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CHARACTERISTICS OF PATIENTS DIAGNOSED WITH FIBROMYALGIA AND THEIR RELATIONSHIP WITH TENDER POINT COUNT AND THE 1990 ACR CLASSIFICATION CRITERIA

BY

GRACE MOE ©

A THESIS

SUBMITTED TO THE FACULTY OF GRADUATE STUDIES AND RESEARCH

IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF

MASTER OF SCIENCE

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The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies and Research for acceptance, a thesis entitled, "Characteristics of patients diagnosed with fibromyalgia and their relationship with tender point count and the 1990 ACR classification criteria", submitted by Grace C. Moe in partial fulfillment of the requirements for the degree of Master of Science.

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ABSTRACT

This study examined the relationships of six biopsychosocial factors—number of painful segments, total pain intensity, functional disability, quality of life, mental health, and social support—first with tender point count and secondly, with the 1990 American College of Rheumatology classification criteria for fibromyalgia. Subjects were 111 women who were referred to rehabilitation services with the diagnosis of fibromyalgia, who met the ACR definition of widespread pain.

Pearson correlation coefficients revealed tender point count to be significantly (p<.001) associated with number of painful segments (r=.542), total pain intensity (r=.458), and functional disability (r=.350). No significant differences in quality of life, mental health, and social support were found between medically diagnosed fibromyalgia subjects who met the ACR criteria and those who did not. In stepwise logistic regression analyses, number of painful segments alone entered a multivariable model and thus was shown to be the only effective independent predictor of the ACR-classification of fibromyalgia (OR: 1.8 for each 5-unit increase).

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CHAPTER ONE

THE PROBLEM

Introduction

Fibromyalgia (FM) is considered a chronic pain syndrome that is increasingly seen in rheumatology practice (Prescott et al 1993). Its prevalence has been estimated at 2-4% of the American population (Wolfe et al 1990). Its etiology is unknown at the present time. Although FM is characterized primarily by a history of widespread pain and decreased pain threshold at multiple body sites, it is also typically associated with persistent fatigue, sleep disturbance, and morning stiffness (Wolfe et al 1990). Other symptoms and conditions such as headache, paresthesias, sensation of swelling, psychological distress, sicca symptoms, Raynaud's phenomenon, irritable bowel and bladder syndromes, as well as other modulating factors may occur (Wolfe et al 1990, Wolfe & Hawley 1993). It has been reported that FM sufferers are adversely affected in their quality of life and their ability to be competitively employed (Henriksson et al 1992).

The 1990 American College of Rheumatology classification criteria for FM are the main criteria in use today (Wolfe et al 1990). The ACR criteria state two diagnostic requirements for FM: 1) 'widespread pain' of over 3 months' duration and 2) pain on palpation of a 'minimum' of 11 out of 18 designated tender points. Widespread pain is defined as pain above the waist, below the waist, on the left and right sides of the body, and in the axial skeleton (Appendix A). No exclusions are made for the presence of concomitant radiographic or laboratory abnormalities.

The Problem

Recent medical literature has documented large individual differences among FM subjects in response to the various management approaches under study by researchers. Generally speaking, the numerous studied interventions for FM including pharmacologic (Carette et al 1994, Santadrea et al 1993), exercise

(Mengshoel et al 1992, Horven et al 1996), stress management (Horven et al 1996, Kaplan et al 1993), psychological counseling (De Voogd et al 1993), education (Burckhardt et al 1994), group treatment (Bennett et al 1996), and cognitive-education (Vlaeyen et al 1996) were shown to provide improvement in symptomatology in various proportions of studied subjects, and for some, the benefits were evident only on a short-term basis.

As care providers of patients with FM, physical therapists have an obligation to search for a long-term efficacious treatment approach for this group of patients. In the author's pursuit of such, several observations were made. First, it was noted that many of those diagnosed with FM did not receive a tender point examination by the diagnosing physician, thus indicating that the diagnosis of FM was not always made on the basis of the 1990 ACR classification criteria. This implied that the methodology used to make the diagnosis of FM varied among physicians. Secondly, for those patients for whom the diagnosis was based on the ACR criteria, their presenting symptoms, signs and musculo-skeletal assessment findings varied among each other. It was also unclear whether the clinical presentation of signs and symptoms differed between those whose FM diagnosis was or was not based on the ACR criteria.

These observations raised several questions: Do all medically diagnosed FM patients meet the 1990 ACR classification criteria for FM? If not, are there any discrete characteristic differences between those who meet the 1990 ACR criteria and those who do not? Do the 1990 ACR criteria truly define the FM syndrome or are they more representative of a distinctive subset? As one of the ACR criteria requires a minimum of 11 tender points among patients medically diagnosed with FM, are there any relationships between the tender point count and some of the FM-related "bio-psychosocial" characteristics that have been documented in the literature? These issues of heterogeneity are relevant to gaining a better understanding of the FM syndrome and when considering management approaches.

Objectives of the Study

The overall purpose of this study was to investigate the relationship of first, number of tender points and secondly, the probability of a subject's being classified with FM according to the 1990 ACR criteria with six biopsychosocial factors among women referred to rehabilitation service providers with the diagnosis of FM. The six biopsychosocial factors investigated were number of painful body segments, total body pain intensity, functional disability, quality of life, mental health and social support. In addition, these factors were compared between two groups of FM subjects, one with 11 or more positive tender points and thus meeting the ACR criteria, and the other with fewer than 11 tender points, and thus failing to meet the same criteria.

It was hypothesized that there would be a linear relationship between the number of tender points and each of the measured variables such that the higher the number of tender points, the more negative the score of each measured variable. It was also hypothesized that the two study groups—those who met and those who failed to meet the ACR criteria—would be different, such that the probability of being classified with FM according to the 1990 ACR criteria would increase with an increase in the severity of each study variable.

Several demographic and socioeconomic factors, medical history, perceived precipitating event, and seven FM-related symptoms listed by Yunus et al (1998) were described for the study sample.

Significance of the Study

Although articles on FM have become commonplace in medical journals in recent years, many gaps remain in the knowledge base of the FM syndrome.

With the exception of an abstract published by Yunus et al (1998), there was no prior work done to examine the group of patients who were diagnosed with FM by their physicians but who did not meet the 1990 ACR criteria. The characteristics of this group of FM patients have not been compared with those who were medically diagnosed with FM and meet the ACR criteria. Therefore, it is not known whether the characteristics of FM patients who meet the criteria are different from their counterparts who do not or whether FM as diagnosed by the ACR criteria represents a relatively discrete clinical entity.

The relationship between tender point count and a number of FM-related features has been investigated by several studies, but none compared the scope of variables examined by this study. For example, Croft et al (1996) in a cross-sectional study investigated the association between tender point count and only one lone factor: number of painful segments. Wolfe (1997) examined and observed a relationship between tender point count and one variable, the Rheumatology Distress Index, which is a composite measure of distress formulated by combining measures of anxiety, depression, global severity, sleep disturbance and fatigue. The present study examined the constructs studied by these two previous studies, as well as a broad spectrum of additional variables, among which included functional disability, quality of life, mental health, and social support. Furthermore, the two studies by Croft et al (1996) and Wolfe (1997) did not focus exclusively on FM patients. Croft et al's sample was selected from the general population through a postal questionnaire screening for pain. Wolfe studied the relationship between number of tender points and the Rheumatology Distress Index in a sample that included patients not only with FM, but also rheumatoid arthritis and osteoarthritis, all of whom were patients from a rheumatology specialty clinic. It is expected that patients attending a rheumatology specialty clinic are likely to be suffering a higher degree of symptom severity in mean than those in the present study, who come from a broad referral base to receive rehabilitation services. Thus, a greater variation in symptom severity was expected among FM patients in the present study.

Results of this study were expected to improve understanding of how tender point count and the ACR classified "FM" status relate to six bio-psychosocial factors. It was hoped that this would shed some light on whether the ACR criteria do in fact discretely define the FM syndrome. Should study results indicate that there is no significant difference in the characteristics of medically diagnosed FM patients, whether they meet the ACR criteria or not, it may then be inferred that the ACR criteria do not appear to identify a discrete condition. Clinically, such a finding implicates that the use of the ACR criteria, which rely on tender point count, may not be adequate for clinical diagnosis and treatment planning. However, should study results reveal a significant difference in the characteristics of FM patients who meet and those who do not meet the ACR criteria, a more difficult set of interpretations follows. If this finding is accompanied by evidence of a linear relationship between number of tender points and the measured variables, it could then be speculated that the ACR criteria might possibly represent just one end of the spectrum of FM. On the other hand, FM as diagnosed with the ACR criteria may be suspected to be a discrete condition only if the correlation scatterplots show the two groups to be clustering around the two extreme ends of the tender point continuum. Clinically speaking, should it be observed that the two FM subject groups were clearly distinct from each other in terms of the measured variables, different treatment considerations could be implied for the two groups.

The results of this study are expected to lead to a better understanding of the characteristics of patients diagnosed with FM and, in particular, with respect to the ACR diagnostic criteria, and may have implications on the planning of management strategies for the FM syndrome. The identification of subgroups of medically diagnosed FM patients and their specific clinical characteristics might be useful in guiding treatment approaches.

Operational Definitions

ACR-Positive:	Subjects experiencing chronic widespread pain as defined by the first ACR criterion, as well as having 11 or more positive tender points, thus meeting the 1990 ACR Classification Criteria for FM.
ACR-Negative:	Subjects experiencing chronic widespread pain as defined by the first ACR criterion, but having fewer than 11 positive tender points, thus failing to meet the 1990 ACR Classification Criteria for FM.
Functional Disability:	According to the World Health Organization (1980), disability is defined as "any restriction or lack of ability to

perform an activity in the manner or within the range considered normal by reason of any medically determinable physical or mental condition."

FM-related Symptoms: A frequently used term in FM medical literature. It refers to a partial or complete list of symptoms that has been documented in the literature to be associated with the FM syndrome. They include: chronic widespread pain, multiple tenderness, fatigue, sleep disturbance, morning stiffness, depression, anxiety, functional disability, headache, subjective swelling, paresthesia, irritable bowel, urinary urgency, sicca symptoms, Raynaud's phenomenon, sensitivities to chemicals, and a list of environmental and personal stress modulating factors.

Medically Diagnosed FM Patients: In the context of this study, the term refers to patients who have been diagnosed with "fibromyalgia" by a physician, either a general practitioner, a rheumatologist, or any other medical specialist; and who had received or were receiving some form of rehabilitation services for their FM-related symptoms.

Rehabilitation Services: In the context of this study, rehabilitation services refer to community and hospital based physical therapy, out-patient group education or exercise programs, or any multi-disciplinary rehabilitation program designed for the management of FM.

CHAPTER TWO

REVIEW OF THE LITERATURE

Introduction

A review of the medical literature was conducted on the existing research on fibromyalgia (FM). The primary purpose of this review was to accumulate the latest knowledge on study results and conclusions reached by other researchers on issues related to the questions of interest of the present study.

This review begins by providing background information on the prevalence and impact of the FM syndrome. The discussion that follows focuses on contemporary researchers' appraisals of the 1990 ACR criteria, the views of some researchers on the rationale of investigating multiple variables, observations made by other investigators on the association of various factors with the FM syndrome, and an analysis of recent cross-sectional studies as they compared to the present study.

Prevalence

A recent epidemiology survey from Kansas found that FM affects 2% of the total population: 3.4% of all women and 0.5% of men (Wolfe et al 1995a). FM was claimed to be one of the three most commonly diagnosed conditions in rheumatology practice in the United States (Bennett 1996, Wolfe et al 1990). The proportion of new patients with FM was found to be 4.6% in a rheumatology practice (Greenfield et al 1992). Therefore, FM is becoming a major public health problem in the Western world. It has an enormous negative impact both on society and on the individual sufferer.

Impact On Society and The Individual

On the societal level, FM is becoming a growing economic and social concern to the public health system, the private insurance sector and the courts. Individuals with FM have become frequent users of the health care system, with the mean number of visits to health care professionals estimated at around five per year (Bennett et al 1996). White et al (1999), in an epidemiology study conducted in London, Canada, noted that FM patients used more medications and twice the outpatient health services at twice the cost compared to controls. They found that the mean difference in direct costs for health services between FM cases and controls was $493Cdn annually ($p$<.001). In Canada, private disability insurers paid over two hundred million dollars per year in long-term disability claims for FM alone in 1989 (McCain et al 1989). In Norway, FM was by far the most frequent single diagnosis used as a reason for disability pension among women in 1988, accounting for 7.2% of new pensioners (Bruusgaard et al 1993). In the United States, Wolfe et al (1997a) found that 26.5% of their 1604 surveyed FM patients were receiving some form of disability payment. Furthermore, FM is also a frequent subject of prolonged litigation in Canadian civil courts (Capen 1995).

On the individual level, quality of life for FM sufferers has been reported to be lower than that of patients with other chronic pain conditions (Burckhardt et al 1993). Compared to a healthy reference group, fewer FM subjects were employed, and those who remained employed had reduced their hours at work. Relations with family and friends were affected in 80% of the subjects, while leisure and household activities were adversely affected in over 90% (Henriksson 1994, Henrikksson et al 1992, Turk et al 1996).

Appraisal of the 1990 ACR Criteria

As the diagnosis of FM cannot be based on any single distinguishable clinical features or identifiable laboratory sign, researchers over the last 3 decades have developed numerous criteria sets to define FM, each with a slightly different concept and a distinct conglomeration of signs and symptoms. The currently used ACR Classification Criteria for FM were result of a multi-center study conducted in 1990 by Wolfe et al (1990). This set of ACR criteria was described in Chapter 1 and Appendix A.

(Not All Medically Diagnosed FM Patients Meet the ACR Criteria)

Since its development in 1990, the ACR criteria have been widely accepted for clinical and epidemiological research. However, their appropriate use as a diagnostic tool in clinical care has been debated. The ACR criteria set has been heavily criticized for its lack of objectivity, its arbitrary designation of the minimum number '11' for a tender point criterion (Bennett 1995), and its failure to account for the group of patients who suffer many FM-like symptoms, but do not satisfy the tender point criterion by a minimum margin (Wolfe 1994a). Furthermore, it has been remarked that the ACR criteria for FM provide no means of taking into account for the possible remission or significant reduction in key clinical features as that postulated by Granges et al (1994). Comments were also made that the criteria do not differentiate between persons with mild to moderate FM symptoms and physical findings, a concept advocated by Granges and Littlejohn's (1993) measurement of the degree of FM disease activity.

It appears that not all patients deemed to have FM meet the ACR criteria. It is common to see a patient with classic FM symptoms with only between 8 and 10 of the ACR designated tender points (Bennett 1995, Forseth and Gran 1993, Wolfe 1994a). Forseth and Gran (1993) found that in a sample of 217 females with musculoskeletal pain, only 40 females met the ACR criteria for FM, and 129 other females who did not meet the same criteria displayed many of the FM-like symptoms and the presence of tender points. They observed that many FM-like symptoms existed rather frequently in the population, although such symptoms were most commonly found in persons satisfying the ACR criteria. However, these symptoms were also noted frequently in subjects not meeting the ACR criteria, but who complained of chronic musculoskeletal pain. Questions such as how to define the group of patients who suffer many FM-related symptoms, but who do not meet the ACR criteria and whether or not to treat and inform patients not meeting the ACR criteria in a way similar to patients meeting the criteria have been raised by many researchers.

(FM: Not A Discrete Disease)

One of the biggest issues raised about the ACR criteria is their implication that FM, a concurrence of chronic widespread pain and multiple tender points, is a discrete disease (Croft et al 1994, Forseth and Gran 1993, Mufson and Regestein 1993, Wolfe et al 1995a). Wolfe (1997) investigated the relationship between measures of pain threshold and symptoms of distress in a clinic sample of FM and other rheumatologic diseases. They observed a linear relation between tender point count and FM variables throughout the entire range of tender point values. Therefore, they concluded that there is a parallel continuum of distress and tender points and that there is no rationale for treating FM as a discrete disorder. Results of several population studies (Croft et al 1993, Forseth and Gran 1993, Wolfe et al 1995a) also suggested that FM is not likely a distinct entity with a unique complex of symptoms. This suggestion was supported by the findings of these population studies that chronic widespread pain, multiple tenderness and many FM-like symptoms were common in the general population; that subjects with these symptoms may or may not meet the ACR criteria; and that those meeting the ACR criteria displayed a higher degree of symptom severity. Some investigators thus postulated that the ACR criteria merely define a subset of FM patients with full-blown clinical symptoms (Forseth and Gran 1993).

The distinctness of FM as diagnosed by the ACR criteria and the question as to how the group of clinically diagnosed FM patients relate to the ACR criteria were some of the issues of concern held by the present study.

Rationale for Investigating Multiple Variables

This research investigated six major factors in relation to the FM syndrome: number of painful body segments, total body pain intensity, functional disability, quality of life, mental health status, and social support. It also attempted to describe a number of other factors: demographic, socioeconomic, disease history, health service utilization, perceived precipitating event, and FM-related symptoms.

Two underlying principles justify the investigation of multiple variables in a study concerning the FM population. First is the 'bio-psychosocial' construct of FM described by Wolfe (1994a). Second is the Multiaxial Assessment Approach of Pain postulated by Turk and Rudy (1987,1988, 1990).

Several classification criteria sets for FM prior to the current ACR criteria have stressed the importance of non-pain variables. For example, sleep disturbance, morning stiffness, and fatigue are three mandatory items in addition to pain and tender points in the Smythe criteria set (Smythe 1979). Anxiety and stress are among a list of modulating factors included in the Yunus criteria (Yunus et al 1981, 1989) (Appendix B). The different emphasis placed on criteria items by the various criteria sets serves to confirm that in addition to widespread pain and multiple tender points, a wide range of other elements exists in the FM syndrome. FM is considered a multifactorial, bio-psychosocial disorder by many current researchers (Bennett et al 1991, Masi and Yunus 1990, Wolfe 1994a). As stated by Wolfe (1994a), FM is not associated with discernible signs of physical impairment, is generally viewed through a 'bio-psychosocial' model of disease, and is thought to be affected by many factors such as genetics, social activity, psychological status, family, financial state, and other rheumatic conditions. Understanding the role of various non-medical factors listed in Wolfe's bio-psychosocial model of FM is important because these factors may shape not only the patients' presentations of the physical manifestations of the syndrome but also the clinicians' approach to its management.

In addition, since FM shares many common features with other poorly described chronic pain conditions such as low back pain and temporomandibular disorders, the cognitive-behavioral transaction model of chronic pain described by Turk and Rudy (1987) has significant relevance for the FM syndrome. This perspective views pain as a complex and multidimensional perceptual phenomenon. To better understand and treat pain, Turk and Rudy (1988) noted the importance of integrating medical-physical, psychosocial, and behavioral data in assessing patients with chronic pain, calling this approach the Multiaxial Assessment of Pain. This approach helps to identify the role of cognition, emotions, behavior and sensory stimuli in the formation of perceptions of pain. It also permits identification of subgroups of patients based on characteristics other than solely physical factors, as is common in traditional diagnoses. According to Turk and Rudy (1987, 1988), subgroups of chronic pain patients are likely to differ from one another with regard to factors such as self-perceived pain intensity, medication use, psychiatric diagnoses, employment, range of motion, and other pain behaviors, as well as objective physical pathology.

This study's attempt to describe a spectrum of bio-psychosocial characteristics of the two FM patient groups may enhance understanding of the presence of related issues and possibly guide multi-disciplinary considerations according to individual patient characteristics.

Factors Associated with the FM Syndrome: Rationale for Their Inclusion as Study Variables

This study examined the association of various FM-related factors with tender point count and with the ACR classification criteria. Some of the variables selected for this study and their relationship with the FM syndrome had been examined to some extent by several other cross-sectional studies. However, none had investigated the spectrum of biopsychosocial variables to the same extent as the present study had and none had examined the associations of FM features specifically with the ACR criteria. The following is an account of the various perspectives concluded by various investigators on similar FM-related issues.

Several recent studies reported finding an association between tender point count and various FM related factors. Wolfe et al (1995b) observed that decreased pain threshold, as measured by tender point count, correlated with all of the symptoms of FM, even in those subjects whom did not meet the ACR criteria for the syndrome. Six factors were found to stand out as the most important correlates of FM: female sex, Symptom Checklist-90-Revised Somatization score, HAQ Disability Index score, VAS pain score, the perception of having "poor health", and "being very dissatisfied" with one's health status. Croft et al's (1993) data showed that self-reported chronic widespread pain was associated with depression, anxiety, tiredness and other somatic symptoms.

Two studies, on the other hand, found a lack of correlation between tender point scores and FM-related symptoms (Jacobs et al 1996, Burckhardt et al 1991). It has been speculated that the reason could be low reliability of the tender point and/or symptoms scores. However, the reliability of the tender point manual examination was proven to be adequate by Jacobs et al (1995), with a mean test-retest reliability coefficient (Cronbach's α) of 0.74 and an inter-observer generalizability coefficient (Cronbach's α) of 0.71. In terms of symptom assessment, there is no generally accepted method for the assessment of symptoms in FM. Self-assessment questionnaires have been considered useful for both clinics and research, as it was felt that many non-specific FM-like symptoms might be subject to major observer interpretation (Jacobs et al 1996). Therefore, this lack of correlation between FM-related symptoms and tender point scores found by Jacobs et al (1996) and Burckhardt et al (1991) may imply the possibility that tender point scores and symptoms are in fact independent aspects of FM.

Number of Painful Body Segments

Wolfe (1994a) reported that the central feature of the FM construct is the patient report of "pain all over". Wolfe et al (1990) observed that 59.5% FM patients had more than 15 painful body locations and 68.8% complained of 'pain all over', compared to 13.3% and 21.7% for two control groups respectively. The Pearson correlation coefficient for the tender point count with 'pain all over' was .37 (Wolfe et al 1995b). Croft et al (1996) investigated the association between musculoskeletal pain and tender points in a cross-sectional study. Based on results from an initial postal questionnaire survey of 1340 adults selected randomly from two general practices in England, 177 subjects were invited for an interview and tender point examination. Study results indicated a moderately strong association between the reported presence of pain in a body segment and the presence of a tender point within that segment. A trend of increasing number of tender points with an increasing number of painful segments was also observed. Their study concluded that pain in a particular segment of the body is associated with an increased likelihood of detecting tenderness at one of the ACR tender points in that segments. The present study investigated number of painful segments as one of the FM subject characteristics.

Total Body Pain Intensity

As indicated already, pain is the primary characteristic of FM (Wolfe 1994a). Wolfe et al (1990) reported that 97.5% of FM patients complained of widespread pain, compared to 71.1% of the chronic pain controls. The Pearson correlation coefficient for tender point count with VAS Pain was around .35 (Wolfe et al 1995b). However, a lack of correlation between 2 self-reported measures of pain and mean tender point score was reported by Jacob et al (1996). Their study assessed 113 Dutch FM subjects with a tender point examination, a self-assessment questionnaire on FM symptoms, and 2 self-reported measures of pain, the pain scales on the Enschede Fibromyalgia Questionnaire (EFQ) and the Dutch Arthritis Impact Measurement Scale (AIMS). Results indicated that although the 2 self-reported measures of pain correlated with many other self-reported symptoms, they did not show any significant association with the mean tender point score. The correlation coefficients for the number of tender points with the EFQ and the Dutch AIMS Pain Scales were 0.20 and 0.22 respectively. This lack of correlation between self-reported pain and mean tender point score was reproduced by other studies. Burckhardt et al (1991) also found no correlation between self-reported pain, assessed by the Fibromyalgia Impact Questionnaire, and the number of tender points in 25 FM patients. In another population study, it was found that tender point counts were associated with measures of depression, fatigue, and poor sleep, independent of the pain status (Croft et al 1994). Van Denderen et al (1992) observed in their sample that while physical exercises resulted in increased pain, it hardly increased the number of tender points, supporting findings by the aforesaid investigators that there was a lack of correlation between self-reported pain and mean tender point score.

The fact that self-reported measures of pain correlated with many other self-reported symptoms (Jacobs et al 1996) indicated that patients who reported severe pain also experienced other signs and symptoms as being of a severe intensity. On the other hand, the failure by Jacobs et al to prove that FM patients with a high mean tender point score would also have a high pain score and vice versa suggested that perhaps tender point scores and self-reported pain represent very different aspects of pain. Based on this finding, Jacobs et al recommended that both tender points and self-reported pain should be assessed in the pain measurement of patients with FM, both in experimental and clinical situations. Therefore, the present study included overall body pain intensity, the sum of the pain intensity of each painful body segment, as one of the FM characteristics for investigation.

Functional Disability

Although the terms "physical impairment" and "functional disability" are often used interchangeably in medical literature, they in fact represent separate concepts. According to the World Health Organization, "impairment" is defined as the anatomic/physiologic loss or a psychological impediment. It thus relates to disorders of function at the organ level. Disability, on the other hand, is defined as a limitation of function that compromises an individual's ability to perform an activity within the range considered normal. Disability is the result of impairment. In the present study, functional disability was chosen as a study variable as it has been documented as an impact of the FM syndrome by many researchers. Functional disability, in the context of this study, was defined by the individual's ability to shop, do laundry, prepare meals, wash dishes, vacuum rugs, make beds, walk several blocks, visit friends, do yard work and drive a car, in accordance with items measured by the Physical Impairment Scale of the Fibromyalgia Impact Questionnaire (Burckhardt et al 1991).

Functional disability and pain are considered the most important outcomes (Hawley and Wolfe 1991) and diagnostic variables (Callahan and Pincus 1990) in rheumatic disease. Schuessler and Konermann (1993), using a German instrument comparable to the Health Assessment Questionnaire (HAQ) to assess functional disabilities, found no significant differences between their FM and RA patient groups, but observed that FM patients perceived their condition as being significantly worse than did RA patients. Two studies using the Yunus criteria have shown significant impact of

FM on an individual's ability to manage daily life routines, ranging from having difficulty with activities of daily living to severe functional disability and inability to work, with consequent changes in both physical and social habits (Henriksson et al 1992, Henriksson 1994). Wolfe et al (1995b) investigated the relationship of tender point count with a list of common clinic FM measures and found the strongest correlate to be the HAQ disability index (r=.472), a measure of functional disability. In a study investigating the characteristics of FM in the general population, Wolfe et al (1995a) found that the odds of having FM with the most severe categories of scores from the HAQ was >18. Hawley and Wolfe (1991) studied how pain, HAQ functional disability, pain/disability ratio and psychological scores might vary among 1522 patients with seven distinct rheumatic disorders. They found the highest score for functional disability and global severity among the 7 rheumatic disorders to be that obtained by FM patients. Walker et al (1997) found that patients with FM had equal or greater functional disability and were less well adapted to their illnesses than patients with RA. Using the SF-36 and the modified HAQ, Walker et al (1997) demonstrated that FM patients had equal or greater functional disability in the SF-36 physical, emotional, family, social, and occupational functioning scales and equal severity of impairment on all measured HAQ physical activity items. They also found that the number of medically unexplained physical symptoms (excluding joint and limb pain) alone was the best predictor of FM group membership, correctly classifying 83% of the cases. The 1993 Copenhagen Consensus Document on FM stated that ergonomic assessment of functional work tests has shown that FM patients have as much disability as rheumatoid arthritis patients and perform at only 60% of normal capacity, a result of limited movement caused by pain. These patients have problems with mobility, arm function, grip strength, and household tasks that are comparable to those of rheumatoid arthritis patients and their functional disability tends to remain stable over time (Consensus 1993).

Quality of Life

Since several prospective studies (Granges et al 1994, Kennedy and Felson 1996, Wolfe et al 1997b) have shown that the physical features of FM do not tend to improve over time, quality of life has been used as an outcome variable in the evaluation of FM patients by many clinicians and researchers in recent years. It has been reported that the FM syndrome adversely affects the quality of life of its sufferers (Burckhardt et al 1993, Henriksson et al 1992, Henriksson 1994, Martinez et al 1995). The 1993 Copenhagen Consensus Document (Consensus 1993) noted that persons with FM perceive their quality of life to be significantly lower than that of healthy persons or those with other rheumatic diseases. It listed health, relationships and ability to engage in recreation as spheres of life with which FM sufferers are particularly dissatisfied with. Burckhardt et al (1993) compared the quality of life of women with FM to that of women with 5 other chronic diseases and that of healthy controls. They found that women with FM scored lowest in all domains measured by the Quality of Life Scale. Accordingly, then, the present study found it important to include quality of life as one of its major study variables.

Mental Health

Mental health is an important dimension of FM. Psychological symptoms and mental disorders were known to be associated with chronic widespread pain (Macfarlane et al 1999). Croft et al (1993, 1994) and Wolfe et al (1995a) have shown that the association between widespread pain and multiple tender points may represent measures of general distress rather than a distinct disease entity. Many studies have suggested that significant psychological disturbance is present in the FM population. A population study by Macfarlane et al (1999) found that one-quarter of patients seeking care for chronic widespread pain from primary care physicians have a mental disorder. Hawley and Wolfe (1991) found that among seven groups with different rheumatic conditions the most abnormal psychological scores occurred in the FM group. In their comparison of psychosocial factors between 36 FM and 33 RA patients using the Diagnostic Interview Schedule (DIS), Walker et al (1997) found that patients with FM had significantly higher lifetime prevalence rates of all psychiatric diagnoses. Ninety percent of their FM patients had at least one lifetime prevalence of one or more of psychiatric disorder, compared with 49% of the RA patients. The odds of a FM patient's having any psychiatric diagnosis is 8.5 times greater than that for the RA patient (OR=8.5, 95CI=2.5-29.5). Schuessler and Konermann (1993) found that compared with RA patients, the FM patients were generally more disturbed with significantly higher self-ratings of depression (*p*=.002) and anxiety (*p*=.01), showing a higher prevalence in depressive (24% versus 6%) and anxiety disorders (17% versus 8%). There were significant differences between the two groups in the State-Trait-Anxiety Inventory score (*p*=.0021), Depression Scale (DS) (*p*=.0006) and psychosomatic symptoms (*p*=.0000). These findings were supported by Norregaard et al (1994), who observed that FM patients score higher on anxiety and depression than patients with other rheumatologic conditions. They also found a correlation between pain score and psychometric scoring.

It has been hypothesized by many that excessive somatization in FM is related to psychopathology rather than core FM features of pain and fatigue. Observations have been made that those with a measured "psychological disturbance" profile were more likely to have multiple somatic and emotional complaints. Wolfe et al (1995a) found FM to be strongly associated with somatization on the SCL-90-R T-score≥60 (OR=10.26; 95%CI: 2.59, 40.69), AIMS depression scale ≥4.0 (OR=2.85, 95%CI: 1.02, 7.94), AIMS anxiety scale ≥6.0 (OR=4.89, 95%CI: 2.13, 11.21), a history of depression (OR=4.22, 95%CI: 1.87, 9.53) and a family history of depression (OR=2.22, 95%CI: 1.08, 4.57). Aaron et al (1996) and Bennett et al (1996) have observed 14-34% of FM patients to be diagnosed with somatization. Although Ahles et al (1991) did not find a higher frequency of vegetative signs of depression in FM patients than in rheumatoid arthritis patients, they however observed that those FM patients with a psychiatric history displayed significantly more somatic symptoms.

Hudson and Pope (1989), who cited FM as a form of "affective spectrum disorder", supported the role of psychological variables as causal or aggravating factors on FM. Other investigators such as Yunus (1994) and Aaron et al (1996) have found psychological distress in FM patients to be mainly a result of symptom severity. While arguments on the causal and consequential roles of psychometric factors on the FM illness continue, one common finding among various investigators is that there appears to be an association of greater disease severity and poor disease outcome with higher levels of psychological distress (Croft et al 1993, 1994, Ledingham, Doherty and Doherty 1993, Wolfe et al 1995a). The severity of pain was found to correlate with psychopathology in FM in a study by Yunus et al (1991). Ledingham, Doherty and Doherty (1993) have found in a retrospective study the association of poor outcomes of FM with high levels of anxiety and depression.

On a different note, only a few studies were found to deny significant high rates of psychopathology in FM patients, compared to other chronic pain conditions. Birnie et al (1991) noted that FM patients' psychological profiles as measured by three tests—the Symptom CheckList-90R, the Illness Behavior Questionnaire, and the Chronic Illness Problem Inventory—were similar to those of other patients with chronic pain syndromes (*p*=not significant). Ahles et al (1991), who found no significant differences in psychopathology between FM patients and those with rheumatoid arthritis, used a scale, the Psychiatric Diagnostic Interview, not previously used in other studies on the psychiatric aspects of FM. Chi-square analysis of the Psychiatric Diagnostic Interview data failed to discriminate between groups of subjects with FM, RA, and those without pain in terms of frequency of lifetime diagnosis of any psychiatric disorder, in major affective disorder, somatization disorder, or anxiety-based disorder. These results seem to indicate that FM is not secondary to a primary psychiatric disorder. The authors argued that FM is neither a form of masked depression nor a variant of a major psychiatric disorder. Both of these studies led to the conclusion that many psychological aspects of FM can be considered as psychological aspects of chronic pain. This conclusion was supported by Goldenberg's statement in his review article (Goldenberg 1989b) that the depressive and somatic symptoms in FM are not more prominent than in other chronic medical conditions. His stance is that the vast majority of patients with FM do not meet criteria for a current psychiatric diagnosis.

Aaron et al (1996) examined the temporal relationship between psychological diagnoses and onset of FM among 2 groups of FM subjects: patients and nonpatients. Patients were those who met the ACR criteria for a diagnosis of FM and who sought medical attention. Nonpatients were those who met the ACR criteria for a diagnosis of

FM but who did not seek medical attention for the symptoms. Using the Center for Epidemiological Studies Depression scale and the Trait Anxiety Inventory to assess current psychological distress, they observed that FM patients reported significantly higher levels of current depression and anxiety than FM nonpatients (p=.001, p=.001 respectively). FM nonpatients reported significantly higher levels of depression and anxiety than healthy controls (p=.026, p=.016 respectively). However, the group differences on current depression and anxiety were eliminated when pain threshold and fatigue levels were statistically controlled (p=.101, p=.445 respectively). Using the Computerized Diagnostic Interview Schedule, they found that lifetime psychiatric disorders were significantly more prevalent in FM patients than in FM nonpatients (p=.002). They stated that the low frequencies of psychiatric diagnoses among their FM nonpatients strongly suggest that psychiatric illness is not intrinsically associated with the FM syndrome, although they do seem to partly determine who becomes a FM patient. They concluded that multiple and higher frequency of lifetime psychiatric disorders among the FM patient group suggested that psychiatric diagnoses may contribute to the decision to seek medical care for FM. These observations conflict with those of Wolfe et al (1995a), who reported that both FM clinic patients and community residents were characterized by high but comparable levels of psychological distress. They therefore suggested that psychological distress is intrinsically related to the FM syndrome. Data from their study showing an equally high level of anxiety and depression in the community and the clinic population, dispelled the suggestion that the commonly observed psychological distress in persons with FM seen in the clinic might be the result of health-seeking behaviors rather than a factor intrinsically associated with the syndrome.

Yunus et al (1991) attempted to determine whether clinical features were related to psychological status as measured by the Minnesota Multiphasic Personality Inventory or were intrinsic to FM per se. Results of their study suggested that the central features of FM (number of pain sites, number of tender points, fatigue, and poor sleep) do not correlate with individual MMPI scales and are independent of psychological status. Therefore, they concluded that the central features of FM are more likely related to the

FM syndrome itself, although pain severity may be influenced by psychological factors. Although Wolfe et al (1995b) claimed that decreased pain threshold as measured by tender point count correlated with all of the symptoms of FM, a careful appraisal of their statistical results indicated that the correlation coefficients between tender point count and various psychological factors were fairly low. For example, Pearson correlation coefficients for the tender point count and AIMS depression, SCL-90 depression, AIMS anxiety, and SCL-90 anxiety were approximately .20, .15, .22, and .16 respectively.

In summary, it is apparent that the overall picture of currently available psychological research gives an impression that psychological disturbance is associated with FM. However, this overall picture becomes obscure when attempts are made to examine specific forms of psychological disturbance. For example, conflicting results were obtained in studies investigating the incidence of anxiety and depression in FM. Many of these inconsistencies may be results of methodological differences; in particular, a wide range of psychological measures have been used in FM research, and some of those used such as the Minnesota Multiphasic Personality Inventory have been criticized for having the tendency to inflate scores among individuals with chronic pain conditions (Goldenberg 1989a, 1989b, Pincus et al 1986, Prokop 1986, Smythe 1984). Patient populations varied greatly and clinical activity of FM or disease severity was not considered in analyses. Many articles used the terms "psychological" and " psychiatric" interchangeably, as though the two represent similar constructs. Without a formal standardization of research methodology, psychological measures, and operational definitions by researchers on issues of the psychopathology of FM patients, these existing FM psychological studies cannot be compared. On the other hand, the differences in research findings perhaps suggest that patients with FM may form a psychologically heterogeneous population. Turk et al (1996) found in their study that FM patients diagnosed with the ACR criteria could be classified into three subgroups based on psychosocial and behavioral characteristics. In their study, these psychologically differentiated subgroups of FM patients showed substantial differences in clinical presentation of their symptoms, physical functioning and perceived disability.

At the present time, there is no clear indication as to whether psychological disturbance is a cause or a consequence of the FM syndrome. Merskey (1993), in his review article, stated that while depression and other psychological problems may complicate muscle pain and FM, and may occasionally promote such illnesses, they are not likely to be the principal cause of more than a minority of cases. However, psychological distress, be it causal or consequential in relation to onset and maintenance of FM, is an important element to examine in an FM population as it probably affects the individual's perception of symptoms and disability. Further research on the association of psychological disturbance and the FM syndrome is needed. In the meantime, the present study finds it safer to remain on neutral ground by considering psychological malaise as an integral consequence of the FM experience rather than as a concomitant marker of FM. Recognizing that the overwhelming number of articles on the psychological aspect of FM patients thus far have focused mainly on the negative rather than the positive perspective of mental health, the present study thus chose to measure mental health as an integrated concept of psychological distress and positive well-being. In the context of this study, mental health is defined as a balanced product of 2 correlated factors: psychological distress consisting of anxiety, depression and loss of behavioral/emotional control, and psychological well-being, consisting of general positive affect and emotional ties (Veit & Ware 1983).

Social Support

For the purpose of this study, social support is defined as "the perceived availability of functional support in terms of five components: 1) emotional support which involves caring, love and empathy, 2) instrumental or tangible support, 3) information, guidance or feedback that can provide a solution to a problem, 4) appraisal support, which involves information relevant to self-evaluation and 5) social companionship, which involves spending time with others in leisure and recreational activities" (Sherbourne and Steward 1991).

As social support tends to facilitate health and reduce or 'buffer' stress (Thoits 1982, 1983), it is thus expected to have a beneficial effect on the health and well-being of FM patients. Therefore, it could be postulated that a positive social support network may enhance the coping mechanism of a FM patient, thus increasing the pain threshold, which in turn reduces the tender point count and the probability of being classified with FM by the ACR criteria. However, Bolwijn et al's (1994) study provided some evidence that the social networks of patients with FM are more restricted than those of RA patients. Furthermore, they found that in the general population, 6–11 intimates form part of a network, whereas in the patient networks, the intimates are restricted to the spouse and, in the case of the FM patients, the physician. There was no intimate friend in 8 out of 10 FM networks in contrast to 5 out of 10 in RA networks. However, this study by Bolwijn et al dealt mainly with the structural component of social support. The emotional and affective components of the social support of FM patients have not been explored by this or other studies. Information on the relationships between social support and tender point count, between it and the ACR-Classified FM status and its variation on subgroups of FM patients, is not available, all of which were examined by the present study.

Descriptive Variables

For descriptive purposes, this study surveyed a list of variables that included demographics, socioeconomic factors, disease history, health service utilization, perceived precipitating events, and seven FM-related symptoms used by Yunus et al (1998) as minor criteria for his proposed diagnosis of "Incomplete FM Syndrome". These descriptive data were used to compare characteristics of FM patients who meet and those who do not meet the ACR criteria, and to examine comparability of the study sample with FM subject samples of other research studies. Several sociodemographic and disease history factors have been studied sporadically either singly or in combinations with other FM-related factors by researchers over the last decade. With respect to those variables that had been researched upon recently, opinions regarding their exact influence on the presentation of the FM syndrome and their interaction with each other vary. The following is an account of recent research findings on the descriptive variables chosen for investigation by the present study.

Demographic: Age, Marital Status

Although Wolfe et al (1995a) found the prevalence of chronic widespread pain to increase with age, rising to a maximum prevalence of 7.4% in the 70-79 year old group, they also noted from the same study that FM was fairly independent of age (OR=1.03; 95%CI: 0.98, 1.07) (Wolfe et al 1995a). The Pearson correlation coefficient for tender point count with age was .228, p=.0001 (Wolfe et al 1995b). FM was found to be associated with divorce (OR=4.32; 95%CI: 1.03,18.12) by Wolfe et al (1995a).

Socioeconomic: Level of Education, Employment Status at Onset, Current Employment Status, Disability Claims Status

Wolfe et al (1995a) noted the odds of having FM when a person fails to complete high school to be 3.52, 95%CI: 1.04, 11.90. The FM causality issue was found to be complicated by the potential influence of the availability of compensation for the syndrome. Littlejohn (1989a, 1989b) observed that in settings where compensation is widely available, illnesses similar to FM have been shown to increase in apparent prevalence; where compensation availability declines, these similar illnesses decrease in prevalence. Wolfe et al (1995a) found FM to be associated with applications for disability benefits with an odds ratio of 5.94; 95%CI: 2.48, 14.21.

Disease History: Duration of Symptom, Duration of Diagnosis

Wolfe et al (1997b) found in a longitudinal outcome study that the markedly abnormal scores for pain, functional disability, fatigue, sleep disturbance, and psychological status did not change substantially over a period of seven years. Correlations between baseline and final assessment values on studied variables were as high as r=.82. Jacobs et al (1996) found no linear or nonlinear association between disease duration and number of symptoms statistically. In their study, the mean number of symptoms was 11 for patients with a disease duration of either <10 years or ≥10 years.

Health Service Utilization: Diagnosing Physician, Attending Physician, Medication, Number of Physician Visits, Number of Other Health Professional Visits

Wolfe et al (1995a) showed that FM was associated with visits to physicians in last 6 months (OR=3.21, 95%CI: 1.56, 6.59), but independent of current medications (OR=1.04, 95%CI: 0.48, 2.26). According to Aaron et al (1996), multiple psychiatric illnesses and high levels of psychological distress and FM-related symptoms may be important factors that impel persons with FM to seek medical care for their pain. MacFarlane et al (1999) reported that72% of their 252 subjects who fulfilled the ACR criterion chronic widespread pain had sought a medical consultation about their pain. Although there was a clear difference in levels of psychological distress, there were no significant differences in terms of levels of fatigue, social dysfunction, and number of somatic symptoms between those who sought medical care and those who did not.

Perceived Precipitating Event or Events: History and Type of Perceived Precipitating Event

Trauma as a 'trigger' or cause of FM has been an important and contentious issue in recent research. Evidence that trauma can cause FM comes from a few case reports (Moldofsky et al 1993, Romano 1990, Wolfe 1994b). Greenfield et al (1992) found that 23% of his 127 subjects with a primary rheumatologic diagnosis of FM reported the onset of FM after having trauma, surgery, or a medical illness. Smythe (1989) indicated that biomechanical disturbances in the cervical spine may play a role in the pathogenesis of FM. This was supported by Buskila et al (1997) who noted that FM was diagnosed in 21.6% of those with neck injury. Radanov et al (1995) have shown that two years after 'whiplash' injury of the neck, 18% of patients still had injury-related symptoms, including fatigue, headaches, anxiety, sleep disturbances, sensitivity to light and noise, and muscle tenderness, manifestations commonly known to be characteristics of FM syndrome. Waylonis et al (1994) found in a follow-up study of 66 patients with a diagnosis of post-traumatic FM that 56 (84.8%) had 11 or more of the ACR designated tender points, 60.7% noted the onset of FM symptoms after a motor vehicle accident, 12.5% after a work injury, 7.1% after surgery, 5.4% after a sports-related injury, 1.8% after physical abuse and trauma and 12.5% after other events. Disturbances in hormonal (Buskila et al 1993), infectious factors (Buskila et al 1990, Leventhal et al 1991), and stressful conditions (Yunus et al 1991) have also been suggested as possible precipitating factors to the FM syndrome. Walker et al (1997) found that compared with RA patients, FM patients had a significantly higher lifetime incidence of all forms of victimization, both childhood and adult. They found childhood maltreatment to be a general risk factor for FM, and adult physical abuse to be associated with FM. They concluded that sexual, physical, and emotional trauma might be important factors in the development and maintenance of this disorder and its associated disability in many patients. Boisset-Pioro et al (1995) studied the prevalence of sexual and physical abuse in 83 female FM patients versus 161 female patients with other rheumatologic conditions. They found that abuse was greater in FM patients than in control patients (53% versus 42%). Significant differences were observed for lifetime sexual abuse (17% versus 6%), combined physical and sexual abuse (17% versus 5%), and childhood sexual abuse (37% versus 22%). Taylor et al (1995), in an epidemiologic study, found that 26(65%) of 40 women with FM reported sexual abuse. The prevalence and types of abuse were not found to be significantly different from those of their 42 healthy controls. Although they found sexual abuse to correlate with the number and severity of associated symptoms ($p<.001$), they noted that sexual abuse does not appear to be a specific factor in the etiology of FM. Schuessler and Konermann (1993) observed that FM patients reported a higher number of stress factors during childhood such as separation, loss of parents, family violence or bad living conditions than RA patients ($p=.0010$).

Greenfield et al (1992) observed that FM patients whose symptoms were brought on by a precipitating event were more disabled than those with FM patients with no history of such, resulting in loss of employment in 70%, disability compensation in 34%, and reduced physical activity in 45%. Their conclusion, supported by findings of Turk et al (1996), was that the occurrence of FM following an initiating event might represent the onset of a longstanding pain syndrome that results in a more considerable physical, social, and financial disability than patients with FM without a precipitating event. Aaron et al (1997) observed that physical trauma was associated with receipt of disability compensation (p=.019). However, they also observed that emotional trauma was associated with a high number of physician visits (p=.013), functional disability ratings (p=.012), and fatigue (p=.029). They thus concluded that perception of physical trauma is a greater determinant of disability compensation for FM than is perceived emotional trauma.

Yunus' "IFMS"Minor Criteria Symptoms: Irritable Bowel Syndrome, Tension Headache, Fatigue, Sleep Disturbance, Morning Fatigue, Swollen Feeling, and Paresthesia

The inclusion of symptoms and modulating factors in criteria sets used in clinical care and research prior to the development of the 1990 ACR criteria implied that there should be more to having FM than just pain and tenderness. Walker et al (1997), using logistic regression analysis, found that the number of medically unexplained physical symptoms alone was the best predictor of FM syndrome versus RA, correctly classifying 83% of the cases. Yunus et al (1998) formulated a list of seven symptoms to be used as a minor criteria set for the diagnosis of Incomplete Fibromyalgia Syndrome (IFMS). These seven symptoms—irritable bowel syndrome, tension headache, fatigue, sleep disturbance, morning fatigue, swollen feeling and paresthesia—are commonly known to be related to the FM syndrome and have been used in various combinations by other studies. Their attempt was to define the group of patients who were diagnosed with FM clinically but who did not fulfill the 1990 ACR criteria. Yunus et al proposed that the diagnosis of IFMS be made in the presence of either one of the 1990 ACR criteria (major criterion) and two or more of these seven symptoms (minor criteria). In their study, number of tender points was found to be fewer in IFMS than in FM (10.9 ± 4.5 versus 15.4 ± 2.4), but there was no significant difference between the IFMS and FM groups in the list of symptoms, except for swollen feeling. As one of the goals of the present study was to describe the group of patients medically diagnosed with FM but who do not meet the ACR criteria, a concept similar to Yunus et al's IFMS, these seven symptoms were included in subject survey.

With the exception of tension headache, the remaining six symptoms described by Yunus et al (1998) were also studied by Wolfe et al (1995a). Wolfe et al (1995a) found irritable bowel syndrome (OR=2.49; 95%CI: 1.27, 4.89), fatigue (OR=3.26, 95%CI: 1.07, 9.95), sleep disturbance (OR=3.84; 95%CI: 1.23, 11.96), morning stiffness (OR=4.43; 95%CI: 1.50, 13.09), paresthesia (OR=4.82; 95%CI: 2.36, 9.84), and swelling (OR=4.92; 95%CI: 1.41, 17.16) to be strongly associated with FM in the general population. Wolfe et al (1995b) observed that the Pearson Correlation Coefficients for tender point count with irritable bowel syndrome, fatigue, sleep disturbance, stiffness, swelling, and paresthesia were approximately .24, .24, .17, .29, .27 and .34 respectively.

Other Cross-sectional Studies on FM

A review of the literature found several recent cross-sectional studies that investigated the association of tender points with various FM symptoms, four surveys examining the occurrence of FM-like syndromes in the general population and one study attempting to subgroup FM patients on the basis of psychosocial attributes. While these studies touched upon various aspects of the proposed study, none appeared to duplicate the proposed study in objectives, subject selection, and method.

Croft et al (1996) investigated the association between musculoskeletal pain and tender points in a two stage cross sectional survey of 1340 adults selected randomly from two general practices in England. An initial postal questionnaire about pain symptoms was used as a sampling frame for a subsequent tender point examination. Based on results of the pain survey, 177 subjects from three pain categories (ACR widespread pain, regional pain, and no pain during the previous month) were invited to attend an interview and tender point examination. Only 59 subjects of this sample had widespread pain, as defined by the ACR criteria. Study results indicated a moderately strong association (odds ratio range: 1.3, 3.1) between the reported presence of pain in a body segment and the presence of a tender point within that segment. This study concluded that pain in a particular segment of the body is associated with an increased likelihood of detecting tenderness at one of the ACR tender points in that segment, that FM does represent one end of a spectrum of pain and tender points, and that both traits are probably continuous in the general population. However, the drawback of this study is its limited scope as only the relationship between tender point and painful segments was examined.

One of the objectives of Jacobs et al's (1996) cross-sectional study was to determine whether tender point scores correlated with self-reported pain and other symptoms in a sample of 113 consecutive outpatients in three rheumatology clinics in The Netherlands. The tender point score refers to the mean of the pain intensity scores, graded between 0 and 3, for the 14 points described by Smythe (1979). All subjects were diagnosed with FM using the Yunus Criteria. Results indicated that there was no correlation between self-assessed symptoms and the mean tender point score. Though this study examined a broader list of FM-related symptoms and modulating factors, as well as other variables such as health perception, anxiety, and depression, its subject inclusion criteria and tender point examination sites render findings of the study not generalizable to FM patients diagnosed with the ACR criteria. However, it is perceived that many of those patients meeting the Yunus criteria would also likely meet the ACR criteria (Wolfe et al 1990).

A cross-sectional study conducted by Wolfe (1997) between 1993 and 1996 bore closest resemblance to the proposed study, both in study objective and design. Wolfe's objective was to investigate the relationship between measures of pain threshold and symptoms of distress to determine whether FM is a discrete construct/disorder in the clinic. While Wolfe's sample consisted of 627 patients, only 267 had a primary diagnosis of FM according to the ACR criteria; others in his sample were patients with rheumatoid arthritis, osteoarthritis and miscellaneous disorders. All subjects were recruited from Wolfe's rheumatology specialty clinic. The major variable used by Wolfe for correlation with tender point count was the Rheumatology Distress Index (RDI), a composite measure of distress constructed from five individual variables: anxiety, depression, global severity, sleep disturbance, and fatigue. The RDI was found to be linearly related to the count of tender point (r^2 =.30). The proposed study differs from Wolfe's study in several details: study subjects may or may not have reached the care of a rheumatology specialist, the association between tender point count and five separate dimensions (pain, disability, quality of life, mental health, and social support) within the bio-psychosocial construct of FM were examined, and finally, two groups of medically diagnosed FM patients—those who met and those who did not meet the ACR criteria—were compared.

Four prominent population surveys conducted between 1992 and 1997 have observed that many FM features are common occurrences in the general population, especially in females with musculoskeletal pain. Croft et al (1993) conducted a cross sectional population survey of 1340 adult subjects aged 18 to 85 randomly selected from the registered population of two general practices in Cheshire, United Kingdom. The point prevalence of chronic widespread pain was found to be 11.2% using the 1990 ACR definition. This study was conducted with a postal questionnaire; no tender point examination was performed. In another population survey undertaken by Wolfe et al (1995a), a random sample of 3,006 persons in Wichita, Kansas was first surveyed with a mailed questionnaire about widespread pain as defined by the ACR criteria. A subsample of 391 persons who reported widespread pain was then examined for a final FM diagnosis with a tender point examination, a further interview about some specific FM features, and the administration of two psychological tests. The reported results indicated a 2.0% prevalence of FM for both sexes, 3.4% for women and 0.5% for men. The study also found associations of FM with many of the demographic, psychological and symptom factors that were investigated by the present study. Study results led to the conclusion that FM is common in the general population. A separate report on the same Wichita, Kansas study by Wolfe et al (1995b) stated that dolorimetry scores were 2.04 kg/cm^2 lower in women than in men, women were almost 10 times more likely to have 11 tender points (OR 9.6) than men, and tender point counts were more correlated with FM symptoms than dolorimetry scores. Similar findings were noted by Forseth and Gran (1993) from an epidemiological survey of all women (2,498 females) in a small town by the coast of southern Norway, in which 217 females with musculoskeletal pain were further examined for the presence of FM as defined by the ACR criteria. Of the 217 females, 18.4% were found to satisfy the diagnostic criteria for FM, and 59.4% suffered musculoskeletal pain, which could not be further diagnosed. It was thus concluded that there was a high prevalence of both FM and FM-like syndromes in the general female population. One limitation of these four population studies is that they did not attempt to describe the characteristics of the group of subjects with FM-like syndromes but did not meet the ACR criteria.

In another cross-sectional study, Turk et al (1996) attempted to subgroup 117 patients diagnosed with FM using the ACR criteria on the basis of psychosocial and behavioral responses to pain. Their results indicated that 87% of the sample could be classified into three cluster groups according to the Multidimensional Pain Inventory (MPI), namely the Dysfunctional, the Interpersonally Distressed and the Adaptive Copers. Although the three groups exhibited comparable levels of physical functioning in terms of spinal mobility, they differed significantly in clinical presentation of their symptoms, opioid use, depression, pain severity, perceived disability, and level of marital satisfaction. Turk et al concluded that FM may be a heterogeneous disorder and that a clinical approach that treats FM patients as a homogeneous group may impede understanding of the mechanisms underlying the FM condition and deter development of effective treatment. While this study provided important confirmation that the classification of FM according to the ACR criteria does not imply homogeneity of the patients classified, it again offered no information on the group of FM patients who fail to meet the ACR criteria. Furthermore, the subgrouping criterion used by Turk and coworkers focused solely on the psychosocial and behavioral characteristics, omitting to integrate the constellations of medical and physical findings of the medically diagnosed FM patients.

Summary and Conclusion

In summary, current literature revealed that the FM syndrome exerts an enormous negative impact on both society and the individual. Many researchers have questioned the appropriateness of using the ACR criteria for clinical diagnosis. A number of commonly known FM-related biopsychosocial characteristics have been investigated to various extent and by different methods, but conflicting results were shown in their correlation with the FM syndrome. No prior cross sectional studies attempted to examine the spectrum of biopsychosocial variables as that undertaken by the present study, and none had described the group of medically diagnosed FM patients who do not fulfil the tender point requirement of the ACR criteria. Therefore, it is expected that the present study may confirm findings of some existing studies and contribute new knowledge on the FM syndrome relating to characteristic differences between FM sufferers who meet and those who do not meet the ACR criteria.

CHAPTER THREE

SPECIFIC OBJECTIVES

The **first objective** of the study was to examine the relationship between each of six biopsychosocial measures and tender point count (range 0-18) among patients diagnosed with FM from a broad referral base, receiving rehabilitation services. The six measured independent variables were:

1. *Number of Painful Body Segments*, measured by the Body Parts Problem Assessment (BPPA) scale
2. *Total Body Pain Intensity*, measured by BPPA scale
3. *Functional Disability,* measured by the Fibromyalgia Impact Questionnaire (FIQ)- Physical Impairment scale
4. *Quality of Life*, measured by the Quality of Life Scale
5. *Mental Health Index*, measured by Rand Mental Health Inventory (MHI)
6. *Social Support Index,* measured by Medical Outcome Study (MOS) Social Support Survey (SSS)

The dependent variable, *number of tender points*, measured by the Manual Tender Point Survey, refers to a range of 0-18 tender points designated for the classification of FM by the 1990 ACR criteria.

It was hypothesized that there would be an association between the number of tender points and each of the measured biopsychosocial characteristics, such that the higher the number of tender points, the more negative the score of each measured variable.

The **second objective** was to examine the relationship of the six biopsychosocial measures and whether or not the 1990 ACR criteria were met in patients receiving the diagnosis of FM. The two groups of FM patients were classified as:

1. ACR-Positive: Subjects experiencing chronic widespread pain as defined by the first ACR criterion, as well as having 11 or more positive tender points, thus meeting the 1990 ACR Classification Criteria for FM, or

2. ACR-Negative: Subjects experiencing chronic widespread pain as defined by the first ACR criterion, as well as having fewer than 11 positive tender points, thus failing to meet the 1990 ACR Classification Criteria for FM.

Specifically, the probability of a subject's being classified with FM according to the 1990 ACR criteria based on the six biopsychosocial variables was determined. The study also investigated whether or not differences in these variables existed between the two ACR classification groups.

It was hypothesized that the probability of a subject's being classified with FM according to the 1990 ACR criteria would increase with an increase in severity of each study variable. It was also hypothesized that the two groups would be different in that the ACR-Positive group would tend to have slightly higher degrees of severity than the ACR-Negative group in the measured variables: *number of painful body segments, total body pain intensity, functional disability, quality of life, mental health index*, and *social support index*.

In addition to the two primary objectives, this study also provided descriptive statistics on a number of the subjects' characteristics for the entire sample and separately for the ACR-Positive and ACR-Negative groups. Subjects were described in terms of demographic and socioeconomic variables (*age, marital status, level of education, employment status at onset, current employment status, and disability claims status)*; medical history *(duration of symptoms, duration of diagnosis, type of diagnosing physician, attending physician, medications, number of physician visits in past 12 months, number of other health professional visits in past 12 months)*; precipitating events (*history of perceived precipitating event, type of perceived precipitating event)*; and Yunus' "Incomplete FM Syndrome-Minor Criteria Symptoms" (*irritable bowel syndrome, tension headache, fatigue, sleep disturbance, morning fatigue, swollen feeling, and paresthesia*).

CHAPTER FOUR

METHODS

Subjects

Subjects were 111 females aged 18 to 74 who had met the inclusion criteria for the present study, that is, they were diagnosed with FM by a physician, they were receiving or had received rehabilitation services for their FM symptoms within a 12 month-period prior to the date of testing, and they were complaining of chronic widespread pain as defined by the first 1990 ACR criterion. This means that the pain was present for more than 3 months and had involved the axial skeleton and at least 2 contralateral quadrants of the body. Rehabilitation services in this context refer to community and hospital based physical therapy direct care treatment, out-patient group education or exercise programs, or any multi-disciplinary rehabilitation program designed for the treatment of FM. There were no exclusion criteria as the 1990 ACR criteria state that "the presence of a second clinical disorder does not exclude the diagnosis of FM".

The initially considered age restriction of 19 to 65 was lifted prior to data collection. Wolfe et al (1995a) have found the prevalence of FM to increase with age, being the highest for women between 60 and 79 years old (>7% in women). Therefore, prior studies which surveyed only females in their middle years, such as the 20-49 year-old female subjects examined by Forseth and Gran (1993), may not truly represent the FM population. This alarming fact alerted the removal of the initially planned age restriction by the present study.

Males were not included in this study as the number of male volunteers was expected to be too small for statistical analysis and inferences to the broader male FM population. The 1993 Copenhagen Consensus Document on FM states that women are affected with FM 10-20 times more than men are. Therefore, results of this study on female FM patients will be generalizable to the majority of individuals diagnosed with FM in the Edmonton area.

All participants were Caucasians from the Greater Edmonton region of Alberta, who spoke and understood English well and had no difficulty completing the self-report questionnaires of this study.

Of the 111 subjects who volunteered and participated for the study, all met inclusion criteria and none were excluded from the analysis. These subjects were referred to the study by physical therapists and other rehabilitation service providers of both private clinics and hospital departments in Edmonton (Appendix C). Among the many referral sites included the University of Alberta Hospital, Good Samaritan Society Auxiliary Hospital, General Hospital Get Set Program, Corona Station Physical Therapy, West End Physiotherapy, Glenora Physiotherapy Clinic and many others. After screening each potential subject to ensure that inclusion criteria were met, the referring practitioner then explained the study to and provided the potential subject with the telephone contact number for the principal investigator. Potential subjects who wished to volunteer for the study would then call the principal investigator to make arrangement for the test session.

In order to assess representation of participants, referring practitioners were asked to complete a "Clinic Profile on Fibromyalgia Patients" form. This form requested a record of the age, duration of FM diagnosis, duration of FM symptoms, medical specialty of attending physician, employment status, and disability claims pertaining to FM patients seen by the referral clinic for the 6 months' duration of the data collection phase. The purpose of this form was to collect basic demographic and historical data on the aggregate of FM patients seen in each referral site so that presence of subject selection bias and the representativeness of the study sample could be discuss during data analysis.

Study Design and Data Collection

This study was a cross-sectional observational study. Subjects were tested at one point in time during a single session. No follow-up was needed. Subjects meeting the inclusion criteria, and who volunteered and signed an informed consent to participate were tested with a physical tender point examination, 5 self-report questionnaires, and 1 medical history inquiry form.

Based on the observed number of positive tender point sites, subjects were assigned to either the ACR-Positive or ACR-Negative group, for the purpose of statistical analyses.

The duration of the data collection phase of this research lasted 6 months between January and June 1999.

Independent Variables

Data were collected on 6 major study variables as well as on a list of descriptive variables. The following variables were considered independent variables for correlation and regression analyses, and dependent variables for multivariate analysis. The validity and reliability of the instruments used to measure these variables are discussed in a later section of this chapter named "Data Collection Instruments".

The 6 Major Study Variables were as follows:

1) *Number of Painful Body Segments* – measured by the self-administered Body Parts Problem Assessment scale (Kabat-Zinn 1983). This is a numerical count of body regions, which were perceived to be painful or problematic by the subject. The subject was asked to circle from a list of 53 body regions the segment(s) presented as a problem to the subject. The score is a ratio scale. It can range from 0 to 53.

2) *Total Body Pain Intensity* – measured also by the self-administered Body Parts Problem Assessment scale (Kabat-Zinn 1983). This variable quantifies the degree of difficulty and pain associated with body parts, by summing the extent to which different regions of a subject's body represent a problem or pain to the patient. The BPPA consists of a list of 53 body regions with a numerical scale from 0 to 5 listed next to each region. "0" represents "no

discomfort, no problem" and "5" represents "great discomfort, very problematic". The subject was asked to circle the number that best describes the degree of problem or discomfort associated with each region, in a time frame of "the past week including today". This variable is a product of a ratio and an ordinal scale. It is the summary score of the BPPA, attained by summing the digits circled for each region, and the score can range from 0 to 265.

3) *Functional Disability* – measured by the self-administered Physical Impairment scale of the Fibromyalgia Impact Questionnaire (Burckhardt et al 1991). The Physical Impairment scale of the FIQ includes 10 physical functioning items, asking the subject to rate her perceived ability on performing shopping, laundry, preparing meals, washing dishes, vacuuming, making beds, walking several blocks, visiting friends or relatives, yard work, and driving a car. Each item is rated on a 4 point Likert-type scale ranging from 0 – 3, representing "always", "most", "occasionally" and "never" respectively. Subjects were given the opportunity of deleting items from scoring if they did not do some of the tasks listed. The FIQ-Physical Impairment score is obtained by summing the scores that have been rated by the subject and then dividing this sum by the number of items rated. A summed raw score between 0 and 3 is thus obtained and it represents the score of the *functional disability* variable. A higher score indicates a greater impact of the syndrome on the person.

4) *Quality of Life* – measured by the self-administered Quality of Life Scale (Burckhardt et al 1989). This variable measures the life satisfaction concept with 16 items: material comforts, health, relationships, children, spouse, close friends, helping others, organizations and public affairs, learning, understanding yourself, work, creative expression, socializing, reading/music/watching entertainment, active recreation, and independence.

Each item is rated on a 7-point Delighted-Terrible Likert scale. Score for this variable is obtained by summing the rating on each item to make a total score. A higher score indicates greater satisfaction. The total satisfaction score can range from 16 to 112.

5) *Mental Health Index* – measured by the self-administered Rand Mental Health Inventory (Veit & Ware 1983). This variable is a measure of the multidimensional concept of psychological well-being by asking the subject to rate each of 38 items, which emphasize 5 factors: anxiety, depression, loss of behavioral/emotional control, general positive affect, and emotional ties. The subject was asked to circle on an ordinal scale, for each item, the one answer that came closest to the way she has been feeling within the past month. Item scores are summed to calculate the *Mental Health Index* score. The higher score on each item reflect more frequent occurrence of favorable mental health symptoms, and higher scores on the *Mental Health Index* indicate greater psychological well being. Scores on the index can range from 38 to 226.

6) *Social Support Index* – measured by self-administered Medical Outcome Study (MOS) Social Support Survey (Sherbourne and Steward 1991). This variable measures the concept of functional social support, in terms of perceived availability of functional support, that is, the degree to which interpersonal relationship serve particular functions. It consists of 19 items representing multiple dimensions: emotional/informational, tangible, affectionate and positive social interaction. For each item, subjects were asked to indicate how often each kind of support was available to them if they needed it on an ordinal scale ranging from 1-5, which represents "none of the time" to "all of the time". The sum of all responses constitutes the Social Support Index. A higher score indicates a greater availability of functional social support. Score can range from 19 to 95.

Descriptive Variables, as surveyed by a self-administered medical history inquiry questionnaire, were as follows:

Age – measured in years

Marital Status – coded as 1=never married, 2=married/common law, 3=divorced or separated, 4=widowed.

Level of Education – coded as 0=no schooling, 1=elementary, 2=high school, 3=vocational certificate, 4= University

Employment Status at Onset – coded as 0=not working, 1=working, 2=others

Current Employment Status – coded as 0=not working, 1=working, 2=others

Disability Claims Status – coded as 0=not receiving or had not received disability benefits on account of FM symptoms, 1=receiving or had received disability benefits on account of FM symptoms

Duration of Symptoms – measured in years

Duration of Diagnosis – measured in years

Diagnosing Physician – coded as 1=family doctor, 2=rheumatologist, 3=other specialist, 4=multiple physicians

Attending Physician – coded as 1=family doctor, 2=rheumatologist, 3=other specialist, 4=psychiatrist, 5=multiple physicians, 6=none

Medication – coded as 0=none, 1=yes

Number of Physician Visits – a numerical count of the number of visits to a physician in the 12-month period preceding date of testing.

Number of Other Health Professional Visits – a numerical count of the number of visits to other health professionals in the 12-month period preceding date of testing. "Other health professionals" refer to any of the followings: physical therapist, occupational therapist, chiropractor, massage therapist, homeopath, herbalist, acupuncturist, and others.

History of Perceived Precipitating Event – coded as 0=no, 1=yes, 2=uncertain. Answer to the question "Was there a trauma or an injury you believe led to the first symptoms of fibromyalgia?"

Type of Precipitating Event – coded as 1=motor vehicle accident, 2=work injury, 3=home or recreational or sports injury, 4=work-related or personal stress, 5=physical or emotional abuse by another person, 6=flu, 7=post-surgical, 8=2 or more of above.

Irritable Bowel Syndrome – surveyed with the question "Did you have irritable bowel syndrome (periodically altered bowel habits with lower abdominal pain or distention, usually relieved or aggravated by bowel movements, no blood) in the past month?" Subject was asked to respond with a choice of "never", "seldom", "often or usually" or "always". "Never" or "seldom" was coded as 0=absence of symptom. "Often or usually" or "always" was coded as 1=presence of symptom. Question and coding were in accordance to system used by the ACR criteria study.

Tension Headache – surveyed with the question "Did you have tension headache in the past month? (Tension headache is defined as steady, bothersome, episodic headaches that are diffuse, at the forehead, the back of your head or the entire head, often experienced during a period of emotional stress, and without the visual or gastrointestinal symptoms of migraine. It is not due to an infection, such as a viral illness, definite sinus infection or congestion of the nose.)" Subject was asked to respond with a choice of "never", "seldom", "often or usually" or "always". "Never" or "seldom" was coded as 0=absence of symptom. "Often or usually" or "always" was coded as 1=presence of symptom. This question combines the wordings used by the ACR criteria study and Dr. M. Yunus' FM clinical and research questionnaire protocol (Yunus et al 1998). Responses and coding were in accordance to system used by the ACR criteria study.

Sleep Disturbance – surveyed with the question "Did you have sleep disturbance (trouble falling asleep, frequent awakening in the night) in the past month?" Subject was asked to respond with a choice of "never", "seldom", "often or usually" or "always". "Never" or "seldom" was coded as 0=absence of symptom. "Often or usually" or "always" was coded as 1=presence of symptom. Question and coding were in accordance to system used by the ACR criteria study.

Fatigue – measured by the "Fatigue" scale of the Fibromyalgia Impact Questionnaire. To the question "How tired have you been?" subject was asked to mark the point on a 10-cm VAS that best indicated how she felt overall for the past month. Any mark made on a line below the 5-cm point was code as 0=absence of symptom, and that above the 5 cm-point was coded as 1=presence of symptom.

Morning Fatigue – surveyed with the question "Did you feel morning fatigue or tiredness (fatigue or tiredness you feel in the morning after waking from sleep) in the past month?" Subject was asked to respond with a choice of "never", "seldom", "often or usually" or "always". "Never" or "seldom" was coded as 0=absence of symptom. "Often or usually" or "always" was coded as 1=presence of symptom. This question was extracted from Dr. M. Yunus' FM clinical and research questionnaire protocol. Response and coding were in accordance to system used by the ACR criteria study.

Swollen Feeling – surveyed with the question "Did you have a swollen feeling in your joints, muscles or other parts of the body in the past month?" Subject was asked to respond with a choice of "never", "seldom", "often or usually" or "always". "Never" or "seldom" was coded as 0=absence of symptom. "Often or usually" or "always" was coded as 1=presence of symptom. This question was extracted from Dr. M. Yunus' FM clinical and research questionnaire protocol. Responses and coding were in accordance to system used by the ACR criteria study.

Paresthesia – surveyed with the question "Did you experience any numbness or tingling in any part(s) of your body in the past month?" Subject was asked to respond with a choice of "never", "seldom", "often or usually" or "always". "Never" or "seldom" was coded as 0=absence of symptom. "Often or usually" or "always" was coded as 1=presence of symptom. This question was extracted from Dr. M. Yunus' FM clinical and research questionnaire protocol. Responses and coding were in accordance to system used by the ACR criteria study.

Dependent Variables

The dependent variables included in the analyses were as follows:

1. *Number of Tender Points* – a count of positive tender points using the 18 sites specified in the 1990 ACR classification criteria for FM. The technique for the tender point count was based on the Manual Tender Point Survey protocol documented by Okifuji et al (1997). Upon the thumb palpation of an ACR-designated tender point site with a manual pressure of about 4-kg./sq. cm, the subject was asked to indicate if there was pain with a response of either "yes" or "no". If the response was a "yes", the subject was then asked to rate the intensity of pain on a scale from 0 to 10. "0" refers to no

pain and "10" refers to the worst pain that one has ever experienced. Any rating above "2" on a specific site is considered a positive tender point.

2. *FM Intensity* – an equivalent to the ACR criteria's total myalgic score. Based on Okifuji et al's (1997) Manual Tender Point Survey protocol, the *FM intensity* score is obtained by summing the intensity rating on a scale of 1 to 10 for each ACR-designated tender point site on digital palpation of approximately 4 kg./sq. cm. and then dividing this sum by 18. Score can range from 0-10.

3. *ACR-Status* – coded 0=ACR-Negative and 1=ACR-Positive. These codes represent the between-subject factors for multivariate analysis and the dependent variables for correlation and regression analyses. Based on the observed number of positive tender point sites, subjects were assigned an ACR-classified group membership. Subjects with widespread pain who fulfilled the second ACR criterion by demonstrating to have 11 or more positive tender points were classified as ACR-Positive. Subjects with widespread pain who failed to satisfy the second ACR criterion as they had fewer than 11 positive tender points were classified as ACR-Negative.

Data Collection Instruments

The test session involved first, a physical examination for tender points by the principal investigator, and second, the administration of five self-report questionnaires and one medical history inquiry form. The Manual Tender Point Survey (Okifuji et al 1997) protocol was used for the physical examination as it had been validated specifically for the assessment of the ACR tender point criterion. The 5 questionnaires were: Body Parts Problem Assessment (BPPA) scale, Fibromyalgia Impact Questionnaire (FIQ), Quality of Life Scale (QOLS), Rand Mental Health Inventory (MHI), and Medical Outcomes Study (MOS) Social Support Survey (SSS). They were chosen for the present study because first of all, they all measure and yield a summary score for the construct that their names imply. Second, each represents an independent construct of the bio-psychosocial spectrum. Third, there is very little redundancy among the questionnaires. Furthermore, these 5 questionnaires have been formally validated and have proven to have acceptable psychometric properties. Lastly, all are brief and easy-to-administer with simple, self-explanatory directions. With the exception of the Rand MHI, which has 38 items spread over 7 pages, the remaining questionnaires are relatively short with only 1 (BPPA, QOLS, MOS-SSS) or 2 (FIQ) pages. Therefore, study participants were not overburdened by the time needed to complete the study questionnaires.

The instruments used for data collection in this study were:

1. Manual Tender Point Survey (MTPS) - The MTPS is a tender point examination protocol developed by Okifuji et al (1997) to be used as a clinical diagnostic procedure to evaluate the ACR tender point criterion for FM. The MTPS uses a pain severity score of 2 (in a range of 0-10) as the optimal threshold point for the identification of a positive tender point. This was validated by Okifuji et al (1997) with a sensitivity of 88.57% and specificity of 71.43%, results that are comparable to data obtained by the 1990 ACR criteria study. The MTPS yields data for the 3 dependent variables of the present study: *number of tender points, FM intensity* and the *ACR-status* of the subject.

   To maintain consistency with the level of pressure applied during digital palpation of tender points, the examiner practiced and calibrated the pressure application of 4 kg of force using a scale as recommended by the MTPS on a regular basis during the course of the study. Accordingly, a practice subject was placed on a standard weight scale with the scale set at the weight of the subject plus 4-kg. The examiner then calibrated her digital pressure by pressing the trapezius survey site of the practice subject with an increase of pressure by 1 kg/s until the scale was balanced.

The reliability of tender point count has been debated upon in literature. It was argued by several investigators (Smythe et al 1992a, 1992b, 1993, Smythe 1998) that the tender point examination was dependent on the experience and training of the examiner; the accurate anatomical localization of tender point sites; the disease severity status; and the measurement methods employed. Dolorimetry was touted as an equal or possible superior alternative by some studies (Buskila et al 1993, Prescott et al 1993). However, dolorimetry had been shown to have less overall accuracy than manual tender point palpation (Wolfe et al 1990, Wolfe and Hawley 1993), and no advantage over tender point palpation in terms of sensitivity and reliability (Cott et al 1992). Cott et al (1992) found a higher number of active tender points by palpation compared with dolorimetry using >4kg/cm^2. Wolfe (1997) observed that manual tender point count is better correlated with FM symptom variables than dolorimetry and that dolorimetry is a poor predictor of the Rheumatology Distress Index. According to Jacob et al (1995), test-retest stability coefficient for manual tender point examination was .70, .72 and .76 for three observers, and inter-observer agreement coefficient was .71. Wolfe et al (1992) stated that trained examiners could quantify tender points and identify patients with and without FM with very high levels of agreement.

Therefore, the use of the standardized MTPS protocol and with one examiner throughout the entire course of the present study should minimize any test-retest inconsistency and eliminate problems relating to inter-observer reliability.

2. Body Parts Problem Assessment (BPPA) Scale – The BPPA is a brief questionnaire developed by Kabat-Zinn (1983) to evaluate the extent to which different body parts represent a problem to the patient. For chronic pain patients, it provides a quick measure of the degree to which specific regions contribute to the overall pain complaints. In addition to being a

useful tool for the ACR criterion 'Widespread Pain' by providing information on the number and locations of painful sites, it also measures the pain intensity of each site. It thus provides an immediate picture of the patient's current problem and non-problem areas from the patient's own perspective.

The BPPA questionnaire consists of a list of 53 body regions with a 6-point numerical rating scale from 0-5 listed next to each region, with 0 representing "no discomfort, no problem" and 5 representing "great discomfort, very problematic". The BPPA summary score is the sum of the digits circled by the patient for each region, which best describes the degree of problem or discomfort of the region. It can range from 0-265. Kabat-Zinn (1983) indicated that scores above 25 usually reflect serious problems in the subject's relationship to his or her body. It is expected that scores for FM patients will likely be much higher than 25 owing to the large number of body regions involved in their primary complaints.

The BPPA has demonstrated good construct validity with significant correlations with the McGill Pain Questionnaire PRI (r=0.57), the Somatization Index of SCL-90-R (r=0.79), and the number of medical symptoms patients reported on a symptom checklist (r=0.68) (Kabat-Zinn 1983).

The BPPA provides 2 scores that measure two of the study's major variables: *number of painful body segments* and *total body pain severity.*

3. Fibromyalgia Impact Questionnaire (FIQ) - The FIQ (Burckhardt et al 1991) is a disease-specific health status measurement tool for FM and it attempts to quantify 10 concepts: functional disability, work status, pain intensity, fatigue, sleep disorder, muscular stiffness, anxiety, depression, and overall sense of well being. It is designed to measure the FM patient health status, progress and outcome. It has been specifically designed to reflect change in a FM patient's general status over a period of up to several years. A higher score indicates a higher impact of the FM syndrome.

Burckhardt et al (1991) has validated the FIQ for sufficient reliability, validity and content relevance. Test-retest reliability correlation (Pearson's r) for each item of the FIQ ranges from an average of 0.56 for pain to 0.95 for physical function. Construct validity through correlation analysis with the Arthritis Impact Measurement Scale (AIMS) demonstrated that the FIQ physical functioning item had a highly significant correlation of 0.67 with the AIMS lower extremity physical functioning component. The pain, depression, and anxiety analog scales also showed highly significant correlation of 0.69, 0.73, and 0.76 with their respective AIMS scales. The FIQ is an easy to administer self-report questionnaire with simple, self-explanatory directions. For the purpose of this study, the 10-items constituting the physical impairment scale of the FIQ was used to measure the study variable *functional disability*; and the 10-cm VAS fatigue scale was used to measure one of the descriptive variables, fatigue.

4. Quality Of Life Scale (QOLS) - The QOLS (Burckhardt et al 1989) is a self-administered generic instrument designed to measure and quantify the variable, quality of life, for chronic disease patients. It measures subjects' rating of their level of satisfaction on 16 items: material comforts, health, relationships, children, spouse, close friends, helping others, participating in organizations and public affairs, learning, understanding yourself, work, creative expression, socializing, reading/music/watching entertainment, active recreation, and independence. Each item is rated on a 7-point Delighted-Terrible Likert scale. A higher score indicates a higher quality of life.

In Burckhardt et al's (1989) validation study of the scale, Cronbach's alpha coefficients averaged .87 for internal consistency and reliability. Test-retest reliability coefficients ranged from .76 to .84 for the two 3-week intervals. Convergent and discriminant validity has also been demonstrated.

Overall, the QOLS is a conceptually clear, content-valid instrument with positive psychometric properties.

For the purpose of this study, the total score of the QOLS provides a measure for the study variable, *quality of life.*

5. Rand Mental Health Inventory (MHI) - The Rand MHI (Veit and Ware 1983) was designed as a screening tool for mental health status in population surveys. It emphasizes 5 factors: anxiety, depression, loss of behavioral/emotional control, general positive affect and emotional ties. The factors are designed to identify two separate dimensions: psychological distress and positive well being. The behavioral control dimension covers emotional stability and control of behavior or thoughts and feelings, including fear of losing one's mind. The Rand MHI is self-administered and its 38 items refer to the past month.

As FM has not been proven to be a strictly biomedical condition, the exploration of mental health status with a non-disease-specific instrument designed for the general population without specific disease has advantages. Many other mental health questionnaires have strong physical orientation, aggregating physical symptoms, physical functioning, general health perceptions, health habits, and symptoms of psychological distress into one instrument (Smythe 1984). They thus may not be able to distinguish changes in mental health from changes in physical health. In the present study, pain, physical functioning and other symptoms were surveyed by separate questionnaires; therefore, the use of an instrument that measures mental health as a separate entity and that focuses not only on psychological distress, but also on positive affect is appropriate for research of the FM population.

The Rand MHI has been validated for reliability and validity by Veit and Ware (1983). The test-retest reliability for the overall score, depression scale, and anxiety scale are .64, .56 and .53 respectively. Internal consistency ranged from .83 to .92 for the 5 scales and .96 for the overall score. (Veit & Ware 1983)

Though it may yield multiple subscores, this study utilized only its summary score, the *mental health index*, a composite score of psychological distress and positive well being, for data analysis.

6. Medical Outcomes Study (MOS) Social Support Survey (SSS) - The SSS (Sherbourne & Steward 1991) is a self-administered, social support survey designed to measure the perceived availability of functional social support, that is, the degree to which interpersonal relationship serve particular functions. The first part of the survey is a single-item measure of structural support, in terms of number of close friends and relatives. It was not included in data analysis of this study. The present study used the 19 items on the second and main part of the SSS instrument to provide a measure for the variable, *social support index*. This part of the SSS covers five dimensions of functional social support: emotional support, informational support, tangible support, positive social interaction, and affection. The scale asks about how often each form of support is available to respondents by the use of a 5-point answer scales. This instrument had been formally validated. Internal consistency for the overall scale was high ($\alpha = 0.97$) and values for the subscales ranged form $\alpha = 0.91$ to 0.96. Item-scale correlations all exceeded 0.72. One-year test-retest reliability was also high at 0.78 (.72 to 0.76 for each subscale). Factor analyses confirmed that the 19 items could reasonably be fit into an overall index, and also that the four subscales were internally consistent and distinct from each other. The MOS Social Support Survey was carefully developed from previous instruments and was based on a sound theoretical formulation. The higher the score, the greater the availability of functional social support.

The survey questions and coding used for each of the items collected to describe the study groups were provided in the previous section titled "Independent Variables".

Data Analyses

All analyses were conducted using the Statistical Package for the Social Sciences (SPSS), Version 8.0 for Windows. The level of statistical significance (α) for this study was established to be 0.05, except where indicated for multiple comparisons.

Objective One:

The relationship between each of the six biopsychosocial measures and tender point count (0-18) was examined by both univariate and multivariate analyses. Pearson correlation coefficients were used to describe the strength of associations between the dependent variable, *number of tender points (*range 0-18*),* and each of six measured independent variables: *number of painful body segments* (range 0-53), *total body pain intensity* (range 0-265), *functional disability* (range 0-3), *quality of life* (range 16-112), *mental health index* (range 38-226), *and social support index* (range 19-95). Scatterplots were used to examine the direction and to screen for linearity in each relationship and for bivariate normality.

It was noted during data screening that the distribution of the dependent variable, *number of tender points,* was negatively skewed, rendering its use in regression analyses to be inappropriate. Therefore, *FM intensity,* the average pain intensity of the 18 tender point sites, was used in regression analyses instead. Simple regressions were conducted to determine the relative proportion of *FM intensity* variance that could be explained by each independent variable. A forward-entry stepwise regression procedure was used to select a model that best predicted *FM intensity*, with an inclusion default significance level set at .05.

Objective Two

To examine the relationship between the six measured biopsychosocial variables and the ACR classification status, study subjects were dichotomized into two groups: the ACR-Positive group with 11 or more positive tender point sites, and the ACR-Negative group with fewer than 11 positive tender point sites.

A multivariate procedure, Hotelling's Trace, was computed to determine whether the ACR-Positive and ACR-Negative groups differed on any of the six measured variables when they were examined simultaneously. This was then followed by univariate t-tests to verify in which variable(s) the two groups differed. To control for multiple variable comparisons, Bonferroni correction was used to adjust the level of statistical significance to an alpha of .008.

To examine the relative probability of subjects' being classified ACR-Positive with each of the six measured variables, odds ratios (OR) for each variable was computed using simple logistic regression. Forward stepwise logistic regression was computed to determine the multivariable model that was most efficient in predicting ACR-Positive group membership. Various entry (p=.05, .10, and .20) and removal (p>.10, .15, and .25) probability levels were used in this analysis, with final results reported on the entry level of p=.05 and the removal level of p>.10.

Description of Study Subjects

Descriptive statistics were used to describe the subject's characteristics in terms of demographics, socioeconomic factors, medical history, perceived precipitating events, and Yunus' "Incomplete FM Syndrome Minor Criteria symptoms." Each variable was described for the entire sample and also separately for the ACR-Positive and ACR-Negative groups. Continuous variables were summarized by means and standard deviations, and differences between the ACR-Positive and ACR-Negative groups were determined by t-test analyses. Categorical variables were summarized by frequencies, percentages and range, and differences in proportions (prevalence of symptoms) between the ACR-Positive and ACR-Negative groups were determined by chi square analyses. To control for multiple variable comparisons, a Bonferroni correction with an adjusted alpha of .0023 was established.

Ethical Considerations

Prior to initiation of subject testing, the principal investigator obtained a signed informed consent from each participant. The "Consent to Participate" form fully informed the participants about the purpose, benefits, and potential risks to subjects, right to withdraw from the study at any point in time, measures to protect subject anonymity, appropriate data management to ensure confidentiality and subject privacy, data usage restriction, researcher's responsibilities and obligations towards participants, and the name and telephone number of an appropriate contact person regarding concerns or complaints. Confidentiality of subject's private information was closely guarded. Subjects' names did not appear on any questionnaires, data entry forms or any other documents relating to the present study. All documents were "ID coded", and are being stored in a locked cabinet in the Department of Physical Therapy, University of Alberta. Collected data was not and will not be released to any third parties or be used for secondary projects. Presentation of research will not identify individuals, but will be reported as an aggregated anonymous group. Prior to onset of data collection, the study was reviewed and accepted by the Joint University and Capital Health Authority Health Research Ethics Administration Board.

CHAPTER FIVE

RESULTS

Of the 133 potential subjects who were referred to the study by their attending rehabilitation practitioners, 111 attended the test session and completed all data collection elements. The 22 potential subjects who failed to attend the scheduled test session telephoned to explain their failed attendance. Eight were working and could not take time off work to attend the test session. Six stated that they were suffering severe exacerbation of symptoms and were not able to get out of the house. Three were leaving town for vacations outside Canada. One lived out of town and could not travel to Edmonton due to weather conditions at the time. Two had family crises. Two had forgotten the scheduled time for testing.

Of the 111 subjects tested for the study, all fulfilled the first ACR criterion of chronic widespread pain. 95 (86%) had 11 or more positive tender points, thus meeting the second ACR criterion and were classified as ACR-Positive for data analyses. The remainder were classified as ACR-Negative.

Data Screening and Test of Assumptions. Data screening procedures revealed that data for all measured variables approximated normal distributions, except for the dependent variable, *number of tender points.* Examination for linearity of relationships and tests of assumptions for multiple regression, multivariable and univariate t-tests, and logistic regressions were computed. Results provided evidence that the collected data were suitable and assumptions were met for the intended analyses.

Description of Major Study Variables. Descriptive statistics of the eight major study variables—*number of tender points, FM intensity, number of painful body segments, total body pain intensity, functional disability, quality of life, mental health index,* and *social support index*—are presented in Table 1. The distribution of the variable, *number of tender points,* was negatively skewed. The mean *number of tender points* for the study sample was 15.5 ± 3.88; whereas that for the ACR-

Positive group was 16.88±1.66, median and mode were both 18; and that for the ACR-Negative group was 7.31±3.09, both median and mode were 9.

Table 1: Descriptive statistics of study variables for all medically diagnosed FM-subjects, ACR-Positive and ACR-Negative groups

Variables		Mean ± SD (Range)	
	ALL (N=111)	ACR+ve (n_1=95)	ACR-ve (n_2=16)
Number of Tender Points (MTPS: 0-18 counts)	15.5±3.88 (0-18)	16.88±1.66 (11-18)	7.31±3.09 (0-10)
FM Intensity (MTPS: 0-10 scale)	5.87±2.17 (.31-10.00)	6.46±1.66 (2.89-10.00)	2.34±1.30 (.31-5.50)
Number of Painful Body Segments (BPPA: 0-53 counts)	41.17±11.47 (9-53)	43.49±9.43 (19-53)	27.38±13.04 (9-50)
Total Body Pain Intensity (BPPA: 0-265 scale)	126.73±51.66 (13-253)	134.78±48.39 (37-253)	78.94±45.26 (13-161)
Functional Disability (FIQ-P. IM.: 0-3 scale)	1.35 ± .71 (0-2.70)	1.43±.69 (0-2.70)	.89 ± .67 (0-2.10)
Quality of Life (QOLS: 16-112 scale)	69.95±13.36 (38-98)	69.31±13.75 (38-98)	73.75±10.35 (51-96)
Mental Health Index (Rand MHI: 38-226 scale)	138.01±32.04 (68-199)	135.66±31.76 (68-199)	151.94±31.07 (101-198)
Social Support Index (MOS-SSI: 19-95 scale)	69.05±15.10 (32-95)	68.38±15.37 (32-95)	73.06±13.14 (44-92)

Relationship of Six Biopsychosocial Variables with Tender Point Count. Only 3 of the 6 measured biopsychosocial variables showed a statistically significant ($p<.001$) relationship with *number of tender points* (Table 2). The strongest correlation was with *number of painful body segments* ($r=.542$), followed by *total body pain intensity* ($r=.458$) and *functional disability* ($r=.350$). The direction of these three pairs of relationships supports the hypothesis that the higher the *number of tender points*, the more negative the score of each measured variable. No significant associations between *number of tender points* and *quality of life*, *mental health index*, and *social support index* were found. It should be noted from scatterplots in Figure 1 that all six biopsychosocial variables show a large variability in scores at the higher end of the tender point continuum, especially for counts of 15-18 tender points. Although these graphs show a general trend of an increasing severity of variable scores with an increasing number of tender points, this trend is notable mainly with counts at the lower half of the tender point continuum. These data do not show a clustering of severity associated with high counts of tender points.

Table 2: Correlations of biopsychosocial variables with number of tender points (n=111)

Variable	Pearson r	*p*-value
Number of Painful Body Segments	.542	<.001
Total Body Pain Intensity	.458	<.001
Functional Disability	.350	<.001
Quality of Life	-.115	.228
Mental Health Index	-.176	.064
Social Support Index	-.080	.407

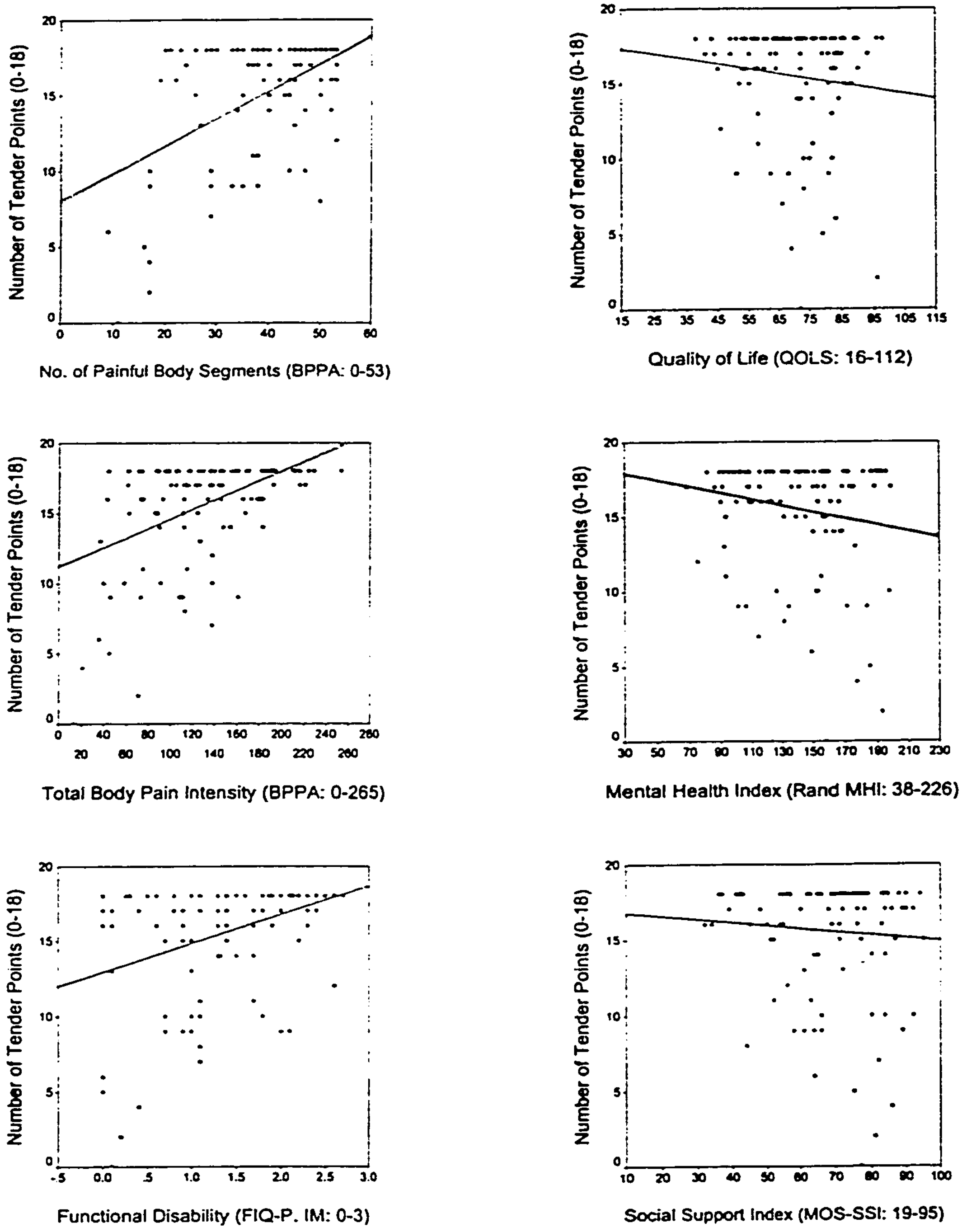

Figure 1: Relationships between tender point count and each biopsychosocial variable (n=111)

As noted earlier, the distribution of *number of tender points* was negatively skewed, but that of *FM intensity* was approximately normal. As *FM intensity* is drawn from the tender point examination and is calculated as the average pain intensity of the 18 tender point sites, *FM intensity* was selected for use in subsequent regression analyses. Simple regression analyses indicated that a large proportion of the variance of the *FM intensity* variable was explained by *total body pain intensity* (41%), *number of painful body segments* (29%) and *functional disability* (24%). *Quality of life* and *mental health index* explained a relatively minor amount of the variance of *FM intensity*. Only *total body pain intensity* and *functional disability* contributed to a multivariable model explaining a total of 43% of the variance of FM intensity. Once *total body pain intensity* had entered the forward stepwise regression model, *functional disability* explained a mere additional 2.8% of the variance of *FM intensity* (Table 3).

Table 3: Association of 6 biopsychsocial variables with FM Intensity: Results of regression analyses (n=111)

UNIVARIATE			MULTIVARIATE			
Simple Regression			Forward Stepwise Regression			
Variables	R^2	*p*-value	Model	Variable(s) Entered Into Model	R^2	*p*-value
Number of Painful Body Segments	.294	<.001	1	Total Body Pain Intensity	.406	<.001
Total Body Pain Intensity	.406	<.001				
Functional Disability	.238	<.001	2	Total Body Pain Intensity and Functional Disability	.434	<.001
Quality of Life	.057	.012				
Mental Health Index	.073	.004				
Social Support Index	.011	.264				

Relationship of Six Biopsychosocial Variables with ACR-Positive Classification. Hotelling's Trace and subsequent univariate t-test analyses demonstrated statistically significant differences between the ACR-Positive and ACR-Negative groups in 3 of the 6 measured variables: *number of painful body segments, total body pain intensity,* and *functional disability.* (Table 4)

Table 4: Comparison of ACR-Positive (n_1=95) and ACR-Negative (n_2=16) groups on 6 biopsychosocial variables. Multivariate analysis and univariate T-Tests

MULTIVARIATE		UNIVARIATE		
Hotelling's Trace	*p*-value	Variables	t	*p*-value
.357	<.001	Number of Painful Body Segments	-5.963	<.001
		Total Body Pain Intensity	-4.519	<.001
		Functional Disability	-2.981	.007
		Quality of Life	1.508	.144
		Mental Health Index	1.932	.067
		Social Support Index	1.285	.212

Logistic regression analyses revealed that only three variables were independently, significantly associated with ACR status. They were *number of painful body segments, total body pain intensity,* and *functional disability,* and the odds of being ACR-Positive were 1.82, 1.32, and 3.09 times greater for every five, ten, and one unit increase in these variables, respectively. Forward stepwise logistic regressions were used in multivariable analyses considering the six biopsychosocial variables and—*number of painful body segments* alone was consistently selected as the only variable to enter into the model for the prediction of ACR group membership ($p<.001$). This variable showed a statistically significant odds ratio of 1.82 ($p<.001$), indicating that the odds of being classified as "ACR-Positive" were

1.82 times greater with each 5-unit increase in *number of painful body segments*. (Table 5)

Table 5: Association of 6 biopsychosocial variables with ACR status. Results of logistic regressions (n=111)

Simple Logistic Regression			
	Risk of Being ACR+ve		
VARIABLES	Odds Ratio	95% Confidence Interval	*p*-value
Number of Painful Body Segments			
(BPPA: Pain Site Counts=0-53)			
-For every 1-unit increase	1.13	1.07, 1.19	<.001
-For every 5-units increase	1.82	1.39, 2.40	<.001
Total Body Pain Intensity			
(BPPA: Summary Score=0-265)			
-For every 1-unit increase	1.03	1.01, 1.04	<.001
-For every 10-units increase	1.32	1.13, 1.53	<.001
Functional Disability			
(FIQ-Physical Impairment Score=0-3)			
-For every 1-unit increase	3.09	1.36, 7.00	.007
Quality of Life			
(QOLS: Summary Score=16-112)			
-For every 1-unit increase	.97	.93, 1.02	.220
Mental Health Index			
(Rand MHI: Summary Score=38-226)			
-For every 1-unit increase	.98	.97, 1.00	.065
Social Support Index			
(MOS-SSI: Summary Score=19-95)			
-For every 1-unit increase	.98	.94, 1.02	.253

Note: In multivariable analysis considering the 6 biopsychosocial variables, forward stepwise logistic regressions were used. Number of painful body segments was consistently selected as the only variable to enter into the model to predict the ACR-Positive status (p<.001).

Subject Characteristics. Descriptive statistics of demographic, socioeconomic, medical history, perceived precipitating events and Yunus' "Incomplete FM Syndrome minor criteria" symptoms are available for the entire sample, and also separately for the ACR-Positive and ACR-Negative groups in Tables 6-9. With the exception of the prevalence of one of Yunus' Incomplete FM Syndrome symptom, *tension headache* (71% versus 19%, $p<.001$), there were no significant differences between the ACR-Positive and ACR-Negative groups on the descriptive variables.

Table 6: Descriptive statistics for demographic and socioeconomic variables for all subjects diagnosed with fibromyalgia, ACR-Positive and ACR-Negative groups. Means, SD, and ranges for continuous variables, and frequencies and percentages ( ) for categorical variables are provided.

VARIABLE	Subjects Dx with FM (n=111)	ACR+ve (n_1=95)	ACR-ve (n_2=16)
Age (years)			
-Mean	47.77	47.39	50.06
-SD	11.03	11.50	7.56
-Range	18-74	18-74	36-64
Marital Status			
-Living with Partner (%)	76 (69%)	65(68%)	11(69%)
Level of Education			
-High School (%)	47(42%)	37(39%)	10(62%)
-Vocational Certificate (%)	45(41%)	41(43%)	4(25%)
-University (%)	19(17%)	17(18%)	2(13%)
Employment Status at Onset			
-Employed (%)	89(80%)	78(82%)	11(69%)
Employment Status-Current			
-Employed (%)	44(42%)	38(42%)	6(43%)
Disability Benefits for FM			
-Receiving/Received Benefits (%)	49(44%)	45(47%)	4(25%)

Nore: All statistical comparisons of ACR-Positive and ACR-Negative groups yielded *p*-values > 0.05.

Table 7: Descriptive statistics for disease history and health service utilization variables for all subjects diagnosed with fibromyalgia, ACR-Positive and ACR-Negative groups. Means, SD and ranges for continuous variables, and frequencies and percentages ( ) for categorical variables are provided.

VARIABLES	Subjects Dx with FM (n=111)	ACR+ve (n_1=95)	ACR-ve (n_2=16)
Duration of Symptoms (years)			
-Mean	10.28	10.18	10.88
-SD	8.59	8.64	8.57
-Range	.2-51	.2-51	1-30
Duration of Diagnosis (years)			
-Mean	4.98	5.08	4.38
-SD	4.31	4.17	5.18
-Range	.1-20	.1-20	1-20
Diagnosing Physician			
-Rheumatologist/Specialist (%)	79(71%)	70(74%)	9(56%)
Attending Physician			
-Rheumatologist/Specialist (%)	40(37%)	35(38%)	5(33%)
Medication for FM			
-Yes (%)	85(77%)	75(79%)	10(63%)
Number of Visits to Physicians In Past 12 Months			
-Mean	11.15	11.27	10.44
-SD	14.53	15.13	10.67
-Range	1-100	1-100	0-30
Number of Visits to Other Health Professionals In Past 12 Months			
-Mean	21.23	22.73*	12.38*
-SD	31.74	33.74	12.44
-Range	1-208	1-208	1-45

* $p < 0.05 > 0.01$, result of t-test comparison of ACR-Positive and ACR-Negative groups.

Note: Statistical comparisons for all other variables yielded p-value >0.05.

Table 8: Descriptive statistics for frequencies and types of perceived precipitating events by all subjects diagnosed with fibromyalgia, ACR-Positive and ACR-Negative groups. Frequencies and percentages ( ) are provided.

VARIABLES	Subjects Dx with FM (n=111)	ACR+ve (n_1=95)	ACR-ve (n_2=16)
History of Perceived Precipitating Event			
-Yes (%)	78(70%)	69(73%)	9(56%)
-No (%)	32(29%)	25(26%)	7(44%)
-Uncertain (%)	1(.9%)	1(1%)	-
Type of Precipitating Event			
-MVA (%)	19(23%)		
-Work Injury (%)	11(13%)		
-Home & Recreational Injury (%)	5(6%)		
-Work-related & Personal Stress (%)	10(12%)		
-Abuse (%)	17(21%)		
-Flu (%)	5(6%)		
-Post-surgical (%)	8(10%)		
-Multiple (2 or more of above) (%)	8(10%)		

Note: Statistical comparison of ACR-Positive and ACR-Negative groups yielded *p*-value > 0.05.

Table 9: Descriptive statistics for Yunus' IFMS minor criteria symptoms for all subjects diagnosed with fibromyalgia, ACR-Positive and ACR-Negative groups. Frequencies and percentages ( ) are provided.

VARIABLES	Subjects Dx with FM (n=111)	ACR+ve (n_1=95)	ACR-ve (n_2=16)
Irritable Bowel Syndrome			
-Present (%)	75(68%)	65(68%)	10(63%)
Tension Headache			
-Present (%)	70(63%)	67(71%)***	3(19%)***
Fatigue			
-Present (%)	106(96%)	92(97%)	14(88%)
Sleep Disturbance			
-Present (%)	97(87%)	85(90%)	12(75%)
Morning Fatigue			
-Present (%)	109(98%)	94(99%)	15(94%)
Swollen Feeling			
-Present (%)	95(86%)	80(84%)	15(94%)
Paresthesia			
-Present (%)	68(61%)	61(64%)	7(44%)

*** $p<0.001$, result of chi square comparison of ACR-Positive and ACR-Negative groups.

Note: Statisitcal comparisons for all other variables yielded p-value >0.05.

No evidence for selection bias. The possibility that potential subjects not contacted or who were contacted but refused to participate in this study may be different than those who participated was considered. In order to assess possible selection bias, this study conducted a survey of four Edmonton rehabilitation service providers for a clinic profile of their FM patient caseloads for the duration of this study. They were asked to complete a brief questionnaire requesting information on the following items: age, duration of FM diagnosis, duration of FM symptoms, attending physician, and receipt of disability benefits. Similar items were also surveyed on the telephone from the 22 volunteers who had booked for the test sessions, but who for the various reasons listed earlier failed to attend the scheduled test sessions. The four service providers surveyed were representative of the various forms of rehabilitation services available to FM patients in Edmonton: the University of Alberta Hospital's rheumatology unit FM program, which only accepts referrals from rheumatologists, the group education and exercise program offered by the Community Rehabilitation Program at the Good Samaritan Auxiliary Hospital, and two private physical therapy clinics in the community, the last three providers accepting referrals of FM patients from a wide range of health professionals and on a patient self-referral basis. The dispersed geographic locations of these service providers also ensured that the FM patients included in this survey were from all zones of the Greater Edmonton region. In total, data from 109 such potential subjects were available. Analyses of these data revealed no evidence of any selection bias on study results (Table 10). There was no significant difference between study participants and potential subjects on surveyed items.

Table 10: Descriptive statistics for age, duration of diagnosis, duration of symptoms, diagnosing physician and disability claims status for study participants and potential subjects. Means, SD and ranges for continuous variables, and frequencies and percentages ( ) for categorical variables are provided.

VARIABLE	Study Participants (n=111)	Potential Subjects (n=109)
Age (years)		
-Mean	47.77	48.50
-SD	11.03	11.93
-Range	18-74	18-71
Duration of Diagnosis (years)		
-Mean	4.98	4.27
-SD	4.31	2.56
-Range	.1-20	.5-10
Duration of Symptoms (years)		
-Mean	10.28	9.86
-SD	8.59	5.03
-Range	.2-51	1-25
Diagnosing Physician		
-Rheumatologist/Specialist (%)	79(71%)	76(69.7%)
Disability Benefits for FM		
-Receiving/Received Benefits (%)	49(44%)	62(57%)

Note: All statistical comparisons of ACR-Positive and ACR-Negative groups yielded *p*-value > 0.05.

Summary

In summary, only 86% of study sample had 11 or more positive tender points. Tender point count was found to significantly correlate with only three measured variables: *number of painful body segments* (*r*=.542), *total body pain intensity* (*r*=.458) and *functional disability* (*r*=.350). In a multivariable model, *total body pain intensity* alone explained 41% of the variance of FM intensity. The addition of *functional disability* to the model provided only a further 2.8% into this explanatory power.

Multivariable analysis showed a statistically significant difference between the ACR-Positive and ACR-Negative groups in *number of painful body segments, total body pain intensity* and *functional disability.* Only these three variables contributed significantly to explaining ACR status, with the odds of being ACR-Positive 1.8, 1.3 and 3.1 times greater for every five, ten and one-unit increase in these variables, respectively. *Number of painful body segments* alone was the only variable to enter into the logistic regression model for the prediction of ACR-Positive group membership.

Large individual variations existed in the scores of all six biopsychosocial variables at the upper levels of tender point count, particularly at the high end (15-18 positive tender points) of the tender point continuum.

CHAPTER SIX

DISCUSSION

Results of this study suggest that 1) not all medically diagnosed FM patients fulfill the 1990 ACR tender point criterion, 2) among patients diagnosed with FM, those who fail to meet the ACR criteria are not clearly different from those who meet criteria in the measured study variables, 3) *number of painful body segments* is the best correlate with tender point count and the strongest predictor of the ACR classification for FM, and 4) there are large individual variations in the measured biopsychosocial factors.

The present study confirmed speculations by others that not all medically diagnosed FM patients meet the ACR criteria (Yunus et al 1998). In this study, although the entire sample of subjects had chronic widespread pain according to the ACR definition, only 86% had 11 or more tender points and was classified as ACR-Positive. Other investigators have noted similar findings. In his study investigating the relation between tender point count and a Rheumatology Distress Index, Wolfe (1997) found among his FM group of 267 subjects that 89.9% had 11 or more tender points. In a study to develop the Manual Tender Point Survey protocol, Okifuji et al (1997) found that 89% of their FM study group of 70 subjects met the ACR tender point criterion.

Coincidentally, the 14% of subjects who failed to meet the ACR tender point criterion in the present study were shown to be insignificantly different from the 86% who met the same criterion in quality of life, mental health, social support, and descriptive variables including demographics, socioeconomic circumstances, medical history and frequencies of precipitating events. The only three study variables that were shown to correlate with tender point count and to differ between the ACR-Positive and ACR-Negative groups were *number of painful body segments*, *total body pain intensity* and *functional disability*. As the two pain variables—*number of painful body segments* and *total body pain intensity*—appear to measure similar constructs as the ACR criteria, they provide similar information to that implied by the ACR criteria. *Number of painful body segments* is a numerical count of body regions, which are perceived to be painful or problematic by the subject, and *total body pain intensity* is the sum of the pain intensity ratings for the painful body regions. Therefore, these two variables may simply serve to validate the ACR criterion of widespread pain by defining the number and locations of painful sites as well as providing a measure of pain intensity at each site. Accordingly then, finding significant differences in these two variables corresponding to the ACR-Positive and ACR-Negative groups is expected. The only other variable shown to differentiate between the ACR-Positive and ACR-Negative subjects was *functional disability*. However, its correlation with *number of tender points* was weak and once *number of painful body segments* entered a stepwise logistic regression model, *functional disability* did not add significantly to the prediction of ACR status. The overall findings of this study indicated that subjects fulfilling the ACR criteria were not clearly different from those who failed to fulfill the criteria. These results are congruent to those noted by Yunus et al (1998), whose research bears the closest resemblance to the present study in both objectives and design, and yielded similar results. In an attempt to define the group of patients with many FM-like features but not meeting the ACR criteria, Yunus et al (1998) compared 35 patients with "Incomplete Fibromyalgia Syndrome" (patients meeting only one of the two ACR criteria) and 536 with FM who met both ACR criteria. As expected, they found the number of tender points to be fewer in IFMS than in FM patients (10.9±4.5 versus 15.4±2.4, $p<.001$). However, they found that the 35 IFMS patients had 2 or more of 7 symptoms: fatigue, sleep difficulty, morning fatigue, swollen feeling, irritable bowel syndrome, tension type headache and paresthesia, and differed from the FM group only on one symptom: swollen feeling ($p<.001$). There were no significant differences in global anxiety (66% versus 67%), depression (26% versus 40%), anxiety score (40±12 versus 42±11) and Zung depression score (40±9 versus 43±9). Yunus et al's concept of IFMS appears to be similar to that of the ACR-Negative group of the present study. In the present study, all 16 subjects who failed to meet the ACR criteria met Yunus' criteria for IFMS. As is the case with the present study, Yunus et al reported that some patients are diagnosed with FM but do not meet the ACR criteria and that the clinical and psychological features of IFMS are similar to those of FM.

There is further evidence to suggest that FM may not be a discrete condition. Wolfe et al (1995a) and others (Croft et al 1993, Forseth and Gran 1993) have made observations that chronic widespread pain, multiple tenderness, and many FM-like symptoms are common in the general population and in other rheumatologic conditions (Wolfe 1997). In addition, Wolfe et al (1995a), Yunus et al (1998) and the present study all found similarities in many demographic, psychological and symptom characteristics between different groups of patients receiving the diagnosis FM.

In the present study, *number of painful body segments* was most highly correlated with tender point count (r=.542) and proved to be the strongest predictor of risk of being diagnosed with FM by the ACR criteria (OR=1.82, 95% CI: 1.39, 2.40 for each 5-unit increase on a BPPA pain site count of 0 to53). A similar finding was observed by Croft et al (1996) in a study examining the relationship between pain and tender points in 177 subjects with varying degrees of topographical pain who were randomly selected from the patient list of two general practices. They found moderately strong associations between the reported presence of pain in a body segment and the presence of an ACR tender point within that segment (OR range 1.3 – 3.1), along with evidence of a trend of higher number of tender points with higher number of painful segments. Our findings of the importance of *number of painful body segments* appear to support findings by Croft et al (1996) and Wolfe et al (1995b) that the statement "I ache all over" is the most discriminatory feature for the identification of high number of tender points in the general populations.

The present study also revealed considerable within group variations in the scores of all measured biopsychosocial variables. Although there was a general trend for an increasing severity of the biopsychosocial variable scores with an increasing number of tender points, this trend is notable mainly with counts in the lower half of the tender point continuum. All measured biopsychosocial variables demonstrate a large variability in scores at the higher end of the tender point continuum, especially at counts of 15 – 18. Furthermore, there was no clustering of severity associated with high counts of tender points.

Clinical Relevance

With the exception of incidence of tension headache, there were no significant differences in the measured characteristics of medically diagnosed FM patients, whether they meet the ACR criteria or not. Thus, the 1990 ACR classification criteria for FM do not appear to identify a discrete condition. Clinically, this implies that the use of the 1990 ACR criteria, which rely on tender point count, may not be adequate for clinical diagnosis and treatment planning. As stated by Wolfe (1997), "in a broader sense, there is no discrete point where FM does or does not exist."

As number of painful body segments proved to be the strongest predictor of the ACR-Positive status, perhaps a simple self-reported statement "I ache all over" as reported by Wolfe et al (1995b) and Croft et al (1996) is as adequate for the diagnosis of the FM syndrome. Alternately, a simple pain questionnaire, such as the Body Parts Problem Assessment scale that was used by this study may be similarly useful in identifying patients with the FM syndrome. The significant variations in scores of the six biopsychosocial variables among subjects diagnosed with FM suggest a need to identify the unique clinical and history characteristics of each FM patient in order to maximize treatment efficacy.

Generalizability of Subject Sample

Characteristics of the present study sample are comparable to FM samples of other reported studies. Sample statistics and many subject characteristics of the present study are similar to previous observations made by other investigators. As discussed earlier, the observed proportion of 86% ACR-Positive subjects almost equals those noted by Wolfe (1997) and Okifuji et al (1997) at 89.9% and 89% respectively. The observed 15.5 ± 3.88 mean *number of tender points* and the 5.87

± 2.17 mean *FM intensity* score are close to means of the same variables (15.31 ± 3.51 and 5.33 ± 1.98 respectively) obtained by the same Manual Tender Point Survey protocol in Okifuji et al's study. The mean age of 47.8 years for subjects of the present study is identical to the mean of 48 years found in Jacobs et al's (1996) 113 FM subjects. The shape of the distribution, rising in middle age and dropping off in the oldest age groups, had previously been described by Croft et al (1993). The observed mean of 10.3 years in duration of FM symptoms is similar to the reported median disease duration of 10 years by Jacobs et al (1996).

Furthermore, study participants were similar to the general FM patient population from which subjects were drawn with respect to age, duration of FM diagnosis, duration of FM symptoms, attending physician and disability claims status (Table 9). Therefore, it would appear that results of the present study could be extrapolated to the general population of medically diagnosed FM patients receiving some form of rehabilitation services.

Study Limitations

One of the study limitations is that subjects were tested at only one point in time. The natural course and remission status of the FM syndrome are unknown and recruited participants are at various stages of their rehabilitation program, which may influence symptoms and tenderness. At best, the tender point count can only be considered as the participants' pain threshold at the point of testing. Secondly, the selection of FM patients from those receiving rehabilitation services may imply a study sample that suffers a more severe condition of the FM syndrome or a group of people with better access to medical or rehabilitation care. However, as health care professionals are most concerned with issues pertaining to the group who seek care for their FM symptoms, perhaps investigating this specific group of FM patients is of interest. Thirdly, the use of a self-report questionnaire in this study was both a strength and limitation. On the one hand, it provided a database free from observer bias, while on the other hand; it may be associated with an element of subject bias, especially in the measures of psychosocial and functional ability variables.

However, such bias, if present, could be expected to be similar for both study groups—those who did or did not meet the ACR criteria—and thus would not be expected to affect comparisons. Hidding et al (1994) found that discordance between self-report questionnaires and observed functional disability was a striking feature in FM. However, they concluded that there is a need to use self-report questionnaires to assess functional disability, especially in FM patients, as the discordance between subjective and objective reports may be an important component of the disease.

A sample size of 16 for the ACR-Negative group of this study may appear to be small. However, there is no well-documented method for the calculation of sample size for multivariate procedures. Consideration of two issues revealed that the ACR-Negative sample of 16 subjects may not be a major limitation to study results. First, according to Glass and Hopkins (1996), when the nominal α_2 is set at .05 or .01—that is, when the critical t-values based on degrees of freedom and a two tailed alpha are used for t-test analyses—the proportion of type I errors decreases when a sample size reaches 15. Therefore, our sample size of 16 for the ACR-Negative group is just above the number "15" where practical difference between the nominal and actual alphas is believed to be nil. Secondly, as already mentioned earlier, our proportional sample size is comparable to that noted by several other researchers.

Critics may also raise concerns about the reliability of the tender point examination of this study. However, tender point examination, for all its strengths and weaknesses, is the key to classifying a subject with or without FM according to the 1990 ACR criteria. While its subjectivity has been questioned (Smythe et al 1992a, 1992b, 1993, Smythe 1998), its reliabilities have also been documented to be satisfactory. Test-retest stability coefficients were above .70 for three observers and inter-rater agreement coefficient was .71 (Jacobs et al 1995). Intra-rater reliability over 26 of 27 paired points was reported by Tunks et al (1995). Wolfe et al (1992) and Cott et al (1992) noted that trained examiners could quantify tender points and identify patients with and without FM with very high levels of agreements. For this study, efforts were made to ensure the highest level of consistency of the tender point examination. Accordingly, the standardized tender point examination technique, the Manual Tender Point Survey (Okifuji et al 1997), which was developed and validated specifically for the assessment of the ACR tender point criterion was used by one examiner throughout data collection to minimize measurement error. Furthermore, intra-rater reliability was maximized by regular calibration of the examiner's pressure application technique during the course of this study.

Future Directions

Study results raised questions about the validity of using the number "11" as a cut-off point for the tender point criterion. Therefore, for researchers who advocate the use of a tender point criterion for the classification of FM, perhaps investigations of the discriminatory effect of the ACR classification status at various cut-off points for the tender point criterion should be considered. The ACR criteria study did not explore the possible use of alternative cut-off numbers of tender points. In the ACR criteria study, the combination of "a minimum of 11 out of 18 tender points" and widespread pain was tested against other symptoms and symptom sets for sensitivity, specificity and accuracy as criteria items, but not against various cut off points of tender point counts.

In addition, as study results indicate individual variations among patients diagnosed with FM, future studies designed to subgroup the FM population according to individual biopsychosocial variations and degree of disease severity may help to determine the heterogeneous needs of FM individuals in respect to medical and rehabilitation management. Subgrouping the FM population according to newly established biopsychosocial definitions in future research would increase comparability of epidemiologic studies. Furthermore, it is apparent that the assessment of a FM patient needs to be multidimensional, involving a spectrum of biopsychosocial variables. However, there is currently no validated assessment procedure for the FM patient in research or clinical practice. Research to develop a multidimensional assessment protocol for FM patients is needed. One potentially important factor, stressful life events, was not examined by the present study. Previous studies have reported an association of the development and exacerbation of FM with the occurrence of major life stresses (Aaron et al 1997, Uveges et al 1990). As high levels of life stress may affect somatic and psychological responses (Dohrenwend and Dohrenwend 1974), future research is needed to investigate the relationship of stress to the symptomatology of FM within the context of a biopsychosocial model.

Descriptive data of the present study raises several issues for future research. For example, 80% of the study sample were employed at the onset of their FM symptoms, but only 42% remained employed at the time of the survey. Furthermore, at the point of testing, 44% were receiving some form of disability claims due to their FM symptoms. These data indicated that almost half of the subjects left their employment after the onset of FM symptoms and went on to some form of disability benefits. Research is needed to investigate the impact of disability benefits on return to work rate in the population. In the present study, 70% of all surveyed subjects reported the presence of a previous event, which they perceived to be the precipitating factor to the onset of their FM symptoms. Studies designed to determine the relationship between type of perceived precipitating events and FM-related symptoms may provide insight into possible etiological factors.

CHAPTER SEVEN

CONCLUSION

In conclusion, results of this study indicate that not all medically diagnosed FM patients meet the 1990 ACR criteria and that the diagnosis of FM using the 1990 ACR criteria appears to merely define a condition of multiple painful body segments and severe overall pain—information implied by the ACR criterion "widespread pain". As study results revealed no clear overall differences between subjects who met the ACR criteria and those who did not meet the criteria, FM as classified by the ACR criteria cannot be considered a discrete disease entity. Clinically, this suggests that the 1990 ACR criteria are not adequate for clinical diagnosis or for treatment planning. Furthermore, self-reported number of painful body segments alone appears to be a sufficient diagnostic feature for the FM syndrome as it was highly associated with ACR status.

The observed heterogeneity among individuals diagnosed with FM implies that there is no single management strategy that is likely to be effective for all patients diagnosed with FM. Instead, management plans for the FM syndrome must be guided by individual differences rather than being mapped according to the 1990 ACR classification groups.

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APPENDIX A

The American College of Rheumatology (ACR) 1990 Criteria for the Classification of Fibromyalgia

(Wolfe et al 1990)

I. HISTORY OF WIDESPREAD PAIN

Definition. Pain is considered widespread when all of the following are present: pain in the left side of the body, pain in the right side of the body, pain above the waist, and pain below the waist. In addition, axial skeletal pain (cervical spine or anterior chest or thoracic spine or low back) must be present. In this definition, shoulder and buttock pain is considered as pain for each involved side. "Low back" pain is considered lower segment pain.

II. PAIN IN 11 OF 18 TENDER POINT SITES ON DIGITAL PALPATION

Definition. Pain, on digital palpation, must be present in at least 11 of the following 18 tender point sites.

Occiput:	Bilateral, at the suboccipital muscle insertions.
Low Cervical:	Bilateral, at the anterior aspects of the intertransverse spaces at C5-7.
Trapezius:	Bilateral, at the midpoint of the upper border.
Second Rib:	Bilateral, at the second costochondral junctions, just lateral to the junctions on upper surfaces.
Lateral Epicondyle:	Bilateral, 2 cm distal to the epidondyles.
Gluteal:	Bilateral, in upper outer quadrants of buttocks in anterior fold of muscles.
Greater Trochanter:	Bilateral, posterior to the trochanteric prominence.
Knees:	Bilateral, at the medial fat pad proximal to the joint line.

Digital palpation should be performed with an approximate force of 4 kg.
For a tender point to be considered "positive", the subject must state that the palpation was painful. "Tender" is not to be considered "painful".

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*According to Wolfe et al (1990), a patient is diagnosed with "Fibromyalgia" only if both criteria are satisfied. Widespread pain must have been present for at least 3 months. The presence of a second disorder does not exclude the diagnosis of fibromyalgia.

*Wofle et al (1990) found that the ACR criteria work equally well in both primary and secondary fibromyalgia.

APPENDIX B

The Yunus Criteria for Classification of Fibromyalgia
(Yunus et al 1981, 1989)

I. ALL MAJOR CRITERIA:

1. Generalized Aches/Pains/Permanent Stiffness in 3 or more anatomic sites
2. Absence of Secondary Causes
3. At least 5 out of 50 Specified Tender Points

II. 3 OUT OF 10 MINOR CRITERIA – MODULATION OF SYMPTOMS:

1. Physical Activity
2. Weather Factors
3. Aggravation of Symptoms by Anxiety or Stress
4. Poor Sleep
5. General Fatigue or Tiredness
6. Anxiety
7. Chronic Headache
8. Irritable Bowel
9. Subjective Swelling
10. Numbness

**Downplay pain location and tender point count.
**Emphasize other symptoms commonly known to be associated with FM.

APPENDIX C

“Letters of Support” from Rehabilitation Service Providers

The CAPITAL CARE *Group*

GRANDVIEW
6215 - 124 Street
Edmonton, Alberta T6H 3V1
Telephone: [403] 496-7100
Facsimile: [403] 496-7150
[Effective Jan. 1, 1999 area code will be 780]

December 7, 1998

Grace Moe
Department of Physical Therapy
Faculty of Rehabilitation Medicine
2050 Corbett Hall
Edmonton, AB
T6G 2G4

Dear Grace:

The outpatient physical therapy at Capital Care Grandview does treat some fibromyalgia clients. We will participate in this study and will provide appropriate clients with the study information.
Good luck in your research Grace.

Yours truly,

Berniece

Berniece Malone

BM/dr
cc: Iris Neumann,
Admininstrator
Capital Care Grandview

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OPERATING CAPITAL CARE DICKINSFIELD • GRANDVIEW • LYNNWOOD • NORWOOD • MCCONNELL PLACE NORTH AND WEST • MEWBURN
STRATHCONA CARE CENTRE • LAURIER HOUSE, AND FAMILY CARE HOMES • COMMUNITY REHABILITATION • C.H.O.I.C.E • YOUNG ADULT
The CAPITAL CARE *Group* is the trade name for CAPITAL CARE GROUP INC

THE GOOD SAMARITAN SOCIETY
A Lutheran Social Service Organization

Good Samaritan Auxiliary Hospital
9649 - 71 Avenue
Edmonton, Alberta T6E 5J2
Tel. (403) 431-3600 Fax. (403) 431-3699

November 25, 1998

Ms. Grace Moe
Master's of Science Candidate
Department of Physical Therapy
University of Alberta
2-50 Corbett Hall
Edmonton AB T6G 2G4

Dear Grace:

In response to your letter of October 30, 1998, please be advised that we do see a small number of clients with the diagnosis of fibromyalgia at the CRP physiotherapy clinic within the Good Samaritan Auxiliary Hospital. We would be interested in supporting your study by providing a copy of the "Study Information to Potential Volunteers," to any clients who fit your Subject Inclusion Criteria.

I hope that by participating we are able to assist you to achieve the large population sample that you require.

Warm personal regards.

Sincerely,

Sonja Taylor, B.P.T.

cc: Queenie Choo
Director of Resident Care
Good Samaritan Auxiliary Hospital

Voluntary Providers of Continuing Health Care and Community Integrated Support Services

Parkland
Rehabilitation
Associates

Grove Plaza
Orthopaedic and Sports Physiotherapy Ltd.
P.O. BOX 5089, BAY 20, 100 KING STREET, SPRUCE GROVE, ALBERTA T7X1AO
PHONE (403) 962-1692 FAX (403) 962-1983
E mail: davidj@telusplanet.net
Web Site http://www.ocii.com/~grove

March 8, 1999

Grace Moe
Graduated Student
Department of Physical Therapy
Faculty of Rehabilitation Medicine
2-50 Corbett Hall
University of Alberta
T6G 2G4

Dear Grace,

Thanks for your letter of January 23rd, informing us of your fibromyalgia study.

I have just had discussion with Dr. Burnham, and he states he would be prepared to approach fibromyalgia patients that he sees about possible involvement in the study. We will deal with the screening and consent forms on his behalf. Additionally we see fibromyalgia patients, from time to time, ourselves.

At this time I cannot speculate as to the population of patients we can identify who will fit your criteria.

Every good wish with this study, as we identify subjects, I will have them contact you. If you have any further questions please contact me. Thank you. God bless.

Yours sincerely,

David James

David James M.Sc., B.App.Sc. (P.T.) C.Ac.

DJ:sp

CC Dr. Robert Burnham

WEST END PHYSIOTHERAPY LTD.

WEST END MEDICAL AND PROFESSIONAL BLDG.

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PHONE: (403) 484-0514

November 16, 1998

Grace Moe
Master's of Science Candidate
Department of Physical Therapy
Faculty of Rehabilitation Medicin
University of Alberta
2-50 Corbett Hall
Edmonton, AB
T6G 2G4

Dear Ms. Moe:

RE: "Comparison of Characteristics of Fibromyalgia between patient who meet ACR criteria and who do not."

Our clinic treats a small number of fibromyalgia patients on a periodic basis.

I would be happy to refer my clients to you for the study.

Yours truly,

D Patry

Don Patry, BSc., B.P.T., M.C.P.A.,. M.C.P.T.A.
DP/dw

CORONA STATION PHYSICAL THERAPY LIMITED
Assessment and Treatment Clinic for Musculoskeletal Disorders

Suite 990, 10665 Jasper Avenue
Edmonton, Alberta, T5J 3S9

We Put Wellness First!

Telephone (403) 424-4804
e-mail corona@compusmart.ab.ca
Fax (403) 424-4811
http://.gsalink.com/corona_web/coronastation/index.html

NOVEMBER 16, 1998

MS. GRACE MOE
MASTER'S OF SCIENCE CANDIDATE
DEPARTMENT OF PHYSICAL THERAPY
UNIVERSITY OF ALBERTA

Dear Grace:

My clientele at Corona Station Physical Therapy Ltd. include those with a diagnosis of fibromyalgia. I would be pleased to support your study of this problem by referring those who meet your inclusion criteria.

Best of luck in your research!

Yours truly

Cheryl Applewhaite, B.P.T., M.C.P.A. Acupuncturist

GRANDVIEW HEIGHTS PHYSICAL THERAPY

A Division of McInnis Physical Therapy Services Ltd.

November 17,1998

Grace Moe
Master's of Science Candidate
Department of Physical Therapy
Faculty of Rehabilitation Medicine
University of Alberta
2-50 Corbett Hall
Edmonton, Alberta
T6G 2G4

Dear Ms. Moe:

RE: "Comparison of Characteristics of Fibromyalgia between patients who meet ACR criteria and who do not."

As you may be aware, Grandview Heights Physical Therapy has a large number of clients who have been diagnosed with fibromyalgia. Over the years, we have developed a comprehensive management program for these clients. It has been my observation, that despite the diagnosis of fibromyalgia, there are different group characteristics of presentation. I would be happy to refer all my clients to you as this presents an excellent opportunity for improved management.

Yours truly,

Jackie McInnis

Jackie McInnis, B.P.T., M.C.P.A.

12307 - 63rd Avenue, Edmonton, Alberta T6H 1R4

Ph 437-8000 or /Fax 434-4383

FROM : WAGNER MANAGEMENT ADVISORY SER PHONE NO. : 403 455 7978 P01

Meadowlark Physical Therapy Ltd.
#307, 8708 - 155 St. Edmonton, Alberta T5R 1W2 voice 448-0880 fax 489-9918

Ray Jocksch [illegible]
Sunni-Michele Wagner B.Sc. P.T., D.O.T., Cert. Med. Acup.
Kevin Hutton B.Sc. P.T., Cert.
Mara Shular B.A., B.Sc. P.T., Cert. Med. Acup.

November 19, 1998

Grace Moe
Master's of Science Candidate
Department of Physical Therapy
Faculty of Rehabilitation Medicine
University of Alberta
2-50 Corbett Hall
Edmonton, Alberta
T6G 2G4

Dear Ms. Moe

RE: Comparison of Characteristics of Fibromyalgia between patients who meet ACR criteria and who do not.

We at Meadowlark Physical Therapy Ltd., would be pleased to support your research. We will refer all appropriate clients and look forward to learning the results of your thesis.

Yours truly,
MEADOWLARK PHYSICAL THERAPY LTD.

Sunni Michele Wagner

Sunni Michele Wagner
B.Sc.P.T., D.O.T.,
Cert. Med. Acup.

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REHABILITATION
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EASTGATE PHYSIOTHERAPY & REHAB CENTRE
Eastgate Physical Therapy (1985) Ltd.

"We Care"

Satish (Steve) Pandya
B. Sc. P.T., M.C.P.A., M.C.P.T.A.

#100 - 937 Fir Street
Sherwood Park, AB.
T8A 4N6
Ph: 467-3848
Fax: 467-3097

February 8, 1999

Grace Moe
Master of Science Candidate
Department of Physical Therapy
University of Alberta

Edmonton, Alberta

Dear Ms. Moe,

RE: Your letter dated January 23, 1999

I understand that you have been doing a study on Fibromyalgia as a part of your master's program.

I am pleased to announce that my clinic is willing to assist you and will participate as a formal referral site for this study.

I wish you good luck for this project. If you have any questions or need any further information, please feel free to contact me at 467-3848.

Sincerely,

Steve Pandya

SATISH (STEVE) PANDYA
Physiotherapist

GLENORA PHYSIOTHERAPY CLINIC LTD.
B1, 10155 – 120th Street, Edmonton, Alberta T5K 2A2
Tel: 488-8582 Fax: 487-0676

Dec. 1, 1998

Grace Moe
Dept. of Physical Therapy
Faculty of Rehabilitation Medicine
2-50 Corbett Hall
Edmonton, AB
T6G 2G4

Dear Grace:

This is to inform you that we like to support your research project on the fibromyalgia syndrome. This is a research oriented clinic and we are pleased to be able to assist you in anyway possible to facilitate the best possible outcome of your project.

We will refer our fibromyalgia patients to your study and we are willing to participate in any way that will be helpful to you and your project.

Yours truly,

per Marcel Dusyk, BScPT