies were found to employ adequate control conditions (Buckelew et al., 1998; Nicassio et al. 1997; Vlaeyen et al., 1996). Importantly, the

results of these three controlled studies show that, overall, CBT for fibromyalgia is not superior to a credible attention placebo. However, some positive outcomes were obtained with CBT and will be reviewed. This is a very different conclusion from that associated with the literature on CBT for rheumatoid arthritis and osteoarthritis. In this literature, there are a large number of well-controlled trials that have produced very positive results. Despite the inconsistent results of CBT for chronic pain (i.e. arthritis vs. fibromyalgia), CBT does hold promise for the treatment of fibromyalgia. Fibromyalgia, although different from other chronic pain disorders, does share many fundamental characteristics. Therefore, it is likely that certain elements of CBT that have been effective for other chronic pain conditions can be effective for patients with fibromyalgia.

Although the attention/placebo controlled studies of CBT for fibromyalgia have not shown overwhelmingly positive results, it is not yet reasonable to discount the potential contributions of CBT for fibromyalgia. In the literature, CBT is widely acknowledged as an empirically validated treatment for certain chronic pain conditions, including arthritis. Since fibromyalgia shares many commonalities with other chronic pain conditions, it is likely that a fibromyalgia population could realize some of the benefits of CBT, if the necessary adjustments are made. This proposal argues that a potentially necessary adjustment is the addition of interpersonal process oriented group therapy. Interpersonal process group therapy can address aspects of living with fibromyalgia that CBT typically does not. For instance, relational patterns can be demonstrated during interactions between group members and the therapist. These patterns can be discussed and processed with respect to their effect on the chronic pain disorder. This differs from cognitive-behavioral approaches, although they certainly do address cognitive patterns, and adaptive and maladaptive behaviours. The intricacies of relational patterns and personality characteristics that affect interpersonal relationships are more delicate than what a psycho-educational cognitive-behavioural group may comfortably address. The importance of addressing interpersonal relationship issues is evident, as reviewed earlier, by the effect psychosocial factors have on chronic pain. For example, marital conflict and a significant others' solicitousness and support are associated with pain and disability. In addition to relational patterns, other important issues may be more appropriately dealt with by an interpersonal process approach. For example, trauma has been associated with pain and disability, these experiences are not appropriate to deal with in a psycho-educational setting

(Grzesiak, Ury, & Dworkin, 1996). These issues, however, are important to the experience of chronic pain and are associated with fibromyalgia.

The challenge is to isolate the critical components of CBT that have been effective with other chronic pain populations. In addition, idiosyncratic characteristics associated with fibromyalgia must be addressed by another therapeutic orientation. The unique issues associated with fibromyalgia may be effectively addressed using interpersonal psychotherapeutic techniques. Therefore, the aim of the current study is to combine the necessary components of both techniques, thereby providing treatment that addresses critical cognitive and behavioural factors, as well as emotional and interpersonal factors that affect pain perception, coping strategies, and hence, disability (Turk & Okifuji, 2002).

Fibromyalgia Intervention Studies

A number of randomized controlled fibromyalgia intervention studies will be reviewed in detail, namely, attention/placebo controlled and no treatment (wait-list) controlled trials. The review focuses on studies that employ a cognitive-behavioural approach either alone, or as part of a multimodal treatment program. Table 1 also provides a description of these studies in addition to a description of the single group uncontrolled trials. Characteristics of each study are described in Table 1, including the design, intervention, outcome measures, and results.

A number of these studies specifically identify a component of their multidisciplinary treatment programs as cognitive-behavioural in nature, whereas others identify an educational component. Some of the educational components include aspects of CBT, for example, cognitive restructuring, coping skills, activity pacing, etc. Fibromyalgia intervention studies that do not employ a CBT component, or an educational component that includes aspects of CBT, are not reviewed in the current study.

Attention/placebo controlled trials by Vlaeyen et al. (1996), Nicassio et al. (1997), Buckelew et al. (1998) and Keel, Bodoky, Gerhard, and Muller (1998) will be reviewed in greater detail, followed by a review of the wait-list controlled trials.

Vlaeyen et al. (1996) examined the effectiveness of outpatient educational-cognitive group treatment with 125 fibromyalgia patients. The authors followed suggestions presented by Bradley (1989) for randomized controlled clinical trials of cognitive treatment for fibromyalgia. For example, Vlaeyen et al. assigned patients to either a treatment condition, an attention-control condition, or a wait-list control condition. An educational program was applied to both the

treatment and the attention-control conditions while a cognitive program was applied only to the treatment condition. The educational program provided information about psychosocial factors that influence pain, ergonomic principles applied to daily activities, and social security legislation. The information did not focus solely on fibromyalgia, but on chronic pain in general. Each session ended with a physical exercise such as swimming or bicycling. The cognitive program was aimed at decreasing distorted pain attributions and at increasing self-efficacy expectations. This group program consisted of 12 sessions of 90 minutes, grouped into 3 phases: a reconceptualization phase, a skills acquisition phase, and a generalization phase. The goal of the reconceptualization phase was to modify the pain experience in terms that imply self-control and resourcefulness. In the skills acquisition phase patients practiced imagery techniques and relaxation. During the generalization phase the patients were gradually exposed to tension eliciting stimuli and were encouraged to use relaxation skills in the presence of these stimuli.

The attention-control condition was included in order to control for the nonspecific effects of the cognitive treatment while the wait-list control condition controlled for natural history effects. The group discussion included in the attention-control condition involved patients reading parts of a book about pain, written for pain patients, and being requested to share the information and their own thoughts with the other group members. In addition, participants listened to various audiotaped music fragments. Each session ended with a homework assignment, consisting of brief reading assignments and listening to audiotaped musical fragments. The group discussion was conducted by the same psychologist who conducted the cognitive treatment, and consisted of the same number of sessions. Neither the subjects nor the rest of the interdisciplinary staff were aware of the difference between the two treatments.

Vlaeyen et al. (1996) hypothesized that the combination of cognitive treatment with group education would be more effective than group education alone on measures of pain coping strategies, pain control, tension levels, quality of life, and health care utilization. The authors hypothesized that both interventions would show improvement on knowledge related to the information provided in the educational program, whereas the waiting list control condition would not show such improvement. The authors found that participants in the cognitive-educational intervention condition improved their knowledge about fibromyalgia and pain coping compared to the education-discussion intervention condition and the wait-list control condition. Participants in the education-discussion condition reported significantly less fear than

those in the cognitive-educational condition. The authors concluded that the addition of a 12-session cognitive treatment could not be supported by their study since fear reduction in the education-discussion condition enhanced pain coping and control, while poor compliance with homework in the cognitive-educational condition limited the effectiveness of the cognitive-educational treatment.

Nicassio et al. (1997) stated that previous studies provide no conclusive evidence of the effectiveness of behavioural or educational approaches in reducing fibromyalgia symptoms and disability. Their research differs from these studies by incorporating a number of methodological improvements to compare a comprehensive behavioural intervention for fibromyalgia with an education/control condition. For example, to separate behavioural and educational elements that have been mixed in other research, the authors compared the behavioural intervention with an educational/control condition in which a range of health-related didactic information was presented. However, they omitted instruction on coping practices to manage pain in the control condition. In addition, this study explored the role of intervening variables as mediating improvement in clinical outcomes.

The behavioural treatment incorporated the following components: 1) education about the nature of fibromyalgia and adoption of the gate control theory of pain as a framework for understanding the role of cognition and emotions in the experience and expression of pain; 2) training in progressive muscle relaxation, deep breathing, and relaxing in the face of stress or an increase in pain; 3) behavioural goal setting and activity pacing to increase functioning through shaping and establishment of reinforcement contingencies; and 4) involvement of a support person who learned the same pain management skills as the subject, and assisted the subject by prompting adaptive coping techniques and reinforcing adherence to the protocol. The first 8 sessions emphasized skill acquisition and practice, while the last 2 sessions reviewed and consolidated pain coping skills and refined strategies for achieving behavioural goals and increasing social and physical activity (Nicassio et al., 1997).

The education/control condition involved 2 major elements: 1) informative lectures presented via videotape by a variety of health professionals on topics of general relevance to fibromyalgia and other health related issues; and 2) group discussion and support. In the first session the co-therapists, a PhD clinical psychologist and a psychology doctoral student, presented an introduction to fibromyalgia and provided an explanation of the benefits of

information and support in dealing with the syndrome. The videotapes were presented in sessions 2 through 9 and addressed topics such as: diagnostic criteria; similarities and differences between fibromyalgia and arthritis; and pain and fatigue. After each videotaped presentation, therapists led a structured group discussion on the relevance of the topic to group members; however, at no time during the course of the intervention was specific information imparted on coping with pain, problem solving, or the use of cognitive-behavioural strategies. At the end of each session, subjects received written summaries of the educational information presented to them. In session 10, educational topics were reviewed, questions were addressed, and information on community resources for fibromyalgia was provided.

The effects of the interventions were assessed on clinical outcomes and intervening variables, which served as potential mediators of treatment efficacy at pretreatment, post-treatment, and 6 month follow-up. The clinical outcomes included: a number of pain indices, including the pain scale of the Fibromyalgia Impact Questionnaire (FIQ) and a composite index; self-reported and observed pain behaviour; depression as measured by the CES-D; and disability measured by the quality of well-being scale. Intervening variables were helplessness, pain coping measured by the pain management inventory, and social support.

A total of 36 participants in the behavioural condition and 35 in the education/control condition completed all phases of the trial. All participants were diagnosed with fibromyalgia by their rheumatologist or primary care physician. Participants were excluded if they had concomitant rheumatologic conditions such as rheumatoid arthritis, or other serious illnesses such as cardiovascular disease or psychiatric disorders such as psychosis. Participants who used antidepressants were required to be stable on their medications for a minimum of 2 months prior to the study and to continue on that dosage throughout the clinical trial. In addition, participants were required to have a family member or friend (support person) who would be willing to participate in the study over the 10-week treatment period. After meeting exclusion and inclusion criteria, participants were blocked on antidepressant use and assigned to the treatment or control condition using a random numbers table.

Nicassio et al. (1997) found improvement across time on several clinical outcomes and mediating variables, but no differential effects between the behavioural and education/control conditions over the course of the trial. Significant reductions in depression, self-reported pain behaviour, observed pain behaviour, and myalgia scores occurred. However, factors such as

history, maturation, and testing could potentially have contributed to change in either condition. Pain, in contrast, did not decline across the trial. The reductions in depression and pain behaviours in both conditions may be indicative of the potential value of psychosocial treatments in treating mood disturbance and functional aspects of the disorder. Improvement in helplessness and the use of passive coping strategies also occurred over the course of the trial, and the two conditions did not differ in the degree of change on these variables. This suggests the existence of a common therapeutic process in both conditions. These improvements mediated the change in several clinical outcomes. Reductions in helplessness predicted improvement in pain and depression, whereas decrease in passive coping independently predicted change in self-reported pain behaviour. The finding that these variables were more highly correlated with improvement in clinical outcomes in the behavioural condition than in the education condition may reflect the association that was made between these factors and clinical change to participants in the behavioural condition (Nicassio et al., 1997). Nicassio et al. suggested that future psychosocial interventions for fibromyalgia should explicitly target the reduction of helplessness beliefs and maladaptive coping, as these may be instrumental to clinical change in fibromyalgia.

Buckelew et al. (1998) compared the effectiveness of biofeedback/relaxation training, exercise, and a combined program for the treatment of fibromyalgia. Participants were randomly assigned to one of 4 conditions: 1) biofeedback / relaxation training, 2) exercise training, 3) a combination treatment, or 4) an educational / attention-control program. Participants were assessed on a comprehensive range of outcome measures prior to treatment, immediately after the 6-week intervention, and at 3-month, 1-year, and 2-year follow-up. The biofeedback/relaxation training condition involved cognitive and muscular relaxation strategies and the application of these strategies to daily living. The intervention included didactics, self-monitoring, homework assignments, practice, and electromyogram biofeedback training to reduce muscle tension. The exercise condition involved motion exercises, strengthening, low to moderate aerobic exercise, and instruction on proper body mechanics. The combination condition involved participation in both the biofeedback/relaxation and exercise conditions. The educational/attention-control condition was designed to control for attention and time with a trainer. Participants in this condition received educational information regarding the diagnosis and treatment of fibromyalgia but no specific problem-solving strategies were taught.

A number of outcome measures were assessed, including, a tender point index, visual analogue scale for pain rating, arthritis impact measurement scales, depression, and self-efficacy. Results demonstrated that all 3 of the treatment conditions resulted in enhanced self-efficacy for function. Self-efficacy refers to the belief that one can competently cope with a challenging situation and has the ability to affect behaviour (Bandura, 1977). For example, people with high self-efficacy beliefs tend to persist with coping behaviours until successful. In contrast, individuals with low self-efficacy beliefs more quickly discontinue coping efforts because failure is anticipated (Buckelew et al., 1998). There were also significant between-group differences on tender point measures. This difference reflects a modest increase in impairment by the attention-control condition rather than improvements by the treatment conditions. There were no significant between-group pre- to post-treatment differences on self-report pain, pain behaviour, sleep, or psychological distress measures. Significant within-group effects for all three treatment conditions reflected modest improvements on pain and psychological distress measures. Participants as a group continued to have significant clinical symptoms of fibromyalgia, despite improvement in self-efficacy for managing symptoms. Only the combination condition maintained improvements on the self-efficacy for function measure at 2-year follow-up.

Buckelew and colleagues' (1998) study demonstrated that biofeedback/relaxation training and structured exercise programs produce short- and long-term benefits for persons with fibromyalgia in the areas of self-efficacy, disease severity, and physical activity. With the exception of the self-efficacy scores, the improvements were modest. Buckelew et al. suggested that future studies examine the relative benefits of exercise and psychologically based treatment interventions versus antidepressant medications to examine the underlying mechanisms of treatment efficacy, and to improve the long-term effectiveness of behavioural treatment programs for fibromyalgia.

Keel et al. (1998) examined the efficacy of an integrated psychological treatment program with 32 fibromyalgia patients. The treatment program consisted of instruction in cognitive-behavioural strategies, relaxation, and physical exercise. The control intervention was relaxation training. They hypothesized that comprehensive cognitive-behavioural training, to improve self-efficacy using various pain-control strategies, would lead to more substantial and longer-lasting improvements than would relaxation training without the comprehensive educational package.

The treatment program consisted of 15 weekly group sessions lasting 2 hours. Each session included: information, instruction in self-control strategies, gymnastics, relaxation, and group discussion. The group discussion was structured and focused mainly on the frequency and effects of the home exercises. A psychiatrist, psychologist, and physiotherapist led the sessions.

The control group was taught relaxation in 15 sessions lasting 45-60 minutes. A psychiatrist and a physiotherapist led the sessions. Patients were asked to practice relaxation at home in the same manner as patients in the treatment program.

Participants were assessed at pre-intervention, post-intervention, and at 3-month follow-up. A general symptom checklist was used to assess the clinical features of fibromyalgia, including symptoms of pain, nausea, and weakness. Sleep disturbance, changes in average pain intensity, and changes of concurrent treatment (i.e., use of medication) were assessed using daily diary entries. The participants' own judgment of the treatment program was also assessed by asking them to rate the degree to which particular treatment elements were helpful and the effectiveness of the entire program.

Three participants dropped out in the initial phase of treatment, one did not complete post-treatment assessment, and one patient's data was not used due to language barriers. Data from 27 of the 32 participants was analyzed; an intention-to-treat analysis was not conducted (please see pages 60-61 for a description of intention-to-treat). Clinically meaningful improvement was defined as at least a 50% improvement from baseline on four of six outcomes (medication use, physical therapies, sleep, pain, global assessment, and general symptoms). After treatment, clinically meaningful improvement was observed in two participants in the treatment condition compared to one control participant. At follow-up, four participants in the treatment condition improved compared to none in the control condition. However, this difference was not statistically significant.

The authors compared the participants who showed improvement to those who did not and found that the successful participants had a significantly shorter duration of pain (6 years vs. 15 years) and they tended to be more active before treatment. Keel et al. (1998) stated that the intervention was too weak for the majority of participants, and perhaps additional sessions would lead to improvement in more participants. The difference in duration of pain in the successful participants led them to conclude that early intervention is important for people with fibromyalgia.

The next set of studies that will be reviewed employed a no-treatment or wait-list controlled design.

Burckhardt, Mannerkorpi, Hedenberg, and Bjelle (1994) examined the effects of education and physical training in women with fibromyalgia. Participants were randomly assigned to one of three groups: a 6-week self-management education program, the education program plus physical training, or wait-list control. The education program consisted of six weekly 1 ½ hour classes. The classes included: information on fibromyalgia, the role of stress in the development and maintenance of symptoms, coping strategies, problem solving techniques, assertiveness training, relaxation strategies, and the importance of physical conditioning. Each session concluded with an individual contract for behaviour change for the upcoming week. Participants in the education plus physical training group received an hour of physical training after each education session. The training included stretching, range of motion exercise, pool therapy sessions, and time to develop a physical fitness training program of walking, swimming, or cycling.

The primary outcome was the total score from the FIQ. Additional outcome measures were: the Fibromyalgia Attitudes Index, the Quality of Life Scale (QOLS), the Self-Efficacy Scale, and the Beck Depression Inventory. Physical fitness and tender points were also assessed. Of the 99 participants who entered the study, data from 13 were not used in the analysis. Therefore, an intention-to-treat analysis was not conducted. There were no between-group differences on the total FIQ score from pre- to post-testing. In addition, there were no significant differences between the two treated groups on any of the outcome variables. Quality of life and self-efficacy (for other symptoms) improved from pre-to post-testing for both treated groups compared to the control group. For other aspects of self-efficacy, including self-efficacy for controlling pain, the group that received both education and physical training was significantly different from the control group. Significant within-group changes for the education only group included improvement on the fibromyalgia attitudes index, the days feeling bad subscale of the FIQ, self-efficacy (for other symptoms), and the myalgic score. The education plus physical training group also improved significantly on the fibromyalgia attitudes index but also on all three subscales of the self-efficacy scale. At follow-up, quality of life and self-efficacy (for pain and other) were significantly improved in the education plus physical training group.

Burckhardt et al. (1994) concluded that there is some indication that education alone and education with exercise benefit patients with fibromyalgia. They stated that the changes in self-efficacy were the most notable and are important due to evidence that changes in self-efficacy are enduring and affect changes in health behaviours and health status.

In a 4.5 year prospective study, Wigers, Stiles, and Vogel (1996) compared the effects of aerobic exercise, stress management treatment, and treatment-as-usual with 60 fibromyalgia patients. The exercise group received 45 minutes of aerobic exercise 3 times a week for 14 weeks. The stress management treatment was cognitive-behavioural in nature and was led by two clinical psychologists. The treatment included applied relaxation and an introduction to cognitive therapy in coping with psychological problems. Sessions were 90 minutes, twice a week, for the first 6 weeks and once a week for the remaining 8 weeks. Participants in the treatment-as-usual condition continued treatments that they had been using prior to entering the study. Treatments included aquatic therapy and medication.

Outcome measures included pain distribution, average intensity of pain, disturbed sleep, fatigue, and depression, tender points, exercise capacity, and global subjective improvement. Of the 60 participants enrolled, 44 completed the study. An intention-to-treat analysis was conducted. At post-treatment, the exercise condition showed significantly reduced pain distribution, tender point tenderness, and exercise capacity compared to the treatment-as-usual participants. The participants in the stress management treatment condition showed reduced tender point tenderness. They rated the relaxation skills as the most beneficial component of treatment. At follow-up, the only between-group difference was reduced tenderness in the stress management treatment condition compared to the treatment-as-usual condition. When the original data was analyzed instead of the intention-to-treat data, this difference was not significant. Based on the effects of the stress management treatment, the authors concluded that a psychological intervention using relaxation and cognitive techniques has beneficial short-term effects by reducing pain, tenderness, and depression. However, this conclusion is based on analysis of completers only, not analysis of the intention-to-treat data. Also, the authors concluded that the stress management treatment was successful with respect to long-term compliance; 69% of participants were still performing relaxation exercises 4 years later.

Mason, Goolkasian, and McCain (1998) compared the effects of a month-long multimodal treatment program for 11 female fibromyalgia outpatients to a control condition.

The control condition consisted of 12 fibromyalgia patients that could not participate in the program for insurance reasons. They completed the same assessment measures on the same schedule as the treatment condition but did not receive any intervention. The treatment program included a daily cognitive-behavioral class, focusing on education, relaxation, maladaptive pain behaviors, and cognitive distortions. The cognitions were challenged and the notion of replacing them with new mental strategies was discussed.

Measures obtained immediately after treatment demonstrated that the treatment condition's positive coping skills and sense of control over pain improved significantly, while use of negative strategies decreased significantly. The authors stated that the significant reduction in self-reported pain ratings indicated that patients felt greater control over their fibromyalgia pain and experienced considerable relief from that pain. Treated patients also reported much less anxiety and depression and had increased ability to accomplish functional tasks when compared to the control condition. However, the 6-month follow-up data demonstrated that the treatment gains were not maintained on a long-term basis. Although the treated patients continued to show a significant decrease in symptomatology, there was a trend toward pre-treatment levels on all measures except pain tolerance. This trend may be related to lack of practice of either coping skills and/or exercise regimen. The authors encouraged future researchers to emphasize relapse prevention and to encourage patients to continue to participate in regular support groups. They also suggested that follow-up studies evaluate the fibromyalgia patient's pain levels and emotional functioning 1 to 2 years after completion of treatment, and include measures of personal adherence to the program components.

Gowans, deHueck, Voss, and Richardson (1999) examined the effects of an exercise and educational program for patients with fibromyalgia. Participants were randomly assigned to a 6-week exercise and educational program or to a wait-list control group. In order to increase sample size, the control participants were entered into the intervention program after the initial 6-week phase and their data was added to the intervention group's data. The intervention program consisted of two exercise classes in a warm pool and two multidisciplinary educational sessions each week. The group educational sessions were 1-hour long and provided information on psychosocial coping strategies, exercise, sleep, relaxation, medication, and nutrition. The sessions included didactic lectures, interactive discussions, and teaching skills, for example, relaxation techniques.

Participants were assessed at pre- and post-intervention and at follow-up (6 months for the original intervention participants and 3 months for the control participants who later received treatment). Outcome measures included the ASES and the FIQ. Unfortunately, the total FIQ score was not analyzed. Physical function and knowledge of fibromyalgia management were also assessed. Between-group analyses showed that the exercise and educational program produced a significant increase in 6-minute walk distances, knowledge of fibromyalgia management, and sense of well-being (FIQ). There was also a significant decrease in morning fatigue (FIQ) compared to control participants. With the addition of the control participants' data (after receiving the intervention), significant improvements were observed in self-efficacy for pain and for controlling other symptoms (ASES). Improvements in well-being, self-efficacy, and walk distance were maintained at follow-up. However, gains in fatigue and knowledge of fibromyalgia management were not maintained.

The authors concluded that short-term exercise and educational programs can produce immediate gains in physical function, sense of well-being, and fatigue. Such programs may also produce immediate gains in self-efficacy (for controlling pain and other symptoms). In addition, gains in physical function, well-being, and self-efficacy can be maintained for up to 3 months. Gowans et al. (1999) note that these results were achieved with a sample that may be more disabled than samples used in other trials. They reported that their participants were largely unemployed, taking multiple medications, and were very deconditioned. Due to the combined exercise and educational intervention, it is not possible to determine whether these gains reflect the effect of exercise, education, or both. Comparing the intervention program to other treatments or to an attention/placebo control would assist in clarifying the contributions of various treatment modalities.

Nielson, Walker, and McCain (1992) employed a quasi-experimental design to assess the efficacy of a 3-week inpatient CBT program for fibromyalgia. The participants acted as their own wait-list control group prior to receiving treatment. Strictly speaking, there is a form of control group, however, the study is likely best classified as a single group uncontrolled trial (Burckhardt, 2006) and it is listed as such in Table 1. It is important to note, Nielson et al. (1992) incorporated a unique element to the design, that is, use of target and non-target variables. The intervention also consisted of cognitive restructuring techniques that can be compared to the

intervention in the current study. For these reasons, a review of the Nielson et al. (1992) study follows, whereas the remaining single group uncontrolled trials are listed in Table 1.

Nielson et al., (1992) employed a quasi-experimental design to assess the efficacy of a 3-week inpatient cognitive-behavioral treatment program for fibromyalgia. The primary goal of the program was to assist patients in developing an active and resourceful self-management approach to coping with their fibromyalgia (Nielson et al., 1992). Each individual received the following interventions: relaxation training, cognitive techniques, aerobic exercise and stretching, pacing and enhancement of pain tolerance, family education, and in vivo rehearsal. More specifically, the relaxation training involved progressive muscle relaxation, which was supplemented with biofeedback for individuals that had difficulty with relaxation. The cognitive techniques involved reconceptualization of pain as something over which the individual could exert some control. Restructuring techniques were also used to challenge negative cognitions and promote positive problem solving strategies.

Participants were assessed at two intervals before beginning the program, approximately 5 months prior and a second time at admission to the program. Post-assessment occurred at the conclusion of the 3-week program. Participants were assessed on a number of variables, including: experience of pain, impact of pain on life, pain behaviour, depression, and marital adjustment. Nielson et al. (1992) classified variables as 'target' or 'non-target'. They expected the target variables to reflect a response to the treatment, while the non-target variables were not expected to change in response to the treatment. Comparison of the pretest and posttest scores indicated that the target variables, such as pain severity, perceived interference with life, sense of control over pain, and emotional distress, showed statistically significant improvement. Nielson et al. (1992) also found that there was no statistically significant change in the non-target variables, such as perceived support by others, response by significant others to pain, marital adjustment, and activity level. The separation of target and non-target variables in an attempt to assess the potential impact of demand characteristics was a valuable component of this study. Because of the combined nature of the treatment it is not possible to determine the impact of particular components of the treatment program on the outcome measures. This is significant since the program consisted of some interventions that were not cognitive behavioural in nature, for example, the exercise component.

Nielson and colleagues (1992) used a small sample of 25 participants, thereby reducing the power of statistical tests. The quasi-experimental design used participants as their own waiting list controls. However, a formal control condition was not included; for example, attention-placebo control conditions have been recommended (Bradley & Alberts, 1999). Medication use, particularly antidepressants, was not controlled for in this study and the authors state that it is possible that medication accounted for some of the observed results. However, improvements in psychological outcome measures were not limited to those individuals taking antidepressants. The authors also suggested that future research include more sophisticated measures of function, for example, the FIQ.

White and Nielson (1995) conducted the first reported attempt to determine the long-term efficacy of a CBT program for the treatment of fibromyalgia. At a mean of 30 months after discharge, they assessed 22 of the 25 participants from the cognitive-behavioral treatment program described above (Nielson et al., 1992). Of the 10 target variables, the following 3 variables remained significantly different from pre-treatment levels: degree of worry, observed pain behavior, and sense of control over illness. In addition, all 10 target variables changed in the direction of improvement, while none of the non-target variables were significantly different between pre-treatment and long-term follow-up. White and Neilson suggested that randomized controlled trials be conducted in order to demonstrate the effectiveness of CBT alone and in combination with other treatment modalities.

In summary, a limited number of controlled studies have examined the effects of CBT on fibromyalgia. The available literature is limited statistically, to some extent, by small sample sizes. This reduces the power of the statistical tests. The literature is also limited by the analysis of a varied and large number of outcome variables. Also, few studies have examined relapse prevention, long-term follow-up, and measures of long-term compliance.

Integrative Psychotherapy Approaches

Before discussing integrative psychodynamic group therapy approaches to the treatment of chronic pain, it is helpful to examine a number of psychodynamic factors that are related to the chronic pain experience. A number of factors will be briefly reviewed prior to presenting two therapeutic approaches: supportive-expressive group therapy and integrative psychodynamic group therapy. Additional factors will be reviewed concurrently with the discussion of the therapeutic approaches, as they are clearly linked to the rationale of the approach.

Psychodynamic Themes and Chronic Pain

Grzesiak, Ury, and Dworkin (1996) highlight some of the psychodynamic themes that they have found useful in their work as psychotherapists with chronic pain patients. Childhood development and early experiences with pain and illness can be significant experiences. These experiences are not limited to traumatic experiences, but also include the behaviour of significant others, especially family members, and their influences on the child. For example, a parent with a chronic illness, or a pain condition, can have tremendous influence on the child with respect to the child's understanding of pain and illness and adaptation to these conditions. Both clinical observations and research have suggested that social modeling and early identifications with ill or disabled family members may play a role in the later development of a chronic pain syndrome (Adler, Zlot, Hurny, & Minder, 1989; Craig, 1978; Engel, 1959). Internalized relationships with parents and significant others are often not immediately accessible to conscious recall, but sometimes the experience and behaviour of a chronic pain patient can be associated with early experiences and exposure to the ways in which significant others have coped with pain and illness (Grzesiak et al., 1996).

Anger, helplessness, depression, and loss are central themes that are often relevant when working with people with chronic pain. Grzesiak et al. (1996) stated "the appropriate acceptance and management of anger constitute one of the central issues in psychotherapeutic work with chronic pain patients". Whale (1992) described a short-term psychotherapeutic approach to the treatment of chronic pain. The author stated that patients had to come to terms with their unadmitted and unaccepted anger over various losses in their lives. One source of anger is often the sense of helplessness that many patients feel as a result of persisting pain and physical limitations. According to Levine, Brooks, Irving, and Fishman (1993), it is the patient's intolerance of the affective experience of helplessness that needs to be addressed in psychotherapy.

The theme of depression may be played out in a number of ways in people with fibromyalgia. Krishnan, France, and Davidson (1988) suggested at least four possible relationships between pain and depression: 1) pain as a symptom of depression, 2) depression as a complication of chronic pain, 3) pain and depression inextricably linked, and 4) pain and depression coexist but may not be related. Experiences of loss and mourning are often integral aspects of depression in chronic pain patients (Grzesiak et al., 1996). Schoffermann et al. (1993)

found that mourning and dealing appropriately with losses were important components of adapting to pain or pain relief. Engel (1959) found that dealing with the loss of loved ones was frequently an important psychodynamic consideration in working with people with chronic pain.

Ercolani et al. (1994) assessed depression and illness behaviour in 327 people with fibromyalgia in Italy. Validated translations of the Center of Epidemiological Studies-Depression scale (CES-D) and the Illness Behaviour Questionnaire (IBQ) were administered. The CES-D was developed by the National Institute of Mental Health, USA, to measure depression in the general population. The IBQ was developed to study abnormal illness behaviour and includes the following scales: general hypochondriasis, disease conviction, and affective inhibition. It is a valid instrument to predict general hospital utilization and degree of somatization (Ercolani et al.). The IBQ helps to elicit the psychopathology of patients with somatic symptoms, particularly in the form of DSM-III-R somatoform pain disorders. For example, patients who score high on the disease conviction, psychological versus somatic focusing, and denial and affective disturbance scales tend to ascribe their personal and social difficulties to pain. In fact, pain is used to cope with difficulties and avoid psychological and social conflicts (Ercolani et al.).

Ercolani et al. (1994) examined whether the combination of depression and abnormal illness behaviour in fibromyalgia patients leads to serious difficulties in: doctor-patient relationships, the number and kind of treatments requested, and the results of treatment. The authors noted that depression observed in general medical practice differs from that observed in psychiatric practice. The former is associated with a lower frequency of suicide, while feelings of helplessness and anxiety are prevalent. There is also a tendency to accuse other people, especially medical staff, as opposed to self-accusation. Depression in general medical practice is also observed in the form of an increased reporting of somatic symptoms. Ercolani et al. argued that patients gain support from health services based on these somatic complaints, allowing them to establish “manipulative interpersonal relationships.” Ercolani et al. described another aspect of illness behaviour whereby manipulative conduct of chronic pain patients is described as a demand for medical care, denigration of received treatments, protests against ineffectiveness, and requests for more suitable treatments. This behaviour, especially in people with fibromyalgia, may in part be based on the frustrations associated with suffering with an illness that does not have a known diagnostic test or ‘cure.’ Fibromyalgia patients may have a greater tendency to

attempt to gain support, or to protest, since they generally do not feel supported based on the difficulties associated with the somewhat controversial nature of the syndrome. These tendencies highlight the contribution that interpersonal psychotherapy can offer to the treatment of fibromyalgia.

Those chronic pain patients who are convinced of the severity of their illness despite medical reassurance, and who find it difficult to express emotion, experience more disabling pain. Ercolani et al. (1994) stated that they exhibit “misadaptive behaviour” that is related but not proportionate to the disease, but is a function of cognitive and affective disturbance rather than physical illness. The belief that the illness is severe despite medical reassurance is likely related to difficulty trusting others, especially when in a vulnerable position. Difficulty with trust and with expressing emotion can be addressed by interpersonal psychotherapy approaches.

An additional theme is that of pain as an affect, which was first addressed by Fenichel (1945). The approach requires the psychotherapist to work with the pain patient to explore and interpret personal meanings related to pain and the functions that the emotion of pain may be serving for the individual. “Such psychotherapeutic explorations of the meaning of pain are relevant, regardless of the relative roles played by organic and psychosocial factors in accounting for the patient’s experience of pain” (p. 160). Although psychological symptoms are present in a proportion of fibromyalgia patients, the question remains, ‘what is the role of psychological symptoms in the clinical picture of fibromyalgia?’ In other words, regardless of the causal influence that psychological variables may or may not play in fibromyalgia, it is important to examine the effect these variables have on patients’ ability to cope and to function interpersonally.

Supportive-Expressive Group Psychotherapy

Spiegel has developed a model of supportive-expressive group psychotherapy which is an integrative model built upon Yalom’s interpersonal process oriented work (M. Leszcz, personal communication, 2003; I. Yalom, personal communication, 2003). Although this model of psychotherapy has not, to my knowledge, been applied to a fibromyalgia population, it has been applied to chronic illness populations including cancer and lupus. Lupus and fibromyalgia are both rheumatologic conditions and share some similarities; therefore, some of the findings from the following study may be helpful in informing interventions for fibromyalgia. However, it is important to consider the differences between the illnesses and not overgeneralize.

Edworthy et al. (2003) investigated whether brief supportive-expressive group psychotherapy might reduce illness-induced interference with valued activities and interests (i.e., illness intrusiveness) among women with systemic lupus erythematosus (SLE). The psychotherapy focused specifically on interpersonal relationships and how to maximize them adaptively despite the constraints imposed by chronic disease. Reduction in illness intrusiveness was examined in relation to three life domains: 1) relationships and personal development (family relationships, other social relationships, self-expression), 2) intimacy (relationship with spouse, sex life), and/or 3) instrumental life (work, finances, active recreation). Fifty-eight women participated in the group psychotherapy sessions while 66 women were assigned to a usual-care control condition. Twelve group sessions, conducted weekly, were provided to the intervention group. Three monthly 'booster sessions' were offered following the termination of intensive treatment to reinforce changes and to encourage the transfer of new experiences into daily life. The primary outcome measures were administered on four occasions: 1) prior to the intervention, 2) immediately post-intervention, 3) 6 months later, and 4) at the final 12-month follow-up occasion. The variables assessed included illness intrusiveness, disease activity and disease damage, and psychological symptoms as measured by the Symptom Checklist 90-R (SCL90-R).

Edworthy et al. (2003) stated that, in many cases, effective coping involves distracting oneself from psychosocial threats or other stressors in order to carry on with life. This can be adaptive when the problems cannot be controlled or eliminated, and the most effective response is to focus on day-to-day challenges. Issues that were associated with significant psychological pain at an earlier point in the disease experience may thus decrease in salience. However, the destructive effect of these issues may be reactivated. For example, when in good health people may be insensitive to others affected by chronic illness but feel guilty about this after the onset of their own illness. Such unresolved conflicts and concerns may threaten psychological well-being repeatedly over the years. Group psychotherapy, according to Edworthy et al., may be especially helpful in relation to such stressors because it assists people in recognizing these issues and in resolving them effectively. However, participation in group psychotherapy may initially be unpleasant if the process temporarily increases awareness of issues that have previously been suppressed.

Edworthy et al.'s (2003) findings following therapy for women with SLE are consistent with the notion that therapy is initially challenging and improvements may not be observed early in the process. The benefits of the group psychotherapy intervention included reduced illness intrusiveness, but this did not emerge until well after the termination of therapy and was not evident until the 6-month follow-up. The reductions were statistically significant by the 6-month follow-up and these reductions were intensified by the 12-month follow-up. The reduced illness intrusiveness was observed in two of the domains, relationships and personal development, and intimacy. This supports the position that women are especially responsive to stressors that arise in domains of life that involve relationships with others as compared to instrumental domains such as work and finances (Gillespie & Eisler, 1992). Edworthy et al. suggested that the key to effective psychological interventions, therefore, may depend on a careful matching of therapeutic processes with the particular vulnerabilities of those affected by the illness. In addition, demonstration of the effectiveness of therapy also depends on the selection of measurement instruments that are sufficiently focused and sensitive.

Integrative Psychodynamic Psychotherapy

There is a subsample of chronic pain patients who fail to benefit from every existing treatment for chronic pain, no matter how efficacious it is (Grzesiak et al., 1996). These patients may benefit initially but return to pretreatment levels of pain, suffering, and disability. Grzesiak et al. argued that psychosocial factors play a role in the development of chronic pain, and some of the psychological factors that have been implicated are unlikely to respond to the relatively short-term psychological interventions that now constitute the standard of care for chronic pain patients (e.g. CBT). This integrative psychotherapeutic approach to the individual with chronic pain emphasizes the importance of “integrating behavioural strategies and cognitive techniques within a psychodynamic perspective that values the importance of developmental history, intrapsychic conflict, interpersonal difficulties, and failure to adapt to chronic illness and persisting pain” (p. 148).

The importance of customizing treatment for people with chronic pain is emphasized in the literature. Turk (1996) has emphasized the importance of examining the biological, psychological, and social processes that operate for each individual patient, and then designing a treatment program to address the relevant and individualized problem areas. Grzesiak et al. (1996) stated that chronic pain patients differ based on a number of individual factors, including:

personality, character, premorbid level of adaptation, capacity to cope with adversity, and varying degrees of resourcefulness and resilience. They argue that differences in personality should form part of the foundation for customizing psychological treatment. The interpersonal component of the manualized treatment proposed in this thesis allows for the expression of personality characteristics and interpersonal patterns to a greater extent than the cognitive-behavioural component of the treatment. The interpersonal component allows for greater customization of treatment. Although the treatment is conducted in a group, the interpersonal component provides opportunity for each participant to express personality traits through interaction with group members and the therapist. These personality traits and styles of interpersonal relating are factors that can affect the individual's ability to cope with fibromyalgia.

The concept of pain-proneness, or vulnerability to suffering, is important in understanding the potential role of psychodynamically-oriented psychotherapy in the management of chronic pain (Grzesiak et al., 1996). Pain-proneness, introduced by Engel (1959), is an unconscious process that has its origins in negative early life experiences such as trauma, loss, and abandonment. These experiences lay a foundation of vulnerability to pain-proneness and psychic suffering. Grzesiak et al. (1996) stated that, in many cases, these unconscious factors lie dormant until life events, such as physical or psychic trauma or illness, provide an opportunity for the expression of these hidden conflicts. The authors argued that it is often not pain, but suffering, that poses the primary problem for chronic pain patients. For example, Harness and Donlon (1988) presented two cases of facial pain that were initially unresponsive to treatment. It was not until the patients developed a strong therapeutic alliance with their therapists that they were able to disclose that they had been physically abused. Following their disclosure of abuse the facial pain abated.

Another characteristic that is important in understanding the potential role of psychodynamically-oriented psychotherapy in the management of chronic pain has been labeled 'ergomania'. Ergomania is a conflicted work ethic that is believed to be an important characteristic of many chronic pain patients (Blumer & Heilbronn, 1989). The authors suggested that ergomaniac pain patients have a history of excessive work performance, relentless activity, and self-sacrifice. These patients also have marked difficulty trusting caretakers, including health providers. In a study examining proposed antecedents of chronic pain, Gamsa and Vikis-

Freibergs (1991) found that ergomania was one of only two psychological variables that were consistently associated with pain, the other being emotional repression. Grzesiak et al. (1996) have observed in clinical practice that many people with chronic pain have the premorbid characteristics of ergomania.

Grzesiak et al. (1996) are not suggesting that chronic pain has a psychogenic origin. Rather, the authors believe that the source of chronic pain is a combination of biological, psychological, and social factors, which is consistent with the biopsychosocial model. They suggested that individuals who have suffered from early trauma are more likely to develop a chronic pain syndrome in response to physical pathology. Early developmental trauma and the personality traits associated with it provide a vulnerability to pain and suffering that, in the presence of current disease or injury, compromises the patient's ability to adapt to the sick role, to rely appropriately on health care providers, and to regain health or make a reasonable adjustment to changes in physical functioning.

Trauma and Fibromyalgia

Based on Grzesiak et al.'s (1996) argument that early developmental trauma and associated personality traits create a vulnerability to pain and, hence, a compromised ability to cope, it is useful to examine literature regarding trauma and fibromyalgia.

Anderberg, Marteinsdottir, Theorell, and Knorring (2000) examined negative life events in female fibromyalgia patients and in healthy controls matched for age and socioeconomic status. Although 'negative life events' may not constitute 'trauma', it can be argued that experiencing an event as traumatic is a subjective perception. Anderberg et al. found that 51% of the fibromyalgia patients had experienced very negative life events as compared to 28% of the controls. Conflict with parents was the most common life event. Before onset, 65% of the patients experienced some negative life event; economic problems and conflicts with husband/partner were common. Also, the life events were experienced as more negative by the fibromyalgia patients than the life events experienced by healthy controls.

Turk et al. (1996) investigated the differences between two types of symptom onset in patients with fibromyalgia: post-traumatic versus idiopathic onset. Symptoms of fibromyalgia occur either following a specific incident (motor vehicle accident, surgery, flu), which is referred to as post-traumatic or reactive; or the symptoms are attributed to an insidious or spontaneous onset with no identifiable precipitating event, referred to as idiopathic. Turk et al. examined

whether type of onset has any specific effect on the adjustment of fibromyalgia patients to their chronic conditions in physical, medical, and psychological domains. The clinical severity of post-traumatic chronic pain may be exacerbated in the presence of persistent, adverse effects of physical injuries. If so, it may be that post-traumatic chronic pain patients will present with greater psychological distress and disability. For example, Greenfield, Fitzcharles, and Esdaile (1992) found that patients with traumatic onset tended to be more impaired socially, financially, and functionally than patients with idiopathic fibromyalgia. Indeed, preliminary results from a number of studies (Turk & Okifuji, 1996; Waylonis & Perkins, 1994) suggest that there might be some specific factors that are uniquely related to fibromyalgia with traumatic onset. On the other hand, pain conditions with idiopathic onset generally lack 'justification' for their pain complaints in the absence of an identifiable incident. This leads some to question the veracity of a patient's complaints, which may aggravate psychological distress. Thus, psychological distress might be expected to be greater for those without an identified trauma. In this case, the distress would be a reaction to the symptoms and to the suggestion that the pain is not real or is exaggerated for secondary gain. In an effort to clarify these issues, Turk et al. (1996) found that patients with traumatic onset reported significantly higher levels of pain severity, perceived disability, affective distress, and life interference as well as lower level of activity, compared to the patients with idiopathic onset. These results are consistent with the results of Geisser, Roth, Bachman, and Eckert (1996) for chronic pain in general and those of Greenfield et al. (1992) for fibromyalgia. The findings were demonstrated even when compensation status, a potential mediator, was controlled. Similarly, the differences between the two onset groups cannot be attributed to the differences in physical abnormalities. Thus, pain severity and disability may not be determined solely on the basis of physical pathology. Results suggest heterogeneity of the fibromyalgia population. The need to identify subgroups of fibromyalgia patients has been argued by others (Turk & Flor, 1987; Turk et al., 1996). Identification of subgroups will help to develop efficient and cost effective treatments for fibromyalgia.

Aaron et al. (1997) examined the relation between perceived physical and emotional trauma and health-care seeking in patients with fibromyalgia. The researchers compared 80 patients with fibromyalgia who had sought treatment, with 33 non-patients who had not sought treatment for their muscular aches and pains in the last 10 years, but met criteria for fibromyalgia upon assessment. Aaron et al. found that only events perceived as emotionally traumatic (e.g.

family member death or illness) significantly differentiated patients who had sought care for fibromyalgia in a tertiary care rheumatology practice from non-patients. Neither physical trauma nor sexual or physical abuse was related to seeking treatment. Patients with a history of emotional trauma also reported making a significantly greater number of physician visits related to fibromyalgia symptoms in the preceding 6 months than did patients with physical trauma or no trauma history. These findings are consistent with a number of studies indicating that perceived stressful life events and reports of emotional distress predict health care-seeking behaviour in the general population and in patients with rheumatic diseases (Bradley & Alberts, 1999). Aaron et al. also found, using the FIQ, that emotional trauma was associated with reports of greater functional disability than was either physical trauma or no trauma. This finding illuminates the importance of tailoring psychological interventions for fibromyalgia to address emotional trauma in addition to addressing cognitive and behavioural components, since emotional trauma appears to be linked to patients' experience of functional disability. Aaron et al. hypothesized that the high ratings of functional disability among fibromyalgia patients with perceived emotional trauma may be related to the higher levels of fatigue reported by these patients. Indeed, the fatigue ratings of the fibromyalgia patients in this study exceeded those of patients with lupus, and the highest mean fatigue levels were among those fibromyalgia patients with a history of emotional trauma. No differences in pain threshold levels or in current pain intensity were found as a function of trauma history. The results of this study reveal the importance of examining trauma history and of tailoring psychotherapeutic interventions to address emotional trauma. It is possible that interventions that specifically address emotional trauma may have an impact on post-treatment measures of fatigue and functioning.

An additional subtype of trauma history has been assessed among chronic pain patients. Finestone et al. (2000) examined chronic pain and health care utilization in women with a history of childhood sexual abuse. Findings demonstrate a higher incidence of current chronic pain in the women with a history of sexual abuse compared to two control groups (nurses and psychiatric controls). Also, women with a history of childhood sexual abuse reported a greater number of painful points over their bodies and reported that the pain was present over larger areas of their bodies than controls. A statistically significant number of the women with a history of childhood sexual abuse stated that they had been diagnosed with fibromyalgia. However, Taylor, Trotter, and Csuka (1995) did not find a significantly higher prevalence of

childhood sexual abuse in women with fibromyalgia compared to a community sample, although they found that individuals with fibromyalgia who report sexual abuse had a greater severity of illness than those fibromyalgia patients not reporting sexual abuse. Finestone et al. suggested that the medical community could profit from supportive literature embracing the concept that dealing with issues of childhood sexual abuse in adulthood can have a positive medical benefit.

In summary, the supportive-expressive and integrative psychodynamic approaches can contribute unique therapeutic components to current psychological treatments for fibromyalgia. Research suggests that the focus on interpersonal relationships and how to maximize their benefits and minimize their interference on coping, despite the constraints imposed by chronic disease, is a critical component of effective treatment. Importantly, these areas are generally not addressed by CBT. Therefore, incorporating aspects of integrative group psychotherapy into a treatment for fibromyalgia would likely be a useful addition to the cognitive-behavioural model. Based on the positive results obtained by CBT with a number of chronic pain conditions, such as rheumatoid arthritis, it seems necessary to supplement the cognitive-behavioural model with additional treatment components, rather than replace it. Supplementing the cognitive-behavioural approach seems necessary since the well-designed randomized controlled trials of CBT for fibromyalgia have yielded modest results.

The current study will investigate the efficacy of a manualized cognitive-behavioural and interpersonal approach to the treatment of fibromyalgia. Efficacy trials test whether a program does more good than harm when delivered under optimum conditions. Such trials often include strong controls, standardization of programs, and narrowly defined target audiences. Effectiveness trials, on the other hand, test a program under real-world conditions. A randomized controlled design using pre- and post-intervention measures of pain and psychological and physical functioning will be employed. Also, because previous studies have identified the importance of follow-up, this study will follow and assess patients after the intervention.

Method

Participants

Adult women with fibromyalgia, as diagnosed by a rheumatologist, were recruited from Saskatoon, Prince Albert, and surrounding areas in Saskatchewan. One hundred and fifty-seven women contacted the investigator to inquire about the study. The majority of patients were

recruited through posters placed in the community advertising the study, letters sent to patients of Dr. Janet Markland, a rheumatologist in Saskatoon, and through an article in the newspaper. See Appendix B for a complete description of recruitment efforts and procedures.

Because of the differential prevalence rates of fibromyalgia in women compared to men, (Wolfe et al., 1995), there would be potential for unequal male/female ratios in the groups which could act as a confounding variable. Therefore, only women were eligible for participation in the current study. Those patients with organic brain disorders, psychotic disorders, DSM-IV axis II pathology, or substance abuse problems were ineligible for participation.

One hundred and fifty-seven women inquired about the study. Thirty-nine women chose not to participate, or were ineligible because they could not confirm that they were diagnosed with fibromyalgia by a rheumatologist. Therefore, they did not attend the intake assessment. Reasons for not participating included: time constraints, distance to travel, lack of transportation, or being asymptomatic, too unwell due to other health problems, involved in another program, or uncomfortable in a group setting. Please see Appendix C for a flowchart based on the Consolidated Standards of Reporting Trials (CONSORT). The flowchart depicts the passage of participants through the study (Moher, Schulz, & Altman, 2001). Thirteen women, who were initially interested in the study and did attend the intake assessment, did not participate in the study and were not randomized. Two of the thirteen were ineligible, one due to substance abuse and one due to a language barrier. Two were eligible but felt that they were too unwell to participate due to other health problems, including visual impairment. Reasons for not participating, provided by the remaining 9 of 13 women, included: time constraints, difficulty with transportation, or uncertainty about what they could gain from the study.

A total of 105 women participated in the study. Demographic information, including age, marital status, and ethnicity, can be found in Table 2. Six women withdrew from the study, five from the treatment condition, and one from the control condition. Reasons included: family emergency, death in the family, illness of a family member, and discomfort in the group. Four women did not drop out of the study, but they missed more than two of eight treatment sessions. Reasons for missing sessions included: conflicting medical appointments, migraine headaches, fatigue, and being busy. Prior to starting the treatment, participants were informed that it was very important to attend at least 6 of 8 sessions and the first and last sessions were mandatory. If they missed more than 2 sessions, it was thought that they could not benefit maximally from the

treatment and it was unfair to others who made the commitment to attend regularly. One participant did complete the treatment but she had a significant hearing impairment. During the course of treatment it became apparent that she did not hear a substantial portion of the information and discussion and, as a result, she likely was not able to participate fully or benefit from the treatment to the fullest extent possible. Nevertheless, all 105 participants' data were used in the analysis. This is a conservative approach, since those participants who missed more than 2 sessions and the participant with the hearing impairment could have been excluded from the analysis. Using the data only from participants who precisely followed protocol, however, would likely not be an accurate reflection of treatment outcomes that would be expected if the treatment were run in a community setting.

Measures

Participants were assessed on a variety of outcome measures at pre-intervention (time 1), post-intervention (time 2), and 1- and 3-month follow-up (time 3 and time 4 respectively). The measures have been utilized in a number of fibromyalgia intervention studies, thereby improving comparability of results (see Table 1). The primary outcome is fibromyalgia impact and a number of secondary outcomes were also measured. Only those measures with demonstrated reliability and validity were used to assess behavioral and psychological variables, unless otherwise specified. For example, in some instances single items are used in addition to subscales or scales. In some cases, a single item reflects a different aspect of a construct and, therefore, can add to our understanding of the effect of treatment on various dimensions of the construct. Tender points were not assessed because a qualified person was not available to conduct standardized tender point assessments for each participant at multiple time periods throughout the study.

Fibromyalgia Impact Questionnaire (FIQ). The FIQ is a brief 20-item self-administered instrument that measures the impact of fibromyalgia, physical functioning, workdays missed, depression, anxiety, sleep, pain, stiffness, fatigue, and well-being (see Appendix D). Responses to the first set of items are given on a Likert scale, ranging from 0 representing 'always able to do' to 3 representing 'never able to do'. The next two items ask patients to circle the number of days in the past week that they felt good and the number of days that they missed work. Responses to the last 7 items are given by marking a category or point on a 100 mm anchored visual analog scale (Burckhardt, Clark, & Bennett, 1991). In a study examining responsiveness

of fibromyalgia clinical outcome measures, Dunkl, Taylor, McConnell, and Alfano (2000) concluded that the FIQ was the most responsive measure to perceived clinical improvement and recommend its inclusion as a primary endpoint in FM clinical trials.

Numerical pain rating scale (NPRS). The NPRS was used to measure pain intensity, frequency, and duration (see Appendix E). The pain intensity rating is a composite of current, worst, least, and average (last 2 weeks) pain intensity ratings. Each of which were rated on a 0-100 scale. The composite was the sum of these four ratings, with a potential range of 0-400. According to Jensen, Turner, Romano, and Fisher (1999), a composite rating should be used rather than an individual 0-100 rating of pain intensity when maximal reliability is necessary, i.e., small sample sizes. Jensen et al. state that 0-100 ratings have sufficient psychometric strengths to be used in chronic pain research. Frequency of pain was measured by indicating ‘the number of days in the past week with pain’ (0-7) and duration of pain was measured by indicating ‘the longest period of non-stop or continuous pain in past week’ (rated in minutes, hours, or days, then converted to hours for analysis).

Chronic Disease Questionnaire (CDQ) – Stanford Patient Education Research Center, Stanford University School of Medicine. This questionnaire assesses a number of variables that are important for evaluation in chronic disease research, including: demographic data, health behaviour, health status, health care utilization, and self-efficacy. The CDQ includes the following disability measure and self-efficacy measure:

Health Assessment Questionnaire – 8 Item Disability (HAQ). The HAQ assesses health status and is available in a number of versions, including a long or short form and a disability scale. In the current study, the 8-item (short) disability scale was used (see Appendix F, items 12a-h). The HAQ was developed by the Stanford Patient Education Research Center as a measure of physical disability, not a measure of activities of daily living. Patients rate their level of ability on functional tasks from ‘without any difficulty’ to ‘unable to do.’ Lorig, Sobel, Ritter, Laurent, and Hobbs (2001) reported that the internal consistency reliability of the 8 item HAQ is 0.85.

Arthritis Self-Efficacy – 8 Item Scale (ASES). This instrument measures participant’s self-efficacy for controlling arthritis symptoms (Lorig, Chastain, Ung, Shoor, & Holman, 1989; see Appendix F, items 13a-h). The scale has been applied to fibromyalgia populations by substituting the word ‘fibromyalgia’ for ‘arthritis’ where applicable, which was done in the

current study (Gowans, deHueck, & Richardson, 1999; Lorig et al., 1989). Items include, “how certain are you that you can decrease your pain quite a bit?” Items are rated on a scale from 1, representing ‘very uncertain,’ to 10, representing ‘very certain.’ The ASES met reasonable standards for construct and concurrent validity and test-retest reliability. Lorig et al. report that the internal consistency reliability for the Arthritis Self-Efficacy – 8 Item scale is 0.92.

Symptom Checklist 90-R (SCL90-R). Depression and anxiety were measured using this 90-item questionnaire (see Appendix G). The SCL90-R assesses the presence of a variety of symptoms, including: depression, anxiety, somatization, and interpersonal sensitivity. Each item is rated on a 5-point Likert scale, ranging from 0 representing ‘not at all’ to 4 representing ‘extremely’. Adequate test-retest reliability and internal consistency have been documented (Derogatis, 1977). The SCL90-R has good reliability and validity (Derogatis, 1994).

Chronic Pain Coping Inventory (CPCI). The CPCI is a 65-item questionnaire, measuring 11 pain coping dimensions (see Appendix H). There are six illness-focused responses (e.g. guarding and resting), four wellness-focused responses (e.g. relaxation or task persistence), and one involving support from others (seeking social support). Responses are based on the number of days (0-7) that the person implemented a coping strategy. For example, participants select the number of days in the past week that they “imagined calming or distracting images to help relax,” or “avoided activity” with the intention of coping with pain (Jensen, Turner, Romano, & Strom, 1995). Hadjistavropoulos, MacLeod, and Asmundson (1999) suggested that the CPCI is a valuable tool, above and beyond established coping measures, in the clinical assessment and research of pain. Tan, Nguyen, Anderson, Jensen, and Thornby (2005) further validated the CPCI after conducting a confirmatory factor analysis. The results strongly support the factor structure and the predictive validity of the CPCI scales, as indicated by their association with measures of patient adjustment to chronic pain.

Quality of life (QOLS). This instrument measures participant’s satisfaction with areas of physical and mental well-being (Flanagan, 1978; see Appendix I). This measure is important, as it allows us to determine improvements outside of pain and coping related areas (e.g., happiness in marital relations). The QOLS is a 15-item questionnaire and the items are rated on a 7-point Likert scale, ranging from 1 (terrible), to 7 (delighted). Burckhardt, Woods, Schultz, and Ziebarth (1989) stated that the QOLS is a conceptually clear and content-valid instrument, with positive psychometric properties.

Procedure

This study includes the construction of a cognitive-behavioural and interpersonal group therapy intervention for the treatment of fibromyalgia. The intervention is presented in manual form, in order to ensure that the group sessions are presented to all participants in a standardized manner (see Appendix J for the manual). The manual may also serve as a resource for other investigators who wish to replicate, or refine, the group therapy intervention.

Manual Construction

Construction of the manual was based on an extensive review of existing psychological treatments for fibromyalgia. Francis Keefe developed a cognitive-behavioural manual for chronic pain, which has been identified as an empirically supported treatment for chronic pain by the Task Force on Empirically Supported Treatments, Section on Clinical Psychology of the Canadian Psychological Association. Keefe's manual acted as the foundation for the manual constructed in this study. CBT for chronic pain, described by Philips and Rachman (1996) and Wilson and Pancyr (revised 2001), were also primary resources upon which the manual was based. During the construction of the manual, a number of researchers and authors were consulted (personal communication, 2002: L. A. Bradley; L. Mason; J. Parker; D. Bakal; P. C. Nielson). The information gained by examining existing treatments and by consulting with various professionals was critical. In addition, practical information was sought that would prove beneficial to the construction of the manual. For example, the author of the manual (Melanie Langford) co-facilitated a CBT group, offered by the Clinical Health Psychology Department of the Royal University Hospital, Saskatoon, Saskatchewan. Laurene Wilson, Ph.D., led the treatment along with psychology intern, Nelson Byrne, M.A. The clinical experience, supervision, and consultation gained through this experience provided rich information that informed the construction of the manual. In addition, Dr. Wilson reviewed the manual and provided detailed feedback, which was used to improve subsequent drafts. A brief description of each session follows.

Session 1. The first session begins with an introduction and an overview of the treatment, followed by a description of fibromyalgia, a review of gate control theory, and an introduction to the formative phase of the interpersonal component.

Session 2. The second session provides a review of sleep difficulties and strategies to improve sleep. Relaxation techniques are also presented. The formative phase of the interpersonal component is continued.

Session 3. The third session provides a rationale for coping skills, and expands on relaxation strategies. The reactive phase of the interpersonal component begins.

Session 4. The fourth session begins with a review of relaxation strategies, and introduces new coping skills. The reactive phase of the interpersonal component is continued.

Session 5. The fifth session presents additional coping strategies, and introduces the topic of identifying and changing cognitions. The reactive phase is continued.

Session 6. The sixth session reviews cognitive techniques, introduces new coping skills, and the mature phase of the interpersonal component begins.

Session 7. The seventh session focuses on the application of coping skills, and provides problem-solving techniques. The termination phase of the interpersonal component begins.

Session 8. The last session provides a review of progress, and a plan for maintaining progress is provided. The termination phase continues and the main theme revolves around saying good-bye.

In accordance with the intervention manual, cognitive-behavioural and interpersonal therapy groups were conducted. Each group, consisting of 4 to 10 patients, met for 8 sessions of 2-hours over an 8-week period.

The study also included an attention-control condition. A number of studies to date have been uncontrolled, or employ a wait list control condition. An attention-control condition can improve upon the wait-list or standard care conditions, because it is more similar to the treatment condition. Some factors are shared between the treatment and control condition, which improves the ability to draw conclusions regarding the effects of treatment. If a wait list control condition was used in the current study, for example, it could be argued that the treatment participants benefited from attention and compassion from the researcher, whereas the control participants would have minimal contact with the researcher. As such, an attention-control condition was used, in which the investigator contacted each participant by phone over the course of the 8 weeks of treatment.

Random Assignment

After providing consent, participants were randomized to the treatment condition, or the attention-control condition. (Please see Appendix K for consent forms, debriefing forms, and ethics approval). Participants completed the NPRS after providing consent, and the total pain score was used to match participants into pairs in order to reduce the chance of pre-existing differences between conditions. For example, two participants with scores of 200 were matched, or two participants with the scores that were closest together, such as 195 and 190, were matched. A coin was tossed to determine which member of the matched pair would be assigned to the treatment condition, and which would be assigned to the control condition. As a result of this procedure, participants were randomly assigned and the treatment and respective control participants had similar total pain scores. This pain data was not used for the pre-treatment data, since it was collected at variable lengths of time prior to starting the treatment or control intervention. The pre-treatment data were collected on the first day of treatment for the treatment condition, and within 2 days of that for the control condition. Identification numbers were used, rather than names, to ensure that the investigator was not aware of the condition to which a particular participant was being assigned.

Data Collection

The pre-treatment data were collected from the participants in the treatment condition on site, at the University of Saskatchewan, on the same day as the first group session began. The data were collected from the attention-control participants on site as close to the same date as possible that the treatment condition began the first session. Generally, it was within 2 days, in order to minimize potentially confounding effects such as weather, or current events that could impact mood or pain. Completion time for the questionnaires ranged from approximately 40 minutes to 1.5 hours. Participants completed the forms either in isolation, but were checked on periodically by the investigator, or in a group, where they were supervised in order to avoid discussion and potential bias of results.

The post-treatment data were collected from the participants in the treatment condition on site, on the day of the last group session, immediately following conclusion of the group. The data were collected from the attention-control participants as close to the same date as possible, either on site or by mail when necessary. All participants were encouraged to complete the forms on site whenever possible at all time periods. However, questionnaires were mailed out when necessary in order to increase the number of participants completing the data. If

participants were required to come to the university each time, data would have been lost, as many people were not prepared to do so.

Study 1. The intervention was first pilot tested with a group of five participants. They were assessed using the procedures outlined above, and feedback was solicited regarding the delivery of the intervention. Anonymous qualitative feedback was requested in order to improve the intervention or make any necessary changes. Feedback was positive overall, and no substantial changes were necessary to the treatment, handouts, or protocol. The assessments measures were administered at pre- and post-intervention and at 1- and 3-month follow-up.

Study 2. The intervention was subsequently administered with approximately half of the group of eligible participants, while the other half of the participants were in the attention-control condition. There were 7 different treatment groups, and 7 respective control groups, in addition to the pilot study treatment group. The number of participants in the treatment groups ranged from five to ten, with an average of six to seven. Treatment participants attended weekly 2-hour sessions, at the University of Saskatchewan, for 8 consecutive weeks (with the exception of one group that was conducted in Prince Albert). Control participants were contacted weekly by telephone by the primary investigator for the same 8-week period. Conversations lasted between 10 and 15 minutes, and the investigator asked scripted questions regarding fibromyalgia symptoms, the effects of symptoms on daily living and interpersonal situations, and coping strategies (see Appendix L for protocol). The investigator did not provide education or coping strategies to the control participants.

Each treatment session involved two components. The first 45 minutes of each treatment session was cognitive-behavioural in nature and was led by the primary investigator (Melanie Langford). The room was set up in a classroom style with a large table in the center and chairs around the perimeter. The investigator/therapist stood at the front of the room and presented information using slides (both verbal and pictorial). The therapist also facilitated discussion and led exercises, for example, relaxation exercises. After the 45 minutes of CBT, participants had a brief break, (5-10 minutes), and proceeded to a therapy room on another floor of the building (this was not the case for the Prince Albert group). It was thought that the transition from CBT to interpersonal therapy could be difficult. Therefore, the environment was purposefully adjusted to represent, and hopefully facilitate, a transition. The therapist facilitating the interpersonal therapy component of each session was not the same as the cognitive-behavioural

therapist. It would be difficult for participants to adjust to a different form of therapy if the same therapist facilitated both components. The same person facilitated all sessions of the interpersonal groups for all 8-treatment groups (Ms. Tarah Hook, PhD student in Clinical Psychology). The interpersonal therapy room was not a classroom, but rather it was designed as a group therapy room. The interpersonal component of each session was also 45 minutes in duration.

Primary Outcome

H1) Fibromyalgia impact. It is expected that the treatment condition's fibromyalgia impact scores will significantly improve (decrease) from time 1 to time 2, while the control condition's scores will not. The change in the treatment condition will be maintained from time 2 to time 4, while the control condition's scores will not change.

Secondary Outcomes

For the following variables, it is expected that scores in the treatment condition will significantly improve (decrease) from time 1 to time 2, while scores in the control condition will not. It is also expected that the change in the treatment condition will be maintained from time 2 to time 4, while the scores in the control condition will not change.

H2) Pain (intensity, frequency, and duration)

H3) Functional disability

H4) Workdays missed

H5) Health care utilization

H6) Depression

H7) Anxiety

For the following variables, it is expected that scores in the treatment condition will significantly improve (increase) from time 1 to time 2, while scores in the control condition will not. It is also expected that the change in the treatment condition will be maintained from time 2 to time 4, while the scores in the control condition will not change.

H8) Coping

H9) Relaxation

H10) Self-efficacy

H11) Quality of life

Results

Data Analysis

The data were analyzed using analysis of covariance (ANCOVA). The most common reason to use ANCOVA is to increase the sensitivity of the test of main effects and interactions by reducing the error term. The error term is reduced by the relationship between the dependent variable and the covariate (Tabachnik & Fidell, 2001). The covariate, in this case, is the pre-treatment score for each variable. The test examines a mean difference between the treatment condition and the control condition on a dependent variable, after post-test scores are adjusted for differences in pre-test scores (the covariate). ANCOVAs were conducted for the primary variable and each secondary variable separately.

When a number of analyses of variance or covariance are conducted, some suggest that a correction, such as the Bonferroni procedure, be made to reduce Type I error (Tabachnick & Fidell). However, others argue that the Bonferroni procedure is too conservative and should not be used. Bender and Lange (1999) state that the Bonferroni ignores dependencies among the data and is, therefore, much too conservative if the number of tests is large. Hence, it should not be routinely used. The current study implemented conservative approaches to statistical analysis, which will be reviewed next. In light of these conservative approaches, it may not be appropriate to implement an additional conservative approach to correct for multiple ANCOVAs.

Intention-to-Treat

First, the data from the 105 participants that were randomly assigned were used in the analysis. This includes data from participants who withdrew from the study (6), participants who missed more than 2 of 8 treatment sessions (4), and a participant who missed information due to a hearing impairment (1). This is a conservative approach, since it could be argued that those participants did not participate in the treatment as it was intended. Their results, therefore, are not reflective of the full potential of the treatment.

Second, there were missing data at time 2, time 3, and time 4 (see Table 3). This was not due solely to participants who withdrew. Some participants who completed the treatment sessions or the control protocol failed to complete or return the questionnaires at certain time points. For example, a participant may have completed the measures at time 1, 2, and 4, but not at time 3.

Intention-to-treat is an important method of analysis in randomized controlled trials of health care interventions (Hollis & Campbell, 1999; Newell, 1992). The concept has become

widely accepted in theory, but it is not always implemented in practice. Failure to analyze results by intention-to-treat can result in misleading interpretations (Newell). Intention-to-treat provides a pragmatic estimate of the benefit of a treatment, including changes in treatment protocol, rather than of the potential benefit to patients who receive the treatment exactly as planned (Hollis & Campbell). The purpose of intention-to-treat is to include the data of all randomized participants, to the greatest extent possible, in order to provide the most realistic picture of the effects of the intervention. Full application of intention-to-treat is possible only when complete outcome data are available for all randomized participants (Hollis & Campbell). In health care research this is rarely the case. In the current study, the missing data were addressed by carrying forward the last observation for that participant. For example, in more extreme cases, time 1 data would be repeated (carried forward) for time 2, 3, and 4. In less extreme cases of missing data, time 2 data may be carried forward for time 3 only because the participant may have completed data for time 4 (and time 1).

The ANCOVAs were conducted with two sets of data: the original data set with missing data and the intention-to-treat data, which replaced missing data by carrying forward the last observation. The main analysis in the current study is the ANCOVA with the intention-to-treat data. The analysis using the original data is presented in Appendix M as background information.

The results of the intention-to-treat analysis represent all patients, rather than only those who were able to complete the program, or all of the measures at each time period. There may be differences between those participants who complete the assessment measures at all time periods, or who complete the study, versus those who do not. If an intention-to-treat analysis is not conducted, selection factors, such as motivation, can bias the results. For example, those participants who are highly motivated and are better therapy candidates are more likely to continue than those who are less motivated. By including all participants, and using the last observation carried forward in the intention-to-treat analysis, the results are more realistic.

Unit of analysis. The question can be raised as to whether the unit of analysis should be the group or the individual. The issue is whether the scores of each individual (each participant) are independent. Since both the treatment condition and the control condition consist of smaller groups (therapy groups and attention/control groups), the argument can be made that each person in the treatment condition is affected by the other people in the group. This is not the case for

participants in the control condition because they do not have contact with each other. It could be argued that each treatment participant's responses on the dependent variables are not independent. It is difficult to determine the manner by which this 'independence issue' could affect results. The responses of group members, on measures of pain intensity for example, may be either reduced or increased due to the influence of another group member with either high or low ratings of pain intensity. However, participants are not directly influenced by each other when completing the assessment measures because they are either isolated or supervised while doing so. It is possible to explore independence but this would require an extremely large sample size, one that is not feasible for this study.

In the chronic pain treatment literature, it appears that authors do not overtly specify whether the unit of analysis is the individual or the group. However, the degrees of freedom reported in the results sections indicate that the unit of analysis is the individual. For example, if the study had 100 participants, the degrees of freedom are of that magnitude. If the unit of analysis was the group, the degrees of freedom would be much smaller and the power to detect change would also be reduced. Therefore, in the current study the unit of analysis is the individual.

Data Matrix

Participants in the treatment condition and the attention-control condition were assessed at four time periods: pre-treatment, post-treatment, 1-month and 3-month follow-up. The number of participants that responded at each time period is shown in Table 3.

All participants whose responses were substantially complete have been included in Table 3. In some cases, participants did not complete all questionnaires in all four time periods. Consequently, the statistical analyses were, in certain cases, forced to use a smaller number of observations than indicated in Table 3.

Questionnaire Responders versus Non-responders

Table 4 compares the pre-treatment means on the variables of interest between those who responded to the questionnaires (responders) and those who did not (non-responders) overall, and for treatment versus control responders and treatment versus control non-responders (P. Faris, personal communication, 2007). For this purpose, responders are defined as those participants who completed the measures (responded to the questionnaires) at T1 and T2. Non-

responders are those who completed the measures at T1 but not at T2.¹ The intention-to-treat analysis was conducted in order to adjust for any differences between participants who completed all measures versus those who did not. Some of the non-responders withdrew from the study, whereas some completed the study but failed to complete measures at all time periods.

There was a significant overall difference between responders and non-responders for one variable: NPRS duration (longest length of time of continuous pain). The mean score for responders was 78.00 and the mean score for non-responders was 99.21. That is, the non-responders reported a longer duration of continuous pain at pre-treatment. Although the continuous pain scores differ, the groups do not differ on the overall pain score, which is a composite of current, worst, least, and average pain (NPRS total).

Data Screening and Assumption Testing

Data screening and assumption testing were conducted on the original data set rather than the intention-to-treat data set. Missing variable analysis was conducted to determine the pattern of missing values. Results indicated that the pattern of missing values was random, that is, there was no selective attrition. Mean substitution was carried out only for participants whose data were substantially complete (Field, 2005; Tabachnik & Fidell, 2001). Mean substitution was conducted by identifying missing items on each scale at each time period. The mean score, based on the existing data for the item at a particular time period, was calculated and substituted for those participants who left that item blank (see Table 5 for the number of items missing and the number of mean substitutions made). Under the circumstance that an entire measure was not completed, or all measures at a certain time period were not completed, data were not substituted with mean substitution. Rather, the last observation was carried forward as discussed in the intention-to-treat section above.

Z-scores were calculated for all variables at all time periods in order to identify outliers. Extreme outliers were truncated to three standard deviations in order to reduce their impact (Tabachnik & Fidell, 2001). The data were tested for normality and homogeneity of variance. The results of the Shapiro-Wilks test demonstrate that 3 of the 11 variables are normally distributed for both the treatment condition and the control condition (fibromyalgia impact,

¹ Non-responders may have completed T3 and/or T4 therefore they did not all withdraw from the study. Similarly, the responders may not have completed T3 and/or T4. As such this is not an examination of completers versus dropouts.

coping, and self-efficacy). Four variables are non-normally distributed for both the treatment condition and the control condition. Four variables are normally distributed for either the treatment condition or the control condition but not both. Zar (1998) stated that analysis of variance is robust with respect to the assumption of the underlying populations' normality. The validity of the analysis is affected only slightly by even considerable deviations from normality, especially as sample size increases. In addition, the analysis is robust when group sizes are equal, or close to equal (Tabachnik & Fidell; Zar). In the intention-to-treat data set, the sample sizes are close to equal for the treatment group and the control group. The results of Levene's test demonstrate that all 11 variables met the homogeneity of variance assumption.

Reliability Analyses

Table 6 provides a summary of the reliability analyses, along with means and standard deviations for each scale and subscale. Reliability analyses were conducted using Cronbach's alpha, the most common measure of scale reliability (Field, 2005). According to Cicchetti (1994), a Cronbach's alpha of less than 0.7 is unacceptable, 0.7-0.79 is fair, 0.8-0.89 is good, and greater than or equal to 0.9 is excellent. Cronbach's alphas were calculated separately at time 1 and time 2 and were not computed for single item subscales.

In addition, corrected item-total correlations, mean inter-item correlations, and Cronbach's alphas if item deleted were examined. When the corrected item-total correlation for a given item on a scale is less than 0.3 it may be appropriate to remove the item (Field, 2005). Items 7, 9, 10, and 11 on the FIQ at time 1 were less than 0.3. However, there is likely no advantage to removing these items since the overall alpha for the scale does not improve if they are deleted. The same can be said for item 10 of the FIQ at time 2, item 1 of the NPRS at time 2, and item 4 of the QOLS.

Overall, the reliability data demonstrate that the measures used in the current study have adequate internal consistency, ranging from 'fair to excellent', with the vast majority in the 'good' reliability category.

ANCOVA Results: Intention-to-Treat Analysis

The means and standard deviations for each variable, along with the F-statistics for the ANCOVAs, based on the intention-to-treat data, are listed in Table 7. The results based on the intention-to-treat data follow. The analyses were conducted using the pre-treatment, post-treatment, and 3-month follow-up data (T1, T2, and T4). Time 3 data (1-month follow-up) was

not used in the ANCOVAs, or included in the tables, because of the paucity of data at time 3 (see Table 3). In addition, there is twice as much data for the treatment condition than the control condition at time 3, which can be problematic for statistical analyses.

The original data set is smaller due to missing data, while the intention-to-treat data set is larger due to data substitution (last observation carried forward). The ANCOVA results differ based on the data sets; a summary is provided in Appendix M. See Appendix M for the ANCOVA results based on the original data and a table with the means and standard deviations for each variable for the treatment condition and the control condition, based on the original data.

Primary Outcome Variable

H1) Fibromyalgia impact. To test the hypothesis that the treatment condition's fibromyalgia impact scores would significantly improve (decrease) from time 1 to time 2, while the control condition's scores would not, an ANCOVA was conducted. The dependent variable for the analysis was fibromyalgia impact time 2. That is, the impact that fibromyalgia symptoms have on various aspects of life, measured by the FIQ total score. The independent variable was condition (treatment condition or attention-control condition). The fibromyalgia impact total score at time 1 served as the covariate.

The covariate, fibromyalgia impact time 1, was significantly related to the fibromyalgia impact time 2 score, $F(1, 102) = 120.10, p < .001$. There was also a significant effect of condition on fibromyalgia impact time 2, after controlling for the effect of fibromyalgia impact time 1, $F(1, 102) = 4.39, p < .05$. At time 2, the treatment condition experienced significantly less impairment due to fibromyalgia symptoms compared to the control condition. A higher score on the FIQ indicates greater impairment due to fibromyalgia symptoms.

To test the hypothesis that the treatment condition's improvement in fibromyalgia impact scores would be maintained from time 2 to time 4 and the control condition's scores would not change substantially, an ANCOVA was conducted. The covariate, fibromyalgia impact time 2, was significantly related to the fibromyalgia impact score at time 4, $F(1, 102) = 111.01, p < .001$. There was not a significant effect of condition; therefore, the treatment effect was not maintained at time 4.

Secondary Outcome Variables

H2) Pain (intensity, frequency, duration). An ANCOVA was conducted to test the hypothesis that the treatment condition's pain intensity scores would significantly improve

(decrease) from time 1 to time 2, while the control condition's scores would not. The dependent variable for the analysis was pain intensity at time 2, which is a composite of current, worst, least, and average pain ratings measured by the NPRS. The independent variable was condition (treatment condition or attention-control condition). The pain intensity score at time 1 served as the covariate.

The covariate, pain intensity time 1, was significantly related to pain intensity time 2, $F(1, 101) = 68.07, p < .001$. There was not a significant effect of condition on pain intensity time 2, after controlling for the effect of pain intensity time 1.

Since a treatment effect was not observed at time 2 there will not be maintenance of a treatment effect at follow-up. However, to test the hypothesis that the treatment condition and control condition would differ on pain intensity at time 4, an ANCOVA was conducted. The dependent variable for the analysis was pain intensity time 4. The covariate, pain intensity time 2, was significantly related to pain intensity time 4, $F(1, 102) = 82.14, p < .001$. There was not a significant effect of condition observed at follow-up.

To test the hypotheses for the frequency of pain and the duration of pain, ANCOVA's were also conducted. Frequency of pain refers to the number of days in a week that a person experienced pain. Duration refers to the longest length of time that a person experienced continuous pain during a week. Frequency and duration of pain were also measured by the NPRS. The effect of condition was not significant for either frequency of pain or duration of pain, after controlling for the effect of frequency at time 1 and duration at time 1. Nor was an effect observed at follow-up (time 4). At time 2 and time 4 respectively, the covariates were significantly related to the independent variables: frequency, $F(1, 101) = 49.18, p < .001$, $F(1, 101) = 38.88, p < .001$; duration, $F(1, 101) = 67.59, p < .001$, $F(1, 100) = 67.91, p < .001$.

H3) Functional disability. To test the hypothesis that the treatment condition's level of functional disability would significantly improve (decrease) from time 1 to time 2, while the control condition's scores would not significantly change, an ANCOVA was conducted. The dependent variable for the analysis was functional disability at time 2, as measured by the HAQ. The independent variable was condition (treatment condition or attention-control condition). The functional disability score at time 1 served as the covariate.

The covariate was significantly related to functional disability time 2, $F(1, 102) = 188.97, p < .001$. The effect of condition was not significant.

To test the hypothesis that the treatment condition and control condition would differ on functional disability at time 4, an ANCOVA was conducted. The dependent variable for the analysis was functional disability time 4. The covariate, functional disability time 2, was significantly related to functional disability time 4, $F(1, 102) = 164.34, p < .001$. There was not a significant effect of condition at follow-up.

H4) Workdays missed. To test the difference between conditions, the dependent variable for the analysis was the number of workdays missed at time 2, and the independent variable was condition (treatment condition or attention-control condition). The number of workdays missed at time 1 served as the covariate. An ANCOVA was used to test the hypothesis that the treatment condition's number of workdays missed would significantly improve (decrease) from time 1 to time 2, while the control condition's scores would not significantly change.

The covariate was significantly related to workdays missed time 2, $F(1,102) = 76.90, p < .001$. The effect of condition was not significant.

Since a treatment effect was not observed at time 2, there will not be maintenance of a treatment effect at follow-up. However, to test the hypothesis that the treatment condition and control condition would differ on number of workdays missed at time 4, an ANCOVA was conducted. The dependent variable for the analysis was workdays missed time 4. The covariate, workdays missed time 2, was significantly related to workdays missed time 4, $F(1,102) = 57.29, p < .001$. There was not a significant effect of condition observed at follow-up.

H5) Health care utilization. An ANCOVA was conducted to test the hypothesis that the treatment condition's use of health care would significantly improve (decrease) from time 1 to time 2, while the control condition's scores would not significantly change. The number of visits to their family physician at time 1 served as the covariate, while the dependent variable was the number of visits at time 2. The independent variable was condition (treatment condition or attention-control condition).

The covariate was significantly related to appointments with physician time 2, $F(1,102) = 53.36, p < .001$. The effect of condition was not significant.

Since a treatment effect was not observed at time 2, there will not be maintenance of a treatment effect at follow-up. However, to test the hypothesis that the treatment condition and control condition would differ on health care utilization at time 4, an ANCOVA was conducted. The dependent variable for the analysis was visits to physician time 4. The covariate, visits to

physician time 2, was significantly related to visits to physician time 4, $F(1,101) = 61.88, p < .001$. There was not a significant effect of condition observed at follow-up, time 4.

H6) Depression. To test the hypothesis that the treatment condition's depression scores would significantly improve (decrease) from time 1 to time 2, while the control condition's scores would not significantly change, ANCOVAs were conducted. Depression was measured by the FIQ and the SCL90-R and an ANCOVA was conducted for each variable. In each case, the independent variable was condition (treatment condition or attention-control condition) and the covariate was the time 1 score.

The covariate, FIQ depression time 1, was significantly related to FIQ depression time 2, $F(1,102) = 157.82, p < .001$. There was also a significant effect of condition on FIQ depression time 2, after controlling for the effect of FIQ depression time 1, $F(1,102) = 5.44, p < .05$. A higher score indicates greater impairment.

To test the hypothesis that the treatment condition's improvement in FIQ depression scores would be maintained at follow-up (time 4) and the control condition's scores would not significantly change, an ANCOVA was conducted. The covariate was significantly related to the FIQ depression score at time 4, $F(1, 102) = 92.26, p < .001$. There was not a significant effect of condition; therefore, the treatment effect was not maintained at time 4.

The covariate, SCL90 depression time 1, was significantly related to SCL90 depression time 2, $F(1,95) = 164.00, p < .001$. The effect of condition was not significant. To examine follow-up effects, the covariate for SCL90 depression was significantly related to the SCL90 depression time 4 score, $F(1,91) = 209.50, p < .001$. However, the effect of condition was not significant.

H7) Anxiety. Anxiety was measured by the FIQ and the SCL90-R. In each case, the independent variable was condition (treatment condition or attention-control condition) and the covariate was the time 1 score. To test the hypothesis that the treatment condition's level of anxiety would significantly improve (decrease) from time 1 to time 2, while the control condition's scores would not significantly change, ANCOVAs were conducted.

The covariate, anxiety FIQ time 1, was significantly related to anxiety FIQ time 2, $F(1,102) = 133.61, p < .001$. The effect of condition was not significant. The covariate, anxiety SCL90 time 1, was significantly related to anxiety SCL90 time 2, $F(1,95) = 112.00, p < .001$. The effect of condition was not significant.

To test the hypothesis that the treatment condition and control condition would differ on anxiety at time 4, ANCOVAs were conducted. The covariate, anxiety FIQ time 2, was significantly related to anxiety FIQ time 4, $F(1, 102) = 126.87, p < .001$. There was not a significant effect of condition. The covariate, anxiety SCL90 time 1, was significantly related to the anxiety SCL90 time 4 score, $F(1, 91) = 190.80, p < .001$. The effect of condition was not significant.

H8) Coping. A number of coping strategies were assessed and are grouped into categories: wellness focused, illness focused, and other. To test the hypothesis that the treatment condition's wellness focused coping strategies would significantly improve (increase) from time 1 to time 2, while the control condition's scores would not significantly change, ANCOVAs were conducted. The dependent variable for each analysis was the strategy (relaxation, task persistence, self-statements) at time 2, as measured by the CPCI. The independent variable was condition (treatment condition or attention-control condition) and the covariate was strategy at time 1.

Each covariate (relaxation, task persistence, self-statements) was significantly related to the strategy at time 2, $F(1, 88) = 99.21, p < .001$; $F(1, 88) = 99.10, p < .001$; $F(1, 88) = 84.87, p < .001$ (respectively). The effect of condition was significant for relaxation, $F(1, 88) = 28.63, p < .001$ and task persistence, $F(1, 88) = 6.00, p < .05$ (higher score indicates greater endorsement of the coping strategy). At time 2, the treatment condition endorsed the use of task persistence less than the control condition.

At follow-up (time 4), relaxation time 2 was significantly related to relaxation time 4, $F(1, 84) = 109.85, p < .001$ and the effect of condition was significant, $F(1, 84) = 4.10, p < .05$. Therefore, the treatment effect for relaxation as a coping strategy was maintained. At time 4, the covariate task persistence time 2, was significantly related to task persistence time 4, $F(1, 84) = 146.17, p < .001$. The effect of condition was not significant; therefore, the effect was not maintained.

To test the hypothesis that the treatment condition's illness focused coping strategies would significantly decrease from time 1 to time 2, while the control condition's scores would not significantly change, ANCOVAs were conducted. The dependent variable for each analysis was the strategy (guarding, resting, asking for assistance) at time 2, as measured by the CPCI.

The independent variable was condition (treatment condition or attention-control condition). The strategy at time 1 served as the covariate.

Each covariate (guarding, resting, asking for assistance) was significantly related to the strategy at time 2, $F(1, 88) = 97.10, p < .001$; $F(1, 88) = 116.56, p < .001$; $F(1, 88) = 158.05, p < .001$ (respectively). The effect of condition was significant for resting, after controlling for the effect of resting time 1, $F(1, 88) = 10.74, p < .01$. The effect was not maintained at follow-up (time 4). The effect of condition was not significant for guarding or asking for assistance. However, for guarding there was a significant effect at follow-up. The covariate, guarding time 2, was significantly related to the guarding time 4 score, $F(1, 84) = 179.72, p < .001$. There was a significant effect of condition on guarding time 4, after controlling for the effect of guarding time 1, $F(1, 84) = 6.04, p < .05$.

Seeking social support is another coping strategy, but it is considered neither wellness focused nor illness focused. To test the hypothesis that the treatment condition's seeking social support coping strategy would significantly improve from time 1 to time 2, while the control conditions scores would not significantly change, an ANCOVA was conducted. The dependent variable for the analysis was seeking social support time 2, as measured by the CPCI. The independent variable was condition (treatment condition or attention-control condition). Seeking social support at time 1 served as the covariate. There was no effect of condition at time 2 or at follow-up.

H9) Relaxation. In addition to relaxation as a coping strategy, relaxation was also measured by the CDQ. To test the hypothesis that the treatment condition's relaxation scores would significantly improve (increase) from time 1 to time 2, while the control condition's scores would not significantly change, an ANCOVA was conducted. The dependent variable for the analysis was relaxation time 2, measured by the CDQ. The independent variable was condition (treatment condition or attention-control condition). The relaxation score at time 1 served as the covariate.

The covariate, relaxation time 1, was significantly related to the relaxation time 2 score, $F(1, 102) = 63.74, p < .001$. There was also a significant effect of condition on relaxation time 2, after controlling for the effect of relaxation time 1, $F(1, 102) = 16.05, p < .001$. A higher score indicates greater use of mental relaxation techniques. Therefore, at time 2 the treatment

condition utilized mental relaxation techniques to a greater extent compared to the control condition.

To test the hypothesis that the treatment condition's improvement in relaxation scores would be maintained at follow-up (time 4) and the control condition's scores would not significantly change, an ANCOVA was conducted. The covariate was significantly related to the relaxation score at time 4, $F(1, 102) = 203.77, p < .001$. There was also a significant effect of condition, after controlling for relaxation time 2, $F(1, 102) = 3.80, p = .05$. Therefore, the treatment effect was maintained at time 4.

H10) Self-efficacy. To test the hypothesis that the treatment condition's self-efficacy scores would significantly improve (increase) from time 1 to time 2, while the control condition's scores would not significantly change, an ANCOVA was conducted. The dependent variable for the analysis was self-efficacy time 2, as measured by the ASES. The independent variable was condition (treatment or attention-control). Self-efficacy at time 1 served as the covariate.

The covariate was significantly related to the self-efficacy time 2 score, $F(1,102) = 68.76, p < .001$. There was also a significant effect of condition on self-efficacy time 2, after controlling for the effect of self-efficacy time 1, $F(1, 102) = 11.51, p < .001$. A higher score indicates greater self-efficacy or greater confidence in ability to do various tasks. Therefore, at time 2, the treatment condition experienced greater self-efficacy compared to the control condition.

To test the hypothesis that the treatment condition's improvement in self-efficacy would be maintained at follow-up (time 4) and the control condition's scores would not significantly change, an ANCOVA was conducted. The covariate was significantly related to self-efficacy time 4, $F(1, 102) = 94.56, p < .001$. There was not a significant effect of condition; therefore, the treatment effect was not maintained at time 4.

H11) Quality of life. An ANCOVA was conducted to test the hypothesis that the treatment condition's quality of life would significantly improve (increase) from time 1 to time 2, while the control condition's scores would not significantly change. The dependent variable for the analysis was quality of life, as measured by the QOLS at time 2. The independent variable was condition and the covariate was quality of life at time 1.

The covariate was significantly related to quality of life time 2, $F(1, 91) = 88.11, p < .001$. There was not a significant effect of condition. The covariate was significantly related to quality of life time 4, $F(1, 85) = 99.26, p < .001$. The effect of condition was not significant at time 4.

Summary

There was a statistically significant improvement from pre-treatment to post-treatment for the treatment condition, compared to the control condition, after controlling for pre-treatment scores, for the following variables:

- primary outcome - impact of fibromyalgia (FIQ)
- secondary outcomes - depression (FIQ), coping - relaxation and resting (CPCI), relaxation (CDQ), self-efficacy (ASES).

There was a statistically significant reduction from pre-treatment to post-treatment in the use of the coping strategy task persistence (CPCI) for the treatment condition, compared to the control condition.

There was a statistically significant improvement from post-treatment to follow-up for the treatment condition, compared to the control condition, after controlling for pre-treatment scores, for the following variables: secondary outcomes - coping - relaxation and guarding (CPCI), and relaxation (CDQ).

The treatment condition did not improve significantly from pre-treatment to post-treatment, compared to the control group, on the following variables:

- secondary outcomes: pain - intensity, frequency, and duration (NPRS), functional disability (HAQ), workdays missed (FIQ), health care utilization (CDQ), depression (SCL90-R), anxiety (FIQ, SCL90-R), coping - self-statements, asking for assistance, seeking social support (CPCI), quality of life (QOLS).

Discussion

The literature on psychological treatment for fibromyalgia is limited and almost exclusively cognitive-behavioural in nature (or based on a comparable education/self-management program), and there are few studies that employ CBT alone (Burckhardt et al., 1994; Nicassio et al., 1997; Vlaeyen et al., 1996). The majority of the studies with a psychological component combine it with other modalities, such as exercise, into a multidisciplinary treatment (Hooten et al., 2007; Mason et al., 1997; Nielson et al., 1992). In

these cases it is difficult, if not impossible, to separate the effects of the psychological treatment from the other treatments (e.g. exercise, education, biofeedback, etc.). Further, a number of the multidisciplinary CBT trials are single condition uncontrolled trials (Bennett et al., 1996; Creamer et al., 2000; Nielson et al., 1992; Turk et al., 1998; White et al., 1995; Worrel et al., 2001). There seem to be more nonpharmacological interventions examining the effects of exercise or physical therapy, often in combination with education, than trials examining the effects of psychotherapy (Bailey et al., 1999; Buckelew et al., 1998; Gustafsson et al., 2002; Mannerkorpi et al., 2000; Mengshoel et al., 1995).

Due to the paucity of research examining CBT in combination with other forms of psychotherapy for the treatment of fibromyalgia, or chronic pain in general, it is not possible to compare the results of the current study to a study employing a similar treatment program (that is combined CBT and interpersonal therapy). Therefore, the discussion will focus on comparing the results of the current study to those studies that employed a strictly CBT approach. However, comparisons will also be made to the multidisciplinary controlled and uncontrolled studies when possible.

The first section of the discussion will highlight the major findings from the current study, based on the intention-to-treat data, in the same sequence as outlined in the hypothesis section. The results of the primary outcome variable will be presented first, followed by the secondary variables. Each finding will be examined in light of current literature, identifying consistencies and/or inconsistencies. After reviewing the major findings, the clinical implications and strengths and weaknesses of the study will be reviewed, followed by suggestions for future research.

The Primary Outcome Variable

The primary variable of interest in this study was fibromyalgia impact, as measured by the FIQ total score. This is a measure of health status that includes: physical functioning, work status, depression, anxiety, sleep, pain, stiffness, fatigue, and well-being (Burckhardt et al., 1991).

The intention-to-treat data did support the hypothesis. That is, the treatment condition experienced significantly less impact of fibromyalgia symptoms compared to the control condition at time 2. Although the means for the treatment and control conditions are similar at time 2, the mean for the treatment condition was higher at time 1 and thus showed more change.

However, the treatment effect was not maintained at 3-month follow-up; therefore, the hypothesis regarding maintenance of a treatment effect was not supported. It may be that post-treatment, the participants practiced the coping skills less over time and this resulted in greater impact of symptoms. During the treatment period, homework was assigned weekly and this was reviewed at each session. Therefore, there was motivation to practice. During the follow-up phase this motivation was not present. This, combined with not having the weekly group support, may have increased the impact of symptoms over time.

In terms of a clinically meaningful difference, the mean and standard deviation for the original FIQ data at time 1 are 55.36 and 15.44 respectively, which is consistent with other findings (Mannerkorpi, Rivano-Fischer, Ericsson, Nordeman, & Gard, 2007). To determine clinically meaningful change, one-third of a standard deviation is proposed, which is approximately 5 points. In terms of effect size, one-third of a standard deviation is between a small and medium effect, according to Cohen's *d* (Howell, 1997). In the original data set, the mean from time 1 to time 2 for the treatment condition changed by 9.22 points. Therefore, by the one-third standard deviation benchmark, this does constitute a clinically meaningful change. In comparison, the change in the control condition from time 1 to time 2 was 0.53 points. There was a clinically meaningful improvement in 27 participants in the treatment condition compared to 10 participants in the control condition. In the intention-to-treat data set, the mean from time 1 to time 2 for the treatment condition changed by 6.13 points, which also constitutes a clinically meaningful change. Therefore, the combined cognitive-behavioural and interpersonal treatment reduced the impact of fibromyalgia symptoms in a statistically and clinically meaningful way, from pre- to post- treatment, compared to the control condition.

The intention-to-treat analysis enables us to generalize the outcomes of the current study to a typical female fibromyalgia population, rather than to only those patients who are more likely to complete treatment or precisely follow protocol. The results show that this 8-week cognitive-behavioural/interpersonal group treatment can significantly improve impairment from fibromyalgia symptoms in a statistically and clinically meaningful way. Next, the results of the primary outcome, fibromyalgia impact, will be compared to the literature.

Comparison of Results to CBT Alone (or Comparable Education Program)

There are a limited number of studies assessing the impact of CBT alone, or a comparable education program, on fibromyalgia symptoms. In a sample of 86 women,

Burckhardt et al. (1994) found no significant between-group change in fibromyalgia impact, as measured by the FIQ total score, when comparing an education condition (similar to a CBT program), an education plus physical therapy condition, and a control condition. When analyzing within group differences, however, it was revealed that the education condition improved significantly on a subscale of the FIQ, which assessed the number of days during a week that the participant 'felt bad'. The education plus physical therapy condition and the control condition did not significantly improve on this subscale. At follow-up the education condition's improvement was maintained and also showed improvement on the physical function subscale but not the total score, while the education plus physical therapy condition had improvements on the fibromyalgia impact total score and additional subscales. The authors suggest that the improvements from the physical therapy component may have taken longer to develop giving rise to more improvement at follow-up compared to the education only condition. Overall, though, Burckhardt et al. (1994) found that both treatments provided some benefit to patients and they did not find a sufficient difference between the education condition and the education/physical therapy condition when taking into account all outcome measures. Unfortunately there was not a physical therapy condition without education to use as a comparison. In the fibromyalgia treatment literature it is necessary to establish which components of treatment are most effective in order to advance therapy.

Comparison of Results to CBT as a Component of Multimodal Treatments

In addition to studies looking at CBT alone there have been a limited number of studies that incorporated CBT into a multimodal treatment approach to fibromyalgia. In a controlled trial of 21 participants, Mason et al. (1998) examined a multimodal treatment program that included a cognitive-behavioural component. The FIQ was used to assess the effect of fibromyalgia on physical and psychological functioning. The results were consistent with the current study's findings, in that there was a significant interaction effect of condition by time. However, this effect was not maintained at 6-month follow-up. The treatment effect observed in both studies may be related to shared elements of the CBT portion of treatment. That is, both studies incorporated education, challenged cognitive distortions, and taught relaxation techniques. The improvements in functional impairment may not have been maintained at long-term follow-up in both studies because maintenance of treatment gains depends largely on consistent practice and use of skills (Mason et al.). Participants who adhere to program regimes

are more likely to maintain post-treatment levels (Basler & Rehfish, 1990). Also, being involved with a group has unique benefits. Some treatment effects may diminish over time due in part to the absence of the group. Mason et al. emphasized relapse prevention by encouraging patients to continue to exercise together and participate in regular support groups. However, without a therapist or trained group leader support groups can be ineffective or detrimental. In fact, many of the participants that were interested in the current study were concerned that it was a support group and if so did not want to be involved based on previous negative experiences. Adding follow-up sessions to the current study's protocol may have helped to maintain gains by bringing the group together and reinforcing previously learned skills and the benefits of practicing those skills consistently over-time.

Luedtke et al. (2005) measured fibromyalgia impact (FIQ total score) following a 1.5-day multidisciplinary program with a sample of 2600. The program included self-management, education, occupational therapy, and time with physicians and nurses. The nurses involved in the program received training to enable them to educate the patients about the process while engaging the patient and building rapport. The authors noted that many patients found this time with the nurse very positive because in the past many were not given time to talk about their "personal stories," the variety of their symptoms, and their beliefs about contributing/alleviating factors. Many stated that prior to this experience they did not feel "heard." The self-management portion focused on CBT techniques that emphasized stress management, relaxation, sleep hygiene, and difficult day planning. Patients also had the opportunity to discuss how fibromyalgia has impacted their lives.

Luedtke et al. (2005) found that the overall impact of fibromyalgia improved significantly from pre-treatment to 6-month follow-up and improvement was maintained at 12-month follow-up. The authors conducted a satisfaction survey before and after the program and found a dramatic improvement in satisfaction: before the program 53% of patients rated their fibromyalgia care as excellent or good and after the program 87% rated the care in these categories. Physician satisfaction also improved. The time patients were able to spend with the health care providers and the opportunity to "tell their stories" about how their lives have been impacted by fibromyalgia appeared to be very important. Research by Rybarczyk and Bellg (1997) supports the importance of listening to patients' stories. They found that for patients facing illness, listening to their life stories was effective in reducing stress and improving

satisfaction. Perhaps these fibromyalgia impact findings are similar to the current study in part due to the positive effects of being heard. The interpersonal therapy component of the current study provided the opportunity (above and beyond the CBT component) for the sharing of experiences, validation, and support. In addition, each participant had a one-to-one assessment interview with the primary researcher, which provided the opportunity to build rapport and tell their personal stories about having fibromyalgia. Unfortunately the Luedtke et al. study did not incorporate a control condition nor did they control for medication adjustments over time. It is also not possible to ascertain which components of the treatment contributed to the effect.

In summary, the literature is relatively consistent with the findings of the current study regarding fibromyalgia impact. In fact, the current study shows much promise since a treatment effect was observed with the psychological intervention alone, whereas comparison studies used more complex and resource intensive multidisciplinary programs with substantial physical activity components (Luedtke et al., 2005; Mason et al., 1998). The CBT alone comparison study (Burckhardt et al., 1991) found only a within group effect on one subscale of the FIQ rather than the total fibromyalgia impact score. This effect was maintained at follow-up, whereas in the current study the effect was not maintained at 3-month follow-up.

The Secondary Outcome Variables

Pain (intensity, frequency, duration). In the current study the data did not support the hypothesis that the treatment condition would have a reduction in pain intensity compared to the control condition after controlling for time 1 scores. Nor was there a significant difference at 3-month follow-up. The data also did not support the hypothesis that the treatment condition would have a statistically significant reduction in pain frequency and pain duration compared to the control condition.

The pain intensity findings are consistent with findings in other research in which there were no significant between group differences for self-reported pain using a visual analogue scale or a composite scale (Buckelew et al., 1998; Gowans et al., 1999; Nicassio et al, 1997; Wigers et al., 1996). Burckhardt, Mannerkorpi, Hedenberg, and Bjelle (1994) and Vlaeyen et al., (1996) also found no effect on pain resulting from psychoeducational approaches. Explanations for this are varied, including: the need for adjunctive pharmacological treatment to improve sleep and pain; identifying subgroups of patients based on pain ratings and coping strategies to cater

treatment more specifically; the need for observer report or objective pain ratings to supplement subjective patient reports of pain (Burckhardt et al., 1994; Turk & Okifuji, 1998).

However, other researchers found a positive effect on pain related measures (Keel et al., 1998; Lemstra & Olszynski, 2005; Mason et al., 1998; Nielson et al., 1992). Keel et al. examined clinically significant improvement. The criterion was at least 50% improvement in a number of parameters. Changes in pain intensity were calculated from participants' daily diary entries. Keel et al. found that there was a clinically significant improvement in the pain score at post-treatment. When examining the differences between participants who benefited from treatment versus those who did not, the authors found that successful participants had suffered from their pain for a significantly shorter period of time (6 years vs. 15 years). Therefore, early intervention may improve outcomes for fibromyalgia patients. Mason et al. found a moderate to large effect size on subjective pain measured by the FIQ pain subscale and a visual analogue scale. Nielson et al. (1992) found a positive effect following inpatient CBT in a sample of 25 participants. It should be noted that, instead of using a measure of pain intensity, frequency, and duration they examined a number of dimensions of the chronic pain experience. This included pain interference, sense of control over life, affective distress, and perceived support. Comparison of the pre-test and post-test scores indicated that the target variables, which included the Multidimensional Pain Inventory (MPI), changed in the expected direction and that this change was statistically significant. Since the pain variable captured broader aspects of the pain experience it may be that the measured effect reflected improved sense of efficacy or coping rather than improvements in pain levels. This study is also limited by a sample size of 25 and instead of a formal wait list or attention-control condition the treatment participants acted as the control condition prior to starting the treatment. Future research directions based on the current study could include a pain measure, such as the MPI, in addition to intensity, duration, and frequency scales in order to gain a broader picture of the pain experience.

Other researchers have chosen to examine pain with respect to coping behaviours or sense of control over pain rather than measuring intensity (Vlaeyen et al., 1996). This will be addressed in the discussion of the coping variables.

Fordyce (1988; cited in Nicassio, 1997) noted that subjective pain and the functional effects of pain represent separate dimensions of the chronic pain problem. Lack of improvement in subjective pain may not necessarily coincide with changes in psychological and behavioural

aspects of the condition. Indeed, despite no improvement in pain ratings in the current study the impact of fibromyalgia on various aspects of life did improve. It is important, therefore, to examine pain behaviours, functional factors, and mood symptoms in addition to pain ratings. For example, Nicassio et al. (1997) found that depressive symptoms and pain behaviours were markedly reduced despite subjective pain levels not improving across the trial. This is indicative of the potential value of psychosocial treatments in treating mood disturbance and functional aspects of fibromyalgia.

Functional Disability. The intention-to-treat data did not support the hypothesis that the treatment condition would have a statistically significant reduction in functional disability compared to the control condition after controlling for time 1 scores. Nor was there a significant difference at 3-month follow-up. Nicassio et al. used the quality of well-being scale to assess the functional effect of fibromyalgia in a sample of 71 participants. The scale measures symptoms, functioning mobility, social activity, and physical functioning. This measure differs from the measure of disability in the current study, which is solely functionally based. Nicassio et al. found no effect of condition or interaction of condition by time on the disability variable. Nor did they observe a time effect. Unfortunately there was not a wait list control condition in this study, instead they compared two treatment conditions (behavioural treatment versus education with group discussion/support). Future studies could contribute to the area by including wait-list or attention-control conditions and by distinguishing between the contributions of particular interventions.

After interacting with the participants in the current study and learning about their abilities and limitations, it is not surprising that there was not a treatment effect for functional disability based on the measure used. The vast majority of patients were able to carry out these tasks without any difficulty, tasks such as lifting a glass to your mouth, washing/drying your body, and turning faucets on/off. The items are rated from 0 to 3 (3 is 'unable to do' the activity) but the highest score was 1.88 and the pre-treatment mean was 0.62. Therefore, pre-treatment status was likely not impaired enough on these tasks to show significant improvement. The mean for the fibromyalgia participants was similar to that found by Lorig et al., 2001, in a large sample of chronic disease patients ($M = 0.38$, maximum 1.88). Measures of fibromyalgia impact, used as the primary variable in the current study, may capture the effects of the

syndrome more specifically, since functional and social tasks, well-being, and severity of symptoms are assessed.

Workdays missed. The data did not support the hypothesis that the treatment condition would have a statistically significant reduction in workdays missed compared to the control condition after controlling for time 1 scores. Nor was there a significant difference at 3-month follow-up. This is consistent with other findings; for example, in a sample of 79 participants Lemstra and Olszynski (2005) did not find statistically significant changes in work status in a multidisciplinary intervention condition compared to a control condition. However, in the current study scores did improve and perhaps with a multiple-item measure and more power significant differences could have been detected. It is important to assess work inside the home and ‘unpaid’ work such as babysitting grandchildren, for example, as many of the participants were not employed, on medical leave, or retired but had other responsibilities that fibromyalgia potentially interfered with.

Health care utilization. The data did not support the hypothesis that the treatment condition would have a statistically significant reduction in visits to their physician related to fibromyalgia compared to the control condition after controlling for time 1 scores. Nor was there a significant difference at 3-month follow-up.

To my knowledge, health care utilization has not been examined in psychological treatment studies for fibromyalgia. However, comparisons can be made to chronic pain literature. Pfingsten et al., (1997) found a statistically significant reduction in physician visits from pre-treatment to 12-month follow-up in chronic low-back pain patients. The multimodal treatment program included CBT and relaxation training. The program was largely focused on functional restoration via stretching, and aerobic, strength, and endurance exercise. It is possible that the intensive physical component of the treatment reduced physician visits either because symptoms improved and/or participants had the support of staff. When concerns arose they may have enjoyed similar support/advice from staff that they would from their physician. The same would not apply over the follow-up period, however. Since the treatment was multimodal and largely functionally based, it is not possible to determine the effects of the psychological component on reductions in health care utilization. Perhaps improved coping skills combined with the benefits of the exercise components led to greater self-efficacy and therefore less reliance on medical intervention.

Depression. Depression was measured by the SCL90-R depression subscale and the FIQ depression item. The data partially supported the hypothesis that the treatment condition would have a statistically significant reduction in depressive symptoms. The FIQ data support the hypothesis for a treatment effect while the SCL90 data did not. The improvement in depression measured by the FIQ was not maintained at follow-up. The FIQ measures only one item related to depression and it is rated on a 0-10 scale: ‘for the past week how depressed or blue have you felt.’ The SCL90 depression subscale is comprised of 13 items many of which are diagnostic and cover physical, cognitive and emotional symptoms. It is possible that the 0-10 scale of the FIQ allowed for smaller improvements to be detected while assessing an overarching ‘blue’ feeling rather than other specific criteria related to the diagnosis of depression.

The results of the literature regarding treatment effects on depression are mixed and drawing conclusions is difficult due to the variability in measures. Gowans et al. (1999) also measured depression using the FIQ, following a combined exercise and education program. At follow-up, they found that compared to a wait-list control group, participants in the treatment program showed a trend toward reduced depression. Although it approached significance, it was not statistically significant. Burckhardt et al. (1994) also measured depression using the FIQ but did not find a statistically significant treatment effect from pre- to post-treatment. However, in the education and physical therapy condition there was a significant difference at follow-up. This difference was not observed in the education only condition. Nicassio et al. (1997) found similar results using the Centre for Epidemiological Studies – Depression scale (CES-D) to measure depression. There was no effect of treatment condition (behavioural vs. education control) on depression. However, overall, there was a time effect such that there was a significant decrease in depression scores from pre- to post-treatment with maintenance of improvement at follow-up. The authors hypothesize that the improvement in both conditions is due to a common therapeutic process related to provision of information and increasing sense of mastery. In addition, the level of education was high in this sample and all participants had a support person participate in the study with them. These differences and the lack of a wait-list control condition limit the ability to generalize the results. Wigers et al. (1996) did not use the FIQ to measure depression; rather, they used a patient administered visual analogue scale. Data analysis, according to the principle of intention-to-treat, showed no between-group differences on depression at post-treatment between the exercise, stress management, and control conditions.

In contrast, Lemstra and Olszynski (2005) and Nielson et al. (1992) found significant improvements on depression scores. Lemstra and Olszynski assessed depression using the Beck Depression Inventory (BDI). The intervention condition had a statistically significant improvement in BDI scores compared to the control condition. The intervention condition maintained statistically significant change in BDI scores, but the degree of improvement was not compared to the control condition. Nielson et al. assessed depression using the CES-D and found a significant improvement from pretest to posttest following a multidisciplinary program.

Overall, the findings regarding symptoms of depression following treatment for fibromyalgia are mixed. In some cases multidisciplinary treatment or the addition of exercise to an education based treatment may improve symptoms of depression. The involvement of a support person during treatment and follow-up may also be a positive contributor (Burckhardt et al., 1994; Lemstra & Olszynski, 2005; Nielson et al., 1992). More consistent use of validated measures to assess all facets of depression, including the cognitive, physical, and emotional symptoms as well as non-clinical symptoms of sadness or loss would contribute to the fibromyalgia treatment literature.

Anxiety. In the current study, anxiety was measured by the SCL90-R anxiety subscale and the FIQ anxiety item. The psychometric strength of this subscale and the single item is less acceptable compared to other multi-item scales. The data did not support the hypothesis that the treatment condition would have a statistically significant reduction in anxiety symptoms compared to the control condition.

Although symptoms of anxiety were not a primary focus of the treatment, there was some focus on reducing worry, negative thinking, and catastrophizing, all of which could arguably contribute to feelings of anxiety. There was also a great deal of focus on relaxation training. Treatment effects were observed for relaxation thus it could be speculated that increased relaxation may decrease anxiety. However, the relaxation effect did not translate into improved measures of anxiety. The SCL90 and FIQ assessed classic anxiety symptoms and perhaps did not capture other aspects of anxiety that may have been moderated by improvements in relaxation. For example, the measures may not have captured anxiety related to illness, illness progression, or pain. Future research may attempt to capture these illness related aspects of anxiety with alternative measures.

Burckhardt et al. (1994) found similar results such that the education condition did not significantly improve compared to the education/physical therapy condition or the control condition on the FIQ anxiety item from pre- to post-treatment. However, at follow-up there was a significant improvement in the education/physical therapy condition. The authors believe that this improvement was not observed at post-treatment due to the short (6-week) nature of the intervention and also because the exercise component may not have been vigorous enough. Whereas during the follow-up phase they found that many of the participants in that condition were doing more vigorous aerobic exercise 3 times a week.

In contrast, Nielson et al. (1992) found a significant improvement from pretest to posttest in state trait anxiety following a multidisciplinary program. Although scores changed in the direction of improvement from pre-treatment through to the 2.5-year follow-up, the improvement was not statistically significant (White & Nielson, 1995). The small sample of 22 may have prevented the detection of significant change.

In the future, examining illness related aspects of anxiety in fibromyalgia patients may capture symptoms related to progression of illness, role change, and loss of ability. It may be that these concerns are not expressed as classic symptoms of anxiety but are poignant for fibromyalgia patients.

Coping (wellness-focused, illness-focused, other). The data partially support the hypothesis that the treatment condition would have a statistically significant improvement in coping compared to the control condition. There was an improvement in the wellness-focused coping strategy of relaxation. The treatment condition used relaxation to cope with pain significantly more than the control condition. The use of relaxation as a coping strategy was maintained at follow-up. Another wellness-focused strategy, called task persistence, distinguished the conditions. However, the control condition used this strategy more than the treatment condition. In the current study the treatment condition was taught 'activity pacing'. Activity pacing is considered to be a key requirement for both increased activity tolerance and adaptive pain management (Hanson & Gerber, 1990; Nielson, Jenson, & Hill, 2001). The goal of activity pacing is to avoid pain flare-ups and consequential days of inactivity by working on activities/errands in small stages with frequent breaks. Patients were taught that in the long-term such a regime would allow them to be more productive, even with the breaks. Therefore,

‘persisting’ on a task is actually counter to the activity pacing philosophy and these results may indicate that patients in the treatment condition were applying the pacing philosophy.

In terms of illness-focused coping strategies, the intention-to-treat data did not show a significant difference in ‘guarding a body part’. The data did show a significant difference in ‘resting’ at post-treatment. However, the treatment condition was using resting to cope with pain significantly more than the control condition. This may also be related to the activity pacing philosophy, since participants in the treatment condition were taught to take breaks and rest for short periods of time while doing activities and chores, particularly those that are physical. In addition, participants in the treatment condition may have considered relaxation training with the CD, or visualization/imagery exercises as a form of ‘resting’. In such cases it seems reasonable to consider resting as a wellness-focused strategy rather than an illness-focused strategy.

The CPCI also assessed ‘seeking social support’ but this is considered neither a wellness-focused nor an illness-focused strategy. A treatment effect was not observed for this strategy nor was there a significant difference at follow-up.

With respect to a comparison of coping strategy research findings, van Wilgen (2007) examined aspects of coping including catastrophizing, pain-coping, and internal and external pain control in a sample of 65 patients with fibromyalgia. Catastrophizing improved significantly at post-treatment following a multidisciplinary program and this was maintained at follow-up. However, the other coping strategies did not improve significantly. The authors reported that catastrophizing is an important variable due to its positive relation to pain severity, affective distress, disability, and poor treatment outcome (Edwards et al., 2005). Perhaps improvement in catastrophizing is a key factor in improving other domains.

The CPCI, used to assess coping in the current study, does not include a catastrophizing subscale. However, it seems reasonable to consider catastrophizing as an ‘illness-focused’ strategy. In that sense the findings of van Wilgen following a multidisciplinary program are consistent on a broader level with the improvements in illness-focused coping (guarding and resting) found in the current study.

Relaxation. Relaxation was examined as a mental relaxation strategy using the CDQ and as a coping strategy using the CPCI. As discussed above, relaxation (as a wellness-focused coping strategy) was used to cope with pain significantly more in the treatment condition compared to the control condition from pre- to post-treatment. The difference between the

conditions remained significant at follow-up. Also, the treatment condition used mental relaxation strategies significantly more than the control condition from pre- to post-treatment and a significant difference between the conditions was maintained at follow-up. Although the difference maintained was significant, the number of times relaxation was used by the treatment condition decreased. This also speaks to the importance of 'booster' sessions or long-term support in order to promote continued use of the skills learned during treatment. Perhaps having an outside support person to report to would be helpful. For example, if family physicians believe that practicing relaxation strategies improves functioning, they may ask patients how often they are practicing relaxation. Alternatively, an on-line group for participants following treatment may be helpful for reiterating the importance of the skills learned and supporting each other to maintain practice. An on-line log or journal outlining progress may help to motivate some participants. Comparing the effectiveness of different types of booster sessions could provide a new avenue for future research.

In a sample of 131 patients with fibromyalgia, Vlaeyen et al. (1996) did not find a significant difference between conditions for relaxation, however, both the cognitive/education condition and the education/discussion control condition improved from pre-to post-treatment while the wait-list control condition did not. Therefore, the cognitive treatment component did not contribute to improvement in relaxation skills above and beyond education/discussion. It is plausible that education about the benefits of relaxation and the techniques would be adequate to improve relaxation skills in participants. However, continuing to use the techniques over the long-term and during times of increased illness or stress is perhaps the greater challenge. This challenge may be better addressed by psychological interventions rather than a purely educational intervention.

Self-efficacy. The data support the hypothesis that the treatment condition would have a statistically significant increase in self-efficacy compared to the control condition after controlling for time 1 scores. However, this was not maintained at 3-month follow-up.

Prior to the study in 1994 conducted by Burckhardt et al., self-efficacy had not been measured in fibromyalgia clinical trials. In that study, both interventions (education alone/comparable to CBT and education with physical therapy) resulted in significant improvements in self-efficacy compared to the control condition. The differences between the two intervention conditions were not significant. The authors reported that the most notable

change following the interventions was the change in self-efficacy. At follow-up self-efficacy (pain related subscale) was significantly higher in the education and physical training condition. Although there was no difference between the intervention conditions at post-treatment the addition of physical training seemed to affect the participants over the follow-up period. The participants continued their activity over this period and according to the authors many increased the rigor and frequency of exercise. The activity may mediate efficacy but this may be a bi-directional relationship. Perhaps prior improvements in efficacy enabled improvements in health behaviour, i.e. exercise, and the increase in exercise in turn improved confidence and sense of control. Indeed, there is strong evidence that changes in self-efficacy are enduring and affect changes in health behaviours and health status (Lorig et al., 1989). In the current study, perhaps consistent practice of coping strategies, such as relaxation, over the follow-up period would have a similar mediating effect as exercise. If the degree to which participants continued to practice coping strategies over the follow-up period was assessed, perhaps those who maintained or increased practice would, in turn, have more confidence in their ability to control symptoms and hence have greater self-efficacy. Conversely, perhaps those with higher levels of self-efficacy post-treatment would be more inclined to continue to practice the coping strategies.

Quality of life. The data do not support the hypothesis that the treatment condition would have a statistically significant improvement in quality of life compared to the control condition after controlling for time 1 scores. Nor was there a significant difference at 3-month follow-up.

van Wilgen et al. (2007) assessed quality of life using the Short Form 36 Health Survey (SF-36). They compared pre-treatment scores to a reference group (of the same age from the general population) and found that the initial scores on health related quality of life were significantly lower in fibromyalgia patients for all domains. In six domains significant improvements were measured at follow-up: physical and emotional role limitations, mental health, vitality, pain, and health changes. However, they remained lower than the reference group.

Luedtke et al. (2005) also used the SF-36 to assess quality of life (Luedtke, personal communication, Jan. 11, 2008). The mental health subscale and the physical function subscale improved from pre-treatment to 6-month follow-up and the improvements were stable at 12-month follow-up.

Burckhardt et al. (1994) found significant differences in quality of life for both treated conditions compared to the control condition. There were no significant differences between the two treated conditions at post-treatment, but at follow-up, quality of life was significantly higher in the education and physical training condition. Perhaps this finding is related to the self-efficacy finding; with increased self-efficacy participants were better able to follow-through with health behaviours such as exercise. With greater exercise participants may feel more control, pride, and higher levels of energy that may contribute to improved quality of life. Although the post-treatment outcomes did not differ between conditions, the follow-up outcomes suggest that the addition of an exercise program is beneficial in improving long-term outcomes.

In the current study, almost half of the items on the quality of life measure focus on relationships and activities with others, for example, rearing children, helping others, and socializing. In contrast, the measure included one item that is health focused (see Appendix I). Perhaps the intervention led participants to focus on other elements of quality of life that are not reflected in these relational items. For example, strategies such as relaxation training and assertiveness are more individually focused. Although they may be important in improving quality of life, the improvements may not be identified by the measure used. The comparison studies assessed quality of life with different measures, which may be more sensitive to various aspects of the construct.

Contributions of the Current Study

The aim of the current study was to expand on the fibromyalgia treatment literature by addressing the limitations of CBT for fibromyalgia. A treatment manual was constructed, which consisted of important components of CBT for chronic pain and added an interpersonal process oriented approach. The addition of this therapeutic approach was meant to address the idiosyncratic characteristics of fibromyalgia patients that have not been successfully addressed by existing cognitive-behavioural approaches. The importance of addressing social and environmental context, sociocultural background, and the meaning of pain is well supported (Turk & Okifuji, 2002). In particular, interpersonal roles and how they are shaped by significant others impact a person's response to illness (Epker & Block, 2001; Romano et al., 1995; Schwartz, Slater, & Birchler, 1996). These factors and their impact on coping with chronic pain can be addressed by an interpersonal therapy approach (Edworthy et al. 2003; Grzesiak et al, 1996).

The current study also contributed to the literature by including a randomized controlled clinical trial. There are few psychotherapy studies for fibromyalgia, cognitive-behavioural or otherwise, that are well designed. That is, there are few studies that consist of an adequate control condition with adequate sample sizes. Therefore, in the current study an attention-control condition was compared to the treatment condition instead of a wait-list control or no control. Also, significant recruitment efforts were made to accrue a reasonable number of participants resulting in a sample of 105 women with fibromyalgia. Importantly, only those patients who had received a diagnosis of fibromyalgia from a rheumatologist were eligible to participate. This is significant, since the literature includes some studies that did not use objective diagnostic inclusion/exclusion criteria. In the current study, the participants were followed and assessed at 1-month and 3-months post-treatment. A limitation of the current study is the short follow-up period. A 6-month or 1-year follow-up would have contributed further to the literature. However, with the resources available and the time constraints for completion of the research this was not possible. By examining dropout rates and incomplete measures over time, it is likely that the return rate at long-term follow-up would be poor. Additional resources would be necessary to improve return rates, either by calling participants to remind them, providing monetary or other incentives, or setting up a booster session in a convenient location that allowed additional time for completing questionnaires.

Implications for Clinical Practice

The results of the current study have several implications for clinical practice with women diagnosed with fibromyalgia. The intention-to-treat analysis allows us to generalize the results to a typical group of women entering treatment, rather than those who are more highly motivated to complete treatment or perhaps higher functioning. The cognitive-behavioural and interpersonal treatment used in the current study was manualized, which enables others to provide the treatment. Many chronic pain programs, and fibromyalgia programs specifically, are multidisciplinary. The treatment used in the current study could be incorporated into multidisciplinary programs and the results may be more promising and/or longer lasting with more intense intervention and by incorporating physical activity and booster sessions during follow-up phases.

As demonstrated by the current study, the cognitive-behavioural and interpersonal group treatment can significantly decrease the impact of fibromyalgia symptoms, reduce symptoms of

depression, increase coping, promote use of relaxation strategies to cope with pain, and increase self-efficacy. The timing of delivery of service may be an important area of study for the future. Perhaps newly diagnosed patients may benefit to a greater degree due to the extensive education about fibromyalgia that is provided by the treatment program. Also, some less adaptive coping strategies and pain behaviours may be less apparent early on in the diagnosis and may be replaced more readily by adaptive coping strategies. Earlier diagnosis and delivery of service may impact other variables of interest in the current study including workdays missed and health care utilization. Presumably, the education and support provided by the treatment program would reduce the need for participants to see their family doctor regarding fibromyalgia related concerns. Perhaps some of these visits to physicians could be replaced by visits to health care providers focusing on adopting health behaviours, maintenance of such behaviours, and addressing barriers to healthy changes/coping strategies using motivational interviewing techniques.

Informing Theory of Fibromyalgia

Interacting with the participants in the current study provided valuable information towards understanding the effects of fibromyalgia. The information further validates a biopsychosocial model for fibromyalgia. Patients experience the syndrome in all aspects of life, including emotionally, spiritually, physically, and socially. Their stories reflect biological changes, including early menopause, hysterectomy, injury, and illness. Many participants believe that the onset of the physiological symptoms of fibromyalgia is linked to these biological changes. It is difficult to know how or whether these experiences are linked to allodynia and hyperalgesia or whether the biological changes, in some cases, precipitate the onset of symptoms to which they are predisposed due to central nervous system abnormalities. The physiological symptoms are experienced differently across time based on the context and environment. Stressors, coping style, personality, mental health, social roles, and degree of support were important themes addressed by participants. It is necessary to address the psychological and social context and its impact on the biological factors. Patients develop patterns of coping and ways to express illness. The length of time prior to diagnosis is likely important since these patterns are developed during a time of stress, when patients are worried about their health, uncertain about their diagnosis and prognosis, they may feel misunderstood or dismissed, and they may be frustrated by lack of support. Similarly, duration of illness is important. If less

adaptive coping strategies are employed for a longer duration they may become more entrenched and therefore more difficult to change with treatment. Furthermore, the coping strategies themselves may alter the expression of symptoms or the development of the disorder. For example, guarding a body part can result in altered biomechanics and chronic tension. Thus, maladaptive attempts to cope can cause or exacerbate other problems. These examples speak to the complexity of fibromyalgia syndrome and the importance of theorizing and designing interventions from a biopsychosocial framework.

Limitations of the Current Study

Two main limitations of the current study are evident and both are in regards to comparison conditions. First, it would be more informative to have additional comparison conditions. That is, in addition to the combined cognitive-behavioural/interpersonal treatment condition and the attention-control condition, it would be ideal to have a treatment condition receiving the CBT alone and another condition receiving the interpersonal process therapy alone. The addition of these conditions would allow for examination of the specific contributions of each therapy type, and would also allow for discussion of whether the combined treatment is more effective than an individual treatment. A limitation of the fibromyalgia treatment literature overall is the lack of well-designed trials and the use of multimodal or multidisciplinary programs in the absence of careful examination of the effectiveness of unimodal programs. Although a multidisciplinary approach to chronic pain is well documented, it seems to be critical to first examine the effectiveness of each individual component. Otherwise, it is impossible to determine which components of a multidisciplinary program are effective and therefore determine where improvements need to be made.

Second, although the attention-control condition is a strength of the current study, it could be improved upon. By including a more comprehensive attention-control condition the effects of the treatment could be more clearly observed above and beyond common factors or biases. An attention-control condition that is able to mimic a treatment condition would allow for double-blind methodology in which case treatment expectancy effects could be accounted for more adequately.

Adherence

An additional limitation of the current study is that adherence to the program was not assessed. This is more frequently done in exercise trials, however, practicing coping skills such

as relaxation exercises could be monitored. In order to improve accuracy this could be done anonymously, but it would be helpful to identify the participants since this information could be used when examining treatment effects and long-term effects. Adherence could be assessed with respect to homework completion and practicing skills. For example, perhaps participants who continue to regularly practice relaxation exercises maintain treatment effects compared to those who do not. Adherence could also be assessed with respect to participation in treatment. For example, the results of those participants who attended all 8 sessions of the group therapy could be compared to those who missed two or more sessions.

Expectancy Factors

The expectations that participants have regarding the effects of the treatment could also be assessed and examined in light of treatment response. It is possible that participants' expectancies about the effectiveness of the treatment could impact their response to the treatment. Those who believe that the therapists are competent, that the program was developed from existing effective programs, and that they will feel better after the program may actually improve to a greater degree than those who are skeptical about the program. In order to assess expectancy effects, prior to starting treatment participants could be asked to rate their confidence in the treatment program and the degree to which they believe it will improve their symptoms or ability to manage their illness. These ratings could be examined in relation to the outcome measures at post-treatment.

Directions for Future Research

It is important to consider differences across chronic pain disorders and to treat them, to some degree, as heterogeneous conditions. When treating fibromyalgia, examining individual patient characteristics may also be important. That is, it is likely inappropriate to view a group of patients with the same illness as a homogeneous group. Researchers have identified subtypes of chronic pain patients and suggest that tailoring treatment based on these subtypes can improve treatment efficacy. For example, coping styles can be used to identify subgroups and treatments can be tailored to various coping styles. Turk and Okifuji (1998) suggest that pre-treatment patient characteristics are important predictors of treatment response and may serve as a basis for matching treatments to patient characteristics.

Efficacy of Treatment

To improve efficacy of treatment, more intense clinical service may be beneficial. When inpatient or day treatment programs are not possible an outpatient group that met more than once a week may be realistic (Stans et al., 1989). Perhaps adding some individual follow-up sessions during and after treatment would increase treatment efficacy since identifying barriers to change, problem-solving, and motivational interviewing may be more feasible on an individual level. Also, some participants have unique stressors that may need special consideration. For example, it may be more challenging for a mother of young children to fit in relaxation time. Or in a troubled marriage it may be more difficult to practice assertiveness skills or activity pacing.

Attrition

The dropout rate in the current study was 5.71%. When including the participants who did not withdraw but missed more than 2 of 8 sessions the rate was 9.52%. In a review by Burckhardt (2006) the dropout range was 0-29% with an average of 12%. Although the attrition rate in the current study is lower than this average this does not speak to the completion or rate of return of the assessment measures at each time period.

It appears that the more individual time participants have with therapists/researchers improves adherence and completion. Luedtke and colleagues (2005) noted that the participants found that the one-on-one time with the nurse to tell their stories was very meaningful. It may be that the individual contact participants had with the researcher in the current study impacted the relatively good attrition rate. However, in future studies it would be important to attempt to improve the completion rate of the questionnaires at post-test and follow-up. If the location was more convenient it may be useful to ask participants to complete the questionnaires on-site. In addition, with adequate resources financial incentive could be provided and reminder phone-calls may also improve completion for packages that are mailed out.

Logistics are also important to consider when attempting to reduce attrition or improve completion of assessment measures. In the current study participants had to attend sessions at the university (except for the group that was conducted in Prince Albert). Although the researcher made every effort to organize parking it did present difficulties for some participants. Some considered the parking lot to be too far away. Finding closer parking was difficult. In hot, cold, or slippery conditions the walk from the parking lot to the building was an issue for some. The cost of parking was covered for participants and this likely led to a larger enrollment since

cost was a consideration for many. For those participants who did not drive, holding the sessions at the university was not a significant barrier since public transit to the university is good. However, the walk from the bus stop to the building was considered fair for some participants. The ideal would be a facility with free parking very close by, easily accessible by public transit, and minimal stairs and/or wheelchair accessible.

Sex and Spousal Involvement

The current study was limited to women with fibromyalgia because there was a concern that relatively few men diagnosed with fibromyalgia would participate. Men are diagnosed with fibromyalgia less than women, and among men that would meet criteria for fibromyalgia it may be that alternative diagnoses are provided that appear more sex appropriate, such as chronic widespread pain, or regional pain disorder. In addition, men may be less likely to seek treatment for fibromyalgia, especially in a group therapy setting. There was concern that a group may consist of only one man or there would be a sex difference between groups in which some may have a male participant and others may not, potentially changing the dynamics of the group. In future studies it would be informative to provide a similar group treatment for men with fibromyalgia.

In addition, providing treatment to mixed groups and involving spouses/support persons in the treatment may be beneficial, particularly for maintaining progress over the long-term. For example, a patient's perception of spousal support may moderate the pain experience and associated depression (Goldberg, Kerns, & Rosenberg, 1993). The effects of chronic pain are not limited to the individual with the diagnosis; rather, the family and social network can be affected. Therefore, educating the primary support person about fibromyalgia and involving them in treatment can impact the roles taken in the home, elicitation of pain behaviours, use of adaptive coping skills, and understanding of activity pacing, relaxation training, and other coping skills.

Summary

The manualized group therapy for fibromyalgia syndrome that was developed for the current study is novel, in that it combined CBT and interpersonal therapy. CBT is widely acknowledged as an empirically validated treatment for chronic pain conditions, including arthritis. However, the results of the well-designed studies examining CBT for fibromyalgia show that, overall, CBT is not superior to a credible attention placebo (L. Bradley, personal

communication, 2002). The aim of the current study, therefore, was to utilize the necessary components of CBT while adding the interpersonal approach with the goal of addressing factors that are idiosyncratic to fibromyalgia and that are better suited to a process based therapy rather than a therapy based on psycho-education. CBT can be effective at addressing patients' beliefs regarding their illness and how their beliefs influence emotional and behavioural factors. For example, negative or unrealistic beliefs regarding pain can result in negative affect, pain, and reduced attempts to develop effective coping strategies (Okifuji and Turk, 1999). There are additional factors that are critical in understanding the patients' experience of living with chronic pain. Interpersonal patterns and personality characteristics affect relationships and the quality of relationships can, in turn, affect symptoms and the ability to cope with illness. The interpersonal therapy component of treatment provided a safe atmosphere for addressing the impact of the social and environmental context, including social support, social roles, and personal history.

The results of the randomized-controlled trial show that the cognitive-behavioural and interpersonal approach was effective with respect to a number of meaningful variables, including fibromyalgia impact, coping, and self-efficacy. The impact that fibromyalgia symptoms had on various aspects of participants' lives was reduced. This improvement was both statistically and clinically significant. This finding is important since the improvement in fibromyalgia impact resulted from a psychological intervention alone, whereas similar findings in the literature resulted from more complex and resource intensive multidisciplinary programs. Therefore, the cognitive-behavioural and interpersonal approach holds promise for improving impact of fibromyalgia symptoms in light of resource utilization considerations.

Some improvement in mood was demonstrated, although not across all measures. This is consistent with the literature; findings regarding depression following treatment for fibromyalgia are mixed. More consistent use of validated measures to assess multiple facets of depression would be an important contribution. Participants in the current study felt significantly less depressed or blue following treatment compared to the control condition.

Notable improvements in coping strategies were observed following treatment. Use of wellness-focused strategies, such as relaxation, increased while illness-focused strategies, such as guarding a body part, decreased. Less guarding behaviour may reduce muscle tension, which can become chronic and exacerbate pain. A philosophy and skill taught during treatment, called activity pacing, also appeared to have positive effects on other coping strategies such as task

persistence and resting. Pacing may have reduced the tendency to persist on activities when in pain or fatigued and to use scheduled rest for short periods of time as a break from activity that may have otherwise led to an exacerbation of symptoms.

Perhaps the most meaningful result of the current study is the improvement in self-efficacy. Self-efficacy beliefs have been related to pain, coping efforts, disability, and psychological functioning (Anderson et al., 1995; Buckelew et al., 1995; Jensen et al., 1999; Stroud et al., 2000; Turk & Okifuji, 1997; Turner, Jensen, & Romano, 2000). In the future, the effectiveness of the combined cognitive-behavioural and interpersonal treatment for fibromyalgia will hopefully be improved upon by focusing on maintaining the treatment effects over the long-term. Perhaps long-term maintenance of improvement on a number of outcomes could be mediated by further improvements in self-efficacy. There is strong evidence that changes in self-efficacy are enduring and affect changes in health behaviours and health status (Lorig, 1989). For example, self-efficacy may promote improvement in health behaviours such as exercise, relaxation training, and the continued practice of adaptive coping strategies. The hope is that greater self-efficacy and positive health behaviour changes will improve people's ability to manage fibromyalgia syndrome and enjoy a greater quality of life.

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Table 1

Description of a Selection of Fibromyalgia Intervention Studies

Author	Design	Sample Size	Intervention	Intervention Format	Outcome Measures	Follow-up	Treatment Efficacy (Significant Differences)
Attention Placebo Controlled Trials							
Vlaeyen et al. (1996)	RCT	131	1. experimental: education/cognitive (includes exercise) 2. attention control: education/discussion (includes exercise) 3. wait-list control	12 sessions over 6 weeks, group format, max 6 people per group. Cognitive: 12, 90 min sessions. Education: 12, 2-hr sessions.	knowledge of FM, pain coping, pain control, relaxation (CSQ), catastrophizing (PCL), pain intensity (MPQ) and behaviour, depression (BDI)	12 mths	Value of cognitive treatment added to group education was not supported.
Nicassio et al. (1997)	RCT	71	1. behavioural intervention 2. education/control	10 weeks, 90 min weekly, group format, 3-7 people per group (plus support persons in behavioural condition).	pain, pain behaviour, depression (CES-DS), disability, pain coping (PMI), social support	6 mths	No signif. differences between conditions.
Buckelew et al. (1998)	RCT	119	1. biofeedback and relaxation training 2. exercise 3. combination therapy (1. and 2.) 4. educational/attention control	6 weeks, 1.5-3 hrs weekly, individual. 2-year group maintenance phase, once a month, 1hr.	tender point index, disease severity, pain behaviour, VAS, health status (AIMS), SCL90-R, depression (CES-D), self-efficacy, sleep problems	2 yrs	No signif. between group differences among treatment groups. All treatment groups had improved self-efficacy for function compared to control.
Keel et al. (1998)	RCT	32	1. integrated group therapy (tx program includes: education, self-control strategies, gymnastics, relaxation, group discussion) 2. relaxation (control group)	15 weeks. Group 1: weekly 2-hr group sessions. Group 2: weekly 45-60 min sessions.	medication use, sleep, pain, patient's global assessment, general symptom checklist	3 mths	Changes in illness parameters for experimental group overall were not signif different from controls.

Table 1 (continued)

Description of a Selection of Fibromyalgia Intervention Studies

Author	Design	Sample Size	Intervention	Intervention Format	Outcome Measures	Follow-up	Treatment Efficacy (Significant Differences)
<u>Wait-list Controlled Trials</u>							
Burckhardt et al. (1994)	RCT	99	1. education (includes: coping strategies, problem solving, assertiveness, relaxation) 2. education and physical therapy 3. delayed treatment control	6 weeks. Education: 1.5 hr self-management class weekly. 5-6 people per group. Physical therapy: 1 hr weekly of exercise training.	FM impact (FIQ), sense of control (FAQ), quality of life (QOLS), self-efficacy (SELF), physical fitness, tender points, depression (BDI)	12 wks	No signif. between group difference from pre to post on FIQ change score. Both intervention groups had signif. improvement on quality of life and self-efficacy.
Wigers et al. (1996)	RCT	60	1. aerobic exercise 2. stress management (includes cognitive behavioural stress management package) 3. treatment as usual	14 weeks, 10 people per group. Exercise: 45 min, 3 times per week. Stress management: 90 min, 2 times a week for first 6 weeks, once a week for remaining 8 weeks.	pain, sleep, fatigue (VAS), tender point threshold, global subjective improvement, depression (VAS)	4 yrs	Exercise and stress management conditions showed positive short-term effects. Exercise overall most effective. No group differences at follow-up in symptom severity between groups.
Mason et al. (1998)	CT	21	1. multimodal treatment (physical therapy, exercise, monitor medication, patient education in cognitive-behavioural techniques) 2. control group	1 month, full day program, 6 days per week. CBT portion of treatment is a 2 hr class daily.	tender point pain, pain intensity (VAS), coping skills (CSQ), FIQ, depression (BDI)	6 mths	Signif. improvement in coping skills, depression, and subjective pain, maintained at follow-up. No treatment effects on objective pain measures.
Gowans et al. (1999)	RCT	41	1. exercise and educational program 2. wait-list control	6 weeks. 2 multidisciplinary group education sessions per week, 1 hr, followed by an exercise class in the pool, 30 min.	FM impact (FIQ), self-efficacy (ASES), knowledge questionnaire, walk test	3 or 6 mths	Signif. improvement in well-being, fatigue, self-efficacy for symptom control, and knowledge. follow-up gains in fatigue, knowledge not maintained.

Table 1 (continued)

Description of a Selection of Fibromyalgia Intervention Studies

Author	Design	Sample Size	Intervention	Intervention Format	Outcome Measures	Follow-up	Treatment Efficacy (Significant Differences)
Uncontrolled Trials							
Nielson et al. (1992)/ White & Nielson (1995)	quasi-experimental follow-up	25	1. inpatient cognitive-behavioural treatment (relaxation, cognitive techniques, exercise, pacing, family education, in vivo rehearsal) 2. participants acted as their own wait-list control group prior to treatment	3 weeks, inpatient.	target variables: pain severity, perceived interference, control over pain, emotional distress. nontarget: perceived support, signif others' response to pain, marital adjustment, activity level	30 mths	Statistically signif. change in target variables but not nontarget variables from pre to post. At follow-up improvements in target variables were maintained.
Bennett et al. (1996)	description of treatment program	117	1. Multimodal approach: education, behaviour modification, exercise, medication by injection for trigger points, (some patients also received counselling and medication)	6 months, group format, 90 min, once a week.	FM impact (FIQ), tender point score, quality of life, coping strategies, attitudes to illness, aerobic conditioning, depression (BDI), anxiety (BAI)	2 yrs	Overall signif. improvement in all measures at post-treatment. At 2-year follow-up FIQ improvement stabilized and quality of life continued to improve.
Turk et al. (1998)	pre, post, follow-up, single group	67	1. interdisciplinary treatment: medical, physical, psychologic (based on cognitive-behavioural model), and occupational therapies	4 weeks. 3 half-day session in first week, 1 half-day session per week for next 3 weeks. 4-7 people per group.	pain severity and interference (MPI), depression (CES-D), perceived disability (ODI), marital adjustment (LWMAS)	6 mths	Signif. improvement in pain (severity, interference, control, affective distress) and maintained at follow-up. FIQ (physical impairment, fatigue, anxiety, depression) improvements not maintained. Relapse in fatigue.
Creamer et al. (2000)	pilot study, single group	28	1. education/cognitive-behavioural component, relaxation/meditation, and Chinese movement therapy (Qi Gong)	8 weeks. 2.5 hr weekly sessions. Each session: 30 min education/CBT, 1 hr relaxation/meditation, 1 hr Qi Gong.	FM impact (FIQ), sleep, health status (RAND), depression (BDI), helplessness (FAI), coping (CSQ), functional disability (HAQ), physical activity, tender points, pain threshold	4 mths	Signif. improvement in FIQ total sleep, disability, some domains of health status, depression, and coping, tender points, pain threshold. Improvements in depression and some domains of health status not maintained.

Table 1 (continued)

Description of a Selection of Fibromyalgia Intervention Studies

Author	Design	Sample Size	Intervention	Intervention Format	Outcome Measures	Follow-up	Treatment Efficacy (Significant Differences)
Uncontrolled Trials (continued)							
Worrel et al. (2001)	quasi-experimental	100	1. self-management approach includes education, stress management, relaxation, sleep hygiene, coping skills, occupational and physical therapy	1 1/2 day program.	FM impact (FIQ) and pain variables (MPI)	1 mth	Improvement in total FIQ score, pain severity and interference. FIQ benefits maintained at follow-up. High pre-treatment level of impairment associated with better response to treatment.
Luedtke et al. (2005)	description of program	1939	1. self-management approach includes education, stress management, relaxation, sleep hygiene, coping skills, occupational and physical therapy	1 1/2 day program.	health status (HSQ) and FM impact (FIQ)	12 mths	Signif. improvement in: impact of FM (FIQ), mental health and physical function (HSQ) from pre to post and stable at follow-up.
Hooten et al. (2007)	prospective case series	159	1. cognitive-behavioural group sessions, physical and occupational therapy.	3 weeks. 8 hrs daily for 15 consecutive working days.	pain (MPI), health status (SF-36), coping (CSQ), depression (CES-D)	no	Signif. improvements include: pain severity, interference, affective distress, life control, social activity, perception of health, physical function, depression.
Rooks et al. (2007)	RT	135	1. aerobic and flexibility exercise 2. strength training, aerobic, flexibility exercise 3. FM self-help course 4. combination of 2 and 3	16 weeks. Exercise sessions: 60 min twice weekly and additional day weekly on own. FM course: 7 session, 120 min, every 2 weeks.	primary outcome: change in physical function. secondary: social and emotional function, symptoms, self-efficacy	6 mths	Signif. improvement in FIQ total score, social function, and mental health in group 4 compared to FM self-help alone.

Table 1 (continued)

Description of a Selection of Fibromyalgia Intervention Studies

Author	Design	Sample Size	Intervention	Intervention Format	Outcome Measures	Follow-up	Treatment Efficacy (Significant Differences)
Uncontrolled Trials (continued)							
van Wilgen et al. (2007)	prospective single group study	65	1. education program: cognitive restructuring, goal setting, assertiveness training, relaxation, and physical therapy sessions.	7 sessions of education and 25 sessions of physical therapy. Groups of 8-12 for education and 4-6 for exercise.	FM impact (FIQ), quality of life (RAND), pain coping and cognitions (PCCL), pain and injury beliefs, step test, vertical row.	3 mths	Signif. improvement from pre to post on domains of feeling good, pain, stiffness. Signif. improvement in catastrophizing from pre to post and pre to follow-up. No changes in anxiety or depression.

Note. CSQ = Coping Strategies Questionnaire; MPCL = Multidimensional Pain Locus of Control Scale; MPQ = McGill Pain Questionnaire; BDI = Beck Depression Inventory; CES-D = The Center for Epidemiological Studies-Depression Scale; PMI = PainManagement Inventory; VAS = Visual Analogue Scale; AIMS = Arthritis Impact Measurement Scales; SCL90-R = Symptom Checklist 90-Revised; FIQ = Fibromyalgia Impact Questionnaire; FAI = Fibromyalgia Attitudes Index; QOLS = Quality of Life Scale; SELF = Self-Efficacy Scale; BAI = Beck Anxiety Inventory; MPI = Multidimensional Pain Inventory; ODI = Oswestry Disability Index; LWMAS = Locke-Wallace Marital Adjustment Scale; RAND = 36-item Health Survey; HAQ = Health Assessment Questionnaire; SF-36 = Short Form-36 Health Status Questionnaire; PCCL = Pain Coping and Cognition List. Signif. = significant. FM = fibromyalgia.

Table 2

Demographic Characteristics of the Sample

Variable	Treatment	Control	Total
Age in years, M (SD)	51.91 (10.11)	53.04 (8.55)	52.44 (9.39)
N	54	47	101
Education in years, M (SD)	13.52 (2.20)	13.39 (2.76)	13.46 (2.48)
N	52	51	103
Ethnic Origin, N (%)			
white	47 (87.00)	47 (94.00)	94 (90.40)
hispanic	3 (5.60)	0 (0.00)	3 (2.90)
asian	1 (1.90)	1 (2.00)	2 (1.90)
german	1 (1.90)	0 (0.00)	1 (1.00)
other	2 (3.70)	2 (4.00)	4 (3.90)
Marital status, N (%)			
married	39 (73.60)	34 (68.00)	73 (69.50)
single	6 (11.30)	2 (4.00)	8 (7.60)
divorced/separated	8 (15.10)	11 (22.00)	19 (18.10)
widowed	0 (0.00)	3 (6.00)	3 (2.90)

Table 3

Number of Participants Completing Measures at Four Time Points

Condition	Time 1 (pre-treatment)	Time 2 (post-treatment)	Time 3 (1-month follow-up)	Time 4 (3-month follow-up)
Treatment	54	41	20	27
Control	51	30	10	20
Total	105	71	30	47

Note. Data represent all participants who completed either part of or all of the measures.

Table 4

Pre-treatment Means Comparing Questionnaire Responders to Non-responders

Variable	Responders <i>M</i>				Non-responders <i>M</i>			
	Total	n	Treatment	Control	Total	n	Treatment	Control
NPRS - Total	207.00	73	212.95	198.10	204.00	32	215.50	199.99
NPRS - Frequency	5.80	73	5.58	6.28	6.25	32	6.16	6.30
NPRS - Continuous*	78.00	73	66.39	95.69	99.21	32	95.58	100.87
FIQ - Total	54.77	73	55.51	53.65	56.00	32	64.85	52.07
FIQ - Work missed	3.00	73	2.73	3.40	2.10	32	3.86	1.29
ASES	4.88	73	4.60	5.32	4.58	32	3.55	5.05
Disability	0.57	73	0.58	0.55	0.67	32	0.74	0.64
Physician visits	3.73	73	3.53	4.03	3.65	32	4.90	3.07
SCL90-R - Anxiety	0.92	71	1.03	0.76	1.12	30	1.95	1.18
SCL90-R - Depression	1.58	71	1.61	1.52	1.44	30	1.61	0.72
QOLS - Total	71.32	69	73.03	68.50	74.86	30	74.55	75.02
CPCI - Coping	3.05	67	3.18	2.85	2.90	30	2.67	3.01
CPCI - Guarding	3.35	67	3.60	2.85	3.12	30	3.03	2.60
CPCI - Relaxing	1.23	67	1.12	1.40	1.21	30	2.19	1.73
CPCI - Task	4.62	67	4.46	4.88	5.01	30	4.48	5.28
CPCI - Asking	2.38	67	2.53	2.14	1.94	30	1.85	1.38
CPCI - Resting	3.19	67	3.34	2.95	2.74	30	4.17	2.71
CPCI - Support	2.52	67	2.51	2.53	1.93	30	1.90	1.89

Note. Responders are defined as those participants who responded to the questionnaires (completed the measures) at T1 and T2. Non-responders are those who completed the measure at T1 but not at T2. Asterisk denotes difference between responder total mean and non-responder total mean. NPRS = Numerical Pain Rating Scale; FIQ = Fibromyalgia Impact Questionnaire; ASES = Arthritis Self Efficacy Scale; SCL90-R = Symptom Checklist 90 Revised; QOLS = Quality of Life Scale; CPCI = Chronic Pain Coping Inventory.

Table 5

Number of Items with Missing Data and the Number of Mean Substitutions Performed for each Measure

Measure (Total # of Items on Scale)	# of Participants with Blank Items	# of Items with Missing Data	# of Mean Substitutions
FIQ (20)			
Time 1	4	3	5
Time 2	5	2	5
Time 4	1	1	1
NPRS (6)			
Time 1	3	3	3
Time 2	1	1	1
Time 4	1	1	1
CDQ (42)			
Time 1	25	20	48
Time 2	16	15	30
Time 4	22	7	25
SCL90-R (90)			
Time 1	14	16	18
Time 2	6	7	7
Time 4	3	3	4
QOLS (16)			
Time 1	4	7	8
Time 2	2	2	2
Time 4	1	2	2
CPCI (63)			
Time 1	8	22	25
Time 2	8	8	8
Time 4	1	1	1

Note. FIQ = Fibromyalgia Impact Questionnaire; NPRS = Numerical Pain Rating Scale; CDQ = Chronic Disease Questionnaire; SCL90-R = Symptom Checklist 90-Revised; QOLS = Quality of Life Scale; CPCI = Chronic Pain Coping Inventory.

Table 6

Cronbach's Alphas, Mean Inter-Item Correlations, Means, and Standard Deviations for Scales

Scale/Subscale	Cronbach's Alpha T1	<i>M</i> Inter-Item Correlation T1	Scale <i>M</i> T1	Scale <i>SD</i> T1	Cronbach's Alpha T2	<i>M</i> Inter-Item Correlation T2	Scale <i>M</i> T2	Scale <i>SD</i> T2
FIQ – Total	0.85	0.22	60.45	15.80	0.91	0.32	59.21	19.92
FIQ - Work missed*			2.75	3.34			2.44	2.82
NPRS – Total	0.75	0.43	206.87	60.42	0.83	0.54	204.11	70.57
NPRS – Frequency*			6.61	6.50			5.39	2.04
NPRS - Continuous*			84.49	67.73			79.32	74.11
Disability	0.84	0.40	5.75	3.45	0.86	0.44	4.43	3.51
ASES	0.86	0.44	38.28	13.33	0.92	0.60	47.61	15.58
Physician visits*			3.71	2.98			3.74	3.56
QOLS – Total	0.88	0.31	72.65	13.34	0.88	0.31	73.08	13.89
FIQ - Depression*								
SCL90-R - Depression	0.90	0.40	19.77	10.67	0.90	0.41	18.22	12.46
FIQ - Anxiety*								
SCL90-R – Anxiety	0.88	0.42	9.54	7.56	0.85	0.36	7.65	7.01
CPCI – Coping	0.89	0.41	33.32	19.22	0.87	0.37	35.78	18.39

Note. Based on original data, does not include the last observation carried forward. Asterisk denotes a single item. FIQ = Fibromyalgia Impact Questionnaire; NPRS = Numerical Pain Rating Scale; ASES = Arthritis Self-Efficacy Scale; QOLS = Quality of Life Scale; SCL90-R = Symptom Checklist 90-Revised; CPCI = Chronic Pain Coping Inventory.

Table 7

Means, Standard Deviations, and F values for the Intention-to-Treat Comparison of the Treatment Condition and the Control Condition over Time

Variable	Group	Time 1		Time 2		Time 4		N	F	N	F
		M	SD	M	SD	M	SD				
Primary Variable											
FIQ total	Treatment	57.37	15.38	51.24	19.28	54.00	18.02	54	4.39**	54	1.96
	Control	53.23	15.36	52.70	15.70	53.96	13.86	51		51	
Secondary Variables											
Pain											
intensity	Treatment	213.42	63.20	203.01	68.90	201.30	75.33	54	0.97	54	0.63
	Control	199.21	56.63	203.86	66.57	198.43	62.85	50		51	
frequency*	Treatment	5.69	1.99	5.25	2.12	5.33	2.21	54	2.56	54	0.68
	Control	6.34	1.48	6.12	1.50	5.98	1.67	50		50	
duration	Treatment	71.80	65.07	70.12	69.46	72.13	68.18	54	2.36	53	0.01
	Control	97.93	68.53	103.57	72.03	89.19	74.83	50		50	
Functional disability	Treatment	0.61	0.48	0.58	0.46	0.54	0.48	54	0.50	54	2.61
	Control	0.59	0.46	0.60	0.44	0.63	0.56	51		51	
Work missed*	Treatment	2.94	3.56	1.65	2.13	1.86	2.34	54	0.09	54	0.28
	Control	2.55	3.08	1.59	1.73	1.89	2.03	51		51	
Health care utilization*	Treatment	3.65	2.68	3.74	3.02	3.56	3.15	54	0.08	53	0.02
	Control	3.63	2.65	3.57	3.47	3.62	3.55	51		51	
Depression											
FIQ*	Treatment	4.44	2.95	3.76	2.82	4.13	2.68	54	5.44**	54	0.64
	Control	3.64	2.52	3.92	2.47	3.90	2.54	51		51	
SCL90-R	Treatment	1.68	0.89	1.51	0.97	1.56	0.94	53	0.51	51	1.21
	Control	1.41	0.76	1.36	0.78	1.44	0.76	45		43	
Anxiety											
FIQ*	Treatment	5.27	2.81	4.80	2.80	4.98	2.75	54	1.11	54	1.15
	Control	4.06	2.70	4.27	2.68	4.49	2.54	51		51	
SCL90-R	Treatment	1.14	0.80	1.06	0.81	1.00	0.72	53	1.18	51	0.05
	Control	0.77	0.66	0.68	0.56	0.71	0.64	45		43	

Table 7 (continued)

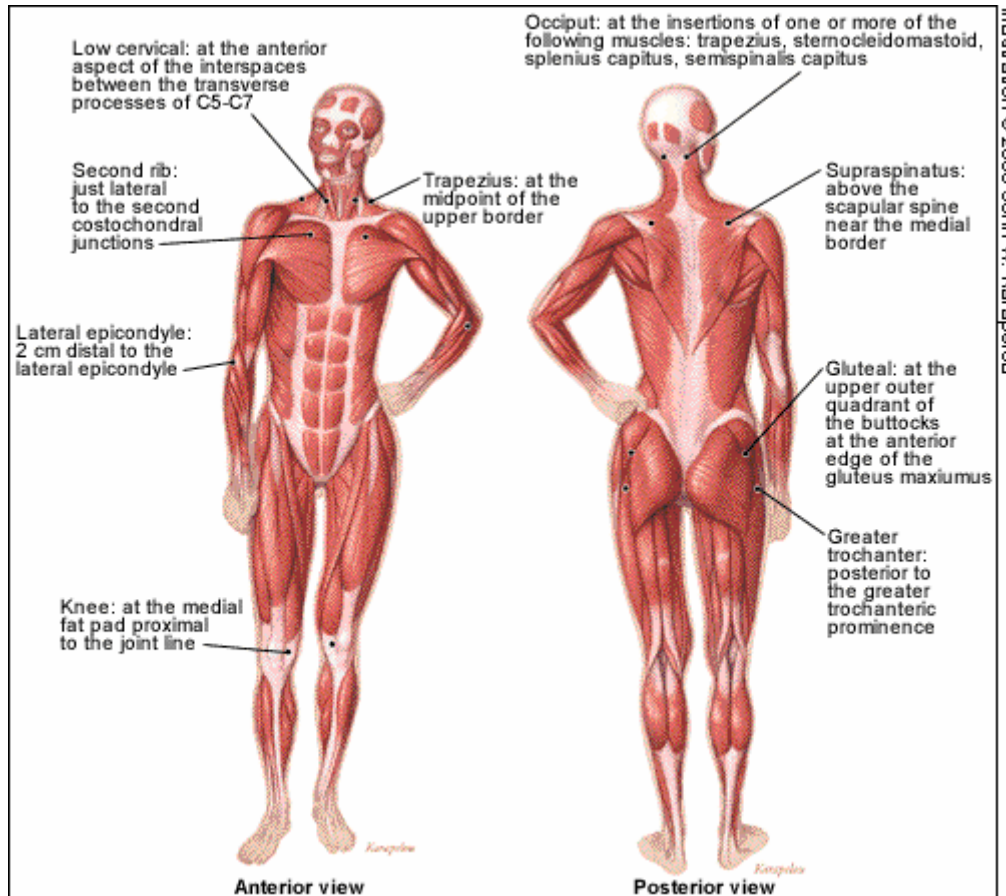
Means, Standard Deviations, and F values for the Intention-to-Treat Comparison of the Treatment Condition and the Control Condition over Time

Variable	Group	Time 1		Time 2		Time 4		N	F	N	F
		M	SD	M	SD	M	SD				
Secondary Variables											
Coping											
self-statements	Treatment	3.08	1.84	3.25	1.65	3.09	1.90	51	0.37	46	0.01
	Control	2.94	1.64	3.11	1.70	2.91	1.58	46		41	
task persistence	Treatment	4.46	1.92	4.15	1.79	4.33	1.99	49	6.00**	46	1.04
	Control	5.04	1.32	5.17	1.31	5.12	1.39	42		41	
relaxation	Treatment	1.96	1.37	3.23	1.51	2.53	1.57	49	28.63***	46	4.10**
	Control	2.01	1.51	197.00	1.71	2.06	1.63	42		41	
guarding	Treatment	3.22	2.13	3.03	1.81	2.71	1.64	49	0.01	46	6.04**
	Control	2.76	1.51	2.68	1.64	2.88	1.76	42		41	
asking for help	Treatment	2.16	1.92	2.46	1.94	2.34	1.95	49	1.01	46	0.26
	Control	1.65	1.52	1.77	1.67	1.79	1.59	42		41	
resting	Treatment	3.89	1.64	4.04	1.44	3.83	1.70	49	10.74**	46	2.6
	Control	3.03	1.42	2.75	1.62	2.79	1.49	42		41	
seeking support	Treatment	2.36	1.46	2.57	1.60	2.40	1.60	49	1.18	46	0.15
	Control	2.15	1.46	2.23	1.49	2.33	1.46	42		41	
Relaxation (CDQ)	Treatment	3.39	4.33	8.80	10.21	6.07	8.55	54	16.05***	54	3.80**
	Control	5.10	13.43	4.06	8.16	5.16	13.61	51		51	
Self-efficacy	Treatment	4.40	1.63	5.80	2.18	5.24	2.03	54	11.51***	54	3.29
	Control	5.14	1.66	5.32	1.70	5.33	1.60	51		51	
Quality of life	Treatment	73.32	12.11	74.80	14.58	73.43	15.20	52	0.23	47	0.26
	Control	71.42	14.88	72.58	11.07	72.93	10.52	42		41	

Note. The means and standard deviations for time 2 and time 4 are based on the ANCOVA results. * indicates a single item. **indicates a statistically significant result ($p =$ or < 0.05), ***indicates a statistically significant result ($p =$ or $< .001$). FIQ = Fibromyalgia Impact Questionnaire, SCL90-R = Symptom Checklist 90-Revised, CDQ = Chronic Disease Questionnaire.

Appendix A

Diagram of the Tender Point Sites in Fibromyalgia Syndrome



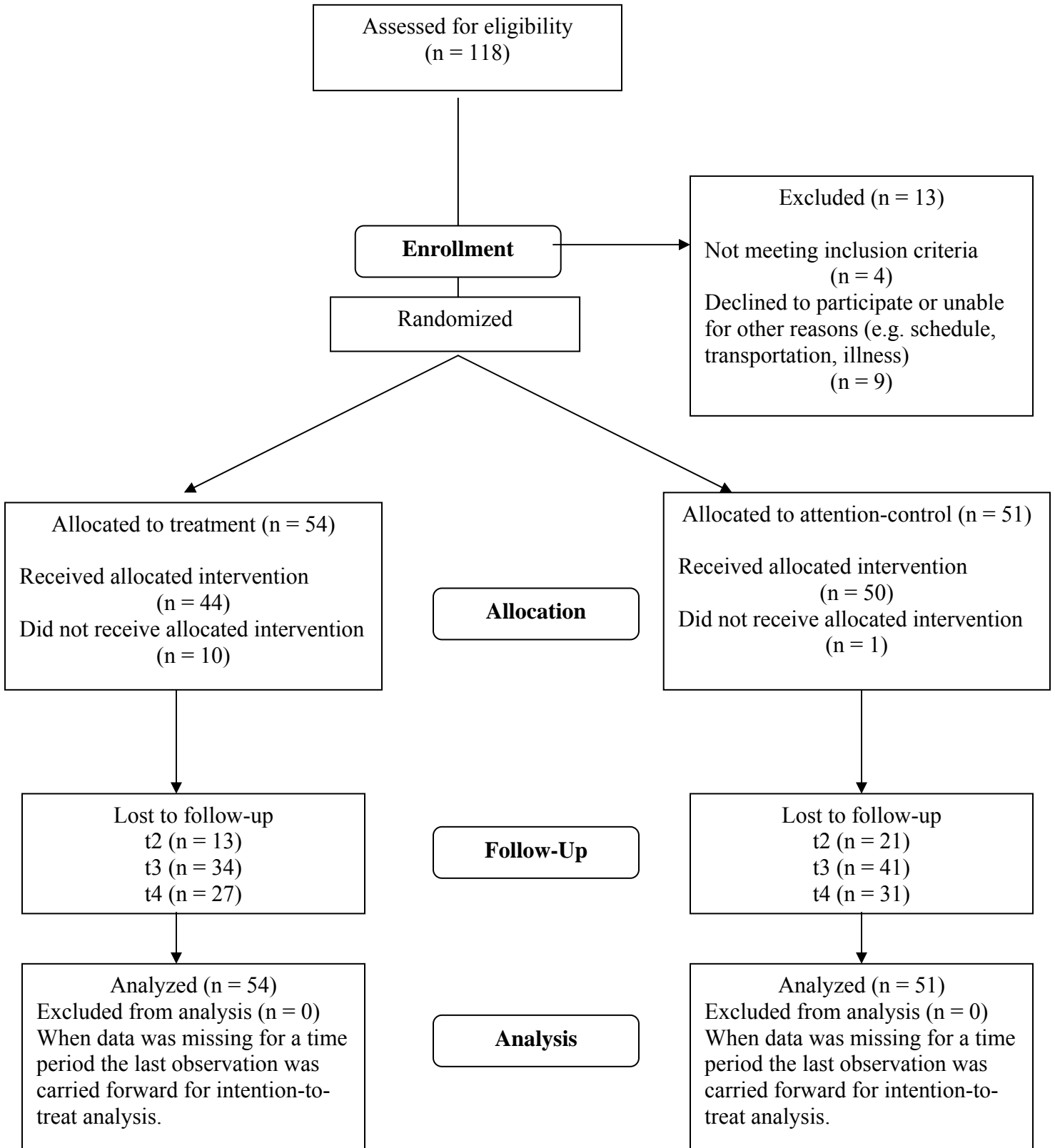
Appendix B

Recruitment Effort List

1. Contacted rheumatologists in Saskatoon by letter.
2. Followed up with phone calls and emails.
3. Dr. Markland offered to help me and we did a mail out from her office to approximately 350 patients. One letter was from Dr. Markland endorsing the study while the other was from Melanie Langford and Michael MacGregor inviting people to participate and to contact us.
4. Posters were placed at RUH, St. Paul's hospital and City Hospital.
5. The Fibromyalgia Society was contacted and I spoke at one of their meetings at RUH. One of the coordinators offered to place my letters in her next mail out to the members.
6. I spoke with Dr. Pancyr and he spoke to a rheumatologist, Dr. Sibley for me. Dr. Sibley invited me to speak at one of the rheumatologist's meetings at RUH. I described the study and asked if anyone would be interested in helping me with recruitment. I provided a number of options, with an emphasis on making it as convenient for them as possible. I did not have offers of help from any of the other rheumatologists present at the meeting.
7. Dr. Sibley took some of my posters and letters to distribute to the rheumatologists that were not present.
8. I followed up by phone with Dr. Sibley and others.
9. Efforts to contact Dr. Joe Schnurr via phone and email. I met him at the Fibromyalgia Grand Rounds and spoke with him about the research.
10. Efforts to contact Dr. Epstein, also involved with the Grand Rounds.
11. Spoke with a physiotherapist at the Pain Clinic downtown, and also placed posters there. The physiotherapist said that she would hand out letters to patients.
12. I have posters in a couple of psychology private practice settings.
13. Placed posters in the arts tunnel.
14. I have been to some chiropractic/exercise facilities with posters.
15. I have asked participants whether they would mind letting other people know about the study. One participant distributed letters to a health cooperative that she is involved in.
16. Met with Angela Busch, researcher in physical therapy, provided recruitment suggestions and is kindly allowing me to do a mail out from her office to 81 of her participants with fibromyalgia who consented to be contacted in the future.
17. Spoke with Dr. M. Z. Hussain in Prince Albert, he runs a fibromyalgia clinic there and passed on letters to 50-60 people and placed posters in waiting area.
18. Sent a package to Dr. Joe Schnurr and he placed posters in 2 offices and is going to tell patients about the study and pass on letters to them.
19. A mail out was done to all family physicians/GPs in Saskatoon, Prince Albert, and surrounding areas with information about the study and posters.
20. Advertising in the Sheaf, Saskatoon Sun, and Star Phoenix. Newspaper article was also written in the Sheaf and the Star Phoenix.

Appendix C

The CONSORT Flowchart Depicting Passage of Participants through the Study



Appendix D

Fibromyalgia Impact Questionnaire (FIQ)

Name: _____

Date: _____

Directions: For questions 1 through 11, please circle the number that best describes how you did overall for the *past week*. If you don't normally do something that is asked, cross the question out.

	Always	Most	Occasionally	Never
Were you able to:				
Do shopping?	0	1	2	3
Do laundry with a washer and dryer?	0	1	2	3
Prepare meals?	0	1	2	3
Wash dishes/cooking utensils by hand?.....	0	1	2	3
Vacuum a rug?.....	0	1	2	3
Make beds?	0	1	2	3
Walk several blocks?	0	1	2	3
Visit friends or relatives?	0	1	2	3
Do yard work?.....	0	1	2	3
Drive a car?	0	1	2	3
Climb stairs?	0	1	2	3

12. Of the 7 days in the past week, how many days did you feel good?

0 1 2 3 4 5 6 7

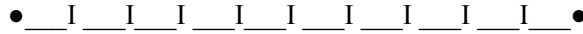
13. How many days last week did you miss work, including housework, because of fibromyalgia?

0 1 2 3 4 5 6 7

(continued)

Directions: For the remaining items, mark the point on the line that best indicates how you felt overall for the past week.

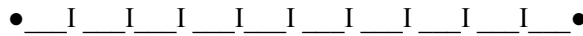
14. When you worked, how much did pain or other symptoms of your **fibromyalgia** interfere with your ability to do your work, including housework?



No problem with work

Great difficulty with work

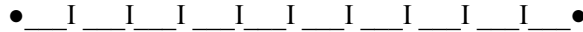
15. How bad has your pain been?



No pain

Very severe pain

16. How tired have you been?



No tiredness

Very tired

17. How have you felt when you get up in the morning?



Awoke well rested

Awoke very tired

18. How bad has your stiffness been?



No stiffness

Very stiff

19. How nervous or anxious have you felt?



Not anxious

Very anxious

20. How depressed or blue have you felt?



Not depressed

Very depressed

Appendix E

Numerical Pain Rating Scale (NPRS)

Please rate your pain on the following 0 to 100 scales by checking one box that best represents your pain on each scale.

0 represents ‘no pain’ and 100 represents ‘worst possible pain’.

For example, less than 30 may be mild, 50 is moderate, and above 70 is severe pain.

Rate your worst pain.

0	5	10	15	20	25	30	35	40	45	50	55	60	65	70	75	80	85	90	95	100	

Rate your pain today.

0	5	10	15	20	25	30	35	40	45	50	55	60	65	70	75	80	85	90	95	100	

Rate your least pain.

0	5	10	15	20	25	30	35	40	45	50	55	60	65	70	75	80	85	90	95	100	

Rate your average (or usual pain) over the last 2-week period.

0	5	10	15	20	25	30	35	40	45	50	55	60	65	70	75	80	85	90	95	100	

Please indicate the number of days that you have experienced pain within the last week. You may use full days or half days (for example, 2.5 days).

_____ days

Please indicate the longest length of time that you have experienced non-stop or continuous pain within the last week.

If the continuous pain lasted less than 60 minutes, write the number in minutes.

If the continuous pain lasted more than 60 minutes, write the number in hours (you can use half hours).

Or, if the continuous pain lasted more than 24 hours (a day) write the number in days (you can use half days).

_____ minutes, OR _____ hours, OR _____ days

Appendix F

Chronic Disease Questionnaire (CDQ)

Stanford Patient Education Research Center, Stanford University School of Medicine

1. Ethnic origin (check **only one**):

- | | |
|---|---|
| <input type="checkbox"/> White not Hispanic | <input type="checkbox"/> Asian or Pacific Islander |
| <input type="checkbox"/> Black not Hispanic | <input type="checkbox"/> Filipino |
| <input type="checkbox"/> Hispanic | <input type="checkbox"/> American Indian/Alaskan Native |
| | <input type="checkbox"/> Other: _____ |

2. Please circle the **highest** year of school completed:

- | | | | | |
|-------------|----------------|-------------|-------------------|----------|
| 1 2 3 4 5 6 | 7 8 9 10 11 12 | 13 14 15 16 | 17 18 19 20 21 22 | above 22 |
| (primary) | (high school) | (college) | (graduate school) | |

3. Are you currently (check **only one**):

- married separated widowed single divorced

4. Other than fibromyalgia do you have any other health problems? No Yes

If yes, what are they?

5. In general, would you say your health is: (**Circle one**)

- Excellent 1
Very good..... 2
Good..... 3
Fair 4
Poor 5

6. How much time during the **past 2 weeks**...

	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
a. Were you discouraged by your health problems?	0	1	2	3	4	5
b. Were you fearful about your future health?	0	1	2	3	4	5
c. Was your health a worry in your life?	0	1	2	3	4	5
d. Were you frustrated by your health problems?	0	1	2	3	4	5

7. **In the past week** (even if it was **not** a typical week) how many **times** did you practice a mental relaxation exercise?

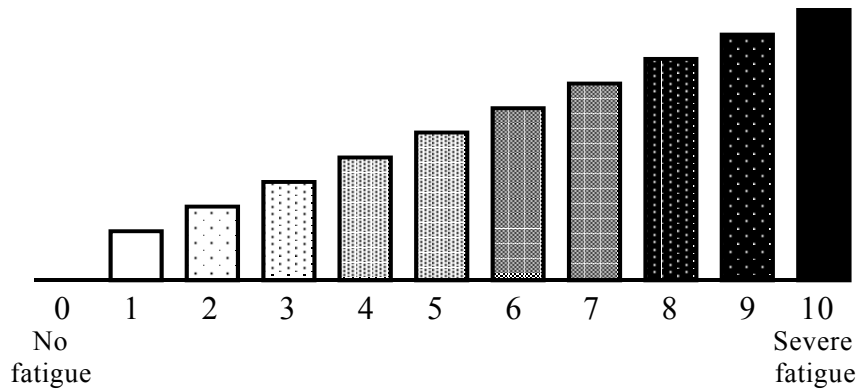
___ None, **OR** _____ times

If you did do a mental relaxation exercise, please describe what it was:

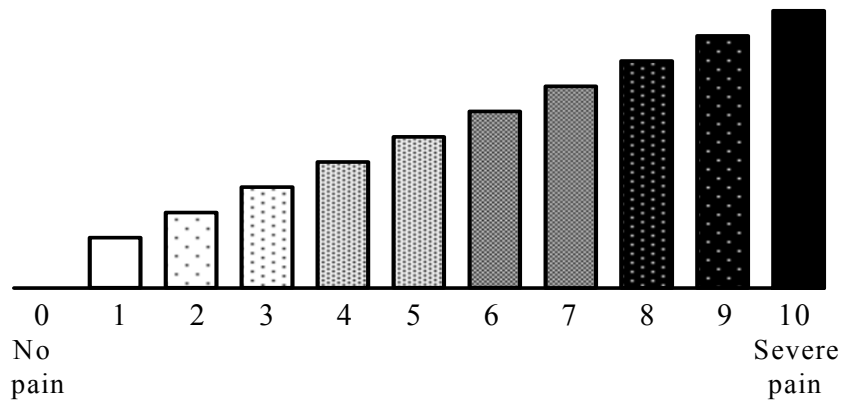
8. **During the past week**, even if it was not a typical week, how much **total** time (for the **entire week**) did you spend on each of the following? (Please circle **one** number for each question.)

	none	less than 30 min/wk	30-60 min/wk	1-3 hrs per week	more than 3 hrs/wk
a. Stretching or strengthening exercises (range of motion, using weights, etc.).....0	0	1	2	3	4
b. Walk for exercise	0	1	2	3	4
c. Swimming or aquatic exercise	0	1	2	3	4
d. Bicycling (including stationary exercise bikes)0	0	1	2	3	4
e. Other aerobic exercise equipment (stairmaster, treadmill, elipse, etc.).....0	0	1	2	3	4
f. Other aerobic exercise Specify _____	0	1	2	3	4

9. We are interested in learning whether or not you are affected by fatigue. Please **circle the number** below that describes your **fatigue** in the **past 2 weeks**:



10. We are interested in learning whether or not you are affected by pain. Please **circle the number** below that describes your **pain** in the **past 2 weeks**.



11. During the **past 2 weeks**, how much...(Circle one)

	Not at all	Slightly	Moderately	Quite a bit	Almost totally
a. Has your fibromyalgia interfered with your normal social activities with family, friends, neighbors or groups?	0	1	2	3	4
b. Has your fibromyalgia interfered with your hobbies or recreational activities?	0	1	2	3	4
c. Has your fibromyalgia interfered with your household chores?	0	1	2	3	4
d. Has your fibromyalgia interfered with your errands and shopping?	0	1	2	3	4

12. Please circle the number that best matches your abilities.

At this moment , are you able to:	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
a. Dress yourself, including tying shoelaces and doing buttons?	0	1	2	3
b. Get in and out of bed?	0	1	2	3
c. Lift a full cup or glass to your mouth?.....	0	1	2	3
d. Walk outdoors on flat ground?.....	0	1	2	3
e. Wash and dry your entire body?	0	1	2	3
f. Bend down to pick up clothing from the floor?.....	0	1	2	3
g. Turn faucets on and off?	0	1	2	3
h. Get in and out of car?.....	0	1	2	3

13. For each of the following questions, please **circle** the number that corresponds to **how certain** you are that you can do the following tasks regularly at the present time.

- a. How certain are you that you can decrease your pain quite a bit?
- | | | | | | | | | | | | | |
|-----------|---|---|---|---|---|---|---|---|---|----|--|---------|
| very | | | | | | | | | | | | very |
| uncertain | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | | certain |
- b. How certain are you that you can keep your fibromyalgia pain from interfering with your sleep?
- | | | | | | | | | | | | | |
|-----------|---|---|---|---|---|---|---|---|---|----|--|---------|
| very | | | | | | | | | | | | very |
| uncertain | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | | certain |
- c. How certain are you that you can keep your fibromyalgia pain from interfering with the things you want to do?
- | | | | | | | | | | | | | |
|-----------|---|---|---|---|---|---|---|---|---|----|--|---------|
| very | | | | | | | | | | | | very |
| uncertain | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | | certain |
- d. How certain are you that you can regulate your activity so as to be active without aggravating your fibromyalgia?
- | | | | | | | | | | | | | |
|-----------|---|---|---|---|---|---|---|---|---|----|--|---------|
| very | | | | | | | | | | | | very |
| uncertain | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | | certain |

e. How certain are you that you can keep the fatigue caused by your disease from interfering with the things you want to do?

very										very
uncertain	1	2	3	4	5	6	7	8	9 10	certain

f. How certain are you that you can do something to help yourself feel better if you are feeling blue?

very										very
uncertain	1	2	3	4	5	6	7	8	9 10	certain

g. As compared with other people with fibromyalgia, how certain are you that you can manage pain during your daily activities?

very										very
uncertain	1	2	3	4	5	6	7	8	9 10	certain

h. How certain are you that you can deal with the frustration of fibromyalgia?

very										very
uncertain	1	2	3	4	5	6	7	8	9 10	certain

14. **In the past 4 months**, how many times did you visit a physician?
Do NOT include visits while in the hospital or hospital emergency room....._____ visits

15. **In the past 4 months**, how many TIMES were you hospitalized for one night or longer?....._____ times

16. How many total NIGHTS did you spend in the hospital **in the past 4 months**?....._____ nights

17. Please list each medication you took for pain **during the past week**, and indicate the **number of days** you took each medication during the past week. Some common medications taken for pain are: Aspirin, Tylenol®, Advil®, Nuprin®, Naprosyn®, Percodan®, Tylenol #3®, Valium®, Soma®, Fiorinal®, and Flexeril®. However, there are many others, so please list ALL of the medications you are taking for pain, not just the ones listed above.

.....0 1 2 3 4 5 6 7

.....0 1 2 3 4 5 6 7

.....0 1 2 3 4 5 6 7

.....0 1 2 3 4 5 6 7

.....0 1 2 3 4 5 6 7

Please place a check mark here if you do not take any medications for pain

Appendix G

Symptom Checklist 90-Revised (SCL90-R)

Below is a list of problems people sometimes have. Please read each one carefully, and on the accompanying answer sheet fill in the answer that best describes **HOW MUCH THAT PROBLEM HAS DISTRESSED OR BOTHERED YOU DURING THE PAST 7 DAYS INCLUDING TODAY**. Only provide one answer for each problem. Please do not skip any items.

Not at All	A little bit	Moderately	Quite a bit	Extremely
0	1	2	3	4

HOW MUCH WERE YOU DISTRESSED BY...

1. Headaches
2. Nervousness or shakiness inside.
3. Repeated unpleasant thoughts that won't leave your mind.
4. Faintness or dizziness.
5. Loss of sexual interest or pleasure.
6. Feeling critical of others.
7. The idea that someone else can control your thoughts.
8. Feeling others are to blame for most of your troubles.
9. Trouble remembering things.
10. Worried about sloppiness or carelessness.
11. Feeling easily annoyed or irritated.
12. Pains in heart or chest.
13. Feeling afraid in open spaces or on the streets.
14. Feeling low in energy or slowed down.
15. Thoughts of ending your life.
16. Hearing voices that other people do not hear.
17. Trembling.
18. Feeling that most people cannot be trusted.
19. Poor appetite.
20. Crying easily.
21. Feeling shy or uneasy with the opposite sex.
22. Feelings of being trapped or caught.
23. Suddenly scared for no reason.
24. Temper outbursts that you could not control.
25. Feeling afraid to go out of your house alone.
26. Blaming yourself for things.
27. Pains in lower back.
28. Feeling blocked in getting things done.
29. Feeling lonely.
30. Feeling blue.
31. Worrying too much about things.

Not at All	A little bit	Moderately	Quite a bit	Extremely
0	1	2	3	4

32. Feeling no interest in things.
33. Feeling fearful.
34. Your feelings being easily hurt.
35. Other people being aware of your private thoughts.
36. Feeling others do not understand or are unsympathetic.
37. Feeling that people are unfriendly or dislike you.
38. Having to do things very slowly to insure correctness.
39. Heart pounding or racing.
40. Nausea or upset stomach.
41. Feeling inferior to others.
42. Soreness of your muscles.
43. Feeling that you are watched or talked about by others.
44. Trouble falling asleep.
45. Having to check and double-check what you do.
46. Difficulty making decisions.
47. Feeling afraid to travel on buses, subways, or trains.
48. Trouble getting your breath.
49. Hot or cold spells.
50. Having to avoid certain things, places, or activities because they frighten you.
51. Your mind going blank.
52. Numbness or tingling in parts of your body.
53. A lump in your throat.
54. Feeling hopeless about the future.
55. Trouble concentrating.
56. Feeling weak in parts of your body.
57. Feeling tense or keyed up.
58. Heavy feelings in your arms or legs.
59. Thoughts of death or dying.
60. Overeating.
61. Feeling uneasy when people are watching or talking about you.
62. Having thoughts that are not your own.
63. Having urges to beat, injure, or harm someone.
64. Awakening in the early morning.
65. Having to repeat some actions such as touching, counting, or washing.
66. Sleep that is restless or disturbed.
67. Having urges to break or smash things.
68. Having ideas or beliefs that others do not share.
69. Feeling very self-conscious with others.
70. Feeling uneasy in crowds, such as shopping or at movies.
71. Feeling every thing is an effort.
72. Spells of terror or panic.
73. Feeling uncomfortable about eating or drinking in public.
74. Getting into frequent arguments.

Not at All	A little bit	Moderately	Quite a bit	Extremely
0	1	2	3	4

- 75. Feeling nervous when you are left alone.
- 76. Others not giving you proper credit for your achievements.
- 77. Feeling lonely even when you are with people.
- 78. Feeling so restless you couldn't sit still.
- 79. Feelings of worthlessness.
- 80. The feeling that something bad is going to happen to you.
- 81. Shouting or throwing things
- 82. Feeling afraid you will faint in public.
- 83. Feeling that people will take advantage of you if you let them.
- 84. Having thoughts about sex that bother you a lot.
- 85. The idea that you should be punished for your sins.
- 86. Thoughts and images of a frightening nature.
- 87. The idea that something is seriously wrong with your body.
- 88. Never feeling close to another person.
- 89. Feelings of guilt.
- 90. The idea that something is wrong with your mind.

Appendix H

Chronic Pain Coping Inventory (CPCI)

During the past week, how many days did you use each of the following, at least once a day, to cope with your pain? Note: you may have used some of these coping strategies on days that you did not have pain, to prevent or minimize pain in the future. On the accompanying answer sheet, please fill in the answer corresponding to the number of days you used each strategy FOR PAIN, whether or not you were experiencing pain at the time.

Number of days**0 1 2 3 4 5 6 7**

- 107. Imagined a calming or distracting image to help me relax
- 108. Kept on doing what I was doing
- 109. Stretched the muscles in my legs and held the stretch for at least 10 seconds
- 110. Ignored the pain
- 111. I took a rest
- 112. Made arrangements to see a friend or family member
- 113. I went to bed early to rest
- 114. I got support from a friend
- 115. Asked someone to do something for me
- 116. Reminded myself that things could be worse
- 117. Avoided using part of my body
- 118. Focused on relaxing my muscles
- 119. Sat on the floor, stretched, and held the stretch at least 10 seconds
- 120. Told myself things will get better
- 121. Held on to something when getting up or sitting down
- 122. I got support from a family member
- 123. Exercised to strengthen the muscles in my arms for at least 1 minute
- 124. I rested as much as I could
- 125. Thought about someone with problems worse than mine
- 126. I talked to someone close to me
- 127. Told myself that I am adjusting to my pain problem better than many other people
- 128. Called a friend on the phone to help me feel better
- 129. Thought about all the good things I have
- 1304. Listened to music to relax
- 131. Asked for help with a chore or task
- 132. Stretched the muscles in my neck (and held the stretch) for at least 10 seconds
- 133. Told myself my pain will get better
- 134. I didn't let the pain interfere with my activities

Number of days
0 1 2 3 4 5 6 7

135. Exercised to strengthen the muscles in my legs for at least 1 minute
136. Thought about a friend who has coped well with a problem
137. Listened to a relaxation tape to relax
138. Engaged in aerobic exercise (that made my heart beat faster) for at least 15 minutes
139. Limited my walking because of pain
140. Just didn't pay attention to the pain
141. Walked with a limp to decrease the pain
142. Meditated to relax
143. Reminded myself that I had coped with the pain before
144. Lay on my back, stretched, and held the stretch for at least 10 seconds
145. Held part of my body (e.g. arm) in a special position
146. Rested in a chair or recliner
147. Avoided putting weight on feet or legs
148. Asked for help in carrying, lifting, or pushing something
149. Exercised to improve my overall physical condition for at least 5 minutes
150. Talked to a friend or family member for support
151. Reminded myself that there are people who are worse off than I am
152. Limited my standing time
153. Lay down on a bed
154. Avoided some physical activities (lifting, pushing, carrying)
155. Reminded myself about things that I have going for me such as intelligence, good looks, and good friends
156. Used self-hypnosis to relax
157. I just kept going
158. Exercised to strengthen the muscles in my stomach for at least 1 minute
159. Got together with a friend
160. Reminded myself that others have coped well with pain problems
161. Stretched the muscles where I hurt and held the stretch for at least 10 seconds
162. Avoided activity
163. Got together with a family member
164. Went into a room by myself to rest
165. Used deep, slow breathing to relax
166. Exercised to strengthen the muscles in my back for at least 1 minute
167. Stretched the muscles in my shoulders or arms and held it for at least 10 seconds
168. Asked someone to get me something (e.g. medicine, food, drink)
169. Did not let the pain affect what I was doing
170. Lay down on a sofa

Appendix I

Quality of Life Scale (QOLS)

Please read each item and use the scale below to describe how satisfied you are with each item. Fill in the answer that best describes how satisfied you are at this time on the accompanying answer sheet. Please answer each item even if you do not currently participate in an activity or have a relationship. You can be satisfied or dissatisfied with not doing the activity or having a relationship.

Delighted	Pleased	Mostly	Satisfied	Mixed	Mostly Dissatisfied	Unhappy	Terrible
7	6	5	4	3	2	1	0

91. Material comforts - home, food, conveniences, financial security
92. Health - being physically fit and vigorous
93. Relationships with parents, siblings, and other relatives - communicating, visiting, helping
94. Having and rearing children
95. Close relationships with spouse or significant other
96. Close friends
97. Helping and encouraging others, volunteering, giving advice
98. Participating in organizations and public affairs
99. Learning - attending school, improving understanding, getting additional knowledge
100. Understanding yourself - knowing your assets and limitations and knowing what life is about
101. Work – a job or in the home
102. Expressing yourself creatively
103. Socializing - meeting other people, doing things, parties, etc.
104. Reading, listening to music, or observing entertainment
105. Participating in active recreation
106. Independence, doing for yourself

Appendix J

Running head: MANUAL FOR FIBROMYALGIA TREATMENT

A Manual for the Cognitive-behavioural and Interpersonal Group Treatment
of Fibromyalgia Syndrome

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University of Saskatchewan

Session 1:

Introduction, Overview, What is Fibromyalgia? Review Gate Control Theory and Biopsychosocial Model, Introduce Coping Skills, and Introduce Interpersonal Issues

I. *Psycho-educational Component*

A. Introduction and Overview [10 min]

- i. Introduce therapist(s) and co-therapist (if applicable)
 - a. clinical psychologist with an interest in health psychology, chronic pain specifically
 - studies behavior, how the mind and body interact
- ii. Overview of what will happen in the group
 - a. sessions divided into 2 sections: psycho-educational component led by therapist 1 and interpersonal component led by therapist 2
 - psycho-educational component: learn about fibromyalgia syndrome and learn skills such as relaxation, imagery, combat negative thinking, pace activities to help manage symptoms (e.g. pain and depression)
 - interpersonal component: group discussion of relationship between various aspects of personal life and FM
- iii. Basic information about the group
 - a. organizational details
 - 8 sessions over 8 consecutive weeks
 - sessions build on each other, crucial to attend every session
 - when, where, time (be on time, allow for parking etc.) of meetings
 - 2 therapists: for first half and second half (change rooms)
 - phone numbers to reach therapist(s)
 - bring your workbook to each session, we will refer to the book
 - stretching: if you need to stand or stretch to be comfortable, do so, please try not to distract others
 - washroom (leave if needed and return), provide directions
 - b. guidelines for group interaction
 - confidentiality of group
 - respect and dignity
 - questions and concerns: raise them in the group or with one of the therapists after a session, if you have a questions chances are others are wondering about the same thing
 - c. groundrules for group (L.Wilson)
 - no focus on pain, everyone here has pain, that is understood, so no need to dwell on pain, it is generally not helpful to do this
 - be positive, sharing but not ‘telling’ others what to do, sharing between group members is very helpful when the sharing is positive and supportive in nature

(not when negative or when dwelling on past difficulties, or when criticizing others)

- learn skills and must practice them and do homework (just attending group will not help, it is up to you to practice the skills on your own, on a daily basis), with practice the skills will become automatic, analogy like driving a car
- willing to keep an open-mind, willingness to be self-reflective, be an active participant; if you have tried some things before you will need to give them another fresh try-might be different this time in combination with other things you are doing (or not doing)
- attitude of openness, possibility, experimentation, like a scientist
- try not to compare yourself to others, everyone progresses at a different rate; focus on your own progress
- group vs. individual, group provides support and the encouragement and support from others in a similar situation is beneficial; people with chronic pain tend to feel that the only other people that can understand are other's with chronic pain
- key to progress in group, set reasonable goals, be actively involved in your own progress, practice skills consistently, learn about health in general

B. Fibromyalgia Syndrome [10 min]

i. Description of fibromyalgia syndrome

a. nonarticular rheumatologic condition

- rheumatism is a painful disorder of the joints, muscles, and connective tissues
- FM is a nonarticular condition though, so the joints are not affected
- not degenerative or deforming and has no known excess mortality

ii. Symptoms (pain, depression, sleep disturbance, fatigue, etc.)

a. pain

- what is pain? unpleasant sensory and emotional experience that is associated with actual or potential tissue damage.
- acute pain, heals and goes away (e.g. burn finger)
- chronic pain, lasts 6 months or more
- statistic on prevalence of chronic pain
- doctors used to look for physical signs of damage, like damage from a cut or sprain; thought that following injury message travels from site of injury to brain; brain receives and registers pain; this enables us to remove self from further damage; we then attempt to reduce injury by resting, use ice, etc. this all leads to healing
- diagram of simple pain response (Handout 1a.).
- however, we now know that this is too simple and does not explain everything, for example, phantom limb pain...no nerves left or even a limb, but still sense pain in that limb; there is not a direct correspondence between amount of damage and amount of pain! with chronic pain there is not always tissue damage

- traditional thinking is too limited, we need a more complex model to understand pain; Gate Control Model
- b. Gate Control Theory (Melzack & Wall)
- use diagram of pain response with the gate (Handout 1b)
 - pain is more than a sensory process, other factors besides message from injury site to brain affect pain experience
 - there are messages sent from injury to brain, but also messages sent from the brain; these messages can intensify or reduce, even block the pain experience; we have a ‘gate’ that controls how much pain is felt
 - theory is that there is a gate located in the spinal cord in the middle of the pain pathway, the gate-like mechanism is related to bundles of nerves at the spinal cord, the brain can send messages to keep gate closed or open, this changes the actual amount of pain the person experiences
- c. Opening and closing the gate
- the gate can be opened or closed, when the gate is closed it can stop pain messages from going up the pain pathway to the brain, but when open, messages can go up the pathway to the brain
 - scientists have discovered that your brain closes the gate by releasing natural pain killers called endorphins, these painkillers are very powerful
 - thought and feeling centers in brain can open or close gate, this is why we notice that our thoughts and feelings have a major effect on pain, e.g. of bad day vs. good day and pain, lottery win and injury/pain vs. root canal (L. Wilson)
- d. Depression, sleep disturbance, fatigue, anxiety
- symptoms in addition to pain that may be experienced
 - can affect opening/closing of the gate
 - vicious cycles; example of pain causing low mood and feelings of low mood (depression) increasing pain (gate)
- iii. Associated disorders
- a. explain associated disorders such as Reynaud’s, Sjogren’s, IBS
- prevalence of comorbid disorders
 - symptoms
- iv. Homework (Handout 1c)
- ask group to think about how gate control theory and aspects of their personal lives are related, e.g. how pain is affected by relationships, mood, activities, etc.
 - what worsens your pain or opens the gate?
 - what helps reduce pain or close the gate?
 - categorize into physical, emotional, mental factors

- you will all have some different factors, this is individual; because you are individual we will learn a number of different coping techniques so each person can find something that suits them

C. Fibromyalgia and Controversy [5 min]

i. Proposed models of FM (model of how it occurs, what causes it)

a. contrast 'medical model' with an 'integrated' or biopsychosocial model (L. Wilson)

- medical model for acute problems
- biopsychosocial model supported in literature for chronic pain

b. health psychologists are interested in thoughts, feelings, and physical health because they are related and act upon each other

- in all chronic pain conditions (back pain, arthritis, migraine, etc.) psychologists have been involved in helping people manage their pain and associated difficulties
- health psychologists also work with people who have cancer, have had strokes, many health problems, because your health affects all areas of life

c. there are scientific organizations such as IASP and CPS to which many psychologists belong because they are interested in the physical, mental and emotional aspects of chronic pain conditions

- chronic pain programs similar to this one are run throughout North America and other countries

ii. Fibromyalgia affects major areas of life

a. ask group to provide examples to be written on board

- social, vocational, mood, physical activity, hobbies, etc.

b. because fibromyalgia and all chronic pain conditions affect many major areas of life, a model which combines these elements was proposed and is widely accepted: The Biopsychosocial Model (an 'integrated model'), this is the model we are operating under

- describe and illustrate
- provide examples of how this pertains specifically to FM and life

D. Introduce Coping Skills and Rationale for Coping Skills and Pain Management [10 min.]

i. Review: research shows that thoughts and feelings can have a big effect on how much pain we feel by opening or closing the gate in the pain pathway, provide example

a. pain coping skills and management techniques will teach you skills for controlling thoughts/feelings/ and actions that affect your pain

b. this will help you gain a sense of control over your pain, may help to decrease your pain and will affect other symptoms too

ii. In each session we will learn a new skill and continue to practice skills learned in previous sessions

- a. in between sessions you will be asked to practice daily in order to learn them well enough to receive the full benefits
 - b. by the completion of the 8 sessions you will have a ‘menu’ of skills
- iii. List of skills (Handout 1d):
- a. deep diaphragmatic breathing (session 1, 2, and 3)
 - b. progressive muscle relaxation (session 2 and 3)
 - c. pleasant activity scheduling (session 4 and 5)
 - d. imagery (session 4, 6 and 7)
 - e. cognition / distraction methods (session 5 and 6)
 - f. pacing (activity/rest cycling) (session 6)
 - g. problem solving (session 7)
 - h. interpersonal communication (sessions 1-8)
- E. Relaxation Fundamental-Diaphragmatic Breathing [10 min.] (Handout 1e)
- i. We will cover deep diaphragmatic breathing today so that you can start practicing a skill right away, emphasis on practice
 - a. demonstrate shallow chest breathing vs. diaphragmatic breathing by lying on floor
 - focus on comfortable position, eyes closed, hands on chest and stomach, and counting with breaths in and out
 - can introduce idea of counting or repeating a relaxing word while breathing
 - b. importance of practicing this breathing, it is at the root of all relaxation exercises, it may not seem difficult at first but it does take practice
 - ii. Homework (Handout 1f)
 - log of times during day when practice breathing
 - 5 minute sessions a minimum of two times each set, throughout the day for 10 cycles
 - do it laying down but not with the intention of going to sleep

II. *Interpersonal Component* [45 min.]

- A. The Formative Phase (Rutan & Stone; Yalom)
- i. members learn groundrules for making group therapy work
 - ii. members will attempt to establish level of intimacy
 - a. level of intimacy that is safe for each individual, will vary
 - iii. themes revolve around gaining information
 - a. asking leader or peers how best to make the group work
 - iv. members orient to group through trial and error
 - a. to see what will be useful and safe
 - b. members approach this task with individual history, conflicts, needs

B. Interpersonal Topics

- i. Importance of interpersonal issues
 - a. manner by which these types of issues affect thoughts/feelings and hence affect the gate, pain, and illness/wellness
 - relationships, activities, career, etc.
 - provide examples
- ii. Members provide examples of ways fibromyalgia affects their lives (not just pain but in general)
 - a. affect on relationships
 - specifics: friendships/ hobbies/ physical activity/ sexually/ fun/ meeting needs of others, e.g. kids/grandkids
 - b. interactions with family and friends
 - how do family and friends react, how do they help, how do they make things difficult?
- iii. Do members feel that people without chronic pain just can't understand?
 - a. simply being part of this group with people who understand can be helpful
 - how do you think it might be helpful?
- iv. Feelings involved with fibromyalgia
 - a. depression, anxiety, fear
 - pain anxiety, learned associations or expectations of pain, increases in specific situations (L. Bradley)
 - b. what can we do about these thoughts and feelings?

Session 2:

Sleep, Introduce Relaxation Techniques, and Review Interpersonal Issues

I. *Psycho-educational Component*

- A. Review Homework [5 min.]
 - i. Questions and comments about last week's session?
 - a. gate control theory
 - b. deep diaphragmatic breathing
 - comments, how did it go?
 - important to address concerns now
 - how often did you practice? what effect did it have on you?
 - did people have difficulty or success?
- B. Sleep Hygiene (L. Wilson; Philips & Rachman) (Handout 2a) [10 min.]
 - i. Regular schedule
 - a. up at same time each morning (exceptions on weekend) and to bed close to same time each night; allows body to adjust to routine
 - exposure to bright light in the morning can help awakening, reset circadian rhythm
 - ii. Necessities for sleep
 - a. comfort and quiet
 - comfortable mattress/bed, dark room, quiet, no disturbances (pets)
 - b. bedroom
 - use of bed and bedroom for sleep/sex only
 - should not lie in bed when not sleeping, perpetuates insomnia; should not be for lounging, reading, tv, snacking
 - c. reduce pressure
 - allow sleep to come, don't try to force it
 - put clock out of sight (clock increases pressure)
 - iii. Stimulus control
 - a. avoid stimulants before bedtime
 - don't exercise close to bedtime, avoid stimulants (caffeine, nicotine) and avoid alcohol (helps fall asleep but disrupts sleep in the night)
 - hypnotics should be used judiciously; if daily not for longer than 4 weeks, consult doctor; if in a 'sleep crisis', save for times when have had 3 nights disrupted sleep in a row
 - b. go to bed and lie down only when tired and ready to sleep, when feel drowsy
 - if cannot sleep after 20 minutes get out of bed and do something monotonous, return to bed when drowsy and ready to sleep
 - avoid napping during the day (unless it helps you fall asleep because less worried about it when going to bed)

iv. Relaxation and cognition

- a. avoid stress and rushing around right up until bedtime
 - physical and psychological hyperarousal contribute to insomnia
 - relaxation can be useful to combat arousal and can be used to help fall asleep and fall back to sleep if wake during night (especially if you ‘panic’ about not being able to sleep)
 - however, you should not use relaxation as a way to fall asleep, it has another purpose, so when you have relaxation homework do not fall asleep while doing it
 - if you worry when you go to bed try scheduling a ‘worry time’ at another time in day or evening (not right before bed)
 - examine your thoughts about sleep, are they worries, ruminations, unrealistic expectations? examine the validity of these thoughts and try to change them

C. Introduce Relaxation Techniques with Deep Breathing [30 min.]

i. Relaxation (Handout 2b)

a. what is relaxation?

- relaxation is an alert and controlled state
- concentration on physical calmness, reduced muscle tension, and emotional calmness
- review muscle tension pain cycle (vicious cycles diagram)
- complex skill, training is required over a number of weeks; in this treatment you can concentrate on this skill for 7-8 weeks

b. what is the purpose? (Philips & Rachman)

- common response to acute injury is to tighten muscles, this tightening limits movement to promote healing; when pain is chronic the sufferer may develop permanent tension in certain muscles
- this tensing, or guarding, can become habitual and unhelpful; the tension does not reduce pain levels but is likely to make pain worse
- when this continues for years patients may lose awareness of how tense the muscles are; it is only after relaxation skills are learned that awareness of tense muscles grows
- relaxation skills allow you to learn the difference between tension and relaxation; become aware of tension in the body and learn to ‘turn on’ a relaxation response in minutes to reduce tension

c. group lists different techniques they use to relax

ii. Different types of relaxation skills/exercises

- a. diaphragmatic breathing, PMR, imagery/visualization, etc.
 - describe each briefly

iii. Group Exercise, Progressive Muscle Relaxation (PMR)

- a. short introduction to PMR (Bernstein and Borkovec method, 1973)

- while practicing deep breathing, tense right fist, notice the tension, relax fist, compare the feeling of tension to that of relaxation
 - continue with left fist; right foot; left foot
 - highlight contrast between tension and relaxation
- b. discuss feelings of warmth, fuzziness, heaviness, or other feelings associated with the lack of tension
 - c. thoughts and reactions, discussion about relaxation
 - important to discuss skepticism, willing to try, open-mind
 - d. important to stress necessity of practice, we will do an exercise each session but members must also practice daily on their own
- iv. Homework
 - a. relaxation exercise
 - continue to practice deep diaphragmatic breathing, it is fundamental for all other relaxation skills, continue to log progress (Handout 1f copy)
 - give clients copy of relaxation tape and Handout 2c

II. *Interpersonal Component* [45 min.]

A. The Formative Phase (Rutan & Stone; Yalom)

- i. Members continue to attempt to establish level of intimacy
- ii. Themes revolve around gaining information
 - a. asking leader or peers how best to make the group work
- iii. Members continue to orient to group through trial and error
 - a. to see what will be useful and safe
 - b. members approach this task with individual history, conflicts, needs
- iv. Common questions are addressed
 - a. for example, ‘what information is relevant?’, ‘are past events significant?’, ‘am I expected to share all my secrets?’
 - b. these questions produce interaction among members and stimulate opinions and conflicts
- v. Under pressure to get to know each other patients usually ‘tell their story’
- vi. Anxiety and apprehension of formative phase represent first commonly shared experience of the group; beginning step for group cohesion

B. Interpersonal Topics

i. Exploration of trauma

a. broadly define 'trauma'

- meaning of trauma is individual, it is not always physical or sexual abuse, many types of experiences can be traumatic for a person
- discuss whether such experiences change a person
- do such experiences change how a person copes, with illness for e.g.

Session 3:

Review Rationale for Coping Skills, Review Relaxation, Exercise on Controlling Pain through Relaxation [Keefe]

I. *Psycho-educational Component*

- A. Review Homework [10 min.]
 - i. Discuss deep breathing and relaxation practice
 - ii. Discuss barriers
 - a. troubleshooting problems with relaxation (in Keefe, Bernstein and Borkovec, 1973)
- B. Functional Task and Relaxation Exercises-Breathing and PMR [30 min]
 - i. Functional Task
 - a. ask patients to assess pain level during a functional task; ask them to do a simple activity for 15 seconds that is likely to increase pain and tension a little bit (walking, getting up out of chair, etc.)
 - b. ask them to rate pain on 1-10 scale (10 is worst possible pain) and rate tension on 'Tension Thermometer' (Handout 3a)
 - after the activity and rating mention that we will return to this later in the session
 - ii. Relaxation Practice
 - a. deep breathing
 - practice breathing from diaphragm instead of shallow chest breathing
 - focus on slow, deep, steady breaths in through the nose (out through nose or mouth), can count (in head) while inhaling and exhaling
 - b. progressive muscle relaxation (PMR)
 - conduct exercise with group
 - similar to brief exercise in previous session but expand to full body PMR (from head to toe)
 - see script (reference L. Wilson & G. Pancyr; Bernstein & Borkovec)
 - c. demonstration of the effects of relaxation on functional task (Keefe)
 - ask patients to hold onto feelings of relaxation while they perform the same functional task that they performed earlier in the session
 - ask patients to rate pain during the task on 1-10 scale (10 is worst possible pain) and rate tension on the 'Tension Thermometer'
 - compare the ratings to pre-session ratings; note likely reasons for decreased pain and tension following relaxation exercise: tension reduction, attention diversion, reduction of emotional distress, improved rest
 - also explain why decreased pain or tension might not have occurred: need more practice, relaxation effect may be preventative not curative, high pain

level, etc.; understanding some of these reasons can help you get through bad episodes of pain

- ii. Mini-practices of relaxation
 - a. learn to relax and calm yourself on command, method for mini-practice (Handout 3b)
 - for relaxation to be of most benefit you need to learn to relax and calm yourself on command; this skill is very helpful when you feel increased tension or pain but are unable to go to secluded area to do progressive muscle relaxation
 - to do a mini practice begin by stopping yourself, take a long deep breath in, say the word 'relax' to yourself, slowly exhale, while you exhale allow yourself to relax and focus on sensations of relaxation
 - allow your jaw to relax, allow sensations of heaviness and warmth to flow downward to shoulders and throughout body
 - after 30 seconds go back to what you were previously doing (regardless of how well you succeeded at relaxation)
 - walk through 2-3 mini-practices with the group, while sitting, standing, walking
 - discuss group's reactions and reinforce necessity of practice
- iii. Homework
 - a. relaxation exercise and mini-practices
 - continue to practice with the tape according to Handout 2c
 - do mini-practices according to Handout 3b

II. *Interpersonal Component* [45 min.]

- A. The Reactive Phase (Rutan & Stone; Yalom)
 - i. Individuality of each member becomes more important
 - a. members attempt to retain own identity while remaining part of the group
 - b. tasks of this phase revolve around moving from sense of 'we-ness' to sense of belonging that includes 'I-ness'
 - ii. Characterized by emotional outbursts and uneven commitment to group
 - iii. Norms that arose in formative phase may be tested and modified
 - iv. Many patients experience presenting problems most powerfully in this phase
 - a. for example, members may say 'this group is no different from my family'
 - b. important for therapist to help patients understand that changes in attitudes about group membership are helpful for therapy and groups are more effective when individuals are experiencing problems within the group

B. Interpersonal Topics

- i. Barriers to relaxation, from an emotional level
 - not just logistics, but emotional challenges to relaxation
 - are there feelings associated with difficulty relaxing
 - do feelings such as anxiety intrude, safety issues

- ii. 'Somatic awareness' and 'letting go' (ref. Bakal; Levine)
 - a. somatic awareness, also called body awareness
 - b. being aware of your body, internally and externally, both physical feelings and your influence over your body; sense of control
 - expand

- iii. Letting go, link back to trauma
 - a. link to broad definition of trauma
 - b. describe animal response to cycle and difficulty moving through cycle
 - consequences of becoming 'stuck' and not passing through cycle

Session 4:

Review Relaxation and Introduce Another Coping Skill-Pleasant Activity Scheduling and Interpersonal Issues

I. *Psycho-educational Component*

A. Review Relaxation Homework from Session 3 [10 min.]

- i. Reactions to relaxation practicing
- ii. Discussion of interference with breathing and relaxation practice
 - a. interpersonal interference
 - b. time
 - c. motivation
- ii. Brain Storming
 - a. how to overcome such interference and make time for relaxation
 - suggestions by group, strategies
 - additional suggestions by therapist may include: making a sign to hang on your bedroom door to let people know that you are doing relaxation exercises and not to disturb you, or turning off the ringer on the phone, or scheduling it for the same time everyday so it becomes routine

B. Introduction to Guided Imagery and Relaxation [25 min.]

- i. Introduce Guided Imagery
 - a. review deep breathing
 - b. imagery can strengthen the progressive muscle relaxation skill and is a good introduction to the skill of distraction
 - c. induce relaxation as done in session 3 B ii.
 - follow 10-15 minutes of induction but spend the last 5 minutes on the use of imagery (peaceful and antagonistic to pain experience); suggest specific images to patients such as lying in a warm bath, sunbathing on a sandy beach, walking through a forest, etc.
 - toward the end of the 5 minutes of imagery encourage patients to generate their own images; explain that the use of peaceful imagery in conjunction with deep relaxation can reduce the pain experience
 - specific peaceful images are very helpful in achieving a calm, relaxed mental state to go along with the relaxed feeling achieved by the body (focus on quieting the mind)
 - d. following exercise allow time for general discussion of patients' increasing ability to relax and addition of imagery; make distinction between relaxed body and relaxed mind clear and emphasize importance of integrating the two

- those with intense pain during the exercise need to be encouraged to ‘ride over the pain’ and attempt to relax despite the pain, this is a task requiring great concentration and demands encouragement from the therapist

iii. Homework

a. relaxation and imagery exercise

- practice relaxation with the tape (according to handout 2c), at the end of the tape continue relaxation for 10 minutes using imagery
- see Handout 4a for guidelines for practice with imagery

C. Coping Skill-Pleasant Activity Scheduling [10 min.]

i. Pleasant Activity: Describe how pleasant activity scheduling can be used to control and decrease pain, rationale

ii. Identify pleasant activities, develop schedule [Handout, Activity Schedule 3-2C]

iii. Homework

II. *Interpersonal Component*

A. The Reactive Phase (Rutan & Stone; Yalom)

- i. individuality of each member remains important
 - a. members attempt to retain own identity while remaining part of the group
 - b. tasks of this phase revolve around moving from sense of ‘we-ness’ to sense of belonging that includes ‘I-ness’
- ii. continued emotional outbursts and uneven commitment to group
- iii. patients continue to experience presenting problems powerfully in this phase
- iv. may be a time of conflict among members, ‘storming period’
 - a. some conflict may be displaced anger felt toward leader, some may be to demonstrate who is most powerful among members
 - b. in emotional transactions that occur in this period, members bond to one another more strongly; this is important if groups are to gain maturity
- v. therapist must appreciate that this is a developmental phase

B. Interpersonal Topics

- i. Focus on activities that can no longer be accomplished or enjoyed due to fatigue, pain, etc.
 - group therapy discussion on related issues

Session 5:

Review Relaxation, Review Pleasant Activity Scheduling, Introduce Topic of Identifying and Changing Negative Automatic Thoughts and Interpersonal Issues

I. *Psycho-educational Component*

A. Review homework [20 min.]

- i. Relaxation homework
 - a. trouble shooting
 - discuss interference and whether brain storming from session 4 provided ways to overcome interference and make time for relaxation
- ii. Assign new relaxation homework
- iii. Pleasant activity scheduling homework
 - a. review rationale
 - b. were members able to follow the schedule?
 - c. what were the difficulties?
 - d. what did the members notice after participating in pleasant activities?
 - e. is this a helpful strategy for pain coping?

B. Identifying and Changing Negative Automatic Thoughts [20 min.]

- i. Cognitive Therapy: discuss how distortion and errors in thinking can contribute to pain and suffering
- ii. Rationale for cognitive therapy
 - a. automatic thinking
 - b. pain and automatic thinking
- iii. Teach basic concepts of cognitive restructuring
- iv. Identify and Change Negative Cognitions: [Handout 4-4C]
 - a. develop skill to recognize negative automatic thoughts
 - b. generate rationale comebacks
 - mini-practice of recognizing irrational negative thoughts
 - mini-practice of changing these thoughts
- v. Homework

II. *Interpersonal Component* (Therapist 2) [45 min.]

A. The Reactive Phase (Rutan & Stone; Yalom)

- i. continued conflict among members, ‘storming period’
 - a. some conflict may be displaced anger felt toward leader, some may be to demonstrate who is most powerful among members

- b. in emotional transactions that occur in this period, members bond to one another more strongly; this is important if groups are to gain maturity
 - ii. therapist must appreciate that this is a developmental phase; therapeutic task is to avoid focusing on individual dynamics or transference; rather, clinician engages others in expressing feelings
- B. Interpersonal Topics
 - i. focus on thoughts about self
 - a. self living with fibromyalgia, 'other or real' self, thoughts of future

Session 6:

Review Identifying and Changing Thoughts, Introduce New Coping Skills: Pleasant Imagery and Pacing

I. Psycho-educational Component

- A. Review Homework [10 min.]
 - i. Discuss identifying and changing thoughts
 - ii. Discuss difficulties encountered with certain thoughts
 - a. difficulty thinking of rational comebacks to some repetitive and engrained thoughts
 - iii. Homework
- B. Pleasant Imagery [20 min.]
 - i. Rationale for pleasant imagery as pain coping skill
 - ii. Relaxation practice with imagery
 - a. control pain using pleasant imagery
 - practice pleasant imagery as distraction technique [Handout 4-5C]
 - iii. Home practice
- C. Pacing: Activity-Rest cycle [15 min.]
 - i. Introduce activity rest cycle
 - a. what it is, why it is important
 - b. focus on the cyclical nature
 - diagram
 - ii. Overactivity
 - a. negative consequences of overactivity
 - b. ask members to provide examples
 - iii. Basic steps in setting up activity/rest cycle
 - a. practice using relaxation in different daily activities [Handout 6-1C, 6-2C, 6-3C]
 - b. homework
 - iv. Fitness/exercise
 - a. research evidence of benefits of exercise on FM
 - b. importance of activity/rest cycle for fitness/exercise

II. Interpersonal Component

- A. The Mature Phase (Rutan & Stone; Yalom)
 - i. group begins to perform and work together in a goal directed manner

- ii. members interact spontaneously and carry themes from session to session
 - iii. leadership is shared and members assume tasks and emotional leadership roles
 - iv. strong emotions and conflicts begin to be better tolerated and are not prematurely cut-off
 - v. flexibility allows for shift of focus from intragroup to extragroup to personal events
 - vi. members begin to develop confidence in ability to tolerate anxiety and examine problems themselves
 - vii. members begin to gain understanding and appreciation for each other's strengths and weaknesses
- B. Interpersonal Topics
- i. introduce termination
 - a. may be temptation to discount the importance of approaching the end of the group

Session 7:

Review Pleasant Imagery and Pacing, Applying Pain Coping Skills

I. *Psycho-educational Component*

- A. Review Homework [5 min.]
 - i. Were group members able to successfully use pleasant imagery as a relaxation technique?
 - ii. Discuss relaxation homework
 - iii. Discuss Pacing
- B. Practice Guided Imagery with Group [15 min.]
 - i. Group Exercise
 - ii. Home practice assigned
 - a. with consideration to difficulties presented by group
 - problem-solving with respect to these difficulties
- C. Applying Pain Coping Skills [25 min.]
 - i. Develop skills in applying pain coping techniques to problematic situations
 - a. write list of coping skills learned on board
 - b. write recommended practice of each skill
 - e.g. progressive relaxation listen to tape twice a day, mini-practices 15 times a day: 1 time with imagery, 1 with focal point, 1 with auditory, etc., calming self-statements, activity scheduling, activity-rest cycle [ref. Keefe session 7]
 - ii. Apply pain coping skills to problem situations: Problem Solving
 - a. rationale for problem solving
 - many members have experienced positive benefits of applying pain coping skills
 - there are some problem situations that make it very difficult to cope with pain using only one coping skill (e.g. relaxation)
 - but can often manage these situations by combining different pain coping skills
 - will teach a 3 step problem solving technique [Keefe session 7]
 - iii. Problem Solving: 3 step technique
 - a. step one: describe the situation (e.g. visitors)
 - b. step two: difficulties you are likely to have in the situation (e.g., tension, worry, pain)
 - c. step three: coping skills you can apply (e.g. relaxation, activity-rest cycle)-specifics, when and how!
 - ask members to identify a problem situation and work through the 3 steps, brainstorm solutions, repeat if time.

- Handout, 7-3C, applying problem solving [keefe]
- Home Practice

II. *Interpersonal Component*

A. The Termination Phase (Rutan & Stone; Yalom)

- i. final sessions are completely devoted to the ending of the group
- ii. members may be tempted to discount the importance of the end of the group
- iii. exploring the forthcoming ending of the group can be complicated by the fact that members may have more work to do
 - a. need to have balance between temptation to discount the end of group and the fact that members have more work to do

Session 8:

Review Progress and Previous Sessions, Develop a Plan for Maintaining Progress and Interpersonal Issues

I. *Psycho-educational Component*

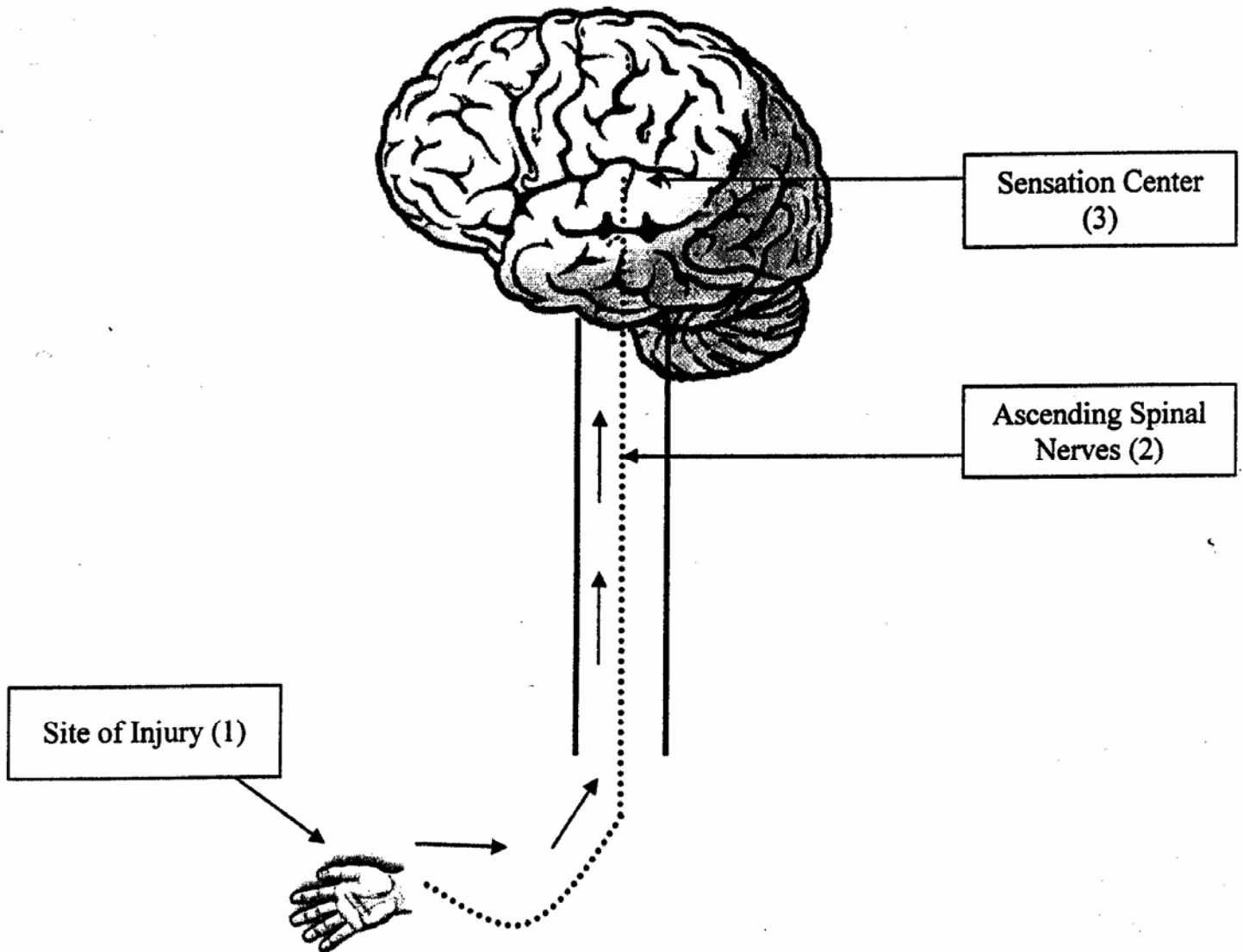
- A. Review homework/home practice from previous session [5 min.]
- B. Review Previous Sessions [10 min.]
 - i. Review gate control theory
 - a. diagram of pain pathway
 - ii. Thought and Feeling Centers in brain can close gate in Pain Pathway
 - a. draw thought and feeling centers on diagram
 - b. draw nerves from these centers to gate
 - iii. Summary and Main Statement of Rationale
 - a. thoughts and feelings can have big effect on how much pain we feel by causing the gate to open or close
 - b. group was designed to teach coping skills for controlling thoughts, feelings, and actions that affect pain and other symptoms of FM
 - c. coping skills you have learned will help control and decrease symptoms
 - d. in each session you learned new skills, you practiced the skills and in between sessions you practiced in order to master the skills. You will need to continue using the coping skills after you've stopped coming here.
[reference Keefe session 9]
- C. Coping Skills [5 min.]
 - i. Review of coping skills menu
 - a. deep diaphragmatic breathing (session 1)
 - b. progressive muscle relaxation
 - c. imagery
 - d. pleasant activity scheduling
 - e. distraction methods
 - f. pacing (activity/rest cycling)
 - g. problem solving
 - h. communicating about your syndrome with others
- D. Plan for Maintaining Progress
 - i. Based on Keefe's Session 10 [25 min.]

II. *Interpersonal Component*

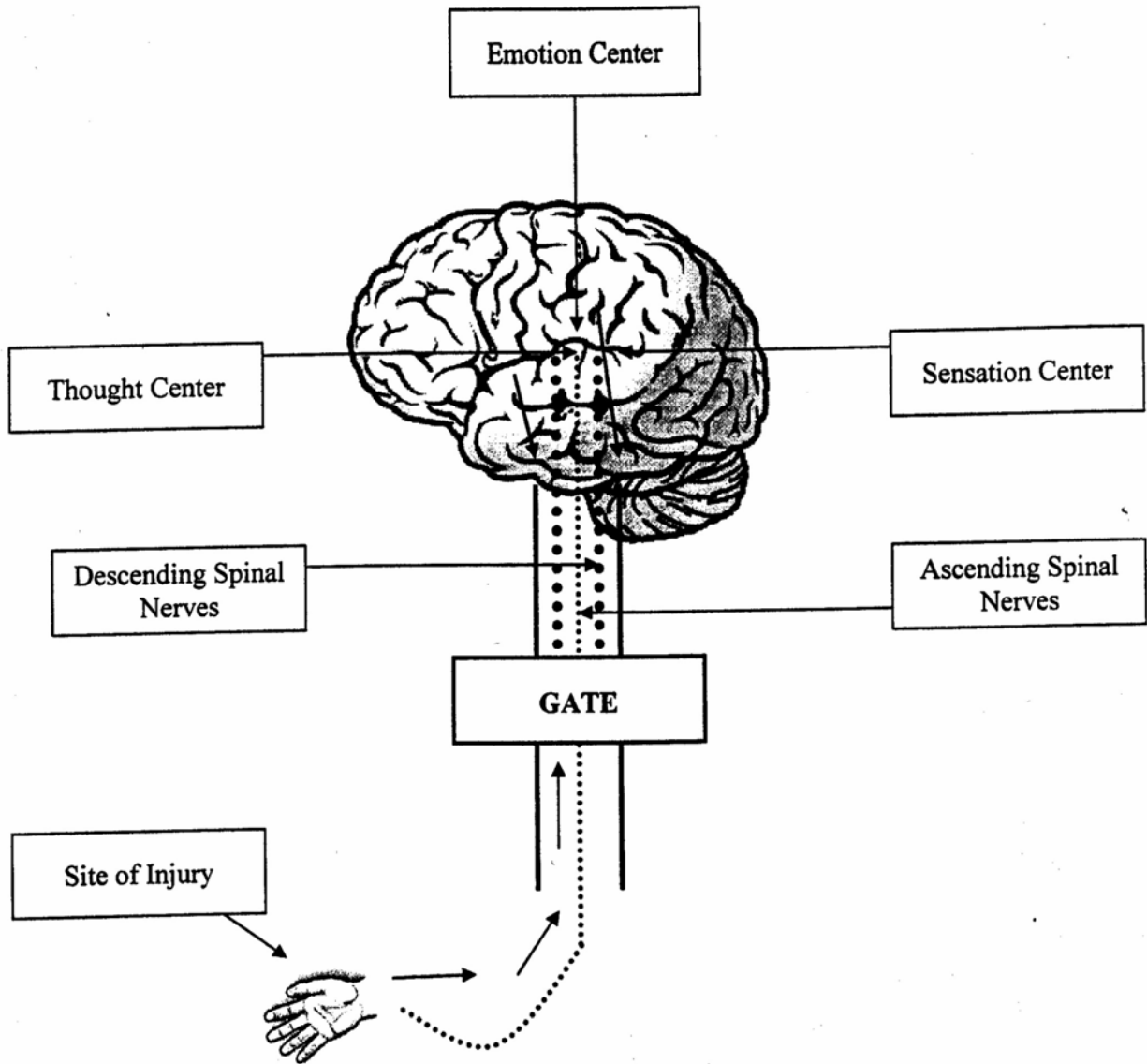
- A. The Termination Phase (Rutan & Stone; Yalom)
 - i. members may still be tempted to discount the importance of the end of the group

- ii. exploring the forthcoming ending of the group can be complicated by the fact that members may have more work to do
 - a. need to have balance between temptation to discount the end of group and the fact that members have more work to do
- iii. therapist can clarify metaphors such as death, divorce, graduation to help patients understand how they are managing feelings about end of group
 - a. may be a time when some members work on unresolved grief
- iv. main theme revolves around saying good-bye

Handout 1a
Simple Pain Pathway



Handout 1b
Gate Control Theory



Handout 1c
Home Assignment

1. How do you make sense of the gate control theory in your life?
How do aspects of your personal life relate to the theory?
For example, do relationships, mood, activities, etc. affect your pain?

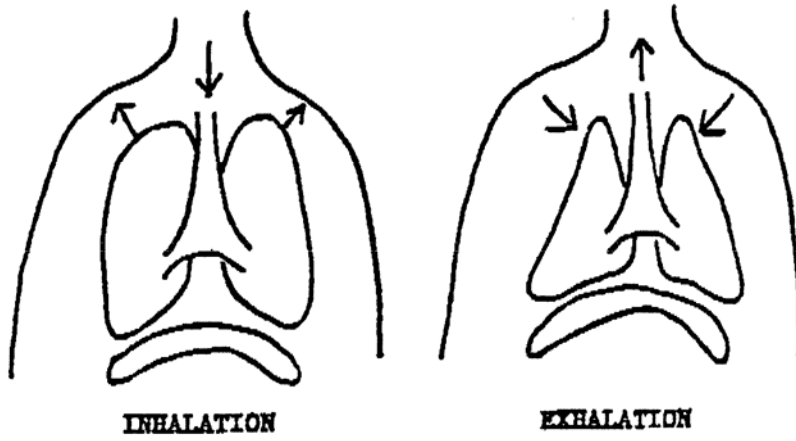
2. What worsens your pain or 'opens the gate'?
What helps reduce your pain or 'closes the gate'?
Try to think of categories such as physical, emotional, and mental factors.
Each person will have different factors that alter the pain experience.

Handout 1d
List of Coping Skills

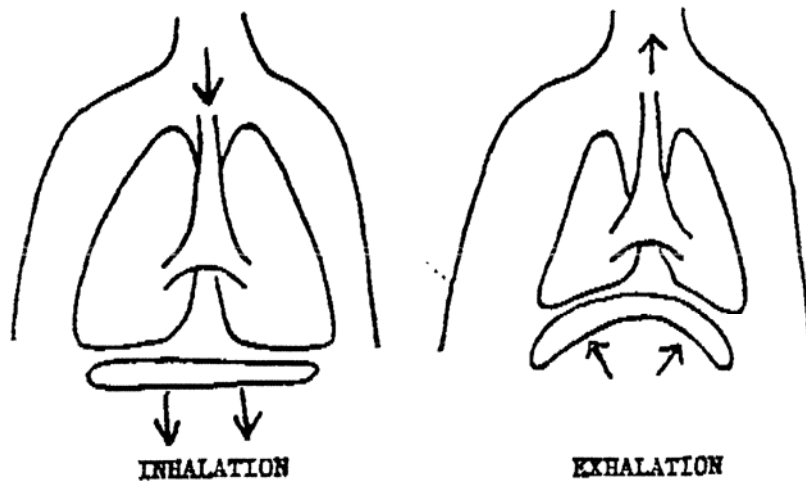
- a. deep diaphragmatic breathing
- b. progressive muscle relaxation
- c. pleasant activity scheduling
- d. imagery
- e. cognition / distraction methods
- f. pacing (activity / rest cycle)
- g. problem solving
- h. interpersonal communication

Handout 1e
Diaphragmatic Deep Breathing
L. Wilson & G. Pancyr, 1997

SHALLOW CHEST BREATHING



DEEP DIAPHRAGMATIC BREATHING



Handout 1f Deep Breathing Log

Cycle	Track	Day 1	Day 2	Day 3	Day 4
1	Time				
	Length				
	Notes				
2	Time				
	Length				
	Notes				
3	Time				
	Length				
	Notes				
4	Time				
	Length				
	Notes				
5	Time				
	Length				
	Notes				
6	Time				
	Length				
	Notes				
7	Time				
	Length				
	Notes				
8	Time				
	Length				
	Notes				
9	Time				
	Length				
	Notes				

Handout 2a
Sleep Hygiene: The Do's and Don'ts of Sleep

Listed below are some suggestions that may help you fall to sleep more easily.

Do's

1. Keep a regular schedule. Go to sleep and wake up roughly at the same time each day.
2. Exercise regularly (in the morning or afternoon).
3. Have a comfortable bed in a quiet and dark room.
4. If hungry before bed, eat a light snack or have a glass of milk.
5. Schedule a relaxing period before retiring to bed.
6. Keep the bedroom just for sleeping and sex. Not as an all-purpose activity area.

Don'ts

1. Don't use alcoholic beverages or street drugs as sedatives.
2. Don't do late evening exercise.
3. Don't have your room too hot or too cold.
4. Don't eat a heavy meal before retiring and do not snack during the night.
5. Don't try too hard to fall asleep. Get out of bed and return only when you feel sleepy.
6. Avoid napping during the day.
7. Avoid smoking or drinking caffeinated beverages several hours before bedtime.

Handout 2b
Vicious Cycles and Relaxation
Philips & Rachman

A common response to acute injury is to tighten muscles, this tightening limits movement, which promotes healing; when pain is chronic the sufferer may develop permanent tension in certain muscles.

This tensing, or guarding, can become habitual and unhelpful; the tension does not reduce pain levels but is likely to make pain worse.

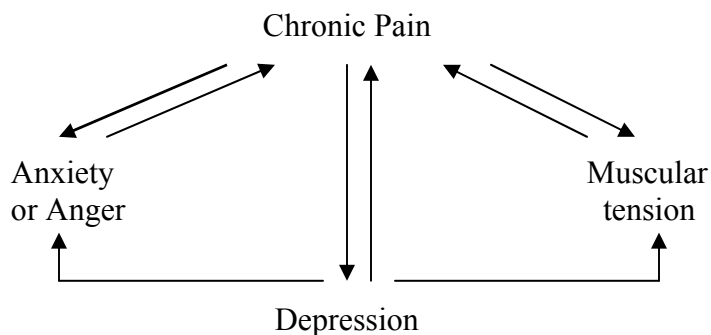
When this continues for years, patients may lose awareness of how tense the muscles are; it is only after relaxation skills are learned that awareness of tense muscles grows.

What is relaxation?

- relaxation is an alert and controlled state
- concentration on physical calmness, reduced muscle tension, and emotional calmness
- review muscle tension pain cycle (vicious cycles diagram)
- complex skill, training is required over a number of weeks; in this treatment you can concentrate on this skill for 7-8 weeks

What is the purpose?

- relaxation skills allow you to learn the difference between tension and relaxation
- learn to become aware of the tension in the body and learn to 'turn on' a relaxation response in minutes to reduce tension



Handout 2c
Progressive Muscle Relaxation
(Keefe)

What is Progressive Muscle Relaxation Training?

1. Progressive muscle relaxation (PMR) is a way to learn how to relax.
2. In order to learn how to relax, you need to pay attention to feelings of tension and relaxation in your body.
3. You will learn to keep tension in your body at a low level.
4. Relaxation is a skill that can be learned, just like any other skill, such as driving a car, playing an instrument, or typing.
5. In PMR you will be tensing and relaxing various muscle groups.

Practicing with the relaxation tape

1. It takes several weeks of daily practice with the relaxation tape to learn the relaxation response. It is recommended that you practice with the relaxation tape twice a day, everyday.
2. It is critical to have a quiet, comfortable place to practice. There should be no interruptions, no phone calls, no worry about doing chores, etc.
3. During the learning phase you should practice at a time when you are most relaxed, usually early in the day. Do not start with a time when your pain or other symptoms are most intense.
4. Don't be discouraged if at first it is difficult for you to relax completely. If you try too hard you will interfere with the relaxation response. It will come naturally with practice.

Handout 3a
Tension Thermometer
(F. Keefe)

When practicing with relaxation and other coping skills you will sometimes be asked to rate your tension using a scale we call the “Tension Thermometer.”

The Tension Thermometer

Describe how tense you feel at the moment by circling the number and word that best describe your tension.

- 0 = absolutely calm and relaxed
- 25 = very relaxed
- 50 = somewhat relaxed
- 75 = very tense and anxious
- 100 = as tense and anxious as I have ever felt



World's Largest Thermometer
Baker, California

Handout 3b
Mini-practices
(Keefe)

For relaxation to benefit you the most, you need to learn how to relax and calm yourself upon your command. This skill can be very helpful when you are feeling increased tension or pain, but are unable to go to a secluded area to do progressive muscle relaxation.

To do a mini-practice:

1. Stop yourself
2. Take a deep breath
3. Say the word “relax” to yourself
4. Slowly exhale
5. As you exhale, focus on the sensations of relaxation
6. Allow your jaw to relax, allow sensations of heaviness to flow downward from your shoulders throughout your body
7. After 30 seconds, go back to what you were doing, regardless of how well you have succeeded in relaxing

Reminders to do mini-practices:

Your goal is to do about 5 mini-practices the first day and then gradually build up to about 20 mini-practices each day over the next few weeks. You can remind yourself to do a mini-practice in many different ways. Some people will do a mini-practice every time they feel annoyed or tense. Some people do one every time they stop at a stoplight or after they have been on the telephone. You can remind yourself by placing adhesive ‘dots’ or ‘sticky notes’ around the house. Every time you see a dot or a note you will be reminded to do a mini-practice. It is important that you practice frequently. Little by little you can develop a habit of keeping yourself relaxed throughout the day.

Handout 4a
Guidelines for Practice with Imagery
F. Keefe

Controlling Pain and Tension using Pleasant Imagery

Thinking about pleasant events can help control pain in several ways. First, when you are concentrating on something pleasant you are not able to attend to pain as much. Second, pleasant imagery can help you relax even more than relaxation training alone. Third, pleasant imagery helps reduce anxiety, frustration, anger, tension, and depression. Finally, this method can help you rest and sleep better.

When you use pleasant imagery you are in control of what imagery you use and the length of time that you use imagery. You may choose to think of a real event from the past, such as a walk on the beach. Or, you may wish to think of something you would like to do, such as visit a tropical island.

There are several guidelines for using pleasant imagery.

1. Induce relaxation prior to practice with imagery.
2. Try to involve all of your senses in imagery.
3. Practice for a specific time period.
4. To end imagery practice, slowly count backwards from 10 to 1.

Imagery Practice

Imagine yourself in a very pleasant scene. This can be a scene that is individually tailored to you. See everything in as much detail as possible. Instead of ‘watching yourself’ as though you were watching a home movie, try to be ‘in the scene’ and see it through your own eyes. Try to be in your imaginary scene as much as possible. Involve all of your senses. What are the scents and sounds, what can you feel? It is important to not only relax but to also experience a pleasant scene as vividly as possible. This will become easier with practice.

Handout 4b
Pleasant Activity Scheduling

List a number of pleasant activities that you would like to do in the next week. These activities should be things that you would enjoy doing that you may not usually make the time to do. They do not have to require a lot of time or money. They may be as simple or as involved as you would like.

List a number of pleasant activities:

- | | |
|----|----|
| 1. | 4. |
| 2. | 5. |
| 3. | 6. |

Try to develop an approximate schedule of when you plan to engage in each of these activities within the next week.

Time	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
7:00							
8:00							
9:00							
10:00							
11:00							
12:00							
1:00							
2:00							
3:00							
4:00							
5:00							
6:00							
7:00							
8:00							
9:00							

Handout 5a Distorted Thinking

We all have thoughts that are automatic. Although some automatic thoughts are true, many are either untrue or have just a grain of truth. These ‘distorted’ thoughts or mistakes in thinking include:

1. All-Or-Nothing-Thinking (also called Black-and-White-Thinking): you view a situation in only two categories instead of on a continuum. Example: “If I’m not a total success then I’m a failure.”
2. Catastrophizing: You predict the future negatively without considering other more likely outcomes. Example: “I’ll be so upset I won’t be able to function at all.”
3. Discounting the Positive: You unreasonably tell yourself that positive experiences, deeds, or qualities do not count. Example: “I did that project well but that doesn’t mean I’m competent; I just got lucky.”
4. Emotional Reasoning: You think something must be true because you “feel” (actually believe) it so strongly, ignoring or discounting evidence to the contrary. Example: “I know I do a lot of things okay at work, but I still feel like I’m a failure.”
5. Labelling: You put a fixed, global label on yourself or others without considering that the evidence might more reasonably lead to a less disastrous conclusion. Example: “I am incapable.”
6. Magnification / Minimization: When you evaluate yourself, another person, or a situation, you unreasonably magnify the negative and /or minimize the positive. Example: “Getting a mediocre evaluation proves how inadequate I am. Getting high marks doesn’t mean I’m smart.”
7. Mental Filter: You pay undue attention to one negative detail instead of seeing the whole picture. Example: “Because I got one low rating on my evaluation (which also had several high ratings) it means I’m doing a lousy job.”
8. Mind Reading: You believe you know what others are thinking, failing to consider other more likely possibilities. Example: “He’s thinking that I don’t know the first thing about this project.”
9. Overgeneralization: You make a sweeping negative conclusion that goes far beyond the current situation. Example: “Because I felt uncomfortable at the meeting I don’t have what it takes to make friends”.
10. Personalization: You believe others are behaving negatively because of you, without considering more plausible explanations for their behavior. Example: “The repairman was curt to me because I did something wrong.”

11. 'Should' and 'Must' Statements: You have a precise, fixed idea of how you or others should behave and you overestimate how bad it is that these expectations are not met. Example: "It's terrible that I made a mistake. I should always do my best."
12. Tunnel Vision: You only see the negative aspects of a situation. Example: "My son's teacher can't do anything right. He's critical and insensitive and lousy at teaching."

Handout 5b
Identifying Negative Automatic Thoughts
F. Keefe

These are some of the thoughts that people with chronic pain sometimes report having when they have a pain episode. Examine whether you have had any of these thoughts. Write down other thoughts that you have had. It helps to identify these thoughts so that you can try to change them.

Negative Thoughts:

- If this keeps up I'll be crippled and unable to walk.
- I can't go on like this.
- I am a weak person.
- I can't do anything I used to do.
- I am useless.
- I can't deal with this pain.
- No one understands my problem.
- I am a burden on my family and friends.
- Why me? I didn't do anything to deserve this.
- If things go on this way, I won't be able to cope.
- I am worthless when I'm like this.

Identify some of your own negative thoughts:

These thoughts can lead to emotions such as: depression, frustration, resentment, alienation, isolation, anger, guilt, jealousy, and fear. Write down the feelings that you have experienced as well as others that are not listed.

A way to deal with these automatic negative thoughts is to try to replace them with more adaptive thoughts, or coping thoughts. These new coping thoughts do not have to be overly positive or optimistic, but they should be more realistic so that you believe them.

For example:

Negative Thought:

I can't do anything I used to do.

Coping Thought:

I may not be able to do everything I used to do, but there are things I can do well.

Negative Thought:

I can't deal with this pain.

Coping Thought:

There are things I can do to control and decrease my pain.

Negative Thought:

I am a burden on my family.

Coping Thought:

My family loves me and cares about me.

Handout 6a
Identifying and Replacing the Most Troublesome Negative Thought

This week, during some episodes of intense pain or interference due to pain, note the thoughts that automatically pass through your mind, such as “here we go again.”

Try to notice one negative automatic thought each day and list them below. Identify the most troublesome thought and then provide an alternative ‘coping thought’.

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____

* Most troublesome thought: _____

* Replacement ‘coping thought’: _____

Cognitive Strategies for Reappraising Pain

1. Transforming the body: Imagine the body to be numb or made of something else, such as rubber, electrical parts, or water.
2. Transforming context in which pain is felt: Imagine the pain is a result of a particular experience. For example, pain in the knee is due to pressing the knee against a wall, pain in the head is from a tight hat, etc.
3. Denial and redefinition: Tell yourself that you are not in pain and think of the sensation as due to stretching or scar tissue, pulling of muscles, pulsing of the arteries, etc.
4. Limiting the scope of pain: Focus only on the area in which you feel pain, noting its depth and area over which it spreads.
5. Relocation of pain: Move the pain to another site on your body. Note: this technique requires a lot of concentration and practice with relaxation and imagery will help to develop this skill.
6. Relocating thoughts: Concentrate on a pain-free site on your body. Try to “think” from that pain-free spot and spread this to the rest of the body.

Handout 6b
Home Practice Sheet
F. Keefe

1. How many times in the past week did you practice with your relaxation CD?

2. How many times did you do mini-practices this week? _____

How many times did you use imagery? _____

3. List any calming self-statements you used this week.

4. List the pleasant activity goals that you engaged in this week.

5. Were there any examples of times when you were able to decrease pain or tension using relaxation, mini-practices, imagery, etc.?

Handout 6c
Activity-Rest Cycle
F. Keefe

Individuals with pain have a tendency to overdo it or push themselves when they are feeling better, but this often results in being caught in a negative cycle. This negative cycle is characterized by overdoing activities, which leads to severe pain, which results in being forced to rest. The need for rest may last several days and may cause you to miss work, activities, or social gatherings. This cycle usually repeats itself time and time again. There are many negative consequences of this cycle, including: anticipating pain, periods of increased pain and fatigue, tension, worry and anxiety, and a tendency to avoid activities that you are capable of doing.

The activity-rest cycle is a better way to pace your activities. To follow the activity-rest cycle you need to:

- 1) identify activities you tend to overdo
- 2) set a time limit for these activities
- 3) when you reach the time limit stop, rest, and relax
- 4) keep count of how many times you stop yourself and then rest and relax

To set up an activity-rest cycle that will work for you, follow these steps:

Step 1. What is one activity you tend to overdo frequently?

Step 2. Set a time limit for this activity.

My time limit is: _____

Step 3. When you reach the time limit STOP, then REST and RELAX.

When I reach my time limit I will stop. Then I will rest and relax for the following length of time: _____

Step 4. Keep count this week of how many times you stop yourself from overdoing it and then rest and relax instead.

This week I used the Activity-Rest Cycle _____ times (insert number of times).

Handout 7a
Applying Problem Solving Skills
F. Keefe

Your pain coping skills menu now includes a number of different skills. As you practice with these skills you will notice many positive benefits.

Menu of Coping Skills

- a. deep diaphragmatic breathing
- b. progressive muscle relaxation
- c. mini-practices
- d. pleasant activity scheduling
- e. pleasant imagery
- f. cognitive strategies (coping thoughts)
- g. distraction methods (focal/auditory)
- h. problem solving
- i. interpersonal communication

Problem Solving

There are some situations in which it seems very difficult to cope with pain using only one of your coping skills (e.g. a mini-practice). These problem situations can often be managed successfully by using a combination of different pain coping skills (e.g. mini- practice plus calming self-statements plus an activity-rest cycle).

The following three steps can help you arrive at solutions for dealing with problem situations. Follow these steps when you think that a future situation may be problematic.

Step 1. Describe the situation in detail.

Step 2. Describe the difficulties you are likely to have in the situation.

Step 3. List the coping skills that you can apply in that situation.

Note: when working on Step 3 it is important to be very specific. For example, write down which coping skills you will use, when, and how. By planning ahead, you will be prepared in that situation and better able to put your skills to work. Also, when other problem situations arise you will be more successful because you have been specific in the past about how to use your skills and you will know what has worked for you.

Handout 7b
Home Practice Sheet for Week 7
F. Keefe

1. How many times in the past week did you practice with your relaxation CD? _____
How many times did you use imagery after a relaxation exercise? _____

2. How many times did you do mini-practices this week? _____
How many times did you use focal point distraction? _____ Auditory stimuli? _____

3. List any negative automatic thoughts ('hot thoughts') that you identified and list the 'coping thoughts' that you used to replace it.

4. List 5 pleasant activity goals that you engaged in this week.

5. How many times were you able to stop yourself from 'overdoing it' this week using the Activity-Rest Cycle? _____

6. Were there any examples of times when you were able to decrease pain or tension using relaxation, mini-practices, imagery, etc.? Describe...

Handout 8a
Recommended Home Practice Schedule
(F. Keefe)

1. Progressive relaxation training (with diaphragmatic deep breathing)
Listen to the relaxation CD one time each day
2. Pleasant Imagery
Practice using pleasant imagery each time you listen to the relaxation CD
3. Mini-practices
Do 15 a day (it only takes less than 1 minute)
Do one with imagery, one with focal point distraction, one with auditory stimuli
4. Activity scheduling
Use log sheets to schedule 5 pleasant activities each week
5. Pacing
Keep track of the number of times you stop yourself from overdoing and use rest and relaxation
6. Cognitive strategies
Always be aware of negative automatic thoughts and use handouts to help you to identify 'hot thoughts' and replace them with 'coping thoughts'
7. Problem Solving
Review the handout on problem solving every time you have a major problem coping with pain or expect that a particular event will be difficult for you

Handout 8b
Plan for Maintaining Progress

1. Make a final plan for monitoring your practice.

2. Schedule a regular time for your weekly practice.

- a. identify a specific time each day of the week
- b. try to select a specific situation for your practice

Monday: _____

Tuesday: _____

Wednesday: _____

Thursday: _____

Friday: _____

Saturday: _____

Sunday: _____

3. Identify short-term and long-term goals that you can attain if you continue to work on the pain coping skills that you have learned. You may find it helpful to consider various types of goals, including physical, social, occupational, mental, emotional goals, etc.

Short-term goals: _____

Long-term goals: _____

We wish you success in maintaining the progress that you have made!

Appendix K



**UNIVERSITY OF SASKATCHEWAN
BEHAVIOURAL RESEARCH ETHICS BOARD**

<http://www.usask.ca/research/ethics.shtml>

NAME: Michael MacGregor (Melanie Langford)
Department of Psychology

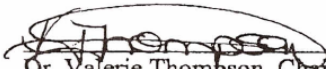
BSC#: 03-902

DATE: March 26, 2003

The Behavioural Research Ethics Board has reviewed the Application for Ethics Approval for your study "Psychotherapeutic Treatment of Fibromyalgia: A Cognitive-Behavioural and Interpersonal Approach" (03-902).

1. Your study has been APPROVED.
2. Any significant changes to your proposed method, or your consent and recruitment procedures should be reported to the Chair for Committee consideration in advance of its implementation.
3. The term of this approval is for 5 years.
4. This approval is valid for five years on the condition that a status report form is submitted annually to the Chair of the Committee. This certificate will automatically be invalidated if a status report form is not received within one month of the anniversary date. Please refer to the website for further instructions: <http://www.usask.ca/research/behavrsc.shtml>

I wish you a successful and informative study.


Dr. Valerie Thompson, Chair
University of Saskatchewan
Behavioural Research Ethics Board
c/o Office of Research Services

VT/ck

Vice-President (Research), University of Saskatchewan
Kirk Hall Room 217, 117 Science Place, Saskatoon SK S7N 5C8 CANADA
Telephone: (306) 966-8514 Facsimile: (306) 966-8736
<http://www.usask.ca/research>

Treatment for Fibromyalgia
Consent Form I

Title

Treatment for Fibromyalgia.

Name of principal investigators

Melanie Langford, BA
Michael Wm. MacGregor, Ph.D.
Department of Psychology
University of Saskatchewan
(306) 270-9224
melanie.langford@usask.ca
michael.macgregor@usask.ca

Purpose

The purpose of this investigation is to assess an educational-interpersonal treatment for women with fibromyalgia.

Benefits

Your participation in this investigation will contribute to a better understanding of how educational-interpersonal approaches can affect the symptoms of fibromyalgia and the ways in which people manage the syndrome. In the future this information may provide a better understanding of how these approaches relate to managing illness. Also, this information may contribute to the construction of future psychological interventions designed specifically for fibromyalgia.

Procedures

We would like to conduct an assessment in order to determine whether people are eligible to participate in this study. Eligibility requires a diagnosis of fibromyalgia by a rheumatologist and the absence of certain psychiatric diagnoses as determined by a psychologist.

This is a randomized controlled study; therefore, eligible participants will be randomly assigned to either Group A or Group B.

Participants in group A will receive phone calls by the principal investigator, once a week for 8-weeks, for discussions of approximately 10 minutes in duration. The discussions will relate to symptoms of fibromyalgia and ways in which participants attempt to manage their symptoms. The discussions will be supportive in nature but will not provide information on strategies or treatments for fibromyalgia. If desired, participants in Group A will have the opportunity to receive the exact same treatment that the participants in Group B receive upon completion of the investigation.

Participants in Group B will attend 8, 90-minute group sessions once a week for 8 weeks. The sessions provide educational information on fibromyalgia, coping strategies, and methods for managing the disorder. The sessions will also involve discussion of interpersonal issues that are related to living with fibromyalgia. Upon completion of the treatment, we may request your feedback regarding the Group B sessions.

We will ask you to complete 6 questionnaires on 4 different occasions: prior to the treatment period, following the treatment period, and at 1 month and 3 month follow-up. We may also ask you to complete these questionnaires at 6-month or 1-year follow-up if you are interested. The questionnaires address the following areas: satisfaction with physical and mental well-being, self-efficacy for physical function, fibromyalgia symptoms, pain management, coping strategies, mood, health status, functional ability, and pain intensity. We would like to ask you about the number of appointments you have with a physician during the duration of the investigation, related to fibromyalgia symptoms/concerns. Also, we would like to ask about any other ongoing physical or psychological treatments that you are involved in related to fibromyalgia. All information provided during the assessment and on the questionnaires will be kept strictly confidential. It is expected that Group A will spend approximately 8 hours to complete this investigation, which includes time required for assessment and questionnaires. It is expected that Group B will spend approximately 20 hours to complete this investigation, which includes time required for assessment and questionnaires.

Risks and ability to withdraw

This investigation will involve some discussion of personal issues. This discussion is held in a safe and confidential environment in a supportive manner. Negative emotion may accompany such discussion, however, this is typical of psycho-educational or psychotherapy groups. There are no known risks or discomforts associated with this investigation beyond this. However, if for any reason you wish to stop taking part in the study you may do so at any time, without any negative effects. If you choose to withdraw, your data will be deleted from the study and destroyed. If you have any questions or are experiencing any difficulties associated with this study, we can arrange for you to speak with the principal investigator or research supervisor. We can also provide a list of names of psychologists in the community if you would like.

Confidentiality

Data collected by questionnaire will be kept on computer and participants will only be identified by research identification numbers. Paper copies of assessment information or questionnaires will be kept in boxes in a secure and locked room. Only the principal investigator, research assistants, and the research supervisor will have access to the collected data. All data will be stored for a minimum of 5 years. Every effort will be made to ensure that participants are not individually identifiable (e.g. by name, etc.). Please do not put any identifying marks on the questionnaires.

There will be one master list identifying each participant by his or her identification number in order to collate data for each participant; however, this list will be kept separate from all other data collected. It will be kept in a secure and locked area separate from the data and will only be used for the purposes of collating data. Once all the data has been collated the list will be destroyed.

Use of data and dissemination of results

Data collected will be disseminated in a Ph.D. thesis, journal articles, conference presentations, and posters. Data will be presented in such a way that individual participants are not identifiable. All data will be presented in aggregate form.

Additional information

If any new information comes to light during this investigation that might influence your decision to continue in this investigation, you will be informed of the information and asked whether or not you want to continue with the investigation.

Debriefing

Following participation, the purpose of the investigation and how the results will be disseminated will be reviewed with you. You will also again be informed that the data will not be used in a way that you can be personally identified and that all data will be kept in a secure environment only available to the principal investigator and research supervisor. Any questions you might have will be answered at this time. If you are interested, your name will be taken and a copy of the results will be mailed to you when the study is complete.

Contact person

If you have any questions about this study you may contact Melanie Langford at (306) 270-9224 in the department of psychology at the University of Saskatchewan. As well, you may contact the Office of Research Services at (306) 966-4053 if you have any questions regarding your rights as a participant.

Treatment for Fibromyalgia
Signature and Consent Form I

I have read and understood the description of this investigation and I agree to participate. I have had the investigation explained to me and I have had any questions I had about the investigation answered. By signing below I acknowledge that I am willing to participate in this investigation on treatment for fibromyalgia and that I have received a copy of the consent form for my records.

This research was approved by the University of Saskatchewan Behavioral Research Ethics Board on

_____.

Name of participant (please print)

Signature of participant

Date

Witness

Treatment for Fibromyalgia
Consent Form II (Assessment)

Title

Treatment for Fibromyalgia.

Name of principal investigators

Melanie Langford, BA.
Michael Wm. MacGregor, Ph.D.
Department of Psychology
University of Saskatchewan
(306) 270-9224
melanie.langford@usask.ca
michael.macgregor@usask.ca

Purpose

The purpose of this investigation is to assess an educational-interpersonal treatment for women with fibromyalgia.

Procedures

In order to participate in this study you need to meet certain eligibility criteria. You need to have a diagnosis of fibromyalgia as diagnosed by a rheumatologist. We will ask you to provide consent to be assessed by a psychologist to determine whether you have certain psychiatric or psychological disorders, for example, psychosis. We would like to audio and video tape the assessment. The information from these tapes will be kept strictly confidential, only the principal investigator, research assistants, and the research supervisor have access to the tapes. The information on the tapes will not be used in the dissemination of results. The purpose of the taping is to ensure that the standard questions involved in the assessment have been asked. By signing this form I am indicating that I agree to participate in the assessment and I am aware that the assessment is taped.

If you do not have a diagnosis of fibromyalgia from a rheumatologist you will not be eligible to participate in this study. If you do not meet eligibility criteria based on the psychological assessment you will not be eligible to participate in this study. If you do meet eligibility criteria you will be able to participate in the study.

If you cannot participate in the study all information that you have provided will be kept strictly confidential and will be destroyed. If you are interested in receiving a copy of the results of this study the principal investigator will make arrangements to provide you with this information. If you have any questions or concerns we can make arrangements for you to speak with the principal investigator or the research supervisor. If you would like, we can also provide a list of names of psychologists in the community.

Contact person

If you have any questions about this study you may contact Melanie Langford at (306) 270-9224 in the department of psychology at the University of Saskatchewan. As well, you may contact the Office of Research Services at (306) 966-4053 if you have any questions regarding your rights as a participant.

Treatment for Fibromyalgia
Signature and Consent Form II

I have read and understood the description of this investigation and all information provided in the consent form. By signing this consent form I am agreeing to participate and agree to the terms outlined in the consent form. I have had the investigation explained to me and I have had my questions about the investigation answered. By signing below I acknowledge that I am willing to participate in this investigation on treatment for fibromyalgia and that I have received a copy of the consent form for my records.

This research was approved by the University of Saskatchewan Behavioral Research Ethics Board on

_____.

Name of participant (please print)

Signature of participant

Date

Witness

Treatment for Fibromyalgia
Consent Form III (Group)

Title

Treatment for Fibromyalgia.

Name of principal investigators

Melanie Langford, BA.
Michael Wm. MacGregor, Ph.D.
Department of Psychology
University of Saskatchewan
(306) 270-9224
melanie.langford@usask.ca
michael.macgregor@usask.ca

Purpose

The purpose of this investigation is to assess an educational-interpersonal treatment for women with fibromyalgia.

Procedures

All information discussed in the group sessions is confidential. Any information shared within the group will not be discussed outside the group, including the names of other group members. Personal issues will be discussed in the context of a safe and confidential group therapy setting. The privacy and dignity of all members of the group will be respected. By reading and signing this consent form I am indicating that I understand that the information discussed in the group sessions is confidential and I will not discuss it with anyone outside the group.

The group sessions will be audio and/or video taped. The information from these tapes will be kept strictly confidential, only the principal investigator, research assistants, and the research supervisor have access to the tapes. The information on the tapes will not be used in the dissemination of results. The purpose of the taping is to ensure that the treatment is delivered in accordance with the treatment manual, and to ensure that each Group B group receives the same treatment. As such, the sessions may be observed by the supervisor, future therapists, and/or research assistants. By signing this form I am indicating that I agree to participate in the group treatment and I am aware that the sessions are taped.

Contact person

If you have any questions about this study you may contact Melanie Langford at (306) 270-9224 in the department of psychology at the University of Saskatchewan. As well, you may contact the Office of Research Services at (306) 966-4053 if you have any questions regarding your rights as a participant.

Treatment for Fibromyalgia
Signature and Consent Form III

I have read and understood the description of this investigation and all information provided in the consent form. By signing this consent form I am agreeing to participate and agree to the terms outlined in the consent form. I have had the investigation explained to me and I have had my questions about the investigation answered. By signing below I acknowledge that I am willing to participate in this investigation on treatment for fibromyalgia and that I have received a copy of the consent form for my records.

This research was approved by the University of Saskatchewan Behavioral Research Ethics Board on

_____.

Name of participant (please print)

Signature of participant

Date

Witness

Fibromyalgia Treatment Study
Debriefing Form

Title

Treatment for Fibromyalgia

Name of principal investigators

Melanie Langford, B.A.

Michael Wm. MacGregor, Ph.D.

Department of Psychology

University of Saskatchewan

melanie.langford@usask.ca

michael.macgregor@usask.ca

Purpose

The purpose of this investigation is to better understand the effectiveness of an educational-interpersonal treatment for women with fibromyalgia. This study compares a treatment group to a control group. The treatment group involves cognitive-behavioural and interpersonal therapy components in order to address the needs of fibromyalgia patients. For example, coping strategies and pain management techniques may reduce symptoms, improve quality of life, or increase sense of efficacy. The control group involves weekly phone contact with the researcher. The data that you have provided will allow us to better understand how psychotherapeutic treatments can help people with fibromyalgia, and how these treatments can be tailored to more specifically meet the needs of fibromyalgia patients.

Confidentiality

Data collected by questionnaire will be kept on computer and participants will be identified by research identification numbers. Paper copies of questionnaires will be kept in boxes in a secure and locked room. Only the principle investigators will have access to the collected data. All data will be stored for a minimum of 5 years. Every effort will be made to ensure that participants are not individually identifiable (e.g. by number, name, etc.).

Use of data and dissemination of results

Data collected will be disseminated in a Ph.D. thesis, journal articles, conference presentations and posters. Data will be presented in such a way that individual participants are not identifiable.

Contact person

If you have any questions about this study you may contact Melanie Langford at (306) 270-9224 or (306) 966-6665 in the department of psychology at the University of Saskatchewan. As well, you may contact the Office of Research Services at (306) 966-4053 if you have any questions regarding your rights as a participant.

Thank you for your participation.

Consent to be contacted in the future
Fibromyalgia Treatment Study

I agree to be contacted in the future for a follow-up on the Fibromyalgia Treatment Study. I understand that by agreeing to be contacted I am not obligated to participate if I have changed my mind.

By signing below I agree to be contacted in the future regarding participation in the follow-up study. I also understand that when contacted any additional risks or benefits will be explained at the time.

Yes I agree to be contacted in the future.

No I do not agree to be contacted in the future.

Name

Permanent address where I can be contacted (please print):

Phone number _____

E-mail address _____

If I have any questions about the investigation I just participated in I can contact Melanie Langford or Michael MacGregor at (306) 270-9224 in the Department of Psychology, University of Saskatchewan. If I have any questions about my rights as a participant in this investigation I can contact the Office of Research Services at (306) 966-4053 at the University of Saskatchewan.

Thank you for your participation.

Appendix L

Protocol for the Attention-Control Condition

The researcher will telephone participants in the attention-control condition once each week for a period of 8 weeks. The days of the week and time of day/evening of the phone calls will be arranged with each participant in order to: maximize convenience for the participant, allow the participant to be prepared for the call, and increase the likelihood of making contact. Each phone call will be of approximately 10-15 minutes in duration.

The researcher will ask each participant the following questions. These specific questions are to be asked, without adding or deleting content. Question 1 should be the first question asked each week and should be asked every week. Apart from question 1, different combinations of questions are to be asked each week, depending on the time the participant requires to answer the questions. For example, if 10-15 minutes have passed after asking only three questions, it is not necessary to ask additional questions. However, each question must be asked at least once during the course of the 8 weeks. It may be necessary to repeat some or all of the questions during the 8-week period. Questions will be asked one at a time, allowing time for the participant to answer after each question. Cues can be given if the participant provides a vague answer or a brief answer. The following cues are permissible: a) 'can you please tell me more about that?' or b) 'can you please provide a specific example?'

Question 1. Please describe your last week, in terms of what you did day by day.

Question 2. Please describe your most stressful day during the past week.

Question 3. Please describe your most pleasant day during the past week.

Question 4. Have you had any thoughts directly related to your fibromyalgia diagnosis in the past week? If so, what was (were) the thought(s)?

Question 5. What was the most effective strategy that you used to cope with or manage symptoms of fibromyalgia this week?

Question 6. Was there a specific interpersonal issue/incident that was upsetting/frustrating for you in the past week?

Question 7. Was there a specific interpersonal issue/incident that was fun/enjoyable for you in the past week?

Question 8. What are your goals for the following week? You may have goals of a work, social, exercise, or recreational nature (or other).

If a participant asks for information or advice related to fibromyalgia, coping, or personal issues, the researcher should respond in a professional and supportive manner. However, the researcher should make every effort not to provide direct answers, as this may jeopardize the attention-control condition. For example, if information is provided regarding fibromyalgia, this may be similar to psychoeducation, a component of the cognitive-behavioural treatment.

Appendix M

The differences between the results of the original data and the intention-to-treat data are as follows:

- The ANCOVA for FIQ total at post-treatment was significant at $p < .05$ for the intention-to-treat data but not for the original data.
- The results for the relaxation strategy for the CPCI were the same at post-treatment. However, at follow-up, the ANCOVA was significant for the intention-to-treat data but not for the original data. Similarly, the ANCOVA for relaxation, as measured by the self-efficacy scale, was significant at follow-up for the intention-to-treat data but not for the original data.

ANCOVA Results Based on the Original Data

Primary Outcome Variable

H1) Fibromyalgia impact. To test the hypothesis that the treatment condition's fibromyalgia impact scores would significantly improve (decrease) from time 1 to time 2 while the control condition's scores would not significantly change, an ANCOVA was conducted. The dependent variable for the analysis was fibromyalgia impact time 2, that is, the impact that fibromyalgia symptoms have on various aspects of life, measured by the FIQ total score. The independent variable was condition (treatment condition or attention-control condition). The fibromyalgia impact total score at time 1 served as the covariate.

The covariate, fibromyalgia impact time 1, was significantly related to the fibromyalgia impact time 2 score, $F(1, 71) = 29.49, p < .001$. There was not a significant effect of condition on fibromyalgia impact time 2 after controlling for the effect of fibromyalgia impact time 1. A higher score on the FIQ indicates greater impairment due to fibromyalgia symptoms.

Although there was not a significant treatment effect, to test the hypothesis that the treatment condition and control condition differed at follow-up (time 4) an ANCOVA was conducted. There was not a significant effect of condition.

Secondary Outcome Variables

H2) Pain (intensity, frequency, duration). To test the hypothesis that the treatment condition's pain intensity scores would significantly improve (decrease) from time 1 to time 2, while the control condition's scores would not significantly change, an Analysis of Covariance (ANCOVA) was conducted. The dependent variable for the analysis was pain intensity at time 2, which is a composite of current, worst, least, and average pain ratings measured by the NPRS. The independent variable was condition (treatment condition or attention-control condition). The pain intensity score at time 1 served as the covariate.

The covariate, pain intensity time 1, was significantly related to pain intensity time 2, $F(1, 70) = 28.28, p < .001$. There was not a significant effect of condition on pain intensity time 2 after controlling for the effect of pain intensity time 1.

Since a treatment effect was not observed at time 2 there will not be maintenance of a treatment effect at follow-up. However, to test the hypothesis that the treatment condition and control condition would differ on pain intensity at time 4, an ANCOVA was conducted. The dependent variable for the analysis was pain intensity time 4. The covariate, pain intensity time 1, was significantly related to pain intensity time 4, $F(1, 46) = 23.08, p < .001$. There was not a significant effect of condition observed at follow-up.

To test the hypotheses for the frequency of pain and the duration of pain ANCOVA's were also conducted. Frequency of pain refers to the number of days in a week that a person experienced pain. Duration refers to the longest length of time that a person experienced

continuous pain during a week. Frequency and duration of pain were also measured by the NPRS. The effect of condition was not significant for either frequency of pain or duration of pain after controlling for the effect of frequency at time 1 and duration at time 1. Nor was an effect observed at follow-up (time 4). At time 2 and time 4 respectively, the covariates were significantly related to the independent variables: frequency, $F(1, 70) = 22.36, p < .001$, $F(1, 45) = 15.61, p < .001$; duration, $F(1, 70) = 21.59, p < .001$, $F(1, 45) = 27.51, p < .001$.

H3) Functional disability. To test the hypothesis that the treatment condition's level of functional disability would significantly improve (decrease) from time 1 to time 2 while the control condition's scores would not significantly change, an ANCOVA was conducted. The dependent variable for the analysis was functional disability at time 2 as measured by the HAQ. The independent variable was condition (treatment condition or attention-control condition). The functional disability score at time 1 served as the covariate.

The covariate was significantly related to functional disability time 2, $F(1, 71) = 74.15, p < .001$. The effect of condition was not significant. Nor was there an effect of condition at time 4, although the covariate was significantly related with the time 4 scores, $F(1, 46) = 72.68, p < .001$.

H4) Workdays missed. To test the hypothesis that the treatment condition's number of workdays missed would significantly improve (decrease) from time 1 to time 2 while the control condition's scores would not significantly change, an ANCOVA was conducted. The dependent variable for the analysis was the number of workdays missed at time 2. The independent variable was condition (treatment condition or attention-control condition). The number of workdays missed at time 1 served as the covariate.

The covariate was significantly related to workdays missed time 2, $F(1, 71) = 29.70, p < .001$. The effect of condition was not significant.

Since a treatment effect was not observed at time 2 there will not be maintenance of a treatment effect at follow-up. However, to test the hypothesis that the treatment condition and control condition would differ on number of workdays missed at time 4, an ANCOVA was conducted. The dependent variable for the analysis was workdays missed time 4. The covariate, workdays missed time 1, was significantly related to workdays missed time 4, $F(1, 46) = 17.86, p < .001$. There was not a significant effect of condition observed at follow-up.

H5) Health care utilization. To test the hypothesis that the treatment condition's use of health care would significantly improve (decrease) from time 1 to time 2 while the control condition's scores would not significantly change, an ANCOVA was conducted. The dependent variable for the analysis was the number of appointments with their physician related to fibromyalgia symptoms at time 2. The independent variable was condition (treatment condition or attention-control condition). The number of visits to their family physician at time 1 served as the covariate.

The covariate was significantly related to appointments with physician time 2, $F(1, 46) = 53.36, p < .001$. The effect of condition was not significant.

Since a treatment effect was not observed at time 2 there will not be maintenance of a treatment effect at follow-up. However, to test the hypothesis that the treatment condition and control condition would differ on health care utilization at time 4, an ANCOVA was conducted. The dependent variable for the analysis was visits to physician time 4. The covariate, visits to physician time 1, was significantly related to visits to physician time 4, $F(1, 101) = 61.88, p < .001$. There was not a significant effect of condition observed at follow-up, time 4.

H6) Depression. To test the hypothesis that the treatment condition's depression scores would significantly improve (decrease) from time 1 to time 2 while the control condition's scores would not significantly change, ANCOVAs were conducted. Depression was measured by the FIQ and the SCL90-R and an ANCOVA was conducted for each variable. In each case the independent variable was condition (treatment condition or attention-control condition) and the covariate was the time 1 score.

The covariate, FIQ depression time 1, was significantly related to FIQ depression time 2, $F(1, 71) = 68.27, p < .001$. There was also a significant effect of condition on FIQ depression time 2 after controlling for the effect of FIQ depression time 1, $F(1, 71) = 7.37, p < .01$. A higher score indicates greater impairment. T4 covariate $F(1, 46) = 38.64, p < .001$.

The covariate, SCL90 depression time 1, was significantly related to SCL90 depression time 2, $F(1, 66) = 85.61, p < .001$. The effect of condition was not significant. To examine follow-up effects, the covariate for SCL90 depression was significantly related to the SCL90 depression time 4 score, $F(1, 40) = 111.72, p < .001$. However, the effect of condition was not significant.

H7) Anxiety. To test the hypothesis that the treatment condition's level of anxiety would significantly improve (decrease) from time 1 to time 2 while the control condition's scores would not significantly change, ANCOVAs were conducted. Anxiety was measured by the FIQ and the SCL90-R and an ANCOVA was conducted for each variable. In each case the independent variable was condition (treatment condition or attention-control condition) and the covariate was the time 1 score.

The covariate, anxiety FIQ time 1, was significantly related to anxiety FIQ time 2, $F(1, 71) = 54.14, p < .001$. The effect of condition was not significant. The covariate, anxiety SCL90 time 1, was significantly related to anxiety SCL90 time 2, $F(1, 66) = 43.92, p < .001$. The effect of condition was not significant.

Since a treatment effect was not observed at time 2 there will not be maintenance of a treatment effect at follow-up. However, to test the hypothesis that the treatment condition and control condition would differ on anxiety at time 4, ANCOVAs were conducted. The covariate, anxiety FIQ time 1, was significantly related to anxiety FIQ time 4, $F(1, 46) = 54.55, p < .001$. There was not a significant effect of condition. The covariate, anxiety SCL90 time 1, was significantly related to the anxiety SCL90 time 4 score, $F(1, 40) = 110.53, p < .001$. The effect of condition was not significant.

H8) Coping. To test the hypothesis that the treatment condition's wellness focused coping strategies would significantly improve (increase) from time 1 to time 2 while the control condition's scores would not significantly change, ANCOVAs were conducted. The dependent variable for each analysis was the strategy (relaxation, task persistence, self-statements) at time 2 as measured by the CPCI. The independent variable was condition (treatment condition or attention-control condition). The strategy at time 1 served as the covariate.

Each covariate (relaxation, task persistence, self-statements) was significantly related to the strategy at time 2, $F(1, 59) = 37.86, p < .001$; $F(1, 59) = 37.99, p < .001$; $F(1, 59) = 27.45, p < .001$ (respectively). The effect of condition was significant for relaxation $F(1, 59) = 22.84, p < .001$ and task persistence $F(1, 59) = 4.48, p < .05$ but not for self-statements. A higher score indicates greater endorsement of the coping strategy. At time 2, the treatment condition endorsed the use of task persistence less than the control condition.

To test the hypothesis that the treatment condition's improvement in coping strategies would be maintained at follow-up (time 4) and the control condition's scores would not

significantly change, ANCOVAs were conducted. There was not a significant effect of condition for relaxation or task persistence; therefore, the treatment effects were not maintained at time 4. Nor was the effect of condition significant for self-statements at time 4.

To test the hypothesis that the treatment condition's illness focused coping strategies would significantly decrease from time 1 to time 2 while the control condition's scores would not significantly change, ANCOVAs were conducted. The dependent variable for each analysis was the strategy (guarding, resting, asking for assistance) at time 2 as measured by the CPCI. The independent variable was condition (treatment condition or attention-control condition). The strategy at time 1 served as the covariate.

Each covariate (guarding, resting, asking for assistance) was significantly related to the strategy at time 2, $F(1, 59) = 36.62, p < .001$; $F(1, 59) = 39.69, p < .001$; $F(1, 59) = 73.70, p < .001$ (respectively). The effect of condition was significant for resting after controlling for the effect of resting time 1, $F(1, 59) = 10.02, p < .01$. The effect was not maintained at follow-up (time 4). The effect of condition was not significant for guarding or asking for assistance. However, for guarding there was a significant effect at follow-up. The covariate, guarding time 1, was significantly related to the guarding time 4 score, $F(1, 40) = 113.17, p < .001$. There was a significant effect of condition on guarding time 4 after controlling for the effect of guarding time 1, $F(1, 40) = 9.53, p < .01$.

Seeking social support is another coping strategy but it is considered neither wellness focused nor illness focused. To test the hypothesis that the treatment condition's seeking social support coping strategy would significantly improve from time 1 to time 2 while the control conditions scores would not significantly change, an ANCOVA was conducted. The dependent variable for the analysis was seeking social support time 2, as measured by the CPCI.

The independent variable was condition (treatment condition or attention-control condition). Seeking social support at time 1 served as the covariate. The covariate was significantly related to seeking support time 1, $F(1, 59) = 87.03, p < .001$. There was no effect of condition at time 2 or at follow-up (time 4).

H9) Relaxation. In addition to relaxation as a coping strategy, relaxation was also measured by the CDQ. To test the hypothesis that the treatment condition's relaxation scores would significantly improve (increase) from time 1 to time 2 while the control condition's scores would not significantly change, an ANCOVA was conducted. The dependent variable for the analysis was relaxation time 2, measured by the CDQ. The independent variable was condition (treatment condition or attention-control condition). The relaxation score at time 1 served as the covariate.

The covariate, relaxation time 1, was significantly related to the relaxation time 2 score, $F(1, 71) = 42.77, p < .001$. There was also a significant effect of condition on relaxation time 2 after controlling for the effect of relaxation time 1, $F(1, 71) = 11.94, p = .001$. A higher score indicates greater use of mental relaxation techniques. Therefore, at time 2 the treatment condition utilized mental relaxation techniques to a greater extent compared to the control condition.

To test the hypothesis that the treatment condition's improvement in relaxation scores would be maintained at follow-up (time 4) and the control condition's scores would not significantly change, an ANCOVA was conducted. The covariate was significantly related to the relaxation score at time 4, $F(1, 46) = 457.81, p < .001$. There was not a significant effect of condition at time 4. Therefore, the treatment effect was not maintained at time.

H10) Self-efficacy. To test the hypothesis that the treatment condition's self-efficacy scores would significantly improve (increase) from Time 1 to Time 2, while the control condition's scores would not significantly change, an ANCOVA was conducted. The dependent variable for the analysis was self-efficacy time 2 as measured by the ASES. The independent variable was condition (treatment or attention-control). Self-efficacy at time 1 served as the covariate.

The covariate, self-efficacy time 1, was significantly related to self-efficacy time 2 score, $F(1, 71) = 56.75, p < .001$. There was also a significant effect of condition on self-efficacy time 2 after controlling for the effect of self-efficacy time 1, $F(1, 71) = 8.27, p < .01$. A higher score indicates greater self-efficacy or greater confidence in ability to do various tasks. Therefore, at time 2, the treatment condition experienced greater self-efficacy compared to the control condition.

To test the hypothesis that the treatment condition's improvement in self-efficacy would be maintained at follow-up (time 4) and the control condition's scores would not significantly change, an ANCOVA was conducted. There was not a significant effect of condition; therefore, the treatment effect was not maintained at time 4.

H11) Quality of life. To test the hypothesis that the treatment condition's quality of life would significantly improve (increase) from time 1 to time 2 while the control condition's scores would not significantly change, an ANCOVA was conducted. The dependent variable for the analysis was quality of life as measured by the QOLS at time 2. The independent variable was condition (treatment or attention-control). Quality of life at time 1 served as the covariate.

The covariate was significantly related to quality of life time 2, $F(1, 62) = 34.24, p < .001$. There was no significant effect of condition after controlling for time 1 scores. Nor was there a significant effect of condition at time 4.

Table M1

Means and Standard Deviations for the Primary and Secondary Variables based on the Original Data for the Treatment and Control Condition at Four Time Periods

Variable	Group	Time 1		Time 2		Time 3		Time 4	
		M	SD	M	SD	M	SD	M	SD
Primary Variable									
FIQ total	Treatment	57.37	15.38	48.15	19.47	52.22	16.50	53.65	16.79
	Control	53.23	15.36	53.08	17.19	64.37	9.86	55.59	13.61
Secondary Variables									
Pain									
intensity	Treatment	213.42	63.20	200.17	70.70	190.71	67.68	198.66	67.31
	Control	199.21	56.63	205.09	76.09	238.33	46.17	195.48	67.67
frequency*	Treatment	5.69	1.99	5.04	2.19	5.29	1.97	5.39	2.29
	Control	6.34	1.48	5.91	1.68	6.50	1.00	5.95	1.88
duration*	Treatment	71.80	65.07	64.33	69.29	69.60	74.09	71.46	70.25
	Control	97.93	68.53	102.07	76.55	120.81	74.43	85.92	78.08
Functional disability	Treatment	0.61	0.48	0.54	0.42	0.54	0.44	0.53	0.44
	Control	0.59	0.46	0.57	0.45	0.81	0.53	0.71	0.71
Work missed*	Treatment	2.94	3.56	2.02	2.80	2.72	3.13	2.45	3.37
	Control	2.55	3.08	2.91	2.71	4.29	2.58	3.30	3.51
Health care utilization*	Treatment	3.65	2.68	3.47	3.01	2.65	1.95	3.52	3.75
	Control	3.63	2.65	3.93	4.20	4.44	4.33	3.26	3.48
Depression									
FIQ*	Treatment	4.44	2.95	3.28	2.70	3.81	2.66	4.02	2.84
	Control	3.64	2.52	4.28	2.48	5.39	2.15	3.83	2.83
SCL90	Treatment	1.68	0.89	1.38	1.02	1.23	0.88	1.47	1.10
	Control	1.41	0.76	1.49	0.85	1.66	0.65	1.56	0.78
Anxiety									
FIQ*	Treatment	5.27	2.81	4.39	2.73	4.31	2.76	4.95	2.82
	Control	4.06	2.70	4.05	2.79	5.39	2.06	4.60	2.55
SCL90-R	Treatment	1.14	0.80	0.91	0.78	0.73	0.78	0.87	0.81
	Control	0.77	0.66	0.62	0.52	1.00	0.80	0.92	0.82

Table M1 (continued)

Means and Standard Deviations for the Primary and Secondary Variables based on the Original Data for the Treatment and Control Condition at Four Time Periods

Variable	Group	Time 1		Time 2		Time 3		Time 4	
		M	SD	M	SD	M	SD	M	SD
Secondary Variables									
Coping									
self-statements	Treatment	3.08	1.84	3.38	1.48	3.08	2.01	3.04	1.89
	Control	2.94	1.64	3.08	1.95	2.72	1.62	2.94	1.94
task persistence	Treatment	4.46	1.92	4.07	1.74	3.92	1.98	4.36	2.11
	Control	5.04	1.32	5.03	1.44	5.07	2.05	5.16	1.46
relaxation	Treatment	1.96	1.37	3.53	1.27	2.44	1.54	2.30	1.43
	Control	2.01	1.51	2.25	1.92	1.78	1.81	2.09	1.49
guarding	Treatment	3.22	2.13	2.94	1.79	3.04	1.88	2.81	1.73
	Control	2.76	1.51	2.86	1.74	3.79	1.72	3.27	1.94
asking for help	Treatment	2.16	1.92	2.88	2.64	2.67	1.96	2.38	2.08
	Control	1.65	1.52	2.22	2.05	2.18	2.09	1.75	1.43
resting	Treatment	3.89	1.64	3.91	1.40	3.80	1.82	3.84	1.80
	Control	3.03	1.42	2.97	1.86	3.35	1.31	2.74	1.54
seeking support	Treatment	2.36	1.46	2.73	1.68	2.33	1.74	2.58	1.75
	Control	2.15	1.46	2.50	1.56	2.18	1.30	2.30	1.25
Relaxation (CDQ)	Treatment	3.39	4.33	10.30	10.69	5.98	6.86	4.00	5.21
	Control	5.10	13.43	5.28	10.28	4.56	6.15	7.86	20.63
Self-efficacy	Treatment	4.40	1.63	6.31	2.01	6.11	2.16	5.14	1.98
	Control	5.14	1.66	5.53	1.75	4.20	1.24	5.02	1.76
Quality of life	Treatment	73.32	12.11	75.14	14.83	77.60	10.94	72.32	16.62
	Control	71.42	14.88	69.19	11.42	64.43	13.96	70.21	11.38

Note. The means and standard deviations for time 2 and time 4 are based on the ANCOVA results.

* indicates a single item. FIQ = Fibromyalgia Impact Questionnaire, SCL90-R = Symptom Checklist 90-Revised, CDQ = Chronic Disease Questionnaire.