THE RELATIONSHIP BETWEEN FIBROMYALGIA SYMPTOMS AND PHYSICAL FUNCTION IN MIDDLE-AGED AND OLDER ADULTS

BY

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Abstract

Background: Fibromyalgia (FM), a debilitating multi-symptom disorder, affects nearly 10 million Americans, with an annual direct cost of over $20 billion per year. As our population continues to age, it is expected that those 65 years of age and older will grow to 70 million people by 2050. Considering approximately 9% of older adults have FM, this syndrome poses a serious health concern. Mechanisms underlying FM are rapidly emerging, yet a single, unifying physiologic framework continues to elude researchers. Therefore treatment relies largely on managing symptoms and promoting physical function. Poor physical function in older adults with FM poses serious limiting effects, and is correlated with greater risk for disability and increased financial burden that ultimately places older adults at risk for loss of independence. Comprehensive symptom management interventions are proposed to be the most effective approach to preventing or minimizing poor physical function for those with FM. However, there is limited study of the relationship between the multiple symptoms of FM and physical function in FM, especially specific to older adults. This gap may impede the development of multi-modal interventions that include appropriate symptom management, aimed to prevent poor physical function.

Objectives: The purpose of this study was to describe symptoms in adults with FM, determine the relationship between symptoms and physical function, and assess the moderating effect of comorbidity and age on this relationship.

Design: This study was a cross-sectional descriptive correlational study. The specific aims of the study were: to describe a comprehensive set of symptoms in terms of the frequency, severity, and distress; to examine which symptoms best predict perceived physical function; and to examine the relationship between co-morbidity, age, symptoms, and perceived physical function.

Methods: Adults over the age of 50 were randomly identified from the Oregon Health & Science University FM patient database. Questionnaires were mailed including an investigator-developed 29-item Likert scale for FM specific symptoms. Individual symptom domains were elicited: frequency (1-4), severity (1-4), and distress (0-4), with higher numbers indicating greater symptom burden, and a composite symptom score (2-12) was calculated using all 3 symptom domains. Additionally, responders completed the Late-Life Function & Disability Instrument: Function Component (LLFDI), a well-validated instrument in which 0-100 scaled scores indicate physical function categories ranging from no functional limitation (>76) to severe functional limitation (<42), and the Charlson Comorbidity Index, a weighted index with scores ranging between 0 to 41.

Analysis: Descriptive statistics were used to characterize demographic and clinical variables. Frequencies and plots were used to describe the frequency, severity, and distress of each symptom experienced within the sample. Hierarchical regression modeling was used to examine influence of each symptom on physical function while controlling for pain. Correlation between each symptom and perceived physical function were evaluated for entering symptoms in the regression analysis. The final regression included all chosen symptoms entered simultaneously to determine the effects of each symptom on perceived physical function controlling for all other symptoms. The moderating effect of age and co-morbidity on the relationship between symptoms and physical function was evaluated in additional regression analyses.

Results: The sample reported experiencing an average of 20 symptoms in the previous seven days. The rank-order for the dimensions of frequency, severity, and distress differed for each symptom. The symptoms most reported by the sample were pain, stiffness, fatigue, non-refreshing sleep, forgetfulness, difficulty staying asleep, and muscle spasms. Symptom composite correlations of the 29 symptoms with perceived physical function revealed significant findings of weak to moderate correlations for fifteen symptoms. The regression model determined that pain, anxiety, fatigue, stiffness, and dizziness accounted for 37% of the variance in perceived physical function. Although a significant difference in the number of symptoms was present between the middle-aged and older-aged groups, age was not correlated with perceived physical function, and therefore did not have a moderating effect on the relationship between symptoms and perceived physical function. Comorbidity did have a significant correlation with perceived physical function, but further analysis revealed no moderating effect for comorbidity.

Conclusions: This study yielded five novel findings: 1) the total sample reported a very high number of symptoms, with the middle-aged group reporting significantly more symptoms than the older-aged group; 2) the distress dimension yielded a markedly different rank-order than the frequency and severity dimensions: the most distressing symptom was fear of symptoms worsening while the most frequent symptoms were pain, fatigue, sleep-related symptoms, and stiffness, and the most severe symptoms were also sleep-related symptoms and fatigue; 3) five symptoms were identified that account for 37% of the variance in physical function: pain, fatigue, anxiety, stiffness, and dizziness; 4) no difference existed between the two age groups on perceived physical function, and 5) while age was not correlated with physical function, comorbidity significantly correlated with physical function and accounts for 6.8% of the variance in perceived physical function; neither age nor comorbidity have a moderating effect on the relationship between symptoms and perceived physical function. Further research is needed to replicate the study in a larger sample consisting exclusively of older adults, and to confirm the self-report findings of perceived physical function with objective measures of physical function.

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CHAPTER 1: INTRODUCTION

Introduction

Chapter 1 presents a brief background of fibromyalgia, the progression of the disease in older adults, and the implications of fibromyalgia in relation to physical function as they pertain to the research purposes and aims of this study. The chapter concludes with a description of the importance of this study and the implications of the findings for nursing practice.

Epidemiology of Fibromyalgia

Fibromyalgia (FM), a debilitating multi-symptom disorder, is classified by widespread pain for more than three months and pain in specific tender-points on physical exam (Wolfe, Smythe, Yunus, Bennett, Bombardier, Goldenberg, et al., 1990). FM affects between 6 and 10 million people, with an annual direct cost of over $20 billion per year (Robinson, Birnbaum, Morley, Sisitsky, Greenberg, & Claxton, 2003; White, Speechley, Harth, & Ostbye, 1999; Wolfe, Anderson, Harkness, Bennett, Caro, Goldenberg et al., 1997b). Approximately 7% of the adult female population (Lindell, Bergman, Petersson, Jacobsson, & Herrstrom, 2000; White, Speechley, Harth, & Ostbye, 1999; White & Thompson, 2003) and up to 9% of all older adults have FM (Gowin, 2000; Wolfe, Ross, Anderson, Russell, Hebert, 1995). Pain and other FM symptoms contribute to declines in physical function. Poor physical function is largely responsible for disability in FM, the rates of which range from 25% to 35% compared to 22% in the overall US population (Bombardier & Buchwald, 1996; Centers for Disease Control, 2001; White, Nielson, Harth, Ostbye, & Speechley, 2002; White, Speechley, Harth, Ostbye, 1999; Wolfe, Anderson, Harkness, et al., 1997).

Symptoms in Fibromyalgia

Mechanisms underlying FM are rapidly emerging, yet a single, unifying physiologic framework continues to elude researchers. Therefore treatment relies largely on managing symptoms and promoting physical function. Symptoms are subjective and multidimensional in nature, and include dimensions such as frequency, severity or intensity, and distress. This study focused on FM symptom dimensions of frequency, severity, and distress because these dimensions best predict physical function in other populations (Bookwala, Harralson, & Parmelee, 2003; Chang, Hwang, Feuerman, Kasimis, & Thaler, 2000; Gaston-Johansson, Fall-Dickson, Bakos, & Kennedy, 1999; Given, Given, Azzouz, & Stommel, 2001; Lutz, Norrell, Bertucio, Kachnic, Johnson, Arthur et al., 2001; Sprott & Muller, 1998). There is a gap in the current understanding of how multiple symptoms in FM relate to physical functioning, and the lack of understanding is most evident for older adults with FM. While little is known about the comprehensive symptom experience in the general FM population, it is particularly critical to understand how FM symptoms contribute to age-related challenges in maintaining optimal physical function.

In order to address this gap, the National Fibromyalgia Association (NFA) recently conducted the first study of a large national sample through an on-line survey (Bennett, Jones, Turk, Russell, & Matallana, 2007). The results of this study revealed not only a comprehensive list of FM symptoms by frequency, but also identified those symptoms in order of severity. FM patients (*N* = 2,595; mean age 47.3 years ± 10.68) reported multiple symptoms. The most frequent were: low back pain (63%), recurrent headaches (47%), muscle spasms (46%), fatigue (40%), depression (40%), anxiety

(38%), restless legs (32%), and irritable bowel/bladder (44/26%) (Bennett et al., 2007). Further, up to 62% of the sample experienced poor physical function.

The current study extends the NFA research by creating a checklist based on the most common and severe symptoms identified by the FM participants. The symptom checklist additionally measured the dimension of distress, which was not measured in the NFA study. Further, the differences in FM symptom experience between adults 50 to 64 years of age and adults 65 years and older were examined. Those over 50 years of age comprised 51% (*n* = 1327) of the sample in the NFA study. Thus, over half of the sample will soon be reaching an age that is considered “elderly” as defined by the American Association of Retired Persons (AARP) and many state boards of nursing. This population will likely experience some of the confounding factors that further complicate disease processes associated with increasing age.

Fibromyalgia in Older Adults

Understanding the symptoms of FM in older adults is important for several reasons. First, Wolfe (1988) as well as Yunus and colleagues (1988) identified early on the complexities of FM in older adults, including the difficulty added by the presence of comorbid conditions and implications of the aging process on the FM disease process that are not currently known. Second, the nature of the symptom is important in choosing interventions, as they may be from other comorbid conditions and not the FM disease process. Finally, symptoms are known to increase in severity and prevalence with advanced age.

Those that have been diagnosed with FM in their forties and fifties over the last 15 years continue to age and it is becoming increasingly important to understand the confounding effects of aging on the FM disease process. Older adults have higher rates of FM than younger adults (Wolfe et al., 1997a). Given that the population of those 65 years and older is projected to grow to 70 million people by 2050 (Federal Interagency Forum on Aging-Related Statistics, 2004), FM poses a serious health concern. It is also imperative that the impact of comorbid conditions on the experience of FM symptoms be understood, as those with more comorbid conditions are more likely to have poor physical function. This understanding will lead to developing interventions that are specifically targeted at alleviating the symptoms having the greatest impact on physical function in a population that already is predisposed to poor function.

Physical Function in Fibromyalgia

Poor physical function in older adults with FM poses serious limiting effects. Poor physical function is correlated with greater risk for disability and increased financial burden that ultimately places older adults at risk for loss of independence. Older adults' ability to function independently in the community has been identified as a public health issue of particular concern. A certain level of physical function is required for older adults to remain living in their own home and avoid transition into institutionalized care settings (Guralnik, 1996; Guralnik, Fried, & Salive, 1996; Guralnik et al., 1993).

Comprehensive symptom management interventions are proposed to be the most effective approach to preventing or minimizing poor physical function for those with FM. However, there is limited study of the relationship between the multiple symptoms of FM and physical function in FM, especially specific to older adults. This gap may impede the development of multi-modal interventions that include appropriate symptom management, aimed to prevent poor physical function.

Specific Aims and Hypotheses

The long-term goal of this program of research is to develop and test interventions for older adults with FM based on their symptom cluster profile. While the NFA study provides a beginning for understanding the complexity of FM symptoms, there is still much to be learned about the comprehensive symptom experience in FM. Symptom clusters introduce a unique way of evaluating multiple concurrent symptoms. A symptom cluster is defined as three or more concurrent symptoms related to each other in such a way that a unique outcome is produced compared to each symptom individually (Armstrong, Cohen, Eriksen, & Hickey, 2004; Barsevick, Whitmer, Nail, Beck, & Dudley, 2006; Dodd, Miaskowski, & Paul, 2001). The concept of symptom cluster avoids the common assumption that all symptoms contribute equally to the overall symptom frequency, severity, and distress. This cluster approach to symptoms is able to capture how people manifest the totality of the symptom experience.

A fundamental first step to achieve this goal of developing interventions for older adults with FM based on their symptom cluster profile is to describe symptoms in adults with FM, determine the relationship between symptoms and physical function, and assess the moderating effect of comorbidity and age on this relationship. The current study utilized a descriptive, cross-sectional design in a sample of community-living adults, over 50 years of age, and diagnosed with FM.

Aim 1

Aim 1 was to describe a comprehensive set of symptoms in terms of the frequency, severity, and distress. This descriptive aim had no hypotheses.

Aim 2

Aim 2 was to examine which symptoms best predict perceived physical function. It was hypothesized that increased frequency, severity, and distress of symptoms would predict poorer perceived physical function.

Aim 3

Aim 3 was to examine the relationship between co-morbidity, age, symptoms, and perceived physical function. In relation to the third aim, it was hypothesized that adults with comorbidities that are 65 years and older would report more symptoms and poorer perceptions of physical function. Support of the proposed hypotheses was expected to reveal the relative impact of multiple symptoms in predicting perceptions of physical function in FM.

Significance to Nursing

Understanding the impact of multiple concurrent symptoms on perceived physical function in FM will inform future clinical trials in terms of both intervention scope and outcome measures. Data from this project is expected to contribute to the development of an instrument aimed at identifying symptom clusters, rather than individual symptoms. This study utilized scientific evidence from symptom cluster research on better understood disease processes such as heart disease and cancer, and innovatively extended these methods by which the findings were derived to FM research. Treatments aimed exclusively at managing the single symptom of FM pain may have limited efficacy for maintaining physical function, whereas targeting a symptom cluster may prove to be more effective.

This study is significant to nursing for key reasons. Nurses are charged with ensuring that, through symptom management, patients are able to maintain their highest possible level of physical function and quality of life. The nursing discipline will share the burden of care for the influx of older adults with declining physical function due to FM and its associated symptoms. This study directly supports the research mission of the National Institute of Nursing Research (National Institute of Nursing Research, 2007) to provide research focusing on chronic illness experiences, including management of symptoms and avoiding complications of disability.

CHAPTER 2: BACKGROUND AND SIGNIFICANCE

Review of the Literature

Fibromyalgia (FM) is a common, debilitating, and costly persistent pain syndrome whose clinical presentation is further characterized by a wide array of symptoms. Up to 10 million people are affected by this disease in the United States, eighty to ninety percent of who are women (Bennett, 2005a; Lawrence et al., 1998). Although the American College of Rheumatology (ACR) 1990 diagnostic criteria for FM was developed only fifteen years ago, just five years later FM was one of the three most common diagnoses made by rheumatologists (White, Speechley, Harth, & Ostbye, 1995). The development of these diagnostic criteria resulted in eleven rigorous epidemiological studies (Carmona, Ballina, Gabriel, & Laffon, 2001; Clark, 1998; Farooqi, 1998; Forseth, 1992; Lindell, Bergman, Petersson, Jacobsson, & Herrstrom, 2000; Lydell & Meyers, 1992; Makela & Heliovaara, 1991; Prescott et al., 1993; White, Speechley, Harth, & Ostbye, 1999c; White & Thompson, 2003; Wolfe, Ross, Anderson, Russell, Hebert, 1995). Results of these studies revealed FM prevalence in the general population ranged from 1.3% to 10.5 %, with 7% of the adult female population consistently found to have FM (Farooqi, 1998; Forseth, 1992; White et al., 1999c; Wolfe, Ross, Anderson, Russell, Hebert, 1995). In older adults, emerging data suggests that the prevalence increases to up to 9% (Gowin, 2000; Wolfe, Ross, Anderson, Russell, Hebert, 1995).

Old age is a socially-determined phenomenon that has varied definitions. Epidemiologic research has used classifications of 60 to 69 years of age as “young-old,” 70 to 79 year as “middle-old,” and 80 years and over as “old-old” (Guralnik, 1996;

Verbrugge, et al., Gowin, 2000). The American Geriatric Society (2002) guidelines define these classifications as 65 to 74 years of age, 75 to 84 years, and 85 years and over, respectively. State boards of nursing clinically define older adults for the geriatric nursing scope of practice to include those 50 years of age and over, as does the American Association for Retired Persons (AARP). Definitions of “older” vary drastically in FM literature, with ranges between 50 years of age and above to 65 years and over constituting this classification. Given these varied definitions of “older adult,” this study evaluated the symptom experience of those aged 50 years and over, and compared the findings for those aged 50 to 64 years to those aged 65 years and over.

Poor physical function is identified as one of the direct causes of disability in patients with FM (Baumstark et al., 1993; Turk, Okifuji, Sinclair, & Starz, 1996; Vollestad & Mengshoel, 2005; White et al., 1999a). This is of particular concern to the aging population. Confounding factors of FM combined with the increased prevalence of comorbid conditions and the aging process potentially place this population at an even greater risk for poor physical function. If particular sets of symptoms are found to predict perceived physical function in older adults with FM, future trials could target those symptoms collectively to optimize physical function.

This chapter synthesizes the literature related to symptom expression and physical function in fibromyalgia. The literature specific to fibromyalgia and physical function in middle-aged and older adult populations will be addressed.

Symptoms

Definition of Symptoms

Symptoms are defined as a subjective experience of an indicator of change in normal biopsychosocial functioning (Armstrong, 2003; Dodd et al., 2001; Lenz, Pugh, Milligan, Gift, & Suppe, 1997). Symptom expression is of vital importance, as symptoms are the warning signs for threats to one's health. Symptom management is the cornerstone of nursing care, and nurses use the presence or absence of symptoms to determine the most appropriate and effective interventions for patients. Symptoms are multidimensional in nature and include an emotional response to the experience of having symptoms.

Dimensions of Symptoms

Dimensions common to all symptoms include frequency, severity or intensity, duration, distress, quality, location, and affective impact. While an all-inclusive approach to measurement of these symptom dimensions would yield the most comprehensive view of the symptom experience, this method would result in an extensive and burdensome evaluation, unrealistic for many research environments and clinical settings. Most studies of symptoms in those with persistent pain syndromes use either the frequency or severity of the symptoms to determine the impact those symptoms have on the subjects' lives (Bennett, 2002; Bookwala, Harralson, & Parmelee, 2003; Sprott & Muller, 1998). Research in symptoms associated with cancer and the treatment of cancer have demonstrated that the severity and distress of symptoms are most predictive for outcome variables such as severity of illness, poor physical function, quality of life, and survival rates (Chang, Hwang, Feuerman, Kasimis, & Thaler, 2000;

Gaston-Johansson, Fall-Dickson, Bakos, & Kennedy, 1999; Given, Given, Azzouz, Stommel, & Kozachik, 2000; Lutz et al., 2001). Based on these understandings of symptom expression, and in order to compare the findings of this study to other studies of symptoms in FM, both symptom frequency and severity were evaluated. In addition to frequency and severity, symptom distress has been shown to have a significant impact in the expression of symptoms in those with FM (Karoly & Ruehlman, 1996; McCarberg et al., 2003; Shaver et al., 1997; White, Nielson, Harth, Ostbye, & Speechley, 2002a). One recent study found that up to 83% of those with FM reported that distress exacerbates their FM symptoms (Bennett, Jones, Turk, Russell, & Matallana, 2007). Therefore, symptom distress was evaluated as well.

Symptom frequency is defined as the rate of occurrence of a symptom based on a determined measure of time, as in number of times per day or average times per week that the symptom is present (Armstrong, 2003; Dodd et al., 2001; Lenz et al., 1997). Frequency is often used to gauge the influence of a symptom on an outcome variable in terms of the amount of time the symptom is actually present. In contrast, symptom severity (also referred to as intensity) is defined as the state of being unpleasant, or the subjective determination of the strength, concentration, or force of the symptom. The subjective report of severity of a symptom constitutes the most easily quantified dimension of a symptom (Lenz et al., 1997). This is the dimension most often addressed in research and clinical practice, as it is most easily identifiable in terms of improvement or worsening in the symptom experience.

Distress is sometimes defined in terms of manifested depression and/or anxiety. However, research in persistent pain populations has shown that distress goes beyond the simple presence of depression and/or anxiety. For these populations, distress is a reduction in activity level, a dependence on pain medications and/or medical treatments and nursing interventions, and the resulting psychosocial impairments (Dodd et al., 2001; Karoly & Ruehlman, 1996; Lenz et al., 1997). In this study, symptom distress is defined as the degree to which a person is bothered by the symptom, or the amount of physical or mental upset, anguish, or suffering that is endured from the experience of having the symptom (Karoly & Ruehlman, 1996). Specifically in FM research, symptom distress is operationalized as a dysfunction in either somatic or psychological symptoms, or in a combination of these, that are part of a continuum of symptom severity (McCarberg et al., 2003; Wolfe, 1997). The more distress present, the more potential there is for increased severity of symptoms. Symptom distress is the dimension that is most influential for seeking treatment, and is the greatest contributor to quality of life (Lenz et al., 1997).

Measurement of Symptoms

Symptom measurement is conducted in two ways: real-time expression or retrospective recall. Real-time expression is the most accurate measure of symptoms. This method consists of a way of capturing the symptom expression at different specified times throughout a day for a number of consecutive days (Gabbay et al., 1996). In FM research, a prompted timer on an actigraph that used a keypad for real-time entry permitted assessment of symptoms on a ten-point scale five times throughout the day for five consecutive days (Kop et al., 2005).

Retrospective recall consists of a subjective questionnaire that asks the participant to recall over the last day, week, or month (depending on the measure) to rate the severity of a specified symptom. Retrospective recall is the most widely used method of symptom assessment, as it is the least invasive and most time efficient means of assessment. While the real-time expression of symptoms is a superior method of symptom assessment for its lack of influence from recall biases (Schwartz & Stone, 1998), the trade-off for choosing a retrospective method of symptom assessment rested in the feasibility of conducting this study. Due to the preliminary nature of the goal of this study, retrospective recall was the most appropriate means of symptom assessment.

Historically, FM symptoms have been measured with visual analog scales. More recently, measures designed to capture the multiple dimensions of one symptom have been used in FM research, such as the Brief Pain Inventory (BPI) (Arnold et al., 2004; Arnold et al., 2005; Burckhardt & Jones, 2005) or the Beck Depression Inventory (BDI) (Burckhardt et al., 1994; Petzke, Gracely, Park, Ambrose, & Clauw, 2003; Zijlstra et al., 2005). Also, the Fibromyalgia Impact Questionnaire (FIQ) provides a more global measure of the severity of a fewer number of multiple symptoms (Arnold et al., 2004; Bennett et al., 1996; Burckhardt & Jones, 2005; Zijlstra et al., 2005). However, these scales are limited by the lack of inclusion of more than one symptom, as with pain on the BPI or depression on the BDI. In addition, they lack assessment of different dimensions of the symptoms, as with the FIQ. Research on measures of cancer symptoms, a disease process with symptoms that parallel the complexity of FM symptom expression, has found that symptom measures that include dimensions of frequency, severity, and distress are more predictive of improved quality of life, extent of disease, and survival rates than unidimensional measures of cancer symptoms (Chang et al., 1998; Lutz et al., 2001). Although FM studies have not specifically included each of these dimensions in a comprehensive appraisal of fibromyalgia symptoms, extensive knowledge in other areas of symptom management clearly support this method of symptom assessment.

Diagnosis of Fibromyalgia

Classification Criteria of Fibromyalgia

Like most chronic illness, FM is not thought to have a single, underlying cause. However, multiple pathophysiologic abnormalities have been identified. There is no generally agreed-upon framework for unifying these theories, yet they are all thought to influence symptom expression. The pertinent pathophysiologic findings for the symptom expression of FM will be presented, including central sensitization, neurotransmitter abnormalities, and peripheral nociception.

Fibromyalgia is diagnosed based on the classification criteria developed by the American College of Rheumatology (ACR) (Wolfe, Smythe, Yunus, Bennett, Bombardier, Goldenberg, Tugwell, Campbell, Abeles, Clark, Fam et al., 1990). These diagnostic recommendations are based on two features: 1) a history of widespread pain of three months or more; and 2) the palpation of eighteen specified muscle tendon junctions (tender points). “Widespread” is defined as axial pain plus pain in three or four body segments for the past three months. “Axial” distribution is cervical spine, anterior chest, thoracic spine or low back pain, and “pain in body segments” is distributed pain of both left and right sides of the body, and pain above and below the waist. Additionally, pain needs to occur on digital palpation of eleven or more out of the eighteen specified tender points. The recommendations specify that the palpation be at a final force of 4 kg (the amount of pressure required to blanch a thumbnail) starting at 1 kg and incrementing by 1 kg at a rate of 1 kg per second. These nine paired tender point locations are described in Table 2.1 and shown in Figure 2.1.

Table 2.1

Description of Fibromyalgia Tender Point Locations

Occiput	Bilateral, at the suboccipital muscle insertions
Low Cervical	Bilateral, at the anterior aspects of the intertransverse spaces at C5-C7
Trapezius	Bilateral, at the midpoint of the upper border
Supraspinatus	Bilateral, at origins, above the scapula spine near the medial 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 epicondyles
Gluteal	Bilateral, in upper outer quadrants of buttocks in anterior fold of muscle
Greater trochanter	Bilateral, posterior to the trochanteric prominence
Knee	Bilateral, medial fat pad of knee proximal to joint line

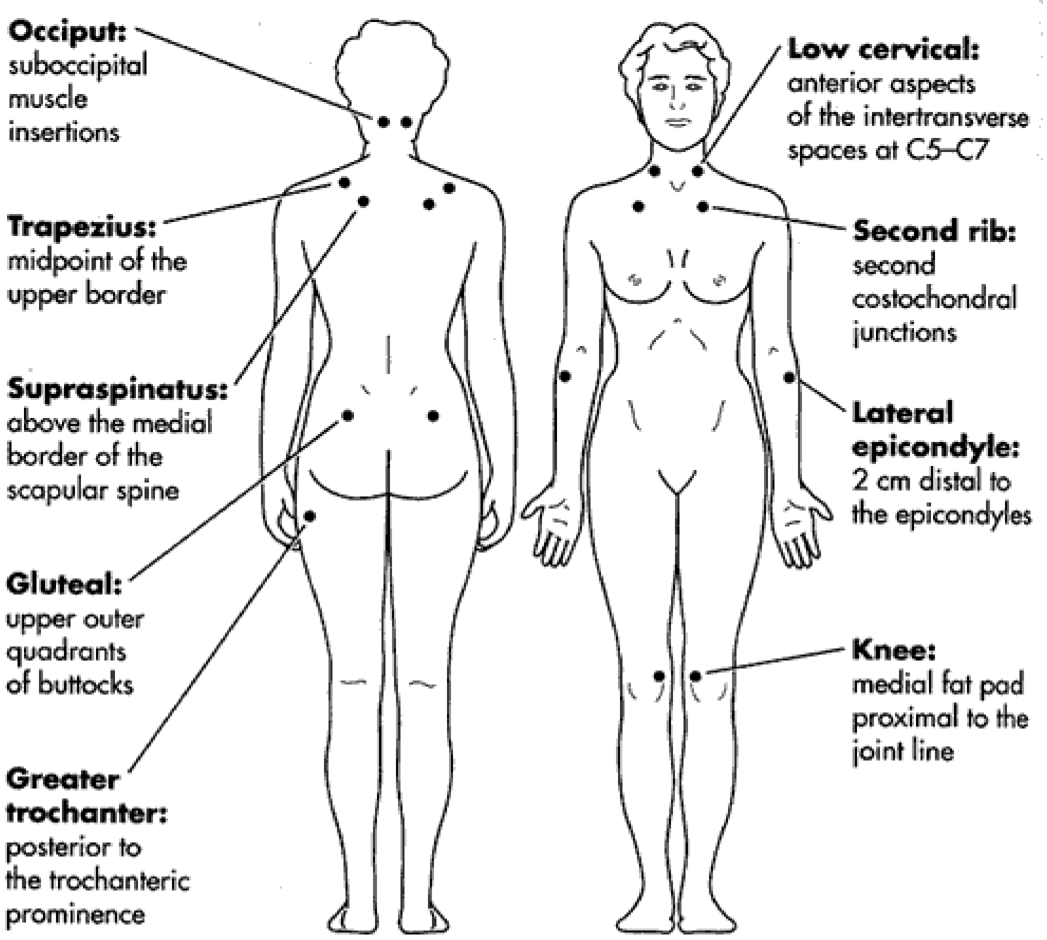


Figure 2.1
Body Representation of Fibromyalgia Tender Point Locations

Central Sensitization or Augmentation

Central sensitization, or augmentation, refers to the hyperexcitability of the nociceptive system that leads to increased muscle sensitivity, or allodynia, in which pain is evoked by a normally non-nociceptive stimulus (Banic et al., 2004; Desmeules, 2003; Graven-Nielsen & Arendt-Nielsen, 2002; Sorensen, Graven-Nielsen, Henriksson, Bengtsson, & Arendt-Nielsen, 1998; Staud, Robinson, & Price, 2005). Central sensitization also contributes to hyperalgesia, a condition of increased pain intensity above that normally evoked by nociceptive stimuli, in addition to the increased sensitivity of peripheral nociceptive neurons (Banic et al., 2004; Graven-Nielsen & Arendt-Nielsen, 2002; Sorensen et al., 1998; Staud et al., 2005). Sensitization of the dorsal root ganglia and spinal dorsal horn interface results in an increase in the afferent somatosensory input, potentially resulting in the development of central sensitization.

An increased sensitivity of n-methyl-d-aspartate (NMDA) sub-type glutamate receptors within the dorsal horn is believed to play a role in central sensitization in FM patients (Willis, 2001). FM patients demonstrate enhanced windup pain, or temporal summation, in response to repetitive noxious stimulation. Temporal summation is a state in which the continued application and release of the same amount of pressure over a period of time not only increases the pain intensity of each subsequent pressure application, but the sensation of pain remains even after the pressure is no longer applied. This is a key aspect of FM pain that supports the concept of central sensitization (Staud, Vierck, Cannon, Mauderli, & Price, 2001).

Neurotransmitter Abnormalities

Subjective awareness of a sensory experience of pain is constituted by the flow of excitatory information from the spinal cord to the thalamus and distributed throughout the brain for processing. Neurohormonal factors modulate the transmission of these stimuli by exercising either excitatory or inhibitory influences. Thus, an imbalance between excitatory and inhibitory factors can result in a generalized amplification of somatosensory data, resulting in the both peripheral and central sensitivity that characterizes FM (Baraniuk, Whalen, Cunningham, & Clauw, 2004; Bennett, 2005a; Bennett, 1996b).

Several changes in cerebrospinal fluid (CSF) have been observed in FM patients that increase central neuronal excitability, including increased concentrations of metabolites of excitatory neurotransmitters (Larson, Giovengo, Russell, & Michalek, 2000), substance P (Russell, 2002; Russell et al., 1994), and nerve growth factor (Giovengo, 1999). A decrease in metabolites of descending inhibitory neurotransmitters such as serotonin, norepinephrine and dopamine has also been found (Dessein et al., 1999; Malt, Olafsson, Aakvaag, Lund, & Ursin, 2003; Russell, 1996). One example of the impact of the decrease in inhibitory neurotransmitters can be found in the analgesic capacity of opioids. This mechanism is at least partly dependent on the activity of dopaminergic neurons (Altier & Stewart, 1998). Thus, a decrease in dopamine may contribute to the apparent failure of endogenous opioids to modulate pain in FM, even though patients with FM have demonstrated an *increase* in the CSF concentration of opioidergic peptides (Baraniuk et al., 2004).

Peripheral Nociception

Increased sensitivity of peripheral nociceptive neurons has been postulated as one of the potential mechanisms underlying the pain of FM (Levine & Reichling, 2005; Price & Staud, 2005). One possible cause of this increased sensitivity could be attributed to hyperalgesia, the condition of increased pain intensity that contributes to central sensitization. Hyperalgesia is thought to stem from a disruption of normal autonomic function characterized by sympathetic domination of the autonomic nervous system (Martinez-Lavin, 2001).

Another potential mechanism behind increased sensitivity of peripheral nociceptive neurons may be an increase in the sensitivity of acid sensing channel 3 (ASIC3) in response to metabolic products of exercise, which supports observations of FM patients experiencing abnormally increased pain sensitivity after exercise (Staud et al., 2005; Vierck et al., 2001). Another explanation of the increased sensitivity and post-exercise-induced pain can be recognized in the reduction in post-exertional growth hormone release, which is a phenomenon known to lead to increased peripheral pain generation (Bennett, 2005b; Maas et al., 2000).

Pathophysiology and the Occurrence of Symptoms

The symptoms experienced with FM extend beyond the defining criteria of pain, and include depression, anxiety, fatigue, disrupted or non-refreshed sleep, exercise-induced symptom flares, and multiple other syndromes (e.g., restless legs, irritable bowel and bladder, and chronic headaches) (Bennett, 2002; Bennett et al., 2007; Pamuk & Cakir, 2005; Uveges et al., 1990; Wolfe et al., 1997a). The emerging data on the pathophysiology of the mechanisms of FM may explain, in part, the experience of multiple concurrent symptoms. The persistent pain induced by a heightened state of hyperalgesia and allodynia drives several feedback loops that contribute to the perpetual development of multiple symptoms (Aaron, Burke, & Buchwald, 2000; Bennett, 1996a; Yunus, 1992). For example, the continuous experience of persistent pain drives the heightened state of the stress response, thereby altering behavior, depression, sleep patterns, and much of the symptom distress found in this population (Bennett, 1996a, 1996b; Shaver et al., 1997).

The altered levels of neurotransmitters common in FM also have implications for the presentation of multiple symptoms. Altered levels of neurotransmitters such as serotonin, dopamine, and substance P all have an effect on the mechanisms that manifest as symptoms such as depression, fatigue, altered sleep pattern, and anxiety (Dessein et al., 1999; Willis, 2001).These pathophysiologic mechanisms can even explain to some degree the overlapping symptom burden of other chronic pain states common in FM (e.g., headaches, restless leg syndrome, or irritable bowel) (Aaron & Buchwald, 2001; Aaron et al., 2000).

Fibromyalgia Symptoms

FM is associated with a wide range of symptoms (see Table 2.2). The most common symptoms associated with FM are pain, fatigue, stiffness, anxiety, depression, and sleep disturbances (Aaron et al., 2000; Wolfe, Smythe, Yunus, Bennett, Bombardier, Goldenberg, Tugwell, Campbell, Abeles, Clark, & et al., 1990). These six symptoms comprise the symptom portion of the FIQ (Burckhardt, Clark, & Bennett, 1991), the most common measure of symptoms in FM studies. Yet there are many other symptoms in FM patients that are potentially overlooked with the use of this instrument. The NFA study identified 26 symptoms commonly experienced by a nationwide sample of 2,596 patients with FM (Bennett et al., 2007).

Table 2.2

Literature Review of Symptoms Experienced with Fibromyalgia

Symptom	**Number of Studies***	**Symptom Measures**	**Relationship with FM**	**Other Symptoms Studied**
Pain	7	FIQ, BPI, simple 0-10 VAS, and SF-36	• Pain most prevalent symptom • Objective measures of ADLs explain 26% of physical function in those with FM • Higher levels of pain significantly correlated with lower levels of physical function	
Fatigue	7	VAS, verbal descriptor scale	• Fatigue, pain and stiffness highly correlated throughout 24-hr and 7-day duration of symptom reporting • Higher severity of all three variables in morning vs afternoon • Lower norepinephrine & dopamine found in FM with higher fatigue • Anxiety & depression correlated with pain & fatigue • 59% of FM patients reported moderate to extreme fatigue on verbal descriptor scale • Fatigue highly correlated with sleep disturbance	• Relationship of fatigue, pain, & depression to lower cognitive function in FM groups – higher severity correlated with more c/o cognitive dysfunction
Anxiety	17	FIQ, SF-36, STAI, Giessener Symptom Complaints Checklist, Hospital Anxiety and Depression index, State-Trait Personality Inventory	• FM group significantly higher in anxiety compared to healthy control (HC) group, functional dyspepsia group, CWP but no FM dx, RA group • Anxiety significant to D2 receptor function, leading to dysfunction of stress response system • Compared to CWP with similar levels of anxiety, FM group had more symptoms • Best predictors of anxiety in FM were total number of symptoms & physical disability • Group of FM w/o co-morbidity correlations b/t anxiety/depression & pain/fatigue; group w/co-morbidity correlations b/t depression & fatigue and anxiety & pain • 92% scored "high" on anxiety measure (n=72)	• QOL (SF-36, FIQ) lower in FM compared to HC • Functional disability • Higher anxiety correlated with higher pain • Prevalence of PTSD in those with FM 57%; PTSD had significantly higher anxiety • Serum vs. plasma levels of serotonin related to pain and anxiety • Anxiety correlated with memory and concentration difficulties in FM

Symptom	Number of Studies*	Symptom Measures	Relationship with FM	Other Symptoms Studied
Anger	2	Visual Analog Scale, Toronto Alexithymia Scale-20 items, Spielberger State-Trait Anger Inventory	• FM group significantly higher anger-toward-self scores than RA group and HC • Higher state scores when compared to trait scores indicating increase d/t pain, not causing pain	Depression – FM group significantly higher BDI scores than HC
Depression	10	CES-D, BDI	• Activity, depression, & pelvic pain explained 23% of affective pain • Flare-up of symptoms & depression explained 25% of intensity of pain • Scores of depression on BDI in FM patients significantly higher than healthy group • According to BDI, 90% FM patients classified as depressed: 50% mild, 38% moderate, 2% severe depression • Higher scores on BDI than RA patients	
Sleep Disturbance	12	Subjective report of sleep patterns; sleep diaries; calculation of circadian phases; polysomnography and lung function tests in sleep studies	• Sleep studies reveal low alpha activity and self-report ratings of poor sleep • Phasic alpha activity noted in 50% of FM patients, and reported worsening of pain after sleep and a longer duration of pain than those in other subgroups • FM pts slept significantly less efficiently than HC , had higher proportion of stage 1 sleep, less slow wave sleep & twice the arousals per hour of sleep • Respiratory patterns show high occurrence of periodic breathing	

Symptom	**Number of Studies***	**Symptom Measures**	**Relationship with FM**	**Other Symptoms Studied**
Concentration/ Memory	9	Auditory Consonant Trigram; Neuro-cognitive tests encoded with a source of stimulus competition; Modified FIQ; Wechsler Memory Scale; Rey Auditory Verbal Learning Test; Paced Auditory Serial Additions Test; Symbol Digit Modalities Test; Test of Everyday Attention;	• No stimulus competition group = 31.4% impairment in test series; stimulus competition group = 85.7% • FM group lost info at rate of 58% after 9-sec distraction compared to HC with memory problems (40%) and normative values (20%) • FM group significantly higher concentration/ memory impairment scores compared to HC • FM group significantly lower on memory indexes and subjective memory than HC • 60% of FM group at least one subset score impaired on attention scale compared to 20% of HC group	• Global well-being scores lower in those with greater concentration/memory problems • Sleep quality significantly lower in FM groups compared to HC groups • Pain-related fear strong predictor of lower reaction times on cognitive tasks • Poor performance on memory/concentration scales correlated with pain and anxiety
Dizziness	2	Subjective history, physical examination, audiometry	• Dizziness/vertigo reported by 72% of FM patients • Dizziness most common otologic complaint, followed by tinnitus, hearing loss and vertigo	
Muscle Spasms	1	Needle electromyographic techniques	• No electrodiagnostic evidence of ongoing muscle spasm found in FM patients	
Fear of Symptoms Worsening	4	Tampa Scale for Kinesiophobia, VAS,	• High fear of pain and activity in FM patients reported greater disability, depressed mood, pain severity, and lower physical function than those with low fear of pain • Pain itself was a greater predictor of activity tolerance than pain-related fear, but pain-related fear was a stronger predictor of reaction times on cognitive tasks	

Pain

Pain is the most prevalent symptom associated with FM. It is most often measured using the FIQ, BPI, simple 0-10 visual analog scale (VAS), and the Short-Form Health Survey (SF-36) for pain measurement. In seven studies correlating pain with physical function in FM using objective outcome measures of activities of daily living, such as the 6-minute walk test or grip strength, pain explained up to 26% of physical function in those with FM. Higher levels of pain as measured by the FIQ, BPI, and pressure pain threshold were significantly correlated with lower levels of physical function (Mannerkorpi et al., 2006; Laursen et al., 2005; Kop et al., 2005; Ta et al., 2002; Buskila et al., 2000; Schanberg et al., 1996; Neumann et al., 2000). FM patients consistently have higher levels of pain severity than those with chronic low back pain, whiplash, or rheumatoid arthritis, and have significantly lower measures of physical function (Laursen et al., 2005; Kop et al., 2005; Neumann et al., 2000).

Fatigue

In studies of fatigue in FM patients, VAS and verbal descriptor scales have been used to measure this symptom. Up to 59% of FM patients reported moderate to extreme fatigue on verbal descriptor scales, and fatigue has been highly correlated with sleep disturbance, another common symptom of FM (Bellamy et al., 2004; Suhr et al., 2003; Guymer et al., 2002; Kurtze et al., 1998). Fatigue, pain, and stiffness were all highly correlated with each other, with higher levels of severity of all three variables reported in the morning versus the afternoon (Bellamy et al., 2004). Notably, lower levels of norepinephrine and dopamine were found in FM with higher levels of fatigue, and fatigue has been effectively treated with the administration of dopamine (Guymer et al., 2002).

Sleep

Sleep disturbance is a well-documented symptom associated with FM (Gold et al., 2004; Klerman et al., 2001; Shaver et al., 1997), and has perhaps the most objective means to describe this symptom (Roizenblatt et al., 2001; Sergi et al., 1999; Older et al., 1998). Sleep studies have revealed low alpha activity and self-report ratings of poor sleep in those with FM. Phasic alpha activity was observed in half of FM patients, with this subgroup reporting worsening of pain after sleep and a longer duration of pain than those in other subgroups (Roizenblatt et al., 2001; Sergi et al., 1999). When compared to healthy controls, FM patients consistently reported significantly less efficient sleep, demonstrated higher proportion of stage 1 sleep and less REM and slow wave sleep, and experienced twice the arousals per hour of sleep (Alvarez et al., 1992; Roizenblatt et al., 2001; Sergi et al., 1999; Branco et al., 1994). Respiratory patterns in those with FM showed high occurrence of periodic breathing, which has been shown to be linked to a reduction of transfer factor of the lung for carbon monoxide, and could be a contributing factor for the symptoms of sleep disturbance (Sergi et al., 1999).

Depression

Depression, often measured in FM studies with the CES-D and the BDI, is reported by up to ninety percent of FM patients, with 50% manifesting mild depression, 38% moderate depression, and 2% severe depression (Given et al., 2005; Hughes et al., 2006). Levels of depression are consistently higher in FM patients when compared to healthy control groups and to those with other diseases such as low back pain and rheumatoid arthritis (Kurtze et al., 2001; Hassett et al., 2000; Kurtze et al., 1999; Kurtze et al., 1998). Depression, in conjunction with flare-up of symptoms, explained 25% of the intensity of pain (Hughes et al., 2006), and those with higher levels of depression exhibited higher levels of pain severity (Okifuji et al., 2000; Kurtze et al., 1998). Depression is also highly correlated with cognitive complaints and impaired memory (Suhr et al., 2003).

Anxiety

Anxiety is quickly becoming an important symptom of study in FM. A range of instruments has been used in research on anxiety in FM, including the FIQ, SF-36, State-Trait Anxiety Inventory, Giessener Symptom Complaints Checklist, Hospital Anxiety and Depression Index, and the State-Trait Personality Inventory. As with most other symptoms, FM groups yield significantly higher scores on measures of anxiety compared to healthy controls, chronic widespread pain patients, and rheumatoid arthritis patients (Pagano et al., 2004; Malt et al., 2003; Cohen et al., 2002; White et al., 2002; Riley et al., 2001; Kurtze et al., 2001). Anxiety has a known relationship with D2 receptor function, leading to a dysfunction of the stress response system. Dysfunction of the stress response system is thought to contribute to the high levels of anxiety reported by up to 92% of FM patients (Malt et al., 2003a).

Anger

In two studies that examined anger as a symptom of FM, a Visual Analog Scale, the Toronto Alexithymia Scale, and the Spielberger State-Trait Anger Inventory were used to measure anger. FM groups had significantly higher anger-toward-self scores than rheumatoid arthritis groups and healthy controls (Sayar et al., 2004; Gulec et al., 2004).

FM groups also had higher anger state scores when compared to trait scores, a finding that suggests that anger is increased in response to pain, rather than anger causing greater pain (Sayar et al., 2004).

Dimensions of Fibromyalgia Symptoms

According to findings from the NFA study (Bennett et al., 2007), the most *severe* symptoms were morning stiffness, fatigue, nonrestorative sleep, pain, forgetfulness, problems with concentration and thirteen others (see Table 2.3). The most *frequent* symptoms reported in the NFA study were low back pain (63%), recurrent headaches (47%), muscle spasms (46%), fatigue (40%), depression (40%), anxiety (38%), restless legs (32%), and irritable bowel/bladder (44/26%). Whereas the finding for low back pain experienced by nearly two-thirds of the sample supports previous findings for pain as the most frequently reported symptom in FM patients, the ranking of pain intensity as the fourth most severe symptom after morning stiffness, fatigue, and nonrestorative sleep, points out the need for including both frequency and severity dimensions in symptom research.

Table 2.3

*Symptom Intensity in Descending Order of Severity**

Symptom	**Mean ± SD**
Morning stiffness	7.2 ± 2.5
Fatigue	7.1 ± 2.1
Nonrestorative sleep	6.8 ± 2.7
Pain	6.4 ± 2.0
Forgetfulness	5.9 ± 2.7
Concentration	5.9 ± 2.6
Difficulty falling asleep	5.6 ± 3.3
Muscle spasms	4.8 ± 3.2
Anxiety	4.5 ± 3.1
Depression	4.4 ± 3.1
Headaches	4.3 ± 3.1
Anger	3.9 ± 2.9
Restless legs	3.6 ± 2.7
Abdominal pain	3.6 ± 2.8
Poor balance	3.5 ± 2.9
Swelling of feet and ankles	3.2 ± 3.1
Dizziness	2.9 ± 2.8
Bladder problems	2.5 ± 2.9
Skin rashes	1.9 ± 2.9

*Scale 0-10 with higher numbers indicating greater severity

In addition to the frequency and severity of symptoms, the distress caused by FM symptoms is emerging as another dimension of the FM symptom experience that not only influences the existing FM symptoms, but precipitates the emergence of new symptoms, and thereby merits further investigation (Ismail, 2006; DaCosta, 2005; Turk, 2004; Nielson, 2004; White, 2002; Grisart, 2002). Another important finding of the NFA study was the discovery of factors that are perceived to worsen FM symptoms. The most frequently reported stressor for worsening of symptoms was emotional distress, reported by 83% of the sample (Bennett et al., 2007). Mental stress (68%) and worrying

(60%), viewed as factors contributing to the distress caused by symptoms, were also reported as stressors for worsening symptoms. Although the NFA study provides a beginning for understanding the complexity of the FM symptom experience, there is still much to be learned about the comprehensive symptom experience of the frequency, severity, and distress of these symptoms and how they vary with comorbidity and increasing age.

Fibromyalgia in Older Adults

Epidemiological studies indicate that new onset FM peaks in the fourth and fifth decades, but there are scant data about the natural history of FM in older adults (Neumann & Buskila, 2003; White & Harth, 2001; White et al., 1999c). Understanding this disease in older adults is important for several reasons. First, discernment of the nature of symptoms can aid in choosing interventions, in that symptoms may be attributed to the disease process of FM, to other disease processes, or even to the treatments of FM. Second, one fourth of women have an onset of FM symptoms at menopause and FM symptoms increase in severity in 26% of diagnosed women during menopause (Pamuk & Cakir, 2005); this exacerbation is likely in older adults, as well. Finally, the prevalence of FM increases with advanced age, with the highest prevalence rates in those over 55 years of age (White et al., 1999c; Wolfe, Ross, Anderson, Russell, Hebert, 1995).

Only six articles were identified that specifically evaluated FM in older adult populations (see Table 2.4). Of these six, only two specifically assessed symptoms, and the findings of these studies are conflicting. Cronan and colleagues (Cronan, Serber, Walen, & Jaffe, 2002) explored the influence of age on symptoms. They found that pain, depression, and sleep disturbance were significantly more severe in the younger (*n* = 58; aged 20-39 years) and middle-aged samples (*n* = 349; aged 40-59 years) when compared to the older sample (*n* = 189; aged 60-85 years). Yet in the context of comparing these results to other studies, the authors suggested that this finding for more severe symptoms in younger and middle-aged adults may be explained by the generalization that older adults generally report better health than do younger adults, even with more comorbid conditions. This phenomenon is typically attributed to older adults' expectation for having a decline in health and they therefore may consider their symptoms as a normal part of aging. Another possible explanation offered was that with the longer duration of symptoms (the older sample had significantly longer duration than the younger groups), older adults are better able to cope with both the symptoms and the expectations they have for their symptom experiences (Burckhardt, Clark, & Bennett, 2001). One noteworthy finding from the Cronan study was the older sample having significantly more comorbid conditions than both the younger and middle-aged samples, prompting the researchers to include number of comorbid conditions as a covariate in their analyses.

In the other study of symptoms in older adults, Pamuk and Cakir (2005) compared symptoms of fatigue, sleep disturbance, morning stiffness, anxiety, and depression between pre-menopausal and post-menopausal women with FM. The age range was 42 to 74 years (*N* = 54.4 ± 7.7) for the post-menopausal group. There were no significant differences in these symptoms between the two groups, although the post-menopausal group had significantly higher ratings of pain severity. Perhaps the most important findings of this study were that one fourth of the post-menopausal group identified that their FM symptoms started after menopause and 26% of previously diagnosed women reported their FM symptoms worsened with the onset of menopause. With the conflicting nature of these findings, the importance of identifying the comprehensive symptoms experienced by older adults with FM is more crucial than ever. It is imperative that the symptom experience in older adults with FM be described as accurately as possible as it may be different than that of younger adults.

Table 2.4

Studies of Fibromyalgia in Older Adults

Author and Research Design	**Subjects**	**Age (years)**	**Research Questions**	**Measures**	**Results**
Gowin, K. (2000); Descriptive Study	N = 76, geriatric clinic patients, recruited consecutively during routine office visits	Over 60 years; FM = 79.2±6.6, Non-FM= 77.7±7.7	1) Prevalence of FM in geriatric clinic 2) Degree of depression and disability in FM compared to non-FM 3) Chronic illnesses and medications associated with FM	Dolorimetry, medical records review, Geriatric Depression Scale, Health Assessment Questionnaire (HAQ) disability index,	Prevalence: 9.2%; probable FM (defined as all criteria but only 9 or 10 tender points) 23.7%; FM patients significantly different compared to non-FM patients in: -Higher Depression -Higher Disability -Lower satisfaction with health -Fewer average number of blocks walked/week (6.8±14.4 vs. 15.4±19.2) -Greater number chronic illnesses (4.4±2.1 vs. 2.9±1.3)
Cronan, T., Serber, E., Walen, H., & Jaffe, M. (2002); Descriptive Study	N = 600; Compared young, middle-age, and older samples	Y = n = 58; 20-39 years M = n = 349; 40-59 years O = n = 189; 60-85 years	Examined symptoms in young, middle-age, and older FM to determine varying degrees of severity b/t groups	MPQ, CES-D, Pittsburgh Sleep Quality Index, FIQ, Quality of Well-Being Scale; Arthritis Self-Efficacy Scale; Arthritis Helplessness Index	<u>Older sample:</u> -Significantly more comorbid conditions, included as a covariate in analysis; -Longer duration of symptoms -Reported less pain, depression, illness impact, sleep disturbance

Author and Research Design	Subjects	Age (years)	Research Questions	Measures	Results
Pamuk, O., & Cakir, N. (2005); Descriptive Study	N = 152 women with FM dx; 80 premenopausal, 72 postmenopausal	Premen: 36.6+8.3 (15-49); Postmen: 54.4+7.7 (42-74)	Evaluated effects of menopausal status & menstrual cycle on symptoms to determine role of hormonal factors in women with FM	Severity via VAS of CWP, fatigue, parasthesia, sleep disturbance Duration CWP in years Minutes of morning stiffness FIQ Duke anxiety-depression scale Symptom diary	Postmenopausal group: -Higher pain severity -Longer duration of CWP FM symptoms started with onset of menopause in 25% of postmenopausal group Severity of FM symptoms increased in 26.4% with onset of menopause
Valkeinen, H., Alen, M., Hannonen, P., Hakkinen, A., Airaksinen, O., & Hakkinen, K. (2004); Intervention Study	N = 36, 10 healthy controls (HC), 26 FM patients: 13 intervention, 13 control	Criteria: 55+ years (range 55-65), no other disease except FM, no hx strength training exercise; FM = 60.2+2.5, FM controls = 59.1+3.5, HC = 64.2+2.7	Effects of systematic strength training on: 1) Strength and voluntary neural activity of the unilateral knee extensor and flexor muscles; 2) Physical functional capacity; 3) subjectively perceived symptoms	Measures of muscle strength: force-time analysis for average force produced during initial phase of contraction, EMG, Maximal walking speed for 10m, Time to climb 10 stairs w/o handrails, HAQ, tender point exam	Significant increases in maximal extension force, flexion, and explosive force of extensors for both training groups, significant improvement in walking speed, stair-climbing time, and HAQ physical function index

Author and Research Design	**Subjects**	**Age (years)**	**Research Questions**	**Measures**	**Results**
Valkeinen, H., Hakkinen, K., Pakarinen, A., Hannonen, P., Hakkinen, A., Airaksinen, O., Niemitukia, L., Kraemer, W., & Alen, M. (2005); Intervention Study	N = 36, 10 HC, 26 FM patients: 13 intervention, 13 control; same study subjects as described above	FM = 60.2±2.5, FM controls = 59.1±3.5, range 55-65	Effects of strength training on: 1) Muscle strength; 2) cross-sectional area (CSA); 3) muscle activation of leg extensors; 4) serum hormone concentrations	One-rep max of leg extensors; CSA (cm^2) of right QF muscle measured with MRI; EMG, blood samples for serum hormone concentrations (T, FT, DHEAS, GH, IGF-1, cortisol)	FM intervention group showed increases in: -Leg extension force -CSA -EMG activity of knee extensors -Maintained normal serum hormone concentrations (as did control group) -No significant decrease in subjective perceived symptoms in either group
Valkeinen, H., Hakkinen, A., Hannonen, P., Hakkinen, K., & Alen, M. (2006); Intervention – subgroup analysis from study described above	N = 23, 10 HC, 13 FM patients of intervention group from studies described above	55-65, same groups as described above	Examine heavy-resistance exercise-induced acute neuromuscular fatigue, blood lactate concentration, and muscle pain before and after strength training intervention	Heavy-resistance fatigue loading protocol: bilateral dynamic leg press exercise on David 210 machine; EMG; blood samples for blood lactate concentration; 100mm VAS for pain on loading day and on 6 successive days after loading	21-week strength training period: -increased maximal force & EMG activity in muscles - improvement in loading performance -lowered pain level in FM group

Wolfe (1988) and Yunus and colleagues (Yunus, Holt, Masi, & Aldag, 1988) identified early on the complexities of FM in older adults, including the difficulty added by comorbid conditions and unknown implications of the aging process on the FM disease process. However, extensive research has not been conducted in this specific population of FM patients. This lack of study is due in part to the attempts of researchers to reduce the confounding physiologic effects of aging on study outcomes. To learn the “normal” trajectory of this disease, it was necessary to control for confounding comorbid conditions with are often present in older adults.

Comorbidity

As those that have been diagnosed with FM in their forties and fifties over the last 15 years continue to age, it is becoming increasingly important to understand the confounding effects of aging on this disease process for several reasons. Older adults have higher rates of FM when compared to rates in younger adults (Wolfe et al., 1997a). The population of those 65 years and older is projected to grow to 70 million people by 2050 (Federal Interagency Forum on Aging-Related Statistics, 2004), and FM poses a serious health concern for this age group. It is imperative that the impact that comorbid conditions have on the experience of FM symptoms be understood, as increasing age is correlated with an increase in the number of comorbid conditions (Bayliss, Bayliss, Ware, & Steiner, 2004; Fried, Bandeen-Roche, Kasper, & Guralnik, 1999; Guralnik, 1996; Guralnik et al., 1993).

Comorbid conditions associated with aging act as a risk factor for the onset or worsening of FM. For example, osteoarthritis and osteoporotic fractures are potent pain generators that can trigger the persistent pain that ultimately results in the clinical course of FM through central sensitization (Bennett, 2004). Persons over the age of 65 years are disproportionately more likely than their younger counterparts to suffer from diseases that cause musculoskeletal pain, such as osteoporosis and arthritis (Federal Interagency Forum on Aging-Related Statistics, 2004; Gallagher, Verma, & Mossey, 2000). Further, chronic painful illnesses, such as arthritis, are particularly complex for older adults with FM, as central sensitization amplifies the peripheral pain of arthritis (Gowin, 2000). Therefore, understanding the complex nature of FM in older adults must begin with a comprehensive evaluation of symptoms to determine the nature of those symptoms and ultimately the development of the most effective interventions for maintaining physical function.

Comorbid conditions are also likely to have an impact on the relationship between symptom experience and physical function. In a sample of older adults over the age of 60, the proportion of the population reporting two or more of the nine most prevalent medical conditions increased with age (Guralnik, 1989). Of the oldest group (80 years and over), 70% of women and 52% of men had two or more of these conditions. As Guralnik (1996) concluded, since there is no standard list of diseases to consider when assessing comorbidity, the prevalence of comorbidity very much depends on how many conditions are being considered. He urged that, while it may be difficult to assess for comorbid conditions, it is imperative that comorbid conditions be taken into consideration in epidemiologic, descriptive, and clinical studies. Increases in the number of comorbid conditions are predictive of poor physical function, and the presence of comorbidities was expected to be a significant covariate in the analysis for the current study (Bayliss et al., 2004; Fried et al., 1999). For example, the existence of certain comorbid conditions (i.e., osteoarthritis, congestive heart failure, or chronic obstructive pulmonary disease) is likely to result in lower physical function. This study attempted to ascertain the influence of FM symptoms on physical function with the consideration of comorbid conditions.

Physical Function in Fibromyalgia

Physical function is operationalized in this study as the variety of physical abilities, ranging from simple mobility to complex activities, that are expected for community-dwelling persons to live independently by adapting to their environment (Bennett, Winters-Stone, & Nail, 2006; Haley et al., 2002). In fibromyalgia, physical function is a critical variable in the progression of the disease process into the development of disability. With the current limited understanding of the exact pathology and cause of impairments in fibromyalgia, it is important to develop comprehensive interventions that maximize physical function in order to prevent disability.

The complexity of evaluating previous literature on physical function in FM is the lack of consistent language. Physical function, physical activity, physical exercise, and physical fitness are used interchangeably. Physical function is comprised of three distinct dimensions: objective mobility, perceived mobility, and participation in life activities (Bennett, Winters-Stone, & Nail, 2006). Objective mobility encompasses physical actions, perceived mobility is the difficulty with which one identifies the ability to conduct those physical actions, and participation in life activities is the self-report of perceived difficulty maintaining role activities, such as work, hobbies, and gardening. Physical fitness is one aspect of this over-arching definition of physical function, and is determined by measurable fitness characteristics such as aerobic capacity or tests of physical performance. Physical activity or exercise is that activity which contributes to the state of physical fitness and again only comprises part of physical function. While physical activity can lead to improved physical fitness and, in turn, may improve physical function, these concepts are distinct in their definitions.

FM is directly associated with changes in perceived physical function. Those with FM reported more impairment in physical function when compared to healthy controls (Cohen, 2000; Hakkinen, 2001; Kop et al., 2005; Mannerkorpi, Burckhardt, Bjelle, 1994), to those with systemic lupus erythematosus (DaCosta et al., 2000), and to those with low back pain or arthritis (Burckhardt, Archenholtz, Mannerkorpi, & Bjelle, 1993; Laursen, Bajaj, Olesen, Delmar, & Arendt-Nielsen, 2005). Most studies of physical function in FM use the Fibromyalgia Impact Questionnaire (FIQ) for evaluation of the perceived impact of FM on daily functioning. Scores for the FIQ range from 0 to 100, with higher scores reflecting greater negative impact on physical function. Most studies report a range of 50 to 70 for the average perceived negative impact of FM on physical function, with perceived severe impact ranging from 70 and above (Cedraschi et al., 2004; Fitzcharles, Da Costa, & Poyhia, 2003; Wolfe et al., 2000).

In studies of physical function in FM, pain is reported to affect many activities that comprise physical function. Activity levels are inversely related to both pain and fatigue, as well as to overall levels of physical function (Kop et al., 2005). Perceived physical function appears to be contingent on rather than predictive of symptoms (Kop et al., 2005), thereby supporting the investigation of symptoms predicting physical function.

One study of activities in FM found that pain affected 97% of the sample in conducting housework, with 62% needing help to carry out household activities

(Henriksson & Burckhardt, 1996). This study also found that 79% reported being less physically active and spending more time at home due to pain. Many studies evaluated physical activity or physical fitness in FM populations, which are earlier precursors to negative changes in physical function (Culos-Reed & Brawley, 2000; Henriksson & Burckhardt, 1996; Kingsley et al., 2005; Oliver & Cronan, 2005). For example, FM patients scored significantly lower on all variables of physical fitness, including a 6-minute walk test, flexibility, and grip strength, than did healthy controls, even when controlling for pain at rest (Mannerkorpi, Burckhardt, & Bjelle,1994). Balance and gait disturbances are also potential indicators of declines in physical function. Gait disturbances have been reported in FM subjects, with changes found in the muscles used for gait and with walking speeds found to significantly diminish as a result of reductions in stride length and cycle frequency (Auvinet, Bileckot, Alix, Chaleil, & Barrey, 2006; Pierrynowski, Tiidus, & Galea, 2005). Balance was found to be worse in both subjective and objective measures in samples of FM patients, and is known to increase the frequency of falls (Jones, Horak, Winters, & Bennett, 2007).

In studies that compare FM to other persistent pain syndromes, FM populations consistently display lower levels of physical function. Wolfe (1999) found that physical function was lower in those with FM compared to those with osteoarthritis and rheumatoid arthritis. The NFA study (Bennett et al., 2007) revealed that 35% of the sample had difficulty performing activities of daily living, 55% had difficulty walking two blocks, 66% had difficulty with shopping, and 68% had difficulty with light household duties such as cooking or dusting.

Disability, although widely studied in fibromyalgia, is evaluated mostly in terms of work-related disability. These findings are important for appreciating the broad impact of FM on physical function but it is acknowledged that these results clearly lack the multidimensional nature of the more comprehensive definition of disability. Work-disability rates in those with FM are reported to range from 25% to 35% compared to 22% in the overall US population (Bombardier & Buchwald, 1996; Centers for Disease Control, 2001; White, Nielson, Harth, Ostbye, & Speechley, 2002b; White, Speechley, Harth, Ostbye, 1999; Wolfe et al., 1997c). The NFA study found that nearly a third of the sample (29%, *n* = 753) reported having filed for disability, and almost one half of the sample (45%, *n* = 1167) perceived they were unable to work due to FM (Bennett et al., 2007). The London Fibromyalgia Epidemiology Study found significant differences in disability when those with FM were compared to pain controls with recent general widespread pain and general controls with no recent pain (White, Speechley, Harth, Ostbye, 1999). Significant findings included reported work disability by 31% of those with FM compared to 10.5% of the pain controls and 2.2% of the general controls; those with FM were four times more likely to be “disabled” than were those without FM.

Physical Function in Older Adults

In conjunction with the dangers of poor physical function in FM patients, poor physical function has even more serious implications for older adults. Older adults’ ability to function independently in the community has been identified as a significant public health issue, given that a certain level of physical functioning is required for older adults to remain living in the home (Guralnik et al., 1996). In populations of older adults, persistent pain is strongly associated with lower physical function (Bennett, 2002;

Bennett, Stewart, Kayser-Jones, & Glaser, 2002; Bookwala et al., 2003; Jakobsson, Klevgard, Westergren, & Hallberg, 2003), loss of mobility (Guralnik et al., 2000; Guralnik, Ferrucci, Simonsick, Salive, & Wallace, 1995; Lamb et al., 2000; Tinetti, Inouye, Gill, & Doucette, 1995), and higher levels of disability (Al Snih, Raji, Peek, & Ottenbacher, 2005; Tsai & Means, 2005). When compared to those without pain, older adults with persistent pain reported two to three times as many problems with walking and up to twice as many problems with impaired mobility (Jakobsson, Hallberg, & Westergren, 2004; Jakobsson et al., 2003). Using a general measure of function, studies of physical function in older adults have consistently reported greater declines in function for those with persistent pain than for those without pain (Al Snih et al., 2005; Croft, Jordan, & Jinks, 2005; Jakobsson et al., 2004). Older adults with lower levels of physical function are four to five times more likely to have significant limitations within 3 to 4 years compared to those with higher levels of function (Fried et al., 1996; Guralnik et al., 1995; Guralnik, Fried, & Salive, 1996).

Decreased physical function also has important implications for utilization of health care and associated costs for older adult populations with FM. Older adults making a transition to some type of dependency in ADLs utilize an additional $26.1 billion in Medicare claims, and incur long-term care costs up to six times that of those not transitioning to any dependent states (Guralnik, Alecxih, Branch, & Wiener, 2002). There is also a significant cost associated with informal caregiving requirements of those needing assistance due to declining physical function (Chiu, Shyu, & Liu, 2001; Chiu, Tang, Shyu, Huang, & Wang, 2000; Hayman et al., 2001). Potential cost implications not only depend on the prevalence of disability, but also the severity of that disability (Spillman, 2004). Those requiring more intensive assistance incur higher care-associated costs (Spector & Fleishman, 1998).

Conceptual Framework

Historically, most conceptual models guiding studies of FM were centered on persistent pain models and how symptoms such as fatigue, depression, and anxiety contribute to the cycle of pain (Hughes, 2006; McLean, Clauw, Abelson, & Liberzon, 2005). Traditional symptom management research has been conducted by evaluating only one or two symptoms at a time (Croft, Jordan, & Jinks, 2005; Parmelee, Katz, & Lawton, 1991; Phillips, 2000; Williamson & Schulz, 1992). This work establishing correlations between single symptoms has been important for determining how they are related. However, the limitation of these approaches lies in that, most often, multiple symptoms are experienced simultaneously (Bennett, 2002; Jakobsson, Klevgard, Westergren, & Hallberg, 2003; Wilcox et al., 2000). Research focusing on pain as a primary outcome has the potential to misunderstand key symptom experiences that are comprised of multiple symptoms. Not every person experiences the same set of symptoms the same way (Call-Schmidt & Richardson, 2003; Phillips, 2000; Reid, Williams, & Gill, 2003; Williamson & Schulz, 1992). Thus, single symptom correlation fails to explain much of the symptom experience of persons with complex conditions such as FM.

The conceptual framework for this study was drawn from three frameworks: the Theory of Unpleasant Symptoms, the Symptom Management Model, and the Concept of the Symptom Experience. The Theory of Unpleasant Symptoms was the first to introduce the idea of multiple dimensions of symptoms and introduced the idea of a comprehensive symptom experience (Lenz, Pugh, Milligan, Gift, & Suppe, 1997; Lenz, Suppe, Gift, Pugh, & Milligan, 1995). The Symptom Management Model expanded on the idea of multiple dimensions of the symptom experience to include the influence not only of the symptom experience, but also of symptom management strategies and of outcomes (Dodd, Janson et al., 2001; Miaskowski, Dodd, & Lee, 2004). The Concept of the Symptom Experience builds on one of the dimensions of the Symptom Management Model, that of the “symptom experience” (Armstrong, 2003).

The Theory of Unpleasant Symptoms

The Theory of Unpleasant Symptoms (TOUS) (Lenz et al., 1997) theorizes that whereas symptoms can occur in isolation from one another, more often multiple symptoms occur simultaneously with the comprehensive symptom experience being different than an isolated symptom experience. The theory hypothesizes that three key interrelated variables act as antecedents to the symptom experience: physiologic factors, psychologic factors, and situational factors. These factors influence each individual symptom, and every symptom is multidimensional in nature. The dimensions comprising the individual symptom include intensity, timing, distress, and quality. As described in the review of literature, the current study will focus on the dimensions of frequency, intensity, and distress.

One premise of TOUS is that symptoms can be evaluated individually and in relationship to the occurrence of other symptoms (Gift, Jablonski, Stommel, & Given, 2004; Lenz et al., 1997). This interrelationship of symptoms ultimately manifests in consequences of the symptom experience. According to the theory, these outcomes of the symptom experience are described as functional and cognitive performance, and include physical activity, activities of daily living, role-related tasks, concentration, thinking, and problem-solving (Lenz et al., 1997). The current study will limit the outcome to the functional performance, focusing on perceived physical function.

The Symptom Management Model

The Symptom Management Model (Dodd, Janson et al., 2001) is based on the premise that effective management of symptoms can be achieved by addressing the three key dimensions of symptom management: symptom experience, symptom management strategies, and outcomes. The collective impact of the three dimensions of this model has a bi-directional relationship with each of the other dimensions.

Symptom experience. The symptom experience includes perceptions of symptoms, evaluation of symptoms, and responses to those symptoms. Perception is the awareness of a change in the way one usually feels. Perception can occur by the person experiencing the symptom, by a family caregiver or parent, or by a health care provider. Complexities of this dimension arise when the perceptions of these three groups of people are incongruent with one another and approaches to management of symptoms conflict. Evaluation includes personal judgment of the meaning of the symptoms. Evaluation can occur for symptom characteristics such as severity, duration, and frequency or for more subjective areas such as the threat imposed by a symptom or the meaning of the symptom in terms of physical function or quality of life. Responses to symptoms include physiological, psychological, or behavioral changes made due to symptoms. Changes in response to symptoms can include anything from changes in breathing patterns due to dyspnea to using assistive devices for pain during ambulation.

Symptom management strategies. A wide range of strategies can be applied to symptom management. Components of these strategies include: the nature of the intervention strategy; the intervention dose; when, where, and how the intervention is to be delivered; and why it is to be delivered. It is important to note that strategies may need to be altered over time due to changes in perception, evaluation, or progression of disease.

Outcomes. The model focuses on eight different factors of the outcome dimension. These include functional status, self-care, costs, quality of life, morbidity and comorbidity, mortality and emotional status. Although the diagram of the model does not indicate directional influences of any of these eight factors, it is inferred that each factor may be related to or dependent upon the other factors.

The current study pulls from several of the relationships in these dimensions. The perception of symptoms as described by the Symptom Experience dimension drives the subjective nature of the symptom dimension reports of frequency, severity, and distress. As well, the Outcomes dimension drives the outcome variable of the current study of perceived physical function as a functional status factor.

The Concept of the Symptom Experience

From the Symptom Management Model, the Concept of the Symptom Experience has evolved. This concept refers to recognition of the expression of all occurring symptoms (Armstrong, 2003; Armstrong et al., 2004). The Concept of the Symptom Experience acknowledges the potentially synergistic influence of multiple symptoms on one another, in that the combined action of two or more symptoms can be greater than the sum of their effects individually. In a concept analysis of the Symptom Experience, Armstrong (2003) described the occurrence of symptoms as a multiplicative condition, meaning that two or more symptoms have a catalytic effect on one another, and that they may act as potential catalysts for the occurrence of other symptoms. According to the Concept of the Symptom Experience, interventions for symptom relief must be based on the experience of multiple concurrent symptoms and not based on individual symptoms in isolation of one another.

The current study pulls from the Concept of the Symptom Experience the idea that multiple symptoms must be evaluated to determine an outcome. This study will determine the relationship between multiple symptoms and perceived physical function. This study lays the groundwork for future work exploring the potentially catalytic or multiplicative effects of these symptoms on physical function.

Conceptual Framework for the Fibromyalgia Symptom Experience

The Conceptual Framework for the Fibromyalgia Symptom Experience (see Figure 2.2) draws from the theoretical frameworks described, with the pictorial design based on the TOUS (Lenz et al., 1997). The major concepts pulled from the TOUS include the ideas that symptoms do not occur in isolation from one another and that every symptom is multidimensional in nature. The concepts of the Symptom Management Model used in the current conceptual model are the ideas that each symptom experience consists of perceptions of symptoms, evaluation of those symptoms, and responses to those symptoms (Dodd, Janson et al., 2001). Finally, the concepts drawn from the Concept of the Symptom Experience focus on the synergistic influence of multiple symptoms on one another and the need to recognize the expression of all occurring symptoms (Armstrong, 2003; Armstrong et al., 2004).

The key assumption of the current conceptual framework was that various symptoms may combine differently and potentially result in unique symptom experiences for middle-aged and older adults with FM. This study lays the foundation for a later program of research on symptom clusters in older adults with FM by describing the symptoms in this population and how those symptoms might differ from their younger counterparts. Current methods of symptom assessment do not fully capture the multiple dimensions of symptoms, thereby potentially missing joint relationships that are not linear in nature.

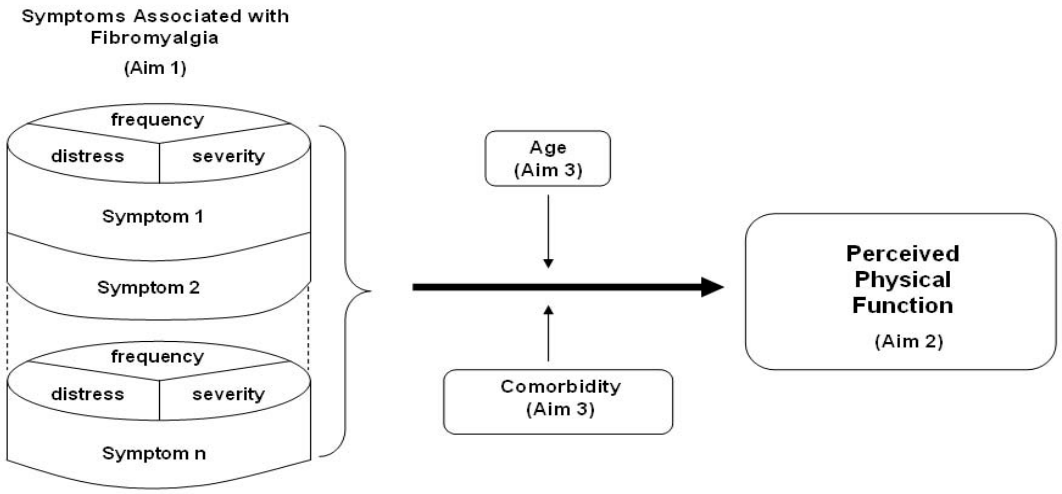


Figure 2.2

Conceptual Framework of Fibromyalgia Symptom Experience informed by Symptom Management Model, the Theory of Unpleasant Symptoms, and the Concept of the Symptom Experience

The model in Figure 2.2 depicts the dimensions of frequency, severity, and distress comprising each individual symptom. All symptoms are described in terms of these three dimensions according to Aim 1 of the study. Symptoms are evaluated in terms of the ability to predict perceived physical function in Aim 2 of the study. Finally, the third Aim determines if there is a moderating effect of comorbidities and age by comparing the relationship between symptoms and physical function for those 50 to 64 years of age to those 65 and over.

The premise of this study was based on the assumption that the occurrence of symptoms is multiplicative rather than additive. This assumption means that two or more symptoms occurring at the same time potentially act as catalysts for one another, producing a different symptom experience outcome when compared to the experience of a single symptom occurring in isolation. This occurrence of multiple concurrent symptoms necessitates the evaluation of the comprehensive fibromyalgia symptom experience. Future research will use the data from this study to understand the hypothesized intermediary step between the Fibromyalgia Symptom Experience and level of physical function, and ascertain whether the symptom experience results in identifiable clusters of symptoms (symptom clusters) experienced differently by the FM population of middle-aged adults compared to older adults.

Summary

Considering that the population of those 65 years and older will double by 2050, growing to 70 million people and comprising one fifth of the population (Federal Interagency Forum on Aging-Related Statistics, 2004), FM poses a serious threat to the independence of older adults. The importance of research on the comprehensive symptom experience of FM posits that multiple symptoms, not just persistent pain, contribute to declines physical function. Therefore, researchers must be able to address multiple concurrent symptoms when developing interventions for the prevention of poor physical function in older adults with FM.

Mounting evidence supports that FM is probably under recognized in hospitalized patients and in older adults in the general population (Buskila et al., 2001; Gowin, 2000), and is possibly misdiagnosed due to the prevalence of comorbid conditions in older adults. FM has been reported in up to 44% of patients with primary Sjogren's, 30% of patients with systemic lupus erythematosus and, 18% of patients with rheumatoid arthritis (Dohrenbusch, Gruterich, & Genth, 1996; Middleton, McFarlin, & Lipsky, 1994; Wolfe & Michaud, 2004). Recognition of FM in other rheumatic disorders is critically important for clinicians to understand, as misdiagnosis of FM may result in a line of inappropriate and potentially dangerous treatments (e.g. steroids, chemotherapeutics). The misdiagnosis and inappropriate treatments are especially dangerous in older adults and can lead to extreme exacerbations of symptoms.

Costs associated with health care utilization for those with FM range between two to two-and-a-half times more when compared to controls or to those with non-FM health-care-uses (Boonen et al., 2005; Penrod et al., 2004; Robinson et al., 2003), with an annual direct cost of over $20 billion per year (Robinson et al., 2003; White, Speechley, Harth, & Ostbye, 1999b; Wolfe et al., 1997b). Studies indicate that those with FM have significantly more healthcare utilization when compared to those without FM (Boonen et al., 2005; White et al., 1999b). One study found significantly greater total clinical visits by FM patients when compared to matched controls for at least ten years prior to an FM diagnosis, with the number sharply rising from less than 1,500 to 2,500 visits per 100 person-years three years prior to diagnosis (Hughes, Martinez, Myon, Taieb, & Wessely, 2006). Further, the number of prescription medications and the number of diagnostic tests were significantly greater in those with FM compared to those without

(Hughes et al., 2006). Total physician visits by those with FM average from ten to fourteen visits per year (Penrod et al., 2004; Wolfe et al., 1997b), significantly higher than the mean number of three physician visits per citizen found in general populations. Additionally, those with FM are anywhere from one to three times more likely than those with non-fibromyalgia rheumatic disorders to undergo surgical procedures (Wolfe et al., 1997b).

This study conducted a pilot testing of a checklist of FM symptoms querying subjects about symptoms based on the NFA study, and also ascertained the frequency, severity, and distress of those symptoms. Whereas the NFA study provided supportive data on multiple concurrent symptoms not reported on the FIQ, it suffered from the same limitations of previous research in not measuring multiple dimensions of each symptom, not targeting older adults, and not using a standardized measure of physical function.

The current study built on the NFA study, targeting FM patients over the age of 50 years and used the Late Life Function and Disability Instrument, a measure that was correlated with physical performance tests and that comprehensively evaluates physical function in older adult populations. The symptom checklist format was based on the dimensions of the Memorial Symptom Assessment Scale (MSAS), a multidimensional symptom assessment measure for cancer populations (Portenoy et al., 1994). The purpose of this study was not to conduct instrument development, but rather was to determine if there were additional data that would be worthy of such undertaking in a future FM study, as it is possible that the symptoms from the FIQ alone may adequately predict physical function.

CHAPTER 3: METHODS

This cross-sectional descriptive study describes the dimensions of FM symptoms, explores the relationship between symptoms and physical function in a sample of adults with FM, and evaluates the impact age has on those results.

Sample

The sampling goal was to attain 200 participants over the age of 50, drawn from the Oregon Health & Science University (OHSU) FM patient database of over 5,000 community-living FM patients. The database consists of persons diagnosed with FM (ICD-9 729.1) because they had been examined in clinical practice and had participated in previous clinical trials. Addresses were updated frequently due to twelve to fourteen yearly mailings to subjects querying their interest in other FM studies. Over-sampling from zip-code-areas known to have higher percentages of minorities is a technique that has increased minority participation in other studies from this database.

The determination of the age of 50 years was based on research findings that indicated the trajectory of younger FM patients often parallels that of normal aging when compared to healthy controls (Dick, Eccleston, & Crombez, 2002; Grace, 1999; Park, Glass, Minear, & Crofford, 2001; Sephton et al., 2003). The inclusion of those between 50 to 64 years of age aided in data analysis to determine if differences exist in FM symptoms between this group and those 65 years of age and over. Another important reason for the inclusion of those aged 50 years and over was to allow for comparison to other studies of FM in older adults. Of the five studies that specifically examined FM in older adult populations, one study defined older adults as 60 years and over (Gowin, 2000), one study had samples defined as “elderly” that only included participants between 55 to 65 years of age (Valkeinen et al., 2004; Valkeinen, Hakkinen, Hannonen, Hakkinen, & Alen, 2006; Valkeinen et al., 2005), and one study had an “older” group with a mean age of 54.4 years (± 7.7; range 42 to 74 years) compared to a “younger” group (Pamuk & Cakir, 2005). Based on a preliminary review of the database, a comparable division of age groups existed in the sample. Therefore, sufficient numbers in each age group were expected to be available for the analysis.

The sample of adults with FM were selected based on the following inclusion criteria: (1) aged 50 years and older; (2) diagnosis of FM based on the 1990 American College of Rheumatology classification criteria; (3) experience of at least one symptom in addition to pain over the last seven days; and (4) speak and read English.

Sample Size and Power

Power was computed with nQuery Advisor 5.0 (Statistical Solutions, 2006). The power was set for the primary analysis of Aim 2 for predicting perceived physical function after controlling for the effect of pain using each symptom measure separately, i.e. frequency, severity, and distress, for one symptom at a time. The power was set to be able to detect a change in R^2 due to the introduction of a symptom variable for one symptom. Such a regression analysis required a sample size of 55 to identify a change in R^2 of .13, a moderate effect size. A sample size of 392 would be required for detection of a change of .02, a small effect size. A sample size of 100 in each age group will be collected in order to have power to identify an intermediate change of .07 or larger. This way, the study will be powered to identify the symptom measures of primary importance for predicting physical function.

Previous experience in research with this database has yielded a 72% response rate of those participating in research utilizing mailed surveys (Jones, 2002). This is an unusually high rate of response likely due to this group having already been active as research participants in previous studies with the investigators. Mailed surveys typically obtain a lower response rate of 30% (Pedhazur & Schmelkin, 1991). To be conservative, a response rate of 50% was estimated for this study. Hence, 400 people were initially invited to participate.

The 400 potential participants were randomly selected from the OHSU FM patient database via stratified random sampling techniques. Limits were set on the database to extract those only between fifty and sixty-four years of age. Those remaining were placed into an excel spreadsheet and a selection by random numbers occurred, selecting 200 FM patients to receive the invitation for participation. The same procedure was employed to determine a sample of 200 FM patients, age 65 years and over.

Procedures

The standardized protocol used for previous FM mailed survey studies was used to maximize response rate and minimize missing items. An invitation letter (Appendix A), information sheet (Appendix B) and questionnaire packet (Appendix C) were sent to the 400 potential subjects identified from the OHSU FM database briefly explaining the purpose of the study and subject responsibility. If interested, the participant completed the questionnaire and returned the questionnaire and enclosed raffle ticket for compensation in the stamped return-mailing envelope.

While offering payment to prospective subjects helps to increase participation rates, this offer must be balanced to ensure there is no undue coercion or inducement (Dickert

& Grady, 1999). It is commonly accepted that an amount of money that is not excessive, but rather is calculated on the basis of time or contribution, indicates respect for the time and contribution that research subjects make (Grady, 2001). The estimated time to complete the study instruments was between 45-60 minutes. The participants received a raffle ticket to be returned with the questionnaire packet, with instructions that the ticket was entered into a drawing with three potential gifts: a $100, $50, or $25 gift certificate to a local grocery store.

If subjects did not return the questionnaires, the principal investigator made a single reminder phone call after 4 weeks of the mailing to ask if the subject has questions. In the past, questions were easily resolved and generally included permission to leave a particular demographic or clinical question blank (non-response).

Measures

Data were collected through four self-report measures and a demographic questionnaire bound together in a single questionnaire packet that was mailed to participants. See Table 3.1 for a description of the measures.

Table 3.1

Concepts and Measures

Concept	Measure	Scale Range and Scoring	Estimated Time to Complete
Fibromyalgia Symptoms	Symptom Checklist	29 symptoms; dimension of frequency, severity, distress for each symptom; each dimension measured on 1-4 or 0-4 Likert scale with higher numbers indicating higher level of intensity	15 minutes
Pain Severity	Brief Pain Inventory (BPI)	12-items: 4 items 0-10 pain rating scales for worst, least, average & now; 7 items 0-10 interference scales with various activities; 1 item % relief from medications; Overall subscale scores calculated with arithmetic average of severity & interference items	5 minutes
Perceived Physical Function	Late Life Function and Disability Instrument (LLFDI): Function Component	32-items with 5-1 rating scale; lower score indicates more limitations in function; Transform raw scores to 0-100 scaled scores; Grouped into No (score greater than 76), Slight (score 66-76), Moderate (score 53-66), and Severe (score less than 42) functional limitation	15 minutes
Co-morbidity Conditions	Charlson Comorbidity Index (CCI)	15-items with “No/Yes” responses co-morbid conditions and treatment; Weighted index takes into account number and seriousness of co-morbid disease; Scores range from 0-41, with higher scores indicating more chronic medical conditions.	5 minutes
Demographic Factors	Self Report Investigator Designed	8-items regarding demographic information and medication usage	5 minutes

Fibromyalgia Symptoms

FM symptoms were assessed with a symptom checklist (Appendix C) consisting of 27 symptoms identified in the NFA study and an additional two symptoms identified from pilot data from 10 subjects (Bennett et al., 2007). The checklist is comprised of frequency, severity, and distress dimensions for each symptom. This checklist provided information on other symptom dimensions not addressed with the Fibromyalgia Impact Questionnaire (FIQ), the standard assessment of the impact of FM symptoms (Burckhardt, Clark, & Bennett, 1991).

Pain Severity

Pain was measured using the Brief Pain Inventory (BPI) (Cleeland & Ryan, 1994; M.D. Anderson Cancer Center, 2004). The BPI (Appendix C) has two subscales, one measuring the severity of pain (4 items), and the other measuring the interference due to pain (7 items). This instrument was originally developed for cancer pain patients and has been validated for use with FM, arthritis pain, diabetic neuropathy, postherpetic neuralgia, and persistent non-malignant pain, and has been validated for use specifically with older adults (Arnold et al., 2002; Coplan et al., 2004; Tan, Jensen, Thornby, & Shanti, 2004; Zelman, Gore, Dukes, Tai, & Brandenburg, 2005). Internal consistency was reported with Cronbach’s alpha = 0.87 for severity items and 0.91 for interference items (Cleeland & Ryan, 1994; M.D. Anderson Cancer Center, 2004). Test-retest reliability correlations have ranged from .62 to .86 in instrument development studies (Daut, Cleeland, & Flanery, 1983).

Perceived Physical Function

Perceived physical function will be measured with the Late Life Function and Disability Instrument (LLFDI) (Haley et al., 2002; Jette et al., 2002). This measure was specifically designed for evaluative purposes in older adult populations. The LLFDI has been correlated with physical performance tests used to determine level of physical function and is supported as an effective substitute when physical testing is not possible

(Sayers et al., 2004). While the FIQ does have a physical function subscale, it has poor validity when compared to objective measures of physical function (Bennett, 2005). The LLFDI was selected over other measures of perceived physical function used previously in FM research, such as the SF-36, Arthritis Impact Measurement, Arthritis Self Efficacy Scale or the function subscale of the FIQ, because of the comprehensive theory-driven development of the instrument. The LLFDI clearly classifies levels of perceived physical function along a continuum of function categories (see Table 3.1). This measure overcomes the lack of sensitivity to detect individual ability over a range of physical function as opposed to other commonly used measures that only identify poor function (Sayers et al., 2004).

The LLFDI (Appendix C) is a self-report measure of perceived physical function developed specifically for use with older adults, but has yet to be tested in FM. The LLFDI has two subscales, the Disability Component and the Function Component. For this study, analysis focused on the Function Component. Factor analysis revealed three separate factors within this component: upper extremity, basic lower extremity, and advanced lower extremity (Haley et al., 2002). Scoring included an overall perceived function score and separate scores for each of these three domains. Internal consistency has ranged between .63 and .86, test-retest reliability reported at above .90, and adequate concurrent, predictive, and content validity have all been reported in samples of older adults (Dubuc, Haley, Ni, Kooyoomjian, & Jette, 2004; Haley et al., 2002; Jette et al., 2002; McAuley, Konopack, Motl, Rosengren, & Morris, 2005; Sayers et al., 2004). To date, this measure has not been used specifically in FM research.

Comorbidity

The Charlson Comorbidity Index (CCI) (Charlson, Pompei, Ales, & MacKenzie, 1987), a weighted index originally developed to predict mortality, measured other medical conditions that can affect the physical function of the participants. The CCI (Appendix C) is used frequently in research, and a validated self-report version (Katz, Chang, Sangha, Fossel, & Bates, 1996), with test-retest reliability ranges between .91 - .92, was used in this study. To date, this measure has not been used specifically in FM research.

Demographic and Clinical Data

Data collection included year of diagnosis with FM, years with FM symptoms (which is usually longer than year diagnosed since diagnostic criteria were not published until 1990), age, race/ethnicity, gender, height in inches without shoes, and weight in pounds. Potential bias in self-report of height/weight did exist, but this method of self-report is often used in large epidemiologic studies. The added burden of height/weight check by a research assistant would have significantly increased the timetable of this dissertation study. Information was also collected regarding current pharmacologic and non-pharmacologic therapies.

Data Analysis

Questionnaires were entered into SPSS version 15.0. There was 100% data verification conducted with a research assistant.

Aim 1

Aim 1 was to describe a comprehensive set of symptoms in terms of the frequency, severity, and distress. Descriptive statistics and plots were used to describe the frequency, severity, and distress of each symptom experienced within the sample and for the demographic information.

Aim 2

Aim 2 was to explore which symptoms best predict physical function.

> *Hypothesis: increased frequency, severity, and distress of symptoms experienced will result in decreased physical function.*

Scores on frequency, severity and distress for each symptom were combined to create a composite symptom severity score. Although this checklist was patterned from the Memorial Symptom Assessment Scale (MSAS), (Portenoy et al., 1994), this was the first use of this checklist, and it is not yet known which symptom dimensions can be combined to form subscale scores. Therefore, instead of calculating averages from certain specified symptom dimensions as is conducted with the MSAS for analysis and interpretation of the data, a total composite score was calculated as a total of all three dimension scores.

Hierarchical regression modeling was used to examine influence of each symptom on physical function. Pain was entered in step 1 (Brief Pain Inventory severity subscale) and the symptom of interest was entered in step 2 to determine the influence of that symptom on physical function over and above the impact of pain. Separate regressions were conducted for each symptom. The final regression included all symptoms entered simultaneously in step 2 to determine the effects of each symptom on physical function controlling for all other symptoms.

Aim 3

Aim 3 was to examine the relationship between age, co-morbidity, symptoms, and physical function.

> *Hypothesis: This exploratory aim will examine whether age and/or the presence of co-morbid conditions moderate the relationship between symptoms and physical function.*

The impact of age and co-morbidity on the results for the analyses conducted as part of Aim 2 were assessed by hierarchical multiple regression. The moderating effect of age and co-morbidity on the relationship between symptoms and physical function was evaluated in two different sets of analysis. In the first set, the correlation between age and physical function was evaluated. As this correlation was not statistically significant, there was no moderating effect. In the next set of analyses, the correlation between comorbidity and physical function was evaluated. This statistically significant correlation led to the analysis of the moderating effect of comorbidity on the relationship between symptoms and physical function. The interaction term between comorbidity and each individual symptom identified in the regression model did not explain a statistically significant amount of the variance in physical function; therefore, a moderating effect of comorbidity on the relationship between symptoms and physical function was not present.

CHAPTER 4: RESULTS

This study utilized a descriptive, cross-sectional design in a sample of community-living adults, over 50 years of age, and diagnosed with FM. This chapter is organized by specific aims.

Sample Description

533 questionnaires were mailed between April and July 2007 and 171 questionnaires were returned (39% response rate). Twice as many respondents were middle-aged (n = 114; 50 to 64 years of age) than older aged (n = 57; 65 years of age and older). The overall sample was predominantly female (96.5%), Non-Hispanic/Non-Latino (75.4%), and Caucasian (95.3%) with a mean age of 60.78 years (SD=6.21) (Table 4.1).The mean duration of FM symptoms was 8.5 ± 12.4 years, and 68.4% of the sample was either overweight or obese. The sample reported a mean number of symptoms of 19.9 ± 5.4 out of a possible total of 29 symptoms. The mean physical function score from the Late Life Function and Disability Instrument (LLFDI) Function Component was 52.7 ± 9.0 on a 0 to 100 point-scale, indicating a moderate functional limitation of the sample based on the scoring criteria of the LLFDI. The mean co–morbidity score from the Charlson Comorbidity Index (CCI) was 1.7 ± 1.5, on a 0 to 41 point-scale, indicating few chronic conditions other than FM.

Table 4.1

Descriptive Data for Total Sample and Between Age Groups

Demographic Variable		**n of total sample (%) *or* mean +/- SD (Range) n = 171**	**Middle-Aged Group n = 114**	**Older-Aged Group n = 57**
Gender	Female Male	165 (96.5%) 6 (3.5%)	110 (96.5%) 4 (3.5%)	55 (96.5%) 2 (3.5%)
Ethnicity	Hispanic/Latino Non-Hispanic/Non-Latino Unknown or Not Reported	1 (0.6%) 129 (75.4%) 41 (24%)	1 (0.9%) 86 (75.4%) 27 (23.7%)	0 (0%) 43 (75.4%) 14 (24.6%)
Race	Multiple Races Indicated Asian American Indian/Alaskan Native White	9 (5.3%) 2 (1.2%) 12 (7%) 163 (95.3%)	7 (6.1%) 2 (0.9%) 10 (8.8%) 107 (93.9%)	2 (3.5%) 1 (1.8%) 2 (3.5%) 56 (98.2%)
Body Mass Index	Underweight (below 18.5) Normal (18.5-24.9) Overweight (25-29.9) Obese (30 or higher)	2 (1.2%) 49 (28.7%) 58 (33.9%) 59 (34.5%)	2 (1.8%) 36 (31.6%) 36 (31.6%) 38 (33.3%)	0 (0%) 13 (22.8%) 22 (39.6%) 21 (36.8%)
Age		60.8 ± 6.2 (50 - 76 years)	57.3 ± 4.3 (50 - 64 years)	67.7 ± 2.7 (65 - 76 years)
Number of years with FM Symptoms		21.8 ± 13.2 (4 - 69 years)	19.1 ± 11.6 (4 - 59 years)	27.3 ± 14.5 (8 - 69 years)
Number of years diagnosed with FM		13.3 ± 7.1 (0 - 39 years)	12.3 ± 7.0 (0 – 37 years)	15.4 ± 7.0 (2 - 39 years)
Physical Function scores (0-100)		52.7 ± 9.0 (31.5 - 77.5)	52.8 ± 9.1 (31.5 - 76.0)	52.5 ± 8.9 (32.6 - 77.5)
Co-morbidity scores (0-41)		1.7 ± 1.5 (0 - 7)	1.6 ± 1.5 (0 - 7)	1.8 ± 1.4 (0 – 6)
Number of symptoms (0-29)		19.9 ± 5.4 (6 - 29)	20.6 ± 5.5 (6 - 29)	18.6 ± 5.1 (6 - 29)

Aim 1 Results

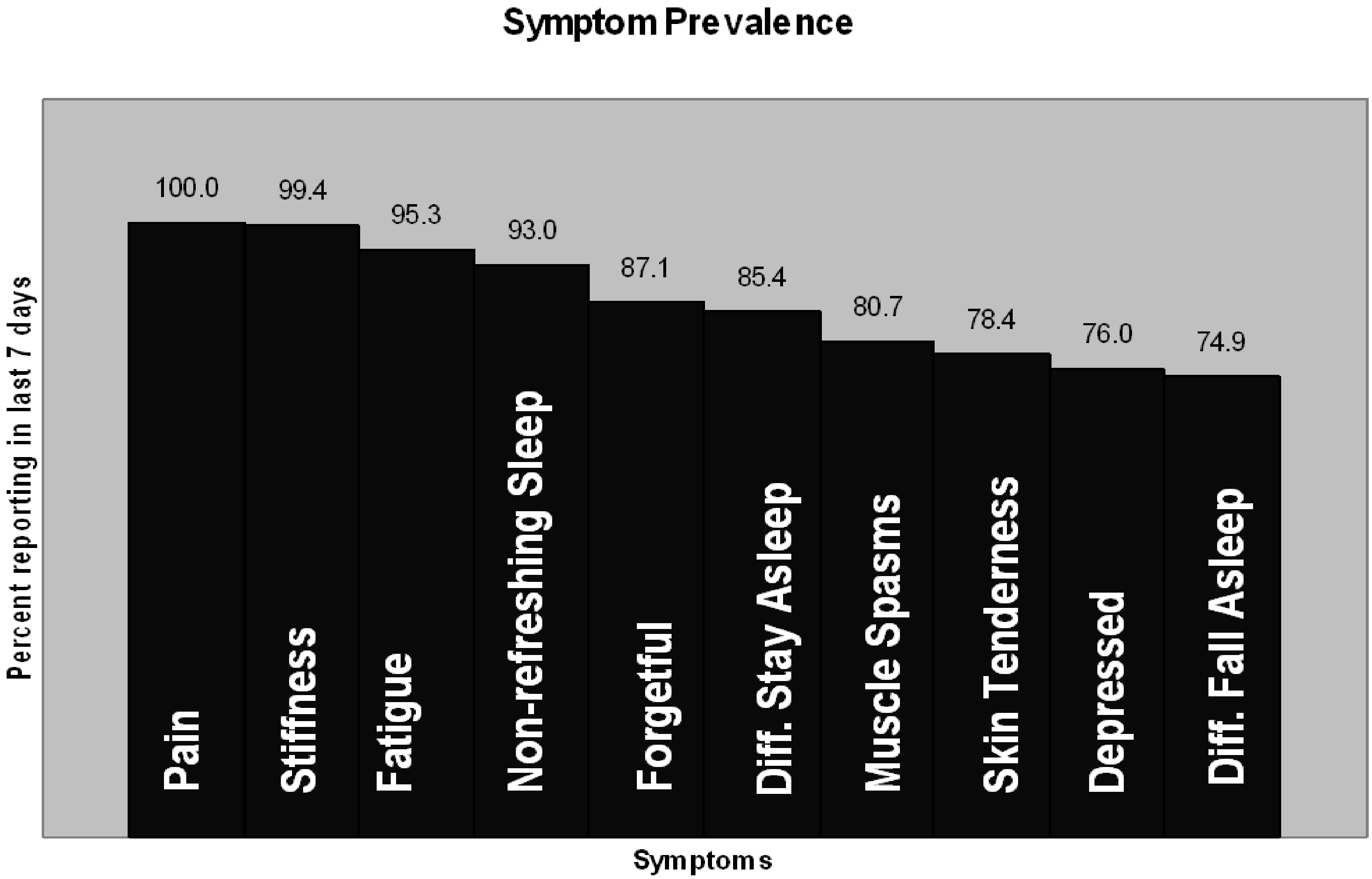
The first aim of this research was to describe a comprehensive set of symptoms in terms of the frequency, severity, and distress (Table 4.2 and Figure 4.1). The symptoms reported by at least 80% of the sample were pain (100%), stiffness (99%), fatigue (95%), non-refreshing sleep (93%), forgetfulness (87%), difficulty staying asleep (85%), and muscle spasms (81%).

Table 4.2. *Descriptive Statistics of the Mean Frequency, Severity, Distress, and Composite Scores of 29 Fibromyalgia Symptoms Ranked in Order of Percentage of Sample Reporting Experience of the Symptom*

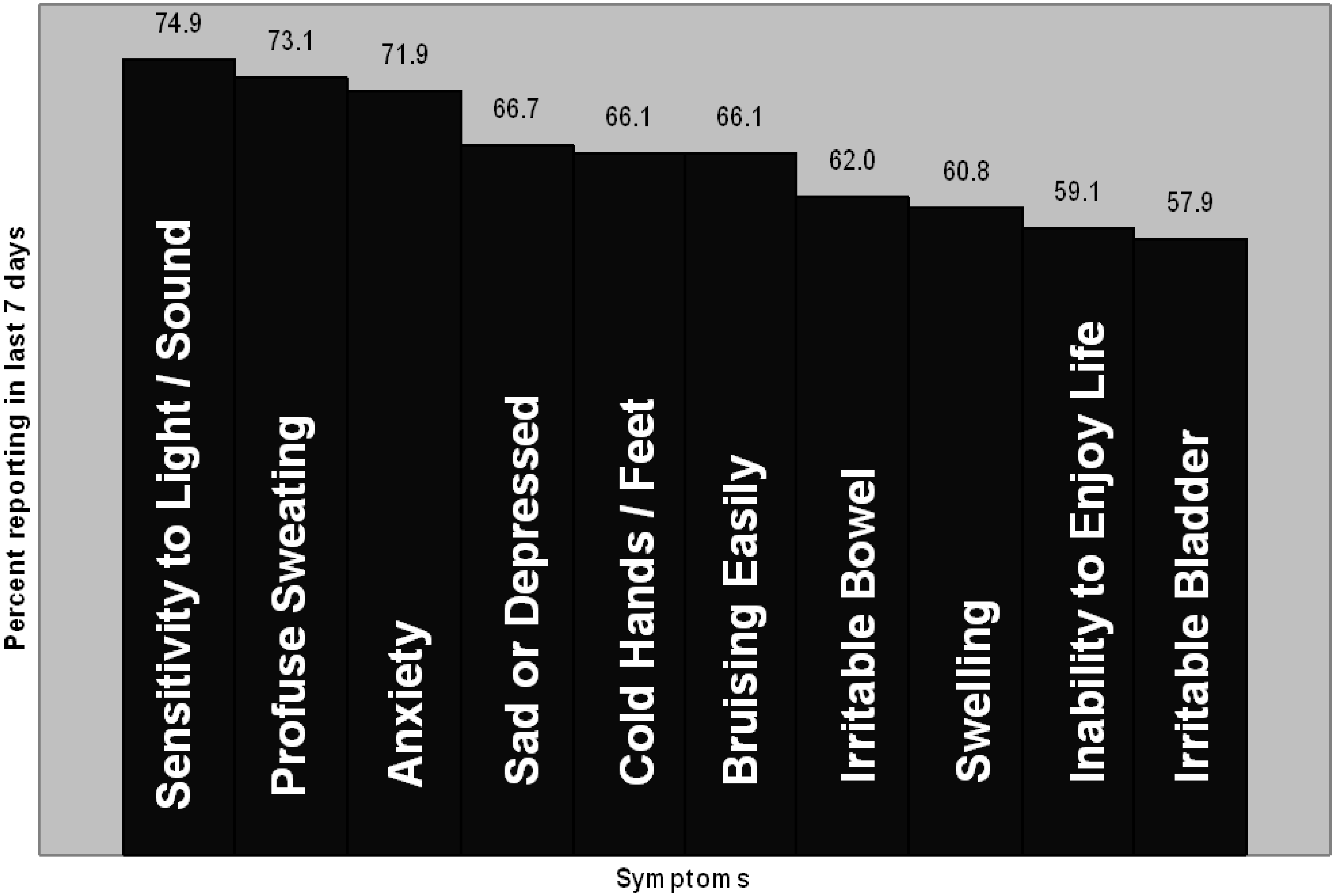
Symptom	**(n)**	**% of Sample Reporting**	**Mean Frequency (1-4) +/- SD**	**Mean Severity (1-4) +/- SD**	**Mean Distress (0-4) +/- SD**	**Mean Composite (0-12) +/- SD**
Pain	171	100	3.43 ± 0.8	2.41 ± 0.8	2.60 ± 1.1	8.45 ± 2.3
Stiffness	170	99	3.22 ± 0.9	2.45 ± 0.9	2.35 ± 1.2	7.99 ± 2.7
Fatigue	163	95	3.37 ± 1.1	2.77 ± 1.1	2.99 ± 1.2	8.69 ± 3.1
Non-refreshing sleep	159	93	3.38 ± 1.2	2.77 ± 1.1	2.87 ± 1.2	8.41 ± 3.4
Forgetfulness	149	87	2.61 ± 1.2	1.95 ± 1.0	2.22 ± 1.3	5.89 ± 3.3
Difficulty Staying Asleep	146	85	3.09 ± 1.4	2.54 ± 1.3	3.08 ± 1.9	6.95 ± 3.8
Muscle Spasms	138	81	2.53 ± 1.3	2.26 ± 1.2	2.26 ± 1.3	5.64 ± 3.6
Skin Tenderness	134	78	2.85 ± 1.4	2.17 ± 1.2	1.95 ± 1.3	5.43 ± 3.7
Difficulty Concentrating	130	76	2.74 ± 1.4	2.26 ± 1.2	2.47 ± 1.4	5.70 ± 3.8
Difficulty Falling Asleep	128	75	3.07 ± 1.6	2.58 ± 1.4	2.50 ± 1.5	6.03 ± 4.3
Sensitivity to Light or Sound	128	75	2.92 ± 1.5	2.39 ± 1.3	2.34 ± 1.5	5.77 ± 4.1
Profuse Sweating or Feeling Hot	125	73	2.75 ± 1.4	2.46 ± 1.3	2.50 ± 1.5	5.65 ± 4.0
Anxious	123	72	2.40 ± 1.3	1.84 ± 1.0	1.87 ± 1.2	4.34 ± 3.4
Sad	114	67	2.51 ± 1.4	2.02 ± 1.2	2.20 ± 1.4	4.45 ± 3.9
Cold Hands	113	66	2.88 ± 1.5	2.28 ± 1.3	2.00 ± 1.3	4.66 ± 4.0
Bruising Easily	113	66	2.79 ± 1.5	2.08 ± 1.2	1.62 ± 1.2	4.26 ± 3.6
Irritable Bowel	106	62	2.73 ± 1.5	2.39 ± 1.3	2.51 ± 1.5	4.75 ± 4.2
Swelling	104	61	2.64 ± 1.5	1.99 ± 1.2	1.86 ± 1.3	3.83 ± 3.7
Inability to Enjoy Life	101	59	2.58 ± 1.4	2.20 ± 1.3	2.54 ± 1.5	4.23 ± 4.1
Irritable Bladder	99	58	2.73 ± 1.5	2.28 ± 1.3	2.35 ± 1.5	4.20 ± 4.2
Falling Easily	99	58	2.39 ± 1.3	1.95 ± 1.1	2.13 ± 1.4	3.72 ± 3.7
Restless Legs	98	57	2.28 ± 1.3	2.07 ± 1.9	2.84 ± 2.0	3.60 ± 3.7
Accident-Prone	97	57	2.18 ± 1.2	1.74 ± 1.0	1.85 ± 1.2	3.24 ± 3.3
Headaches	96	56	2.41 ± 1.4	2.28 ± 1.3	2.19 ± 1.4	3.81 ± 3.9
Easily Angered	94	55	2.18 ± 1.2	1.85 ± 1.1	1.97 ± 1.3	3.27 ± 3.5
Fear of Symptoms Worsening	93	54	2.67 ± 1.5	2.28 ± 1.3	3.24 ± 2.0	3.98 ± 4.2
Feeling Dizzy	90	53	2.03 ± 1.2	1.59 ± 1.0	1.70 ± 1.1	2.75 ± 3.1
Feel Like a Burden to Others	66	39	2.52 ± 1.4	2.27 ± 1.3	2.58 ± 1.5	2.78 ± 4.0
Pelvic Pain	59	35	2.54 ± 1.3	2.02 ± 1.1	1.98 ± 1.1	2.24 ± 3.4

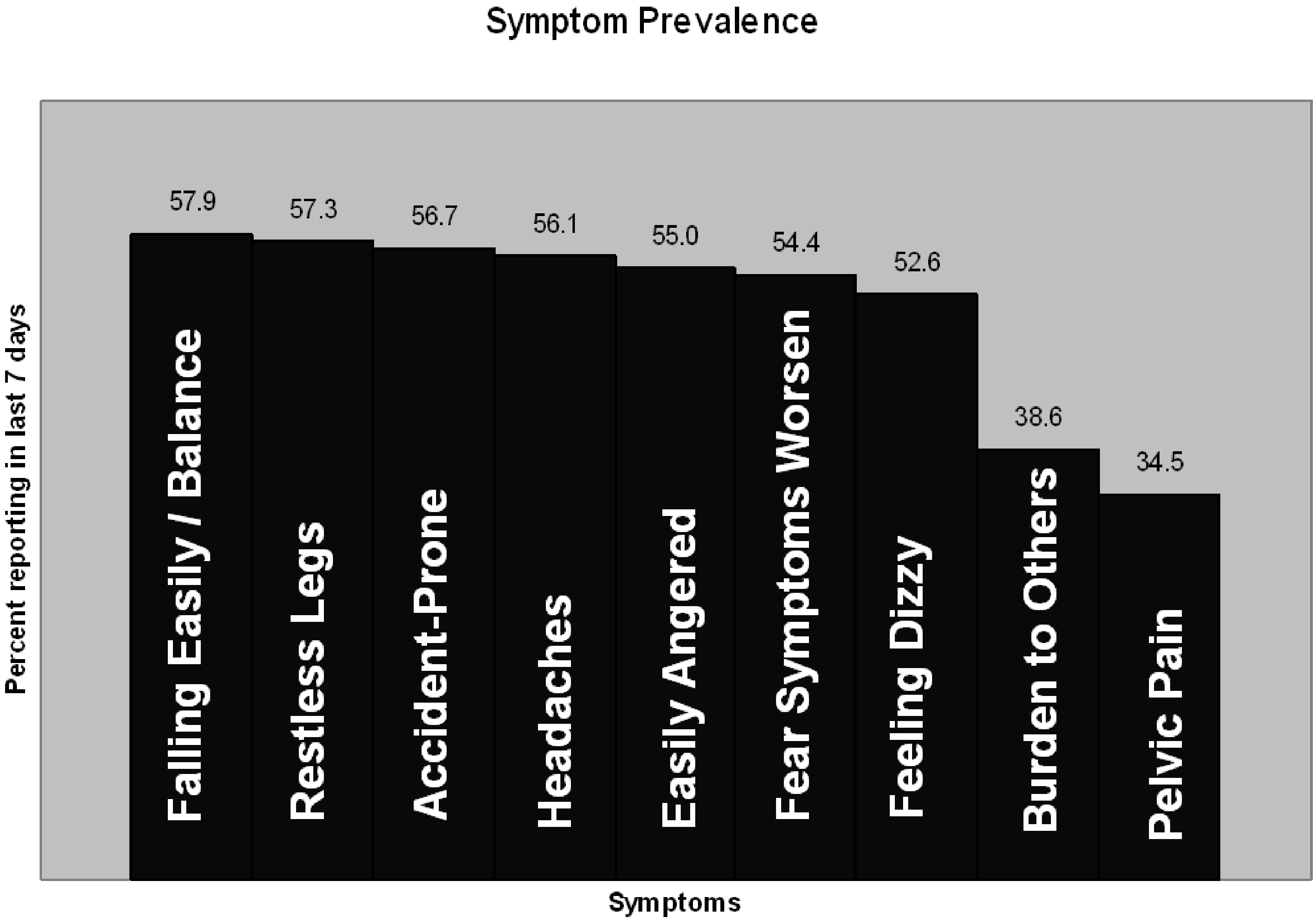
*All dimension score ranges of higher numbers indicate more frequency, severity, distress, or impact

Figure 4.1
Symptoms in Order of Prevalence



Symptom Prevalence




Symptom Prevalence
Percent reporting in last 7 days
Symptoms
57.9
Falling Easily / Balance
57.3
Restless Legs
56.7
Accident-Prone
56.1
Headaches
55.0
Easily Angered
54.4
Fear Symptoms Worsen
52.6
Feeling Dizzy
38.6
Burden to Others
34.5
Pelvic Pain

The symptom dimensions of frequency, severity, and distress differed in rank-order for each symptom. Symptom dimensions were measured on a 1 (least frequent or severe) to 4 (most frequent or severe) Likert scale for frequency and severity, and 0 (least distressing) to 4 (most distressing) Likert scale for distress. Mean frequency scores ranged between 2.03 and 3.43, thereby all 29 symptoms consist of a mean frequency score greater than 2 on the 1 to 4 Likert scale. Mean severity scores ranged between 1.59 and 2.77, significantly lower than the mean frequency scores ($t_{(170)}$ = 31.46, p = .00). Mean distress scores ranged between 1.62 and 3.24 on the 0 to 4 Likert scale, and were also significantly lower than the mean frequency scores ($t_{(170)}$ = 26.76, p = .00).

The most frequent symptoms were pain (3.4 ± .8), non-refreshing sleep (3.38 ± 1.22), fatigue (3.37 ± 1.11), stiffness (3.22 ±.87), difficulty staying asleep (3.09±1.38), and difficulty falling asleep (3.07±1.59) (Table 4.3). However, the most severe and most distressing symptoms did not mirror those most frequent. Instead, the most severe symptoms were non-refreshing sleep (2.77±1.13), fatigue (2.77±1.05), difficulty falling asleep (2.58±1.40), difficulty staying asleep (2.54±1.26), profuse sweating (2.46±1.34), stiffness (2.45±.92), and pain (2.21±.79) (Table 4.4). The most distressing symptoms were fear of symptoms worsening (3.24±1.34), difficulty staying asleep (3.08±1.26), fatigue (2.99±1.18), non-refreshing sleep (2.87±1.23), restless legs (2.84±1.22), and pain (2.6±1.08) (Table 4.5).

Of note, although pain is the most frequent symptom, and reported by 100% of the sample, pain is seventh in order of most severe, and sixth in order of most distressing (Table 4.6). Non-refreshing sleep, the most severe symptom and reported by 93% of the sample, is the second most frequent symptom, and the fourth most distressing. Another inconsistency in the rank-order is noted with profuse sweating, the fifth most severe symptom and reported by 73% of the sample, yet this symptom rank-ordered as 11th for both symptom frequency and symptom distress. Finally, while fear of symptoms worsening was only reported by 54% of the sample and was the 15th most frequent and 12th most severe symptom, this was the most distressing symptom reported by the sample. This same pattern is noted with restless legs, being the fifth most distressing symptom reported, yet is only reported by 57% of the sample and is 26 in the order of most frequent symptoms and 20 in order of most severe symptoms. This finding indicates that while a symptom may not occur frequently in a population of those with FM or be considered to be very severe in nature, it causes those that do have the symptom great distress.

Table 4.3

*Symptoms in Order of Mean Frequency Score from Most to Least Frequent**

Symptom	**Mean Frequency Score**	**n= subjects reporting symptom (% of sample)**
Pain	3.43	171 (100%)
Non-refreshing sleep	3.38	159 (93%)
Fatigue	3.37	163 (95%)
Stiffness	3.22	170 (99%)
Difficulty Staying Asleep	3.09	146 (85%)
Difficulty Falling Asleep	3.07	128 (75%)
Sensitivity to Light or Sound	2.92	128 (75%)
Cold Hands	2.88	113 (66%)
Skin Tenderness	2.85	134 (78%)
Bruising Easily	2.79	113 (66%)
Profuse Sweating or Feeling Hot	2.75	125 (73%)
Difficulty Concentrating	2.74	130 (76%)
Irritable Bowel	2.73	106 (62%)
Irritable Bladder	2.73	99 (58%)
Fear of Symptoms Worsening	2.67	93 (54%)
Swelling	2.64	104 (61%)
Forgetfulness	2.61	149 (87%)
Inability to Enjoy Life	2.58	101 (59%)
Pelvic Pain	2.54	59 (35%)
Muscle Spasms	2.53	138 (81%)
Feel Like a Burden to Others	2.52	66 (39%)
Sad	2.51	114 (67%)
Headaches	2.41	96 (56%)
Anxious	2.4	123 (72%)
Falling Easily	2.39	99 (58%)
Restless Legs	2.28	98 (57%)
Accident-Prone	2.18	97 (56%)
Easily Angered	2.18	94 (55%)
Feeling Dizzy	2.03	90 (53%)

*Scores range from 1 to 4, higher numbers indicate more frequency

Table 4.4

*Symptoms in Order of Mean Severity Score from Most to Least Severe**

Symptom	Mean Severity Score	n= subjects reporting symptom (% of sample)
Non-refreshing sleep	2.77	159 (93%)
Fatigue	2.77	163 (95%)
Difficulty Falling Asleep	2.58	128 (75%)
Difficulty Staying Asleep	2.54	146 (85%)
Profuse Sweating	2.46	125 (73%)
Stiffness	2.45	170 (99%)
Pain	2.41	171 (100%)
Sensitivity to Light or Sound	2.39	128 (75%)
Irritable Bowel	2.39	106 (62%)
Cold Hands	2.28	113 (66%)
Irritable Bladder	2.28	99 (58%)
Fear of Symptoms Worsening	2.28	93 (54%)
Headaches	2.28	96 (56%)
Feel Like a Burden to Others	2.27	66 (39%)
Difficulty Concentrating	2.26	130 (76%)
Muscle Spasms	2.26	138 (81%)
Inability to Enjoy Life	2.2	101 (59%)
Skin Tenderness	2.17	134 (78%)
Bruising Easily	2.08	113 (66%)
Restless Legs	2.07	98 (57%)
Pelvic Pain	2.02	59 (35%)
Sad	2.02	114 (67%)
Swelling	1.99	104 (61%)
Forgetfulness	1.95	149 (87%)
Falling Easily	1.95	99 (58%)
Easily Angered	1.85	94 (55%)
Anxious	1.84	123 (72%)
Accident-Prone	1.74	97 (57%)
Feeling Dizzy	1.59	90 (53%)

*Scores range from 1 to 4, higher numbers indicate more severity

Table 4.5

*Symptoms in Order of Mean Distress Score from Most to Least Distress**

Symptom	**Mean Distress Score**	**n= subjects reporting symptom (% of sample)**
Fear of Symptoms Worsening	3.24	93 (54%)
Difficulty Staying Asleep	3.08	146 (85%)
Fatigue	2.99	163 (95%)
Non-refreshing sleep	2.87	159 (93%)
Restless Legs	2.84	98 (57%)
Pain	2.6	171 (100%)
Feel Like a Burden to Others	2.58	66 (39%)
Inability to Enjoy Life	2.54	101 (59%)
Irritable Bowel	2.51	106 (62%)
Difficulty Falling Asleep	2.5	128 (75%)
Profuse Sweating	2.5	125 (73%)
Difficulty Concentrating	2.47	130 (76%)
Stiffness	2.35	170 (99%)
Irritable Bladder	2.35	99 (58%)
Sensitivity to Light or Sound	2.34	128 (75%)
Muscle Spasms	2.26	138 (81%)
Forgetfulness	2.22	149 (87%)
Sad	2.2	114 (67%)
Headaches	2.19	96 (56%)
Falling Easily	2.13	99 (58%)
Cold Hands	2	113 (66%)
Pelvic Pain	1.98	59 (35%)
Easily Angered	1.97	94 (55%)
Skin Tenderness	1.95	134 (78%)
Anxious	1.87	123 (72%)
Swelling	1.86	104 (61%)
Accident-Prone	1.85	97 (57%)
Feeling Dizzy	1.7	90 (53%)
Bruising Easily	1.62	113 (66%)

*Scores range from 0 to 4, higher numbers indicate more distress

Table 4.6

Symptoms Compared by Rank-order for Frequency, Severity, and Distress Dimensions

Rank Order	Symptom Frequency	Symptom Severity	Symptom Distress
1	**Pain**	***Non-refreshing sleep***	Fear of Symptoms Worsening
2	***Non-refreshing sleep***	Fatigue	Difficulty Staying Asleep
3	Fatigue	Difficulty Falling Asleep	Fatigue
4	Stiffness	Difficulty Staying Asleep	***Non-refreshing sleep***
5	Difficulty Staying Asleep	Profuse Sweating	Restless Legs
6	Difficulty Falling Asleep	Stiffness	**Pain**
7	Sensitivity to Light or Sound	**Pain**	Feel Like a Burden to Others
8	Cold Hands	Sensitivity to Light or Sound	Inability to Enjoy Life
9	Skin Tenderness	Irritable Bowel	Irritable Bowel
10	Bruising Easily	Cold Hands	Difficulty Falling Asleep
11	Profuse Sweating or Feeling Hot	Irritable Bladder	Profuse Sweating
12	Difficulty Concentrating	Fear of Symptoms Worsening	Difficulty Concentrating
13	Irritable Bowel	Headaches	Stiffness
14	Irritable Bladder	Feel Like a Burden to Others	Irritable Bladder
15	Fear of Symptoms Worsening	Difficulty Concentrating	Sensitivity to Light or Sound
16	Swelling	Muscle Spasms	Muscle Spasms
17	Forgetfulness	Inability to Enjoy Life	Forgetfulness
18	Inability to Enjoy Life	Skin Tenderness	Sad
19	Pelvic Pain	Bruising Easily	Headaches
20	Muscle Spasms	Restless Legs	Falling Easily
21	Feel Like a Burden to Others	Pelvic Pain	Cold Hands
22	Sad	Sad	Pelvic Pain
23	Headaches	Swelling	Easily Angered
24	Anxious	Forgetfulness	Skin Tenderness
25	Falling Easily	Falling Easily	Anxious
26	Restless Legs	Easily Angered	Swelling
27	Accident-Prone	Anxious	Accident-Prone
28	Easily Angered	Accident-Prone	Feeling Dizzy
29	Feeling Dizzy	Feeling Dizzy	Bruising Easily

Scores on frequency, severity and distress for each symptom were combined to create a composite symptom impact score ranging between 0 and 12, with higher numbers indicating more overall symptom impact. While pain did not have the highest overall symptom impact, it falls closely behind fatigue, and all three sleep-related symptoms were in high in the rank-order for the most overall symptom impact (Table 4.7). The highest composite scores were for fatigue (8.69±3.11), pain (8.45±2.26), non-refreshing sleep (8.41±3.36), stiffness (7.99±2.66), difficulty staying asleep (6.95±3.84), and difficulty falling asleep (6.03±4.29).

Table 4.7

*Symptoms in Order of Mean Composite Score**

Symptom	Mean Composite Score	n= subjects reporting symptom (% of sample)
Fatigue	8.69	163 (%)
Pain	8.45	171 (%)
Non-refreshing sleep	8.41	159 (%)
Stiffness	7.99	170 (%)
Difficulty Staying Asleep	6.95	146 (%)
Difficulty Falling Asleep	6.03	128 (%)
Forgetfulness	5.89	149 (%)
Sensitivity to Light or Sound	5.77	128 (%)
Difficulty Concentrating	5.7	130 (%)
Profuse Sweating	5.65	125 (%)
Muscle Spasms	5.64	138 (%)
Skin Tenderness	5.43	134 (%)
Irritable Bowel	4.75	106 (%)
Cold Hands	4.66	113 (%)
Sad	4.45	114 (%)
Anxious	4.34	123 (%)
Bruising Easily	4.26	113 (%)
Inability to Enjoy Life	4.23	101 (%)
Irritable Bladder	4.2	99 (%)
Fear of Symptoms Worsening	3.98	93 (%)
Swelling	3.83	104 (%)
Headaches	3.81	96 (%)
Falling Easily	3.72	99 (%)
Restless Legs	3.6	98 (%)
Easily Angered	3.27	94 (%)
Accident-Prone	3.24	97 (%)
Feel Like a Burden to Others	2.78	66 (%)
Feeling Dizzy	2.75	90 (%)
Pelvic Pain	2.24	59 (%)

*Scores range from 0 to 12; higher numbers indicate more symptom impact

Aim 2 Results

The second aim of this study was to examine which symptoms best predict perceived physical function. The hypothesis of this aim was that increased frequency, severity, and distress of symptoms experienced would be associated with lower levels of perceived physical function. Perceived physical function was scored using the LLFDI (Cronbach’s α = .96), with variance of scores in this sample demonstrating a normal distribution (52.7 ± 9.0, range 31.5 to 77.5) (Figure 4.2).

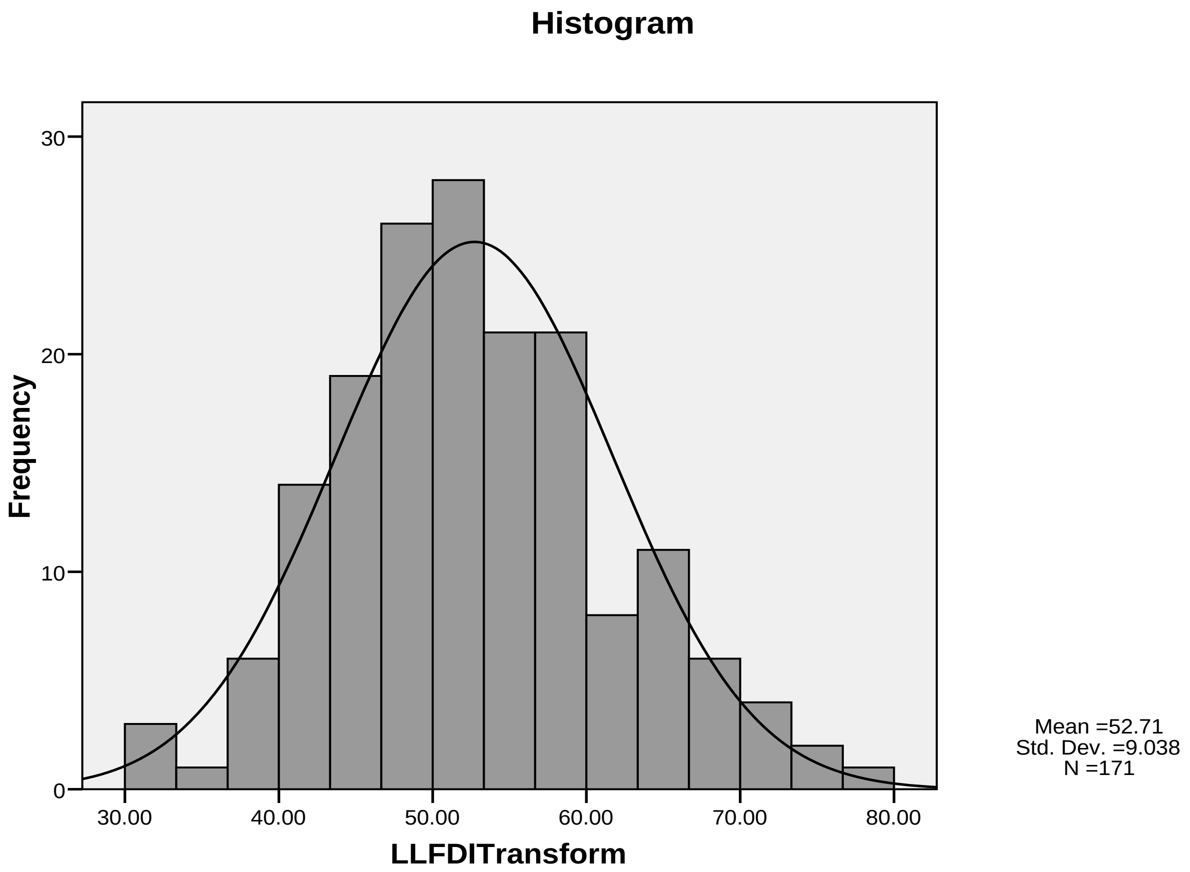


Figure 4.2
Distribution of LLDFI: Perceived Physical Function Scores

Correlation Analyses of Symptoms and Physical Function

Correlations for all symptom composite scores with the transformed physical function score were analyzed for determining which symptom scores to place in the regression model. To reduce the risk of reporting spurious correlations, we chose Pearson correlation coefficients of r = .30 as a conservative cut-off for the criteria of entering symptoms into the regression analysis between the individual symptom composite scores and transformed physical function scores (Tabachnik & Fidell, 2001). This reduction resulted in 15 of 29 symptoms to be included in the final regression analyses. Two of the 15 symptoms were removed for conceptual reasons. These two symptoms, falling and accident-prone, are not causal variables for declines in physical function; rather they are known to be the consequences of declines in physical function (Bennett, Winters-Stone, & Nail, 2006). Of the 13 remaining symptoms, the correlations with physical function ranged from .31 to .39, and all were statistically significant at $p < .01$ (Table 4.8).

Table 4.8

Correlations between Perceived Physical Function Scores and Composite Scores of the 13 Symptoms for Regression Analysis

	Physical Function	Fatigue	Anxiety	Non-refreshing Sleep	Stiffness	Forgetful	Inability to Enjoy Life	Dizziness	Muscle Spasms	Difficulty Falling Asleep	Sad	Feel Like a Burden to Others	Sensitivity to Light, Sound, Smells
Fatigue	-.40**												
Anxiety	-.35**	.36**											
Non-refreshing Sleep	-.38**	.67**	.28**										
Stiffness	-.39**	.36**	.30**	.39**									
Forgetful	-.34**	.42**	.40**	.28**	.35**								
Inability to Enjoy Life	-.39**	.45**	.48**	.36**	.35**	.38**							
Dizziness	-.32**	.22**	.20**	.30**	.25**	.37**	.18*						
Muscle Spasms	-.32**	.27**	.22**	.27**	.28**	.21**	.21**	.20**					
Difficulty Falling Asleep	-.34**	.27**	.25**	.34**	.30**	.25**	.24**	.26**	.33**				
Sad	-.31**	.41**	.63**	.40**	.29**	.49**	.66**	.24**	.24**	.21**			
Feel Like a Burden to Others	-.32**	.39**	.43**	.33**	.24**	.32**	.60**	.16*	.20*	.22**	.60**		
Sensitivity to Light, Sound, Smells	-.31**	.41**	.35**	.44**	.31**	.35**	.27**	.23**	.13	.23**	.39**	.35**	
Fear of Symptoms Worsening	-.36**	.35**	.46**	.36**	.23**	.37**	.49**	.28**	.27**	.28**	.48**	.49**	.30**

** Correlation is significant at the 0.01 level (2-tailed).

* Correlation is significant at the 0.05 level (2-tailed).

Correlations between the 13 symptoms were evaluated to ensure that there were no concerns for multicolinearity. Bivariate correlations that cause concern for multicolinearity in a regression analysis appear in a correlation matrix above .70 to .90 (Tabachnick & Fidell, 2001). The highest correlation between symptoms was .67 between non-refreshing sleep and fatigue. As well, colinearity diagnostics in the regression analysis generated tolerance values for each predictor variable, ranging from .84 to .94 for all 13 individual symptoms. These tolerance values are well above the values of concern for multicolinearity, as values below.25 are considered “worrisome” and values below .10 are “serious” (Katz, 2001).

In order to determine if a single dimension of symptom impact was predominantly responsible for the significant correlations with physical function, we examined the frequency, severity, and distress separately for each of the thirteen symptoms. For twelve of the thirteen symptoms, frequency, severity, and distress correlations were closely aligned (ranging from .24 to .39) with the composite score correlation with physical function (Table 4.9).

Table 4.9

Correlations of Symptom Dimensions with Perceived Physical Function

Symptom	Symptom Dimension	Correlation with Physical Function
Fatigue	Frequency	-.34*
	Severity	-.39*
	Distress	-.39*
Anxiety	Frequency	-.32*
	Severity	-.34*
	Distress	-.35*
Non-refreshing Sleep	Frequency	-.35*
	Severity	-.35*
	Distress	-.37*
Stiffness	Frequency	-.32*
	Severity	-.34*
	Distress	-.39*
Forgetful	Frequency	-.33*
	Severity	-.32*
	Distress	-.32*
Inability to Enjoy Life	Frequency	-.39*
	Severity	-.37*
	Distress	-.37*
Dizziness	Frequency	-.32*
	Severity	-.30*
	Distress	-.31*
Muscle Spasm	Frequency	-.31*
	Severity	-.29*
	Distress	-.29*
Difficulty Falling Asleep	Frequency	-.32*
	Severity	-.34*
	Distress	-.31*
Feeling Sad or Depressed	Frequency	-.25*
	Severity	-.32*
	Distress	-.34*
Feel like a Burden to Others	Frequency	-.32*
	Severity	-.30*
	Distress	-.30*
Sensitivity to Light, Sound, Smell	Frequency	-.24*
	Severity	-.30*
	Distress	-.34*
Fear of Symptoms Worsening	Frequency	-.35*
	Severity	-.35*
	Distress	-.12

*$p < .01$ (2-tailed)

However, the symptom of fear of symptoms worsening did not follow a similar pattern. The fear of symptoms worsening yielded a composite score correlation with physical function of -.36, with a frequency correlation of -.35, a severity correlation of -.35, and a distress correlation of -.10 all correlated with physical function. The distress score was the only correlation that was not significant. The composite score of fear of symptoms worsening was ultimately selected for inclusion, as two of the three symptom dimensions were strongly correlated with physical function. In other words, a single symptom dimension did not appear to drive the composite score in any of the thirteen symptoms.

Regression Model for Variance of Physical Function

In performing the regression analyses, pain severity, using the Brief Pain Inventory (BPI) severity subscale (Cronbach's α = .89), was controlled. Conceptually, pain is known to contribute to physical function, and pain is the defining criteria for the diagnosis of FM. However, level of pain varied in this sample, as expected (5.07±1.8, range 0 to 9.5). Figure 4.3 displays normal distribution of BPI scores. In this sample, pain accounted for 23% of the variance in physical function scores ($p < .001$).

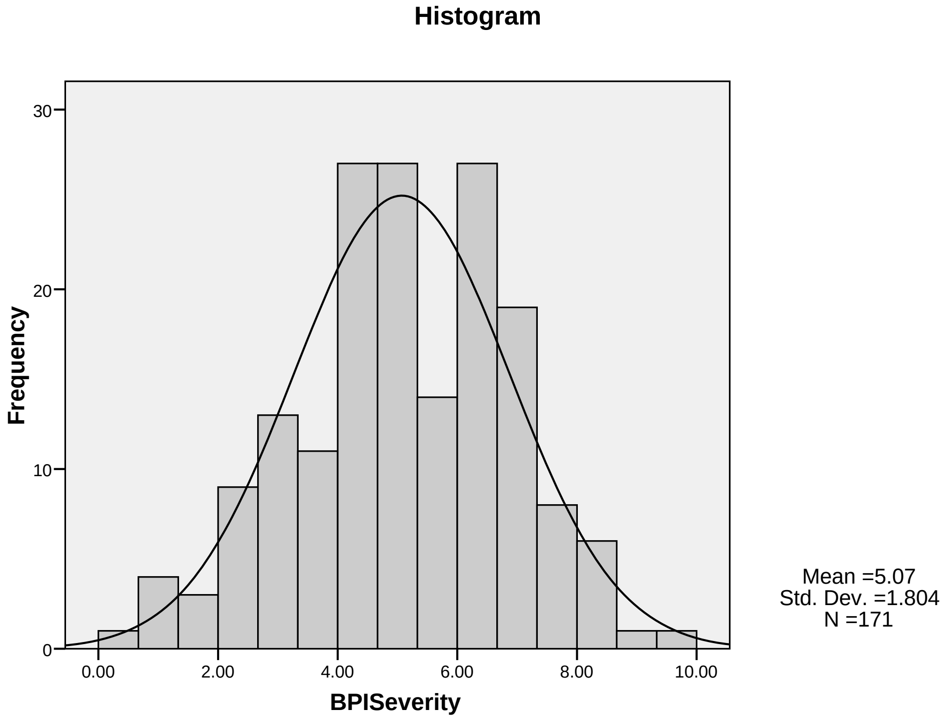


Figure 4.3
Distribution of Brief Pain Inventory Severity Subscale

In order to select the symptoms that contributed the greatest amount of variance to physical function, the theoretical support for entering symptoms into the final model eliminated cognitive and emotional symptoms: forgetful, inability to enjoy life, difficulty falling asleep, feeling sad or depressed, feeling like a burden to others, and fear of symptoms worsening. While it is not known for certain whether emotional symptoms impact physical function, to date no research support exists for the inclusion of these symptoms in a prediction model of physical function.

In the hierarchical regression model, pain was entered in the first step and the remaining symptoms of fatigue, anxiety, non-refreshing sleep, stiffness, dizziness, sensitivity to light, sound, or smell, and muscle spasms were entered in the second step. Results indicate that these seven variables accounted for 15% of the variance in physical function over and above the 23% of variance accounted for by pain (Table 4.10); the model accounts for a total of 38% of the variance in perceived physical function.

Table 4.10
Hierarchical Multiple Regression Analysis: Perceived Level of Physical Function Regressed on Pain and Seven Symptom Composite Scores

Predictor Variable	*b*	Std. Error	Beta	*t*	Significance
BPI Pain	-1.408	.351	-.281	-4.007	.000
Fatigue	-.396	.254	-.136	-1.555	.112
Anxiety	-.355	.185	-.134	-1.916	.057
Stiffness	-.422	.246	-.124	-1.720	.087
Dizziness	-.368	.196	-.126	-1.874	.063
Sensitivity	-.052	.163	-.024	-.320	.749
Non-Refreshing Sleep	-.090	.240	-.034	-.376	.707
Muscle Spasms	-.266	.170	-.105	-1.564	.120

$F = 12.31$ $df = 8, 162$ $p < .001$ $R^2 = .38$ Adjusted $R^2 = .35$

Due to the exploratory nature of this study, to confirm the findings of the hierarchical regression, stepwise multiple regression analyses were conducted. Pain was entered in step 1 and all 13 symptom composite scores in step 2, with physical function as the dependent variable. Both forward selection and backward deletion regression analyses were conducted to compare the models to each other and to the hierarchical regression model. Results indicate that both statistical forward selection (Table 4.11) and backward deletion (Table 4.12) comprise models that closely align with the hierarchical regression model, with exclusion of non-refreshing sleep, sensitivity to light, sound, or smell, and muscle spasms.

Table 4.11

Stepwise Forward Selection Regression Analysis: Perceived Level of Physical Function Regressed on Pain and Symptom Composite Scores

Predictor Variable	*b*	SE	Beta	*t*	Significance
BPI Pain	-1.510	.344	-.301	-4.391	.000
Anxiety	-.390	.181	-.147	-2.155	.033
Stiffness	-.491	.240	-.144	-2.042	.043
Dizziness	-.412	.193	-.140	-2.132	.034
Fatigue	-.510	.204	-.175	-2.494	.014

Table 4.12

Stepwise Backward Deletion Regression Analysis: Perceived Level of Physical Function Regressed on Pain and Symptom Composite Scores

Predictor Variable	*b*	SE	Beta	*t*	Significance
BPI Pain	-1.510	.344	-.301	-4.391	.000
Anxiety	-.390	.181	-.147	-2.155	.033
Fatigue	-.510	.204	-.175	-2.494	.014
Stiffness	-.491	.240	-.144	-2.042	.043
Dizziness	-.412	.193	-.140	-2.132	.034

Tests of the model included evaluation of the underlying assumptions of multiple regression analysis: absence of outliers among the independent and dependent variables, absence of multicolinearity and singularity, independence of errors, and normality, linearity, and homoscedasticity of residuals (Tabachnick & Fidell, 2001). All tests for these underlying assumptions determine that the assumptions were all met with the final regression model. The final model including four predictor variables yields a parsimonious model which accounts for 37% of the variance on perceived physical function (Table 4.13). For roughly each 2 points increase in pain score, perceived physical function decreased by about 3 points. For roughly each 2 points increase in fatigue score, perceived physical function decreased by about 1 point. For roughly each 3 points increase in anxiety score, perceived physical function decreased by about 1 point. For roughly each 2 points increase in stiffness score, perceived physical function decreased by about 1 point. For roughly each 2.5 points increase in dizziness score, perceived physical function decreased by about 1 point. Perceived physical function = 71.290 – 1.510(pain) – .510(fatigue) – .390(anxiety) – .491(stiffness) – .412 (dizziness). The Beta coefficients suggest that while fatigue may be a slightly more important predictor variable, all four symptoms are fairly equal predictors of physical function.

Table 4.13

Hierarchical Multiple Regression Analysis: Final Model of Perceived Level of Physical Function Regressed on Pain and Four Symptom Composite Scores

Predictor Variable	*b*	Std. Error	Beta	*t*	Significance
Constant	71.290	-	-	-	-
BPI Pain	-1.510	.344	-.301	-4.391	.000
Fatigue	-.510	.202	-.175	-2.494	.014
Anxiety	-.390	.181	-.147	-2.155	.033
Stiffness	-.491	.240	-.144	-2.042	.043
Dizziness	-.412	.193	-.140	-2.132	.034

F= 19.167 df = 5, 165 p = .000 $R^2 = .37$ Adjusted $R^2 = .35$

Aim 3 Results

The third aim of this study was to examine the relationship between age, co-morbidity, symptoms, and physical function. This exploratory aim examined whether age and/or the presence of co-morbid conditions moderate the relationship between symptoms and physical function. Although the investigator expected that age might have a moderating effect on perceived physical function, age was not correlated with perceived physical function. Therefore age can have no moderating effect on the relationship between symptoms and perceived physical function.

Symptoms in the Age Groups

The duration of FM symptoms were significantly different between the middle aged and older groups (19 years duration and 27 years duration respectively, $p = .001$). Both groups reported pain, fatigue, and unrefreshing sleep as the most frequently experienced symptoms, and fatigue and unrefreshing sleep as the most severe symptoms. However, differences in the distress caused by symptoms were noted, with fear of symptoms worsening, difficulty staying asleep, and restless legs as the most distressing to the middle aged group, and fatigue, unrefreshing sleep, and irritable bowel as the most distressing to the older group. The middle-aged group experienced a significantly greater number of total symptoms (21.4 ± 5.9 versus 19.3 ± 5.2, $p<.01$), and significantly greater overall symptom impact than the older aged group in five symptoms: difficulty falling asleep, difficulty staying asleep, accident prone, easy bruising and unexplained sweating. Both groups experienced similar rates of moderate functional limitation (middle-aged 52.9 ± 9.2 versus older aged 53.2 ± 8.7, p = *ns*).

Comorbidity in the Age Groups

Comorbidity scores were summed on the Charlson Comorbidity Index (CCI) (Cronbach's $\alpha = .78$), with a potential range of 0 to 41 and higher scores reflecting more chronic conditions. Scores in this sample ranged from 0 to 7, with 77% of the sample having a score of at least one, indicating at least one comorbid condition (Table 4.14). The most common comorbid conditions included osteoarthritis ($n = 85$, 49.7%), thyroid disease ($n = 64$, 37.4%, $n = 52$ hypothyroid), difficulty hearing ($n = 52$, 30.4%), asthma ($n = 41$, 24%), diabetes mellitus ($n = 18$, 10.5%), chronic obstructive lung disease ($n = 15$, 8.8%), stroke ($n = 11$, 6.4%), and rheumatic arthritis ($n = 11$, 6.4%). There was no significant difference in the comorbidity scores between the two age groups ($t_{(169)} = -.59$, $p = .55$). However, comorbidity was significantly correlated with physical function ($r = -.31$, $p = .000$), and as well was significantly correlated with two of the four symptom variables in the final model: fatigue ($r = .21$, $p = .00$), and dizziness ($r = .18$, $p = .02$).

Table 4.14
Comorbidity Information from Charlson Comorbidity Index (CCI)

CCI Score	**(Mean ± SD)**
Total Sample	1.7 ± 1.47
50 to 64 year-old-group	1.6 ± 1.50
65 and older group	1.8 ± 1.42
Range of CCI Scores	**n (% of sample)**
0	40 (23.4%)
1	48 (28.1%)
2	37 (21.6%)
3	29 (17%)
4	9 (5.3%)
5	5 (2.9%)
6	1 (.6%)
7	2 (1.2%)

Regression Model for Variance of Physical Function

Based on the significant correlation between comorbidity scores and perceived physical function scores, additional regression analyses were performed to evaluate the potential moderating effect of comorbidity on the relationship between symptoms and perceived physical function. In the first regression, the BPI severity score was entered in first step, with the CCI comorbidity score entered in the second step. Results indicate that comorbidity accounted for 6.8% of the variance in physical function over and above the 23% of variance accounted for by pain (Table 4.15).

Table 4.15
Hierarchical Multiple Regression Analysis: Perceived Level of Physical Function Regressed on Pain and Comorbidity Scores

Predictor Variable	*b*	Std. Error	Beta	*t*	Significance
BPI Pain	-2.38	.34	-.48	-7.03	.000
CCI Comorbidity	-1.61	.40	-.26	-4.01	.000

F= 16.08 df = 1, 168 $p < .001$ $R^2 = .29$ Adjusted $R^2 = .29$

This model of controlling for both pain and comorbidity resulted in a model accounting for a total of 40.3% of the variance in perceived physical function. The total model resulted in comorbidity accounting for 9.5% of the variance, pain accounting for 19.9% of the variance, and the four symptoms of fatigue, anxiety, stiffness and dizziness accounting for 11% of the variance in total perceived physical function.

Evaluation of the moderating effect of comorbidity on perceived physical function consisted of conducting four separate regression analyses on perceived physical function with the CCI comorbidity score and each individual symptom composite score entered in the first step, and the interaction term between these two variables entered in the second step. All of these regression analyses yielded results that were not significant (Table 4.16). To evaluate a potential moderating effect on the relationship between the total number of symptoms and perceived physical function, the CCI comorbidity score and the total number of symptoms were entered in the first step, and the interaction term between these two variables were entered in the second step. Again, this analysis did not reveal significant findings, indicating that comorbidity does not have a moderating effect on the relationship between symptoms and perceived physical function.

Table 4.16

Analysis of Moderating Effect: Change in Significance after Entering Interaction Term of Comorbidity with Each Individual Symptom Composite Score and Total Number of Symptoms

Symptom Interaction Term with Comorbidity	Δ F (df)	Significance
Anxiety	$.33_{(1,\ 167)}$	.569
Stiffness	$2.96_{(1,\ 167)}$	.087
Fatigue	$.71_{(1,\ 167)}$	.401
Dizziness	$1.94_{(1,\ 167)}$	.165
Total Number of Symptoms	$.33_{(1,\ 167)}$	.570

Summary

The final sample of 171 subjects was predominantly female and Caucasian with a mean age of 60.78 years (SD = 6.21), and moderate functional limitation. Most subjects had at least one comorbid condition and reported a mean number of symptoms of 19.9 (SD = 5.4). The rank-order for the dimensions of frequency, severity, and distress differed for each symptom. The symptoms most reported by the sample were pain, stiffness, fatigue, non-refreshing sleep, forgetfulness, difficulty staying asleep, and muscle spasms. Symptom composite correlations of the 29 symptoms with perceived physical function revealed significant findings of weak to moderate correlations for fifteen symptoms. After controlling for pain, a parsimonious predictor model determined that anxiety, fatigue, stiffness, and dizziness accounted for 14% of the variance in perceived physical function. Although a significant difference in the number of symptoms was present between the middle-aged and older-aged groups, age was not correlated with perceived physical function, and therefore did not have a moderating effect on the relationship between symptoms and perceived physical function. Comorbidity did have a significant correlation with perceived physical function, but further analysis revealed no moderating effect for comorbidity, either.

CHAPTER 5: DISCUSSION AND CONCLUSIONS

This study yielded 5 novel findings: 1) the total sample reported a very high number of symptoms (19.9 ± 5.4), with the middle-aged group reporting significantly more symptoms than the older-aged group: 21.4 ± 5.9 versus 19.3 ± 5.2 respectively; 2) the distress dimension yielded a markedly different rank-order than the frequency and severity dimensions: the most distressing symptom was fear of symptoms worsening while the most frequent symptoms were pain, fatigue, sleep-related symptoms, and stiffness, and the most severe symptoms were also sleep-related symptoms and fatigue; 3) four symptoms were identified that account for 14% of the variance in physical function: fatigue, anxiety, stiffness, and dizziness; 4) no difference existed between the two age groups on perceived physical function, and 5) while age was not correlated with physical function, comorbidity significantly correlated with physical function and accounts for 6.8% of the variance in perceived physical function; neither age nor comorbidity have a moderating effect on the relationship between symptoms and perceived physical function.

The remainder of chapter 5 is organized by important findings from each aim. This study revealed a high number of symptoms reported by the total group, with an average of 20 symptoms experienced by the sample in the previous seven days. As expected, pain, fatigue, and sleep disturbances were the most frequent and severe symptoms in the total sample. However, an unexpected finding was that of fear of symptoms worsening being the most distressing symptom. While the frequency, severity, and distress dimensions of the pain, fatigue, and sleep disturbance symptoms were relatively similar in their rank-order, the most distressing symptom of fear of symptoms worsening was rank-ordered as 15 in terms of the frequency with which the symptom was experienced, and 12 in terms of how severe the symptom was when it did occur.

Number of Symptoms

The total sample experienced an average of 20 symptoms, with 53% of the sample reporting they experienced at least 20 symptoms in the past seven days. This average is higher compared to other FM studies reporting an average of 8 to 15 symptoms (Anderberg, Marteinsdottir, Hallman, & Backstrom, 1998; Wolfe & Rasker, 2006). These studies evaluated general populations of FM patients from either primary care or general rheumatology clinical settings. The current study utilizes a sample from a tertiary care setting that specifically focuses on the treatment and management of fibromyalgia. Therefore, the sample may represent a population of FM patients that have a higher number of more severe symptoms that prompt them seek care at this type of setting.

The prevalence of symptoms for this study was different for the sample in this study when compared to the National Fibromyalgia Association (NFA) study. The current study identified pain (100%), stiffness (99%), fatigue (95%), non-refreshing sleep (93%), forgetfulness (87%), difficulty staying asleep (85%), muscle spasms (81%), and skin tenderness (78%) as the most prevalent symptoms, while the NFA study identified low back pain (63%), recurrent headaches (47%), muscle spasms (46%), fatigue (40%), depression (40%), anxiety (38%), restless legs (32%), and irritable bowel/bladder (44/26%) (Bennett, Jones, Turk, Russell, & Matallana, 2007). While two of these symptoms, muscle spasms and fatigue, are similar in the two samples, it is important to note the multitude of sleep-related symptoms in the current study, as well as the high prevalence of stiffness, forgetfulness, and skin tenderness in this sample. Also of interesting note, a much higher percentage of the sample experienced this range of symptoms in the current study (78% to 100%) than those most prevalent in the NFA study (26% to 63%). This discrepancy may be due to sampling methods. The NFA study enrolled any patient with FM, while the current study drew its sample from a tertiary health care setting that is a specialty FM clinic, and therefore they may have greater numbers of more severe symptoms.

Differences in Symptoms between Age Groups

The total number of symptoms differed significantly between the middle-aged group and the older-aged group. As expected, the middle-aged group had significantly more symptoms than the older-aged group, 21.4 versus 19.3. The significant difference in the mean number of symptoms, as well as the middle-aged group's significantly greater overall symptom impact than the older aged group for difficulty falling asleep, difficulty staying asleep, accident prone, easy bruising and unexplained sweating, support previous research findings. Similarly, research comparing younger and middle-aged groups to older groups yielded findings of greater numbers of symptoms and greater symptom severity (Burckhardt, Clark, & Bennett, 2001; Cronan, Serber, Walen, & Jaffe, 2002; Pamuk & Cakir, 2005; Yunus, Holt, Masi, & Aldag, 1988). Some speculate that older adults with FM may report better health than do younger adults, even with more comorbid conditions or longer duration of symptoms (the older sample had significantly longer duration than the younger groups). Older adults may be better able modify their daily routines, and may cope better with both the symptoms and the expectations they have for their symptom experiences (Burckhardt, Clark, & Bennett, 2001; Yunus, Holt, Masi, & Aldag, 1988).

Both groups individually reported the same rank-order of the four symptoms having the most overall impact: fatigue, pain, non-refreshing sleep, and stiffness. The preponderance of evidence supports the selection of fatigue, pain, and non-refreshing sleep as common symptoms in FM (Bennett, 2002; Burckhardt, Clark, & Bennett, 1991; Pamuk & Cakir, 2005; Uveges et al., 1990; Wolfe et al., 1997a). A few more recent studies also report stiffness as a common and burdensome symptom (Bennett et al., 2007; Rutledge, Jones, & Jones, 2007; Pamuk & Cakir, 2005; Sarzi-Puttini, Atzeni, Di Franco, Lama, Batticciotto, Iannuccelli, et al., 2008).

As expected, the duration of FM diagnoses was significantly different, as well, with the middle-aged group at 19 years duration, and the older-aged group at 27 years duration. Time since diagnosis or duration of FM is an important factor, as there is conflicting evidence regarding symptom expression over time in FM. While FM is increasingly recognized and diagnosed by clinicians, there is often up to a 7 year difference between the time of symptom onset and FM diagnosis (Undeland & Malterud, 2007; Liedberg, Burckhardt, & Henriksson, 2006). Like most chronic illnesses, initial onset and early years of FM symptoms are fraught with distress, fear, symptom burden, and catastrophic thinking (Asbring, 2001; Burckhardt, Burwinkle, Robinson, & Turk, 2005; Liedberg, Burckhardt, & Henriksson, 2006). Other studies report similar findings in which younger and middle-aged samples expressed more severe symptoms than older samples (Cronan et al., 2002; Liedberg, Burckhardt, & Henriksson, 2006). Younger persons who are newer to the diagnosis of FM are known to improve in a number of symptom and functional status measures over 1 to 3 years (Liedberg, Burckhardt, & Henriksson, 2006; White et al., 2002). Some patients resolve these issues with lifestyle changes (fewer hours of employment and pacing for example), creation of a new concept of identity, and improved medical management, but their symptoms may still remain frequent and intense (Asbring, 2001; Liedberg, Burckhardt, & Henriksson, 2006; Mannerkorpi, Kroksmark, & Ekdahl, 1999). They may also continue to experience fear of activity due to the potential for symptom exacerbation (Mannerkorpi et al., 1999; Turk & Okifuji, 1997; Turk, Robinson, & Burwinkle, 2004). It is unclear whether fear of activity is more closely linked with age or with time since diagnosis.

Rank-order Differences in Symptom Dimensions

Although the symptom frequency and severity dimension displayed similar rank-ordered symptoms, the distress dimension yielded a markedly different rank-order. Symptoms reported by this sample followed similar patterns from previous studies, with pain, sleep-related symptoms, fatigue, and stiffness rounding out the most frequent and severe symptoms (Bennett, Jones, Turk, Russell, & Matallana, 2007; Burckhardt, Clark, & Bennett, 1991; Liedbert, Burckhardt, & Henriksson, 2006). However, the most distressing symptom was fear of symptoms worsening; as well, feeling like a burden to others and inability to enjoy life were ranked 7and 8 respectively – much higher than the frequency and severity dimensions. While fatigue, non-refreshing sleep, and pain were also in the top six symptoms in order of distress, the emotional symptoms of fear, burden, and inability to enjoy life are of important consequence. The literature supports this finding that while other symptoms may be present more often, when these emotional symptoms are present, they cause great distress (Liedberg, Burckhardt, & Henriksson, 2006; Shaver, Lentz, Landis, Heitkemper, Buchwald, & Woods, 1997). This finding may indicate that clinicians should assess for the presence of emotional symptoms in conjunction with the physical symptoms and target interventions at both types of symptom expression.

Model of Predicting Perceived Physical Function

Five symptoms accounted for 37% of the variance in perceived physical function. As expected, pain accounted for 23 % of the variance, however, unreported in the literature to date, fatigue, anxiety, stiffness, and dizziness accounted for an additional 14% of the variance in perceived physical function. While the symptoms of non-refreshing sleep and muscle spasms remained in the model until the confirmatory regression analysis, it is important to note that stepwise multiple regression analysis is a very conservative approach to regression analysis, and does not take into account any theoretical implications for the inclusion or exclusion of variables in a regression model (Tabachnick, & Fidell, 2001). Therefore, these two symptoms may need to be further evaluated in future studies as possible significant predictors of perceived physical function.

The literature supports this relationship between these symptoms in the model and perceived physical function. Fatigue is significantly correlated with lower levels of physical activity, a pre-determinant to lower physical function, in those with FM (Kop et al., 2005; Jones, Burckhardt, Deodhar, Perrin, Hanson, & Bennett, 2008;), and is associated with lower levels of physical function in older adults with persistent pain (Jakobsson, Hallberg, & Westergren,2007). Anxiety (Meyer & Lemley, 2000), and stiffness (Altan, Bingol, Aykac, Koc, & Yurtkuran, 2004; Meiworm, Jakob, Walker, Peter, & Kuel, 2000) are significantly correlated with low levels of physical function in those with FM. While dizziness has not previously been identified as having an association with physical function specifically in FM populations, it is significantly correlated with physical function in populations of those with multiple sclerosis (Cattaneo, Regola, & Meotti, 2006), and vestibular disorders (Whitney, Marchetti, Morris, & Sparto, 2007).

Non-refreshing sleep and other sleep disturbances are highly correlated with physical function and other measures of function, such as physical activity and exercise (Roizenblatt et al., 2001; Gary & Lee, 2007). However, the relationship between muscle spasms and physical function is not well documented, with only one study reporting muscle spasm as a predictor of physical function (Rutledge, Jones, & Jones, 2007). Neuromuscular spasms are not objectively seen in patients in FM, although one large study indicates self report of "muscle spasms." Further study is needed to determine what FM patients mean when they report muscle spasm. Due to a paucity of evidence, we ultimately elected to build the model through statistical modeling rather than clinical or theoretical decisions for symptom inclusion. However, clinical implications may indicate that these sleep-related symptoms and muscle spasms must also be evaluated in the context of understanding perceived physical function.

Perceived Physical Function: Moderate Limitations

Surprisingly, no difference existed between the two age groups on perceived physical function. While low levels of physical function, physical performance, and physical activity are common in all of those with FM (Rutledge, Jones, & Jones, 2007; Mannerkorpi, Burckardt, & Bjelle, 1994; Shaver, Wilbur, Robinson, Wang, & Buntin, 2006), physical function is typically lower in younger and middle-aged groups compared to older groups (Burckhardt, Clark, & Bennett, 2001). Burckhardt and colleagues studied 343 people between 20 and 64 years of age, with age groups separated into 20 to 34 years of age, 35 to 54 years of age, and 55 to 64 years of age, and noted significantly lower levels of physical function in the middle-aged group when compared to the older group. The current study targeted an older group specifically over 65 years of age, and the results show moderate function limitations in both the middle-aged and older groups, 52.8 versus 52.5 respectively. There are two possible explanations for this finding: 1) previous studies determined “older adult” populations to be younger than 65 years of age; or 2) measures of physical function in previous work have not been specific or sensitive enough to accurately measure levels of physical function specifically in older adult populations.

One study has identified that younger and middle-aged samples reported lower physical function scores than an older-aged group (Burckhardt, Clark, & Bennett, 2001). However, the older group consisted of women only 55-64 years of age, whereas the current study’s older group age range is 65 to 76 years of age. The body of evidence in general populations of older adults with persistent pain supports this finding. Lower levels of physical function have been noted in numerous studies of older adults with other types of persistent pain (Al Snih et al., 2005; Croft, Jordan, & Jinks, 2005; Jakobsson et al., 2004). Previous research in populations of older adults, specifically those 65 years of age and older, reveals that persistent pain is strongly associated with lower physical function (Bennett, 2002; Bennett, Stewart, Kayser-Jones, & Glaser, 2002; Bookwala et al., 2003; Jakobsson, Klevgard, Westergren, & Hallberg, 2003), and loss of mobility (Guralnik et al., 2000; Guralnik, Ferrucci, Simonsick, Salive, & Wallace, 1995; Lamb et al., 2000; Tinetti, Inouye, Gill, & Doucette, 1995).

This finding of both age groups having moderate functional limitation contradicts the body of literature in physical function in FM. One possible explanation may be due to measures of physical function in previous studies may lack sensitivity or specificity to accurately measure perceived physical function specifically in older aged samples. Most studies that compare the level of physical function between different age-group samples of those with FM use the FIQ physical function subscale (Burckhardt, Clark, & Bennett, 2001; Pamuk & Cakir, 2005). This subscale, while specific for FM, has poor validity when compared to objective measures of physical function (Bennett, 2005). The LLFDI, on the other hand, was developed specifically for evaluative purposes in older adult populations and has been correlated with physical performance tests used to determine level of physical function (Haley et al., 2002; Jette et al., 2002). It is possible that function was similar in older versus middle aged adults because the LLFDI was designed specifically for use in older adults, and therefore detected the trend for middle-aged samples to have greater functional impairment than older samples, yet was also able to detect a more accurate representation of moderate functional limitation in a more advanced-age sample. These conflicting findings between previous work and the current study supports the need for further exploration of the impact of fibromyalgia on physical function in older adults. These further studies must target those specific age groups classified by the American Geriatric Society (2002) guidelines that categorize “older adult” populations to be 65 to 74 years of age as “young-old,” 75 to 84 years as “middle-old,” and 85 years and over as “old-old.” As the sample in current study only reached 76 years of age, the ramifications of declines in physical function in the oldest-old with FM are yet undiscovered. On the other hand, it is possible that the physiologic effects of FM on perceived physical function manifest early in the disease process, and as such, may supersede age-related declines in physical function.

Relationship of Age and Comorbidity to Physical Function

An unexpected finding was that age was not correlated with physical function. After the previous discussion of the similar functional limitation in the two age groups, it is apparent that further inquiry must look at the pattern of declines in physical function over a more wide-spread age range. As physical function has been shown to be lower in younger and middle-aged samples of those with FM than older samples (Burckhardt, Clark, & Bennett, 2001; Pamuk & Cakir, 2005), yet older adults with persistent pain have greater functional declines as they age (Bennett, Stewart, Kayser-Jones, & Glaser, 2002; Bookwala et al., 2003; Jakobsson, Klevgard, Westergren, & Hallberg, 2003; Guralnik et al., 2000; Lamb et al., 2000), future research must clearly distinguish “elderly” or older adult populations by consistent national guidelines that target a truly geriatric population. As well, the causal-relationship between FM and lower levels of perceived physical function in older samples must be evaluated. It is unclear if the limitations in perceived physical function in advancing age occur as a result of the disease process of FM or from aging, itself.

As expected, comorbidity was significantly correlated with perceived physical function and accounts for 6.8% of the variance in perceived physical function. However, an unexpected finding revealed no significant difference in comorbidity between the two age groups. In a sample of older adults over the age of 60, the proportion of the population reporting two or more of the nine most prevalent medical conditions increased with age (Guralnik, 1989). Of the oldest group (80 years and over), 70% of women and 52% of men had two or more of these conditions. The similar findings in comorbidity between the two age groups may be contributed to the limited range of the older-aged group between 65 and 76 years of age.

Another unexpected finding was the Charlson Comorbidity Index comorbidity score being lower than expected. Again, this may be due to the sample only reaching 76 years of age. As noted in previous research, higher numbers of comorbid conditions are found with increasing age in those over 60 years of age (Guralnik, 1989; Boyd et al., 2007). One study found that in those 80 years of age and over, 70% of women and 52% of men had two or more of the nine most common comorbid conditions (Guralnik, 1989). Increased rate of osteoarthritis, Type II Diabetes, obesity, and cancer are over-represented in the FM population compared to the general population (Bernatsky, Dobkin, De Civita, & Penrod, 2005; Shaver, Wilbur, Robinson, Wang, & Buntin, 2006; Tishler, Smorodin, Vazina-Amit, Ramot, Koffler, & Fishel, 2003). The most common comorbid conditions in the current study were similar in findings, The literature is replete with reference to comorbidity in FM: osteoarthritis (Wolfe, 1999), thyroid disease (Bazzichi, Rossi., Giuliano, De Feo, Giacomelli, Consensi, et al. 2007), diabetes mellitus (Bernatsky, Dobkin, De Civita, & Penrod, 2005), and rheumatic arthritis (Shaver, Wilbur, Robinson, Wang, & Buntin, 2006). It is possible that this FM sample has been socialized not to participate in research, as in the early years of FM research. The paucity of evidence about the management of FM in people with comorbid medical conditions is cause for great concern, particularly in an aging population.

Relation of Findings to the Conceptual Framework

In reflecting on the conceptual framework outlined in chapter 2, the guiding premise that a combination of symptoms would predict perceived physical function was supported (aims 1 and 2). The evaluation of each symptom dimension yielded an important finding in that frequency, severity, and distress of all symptoms were different, yet a single symptom dimension did not drive the composite score for any of the symptoms. This finding is important for both clinical practice and research purposes. The finding supports the need to evaluate symptom dimensions individually for treatment options based on frequency, severity, or distress; however, if seeking to determine the impact of a symptom on an outcome variable, such as physical function, the composite score appears to be more effective.

The third aim examining the relationship of age and comorbidity on symptoms and physical function was not fully supported by the theoretical model. Surprisingly, age was not correlated with physical function, and both age groups equally displayed a moderate functional limitation. Therefore, age did not moderate the relationship between symptoms and perceived physical function. Also unpredicted, no significant difference in comorbidity was noted between the two age groups. However, comorbidity was significantly correlated with physical function and with two of the four variables included in the final model: fatigue and dizziness. Despite these significant correlations, comorbidity did not have a moderating effect on the relationship between symptoms and perceived physical function.

Based on these findings, it may be logical to consider the predisposing variables in the Theory of Unpleasant Symptoms to evaluate the influence of these variables on physical function. The theory hypothesizes that three key interrelated variables act as antecedents to the symptom experience: physiologic factors, psychologic factors, and situational factors. These factors influence each individual symptom, and therefore will need to be accounted for in future studies. These factors may include the physiologic factors such as smoking, BMI, and comorbidity, psychologic factors such as the distress component of variable dimensions as identified in the current study, and situational factors such as medications.

Limitations to the Study

This study had the following limitations. The study design of a descriptive, correlational, cross-section study limits causal analysis or inferences, and therefore reports relationships only. The sample was drawn from a tertiary health care setting specifically for FM consultation and treatment, and may not be representative of the greater population of those with FM (e.g., patients may have more severe or recalcitrant FM). Therefore, this sample’s symptom experience may have been more severe than those patients not referred to specialty care. As well, persons who are uninsured or are insured with Medicaid only are not accepted by this academic medical center, and may not accurately represent those that have limited or no access to healthcare, or choose who seek alternative methods of treatment. Results of this study may not be generalized to men or minority populations, as the representation in this sample was not sufficient for gender or racial sub-group analysis. Considering the significant novel findings of this study, a logical extension would be to replicate the survey in a larger sample with more diverse participants.

The impact of comorbidities may have been limited due to how people were recruited and asked to report comorbidities. This notion is supported by two ideas: 1) several potential participants did not believe they were eligible for the study because of other co-existing conditions; and 2) 75% of the older-aged group received a score of 2 or less on the CCI comorbidity score, compared to 72% of the middle-aged group. During the study recruitment phase, 7 phone calls and 8 questionnaires were received indicating the participants previously had been excluded from FM research because of comorbid conditions. The letter of invitation to this study did not emphasize that those with comorbid conditions were of great interest in this study, and this omission may have led potential participants to self-exclude based on the traditional approach of FM research excluding those with comorbidities. The similarity between the two age groups in the relatively low CCI comorbidity scores may indicate that those older adults, who are known to have increased comorbid conditions with advanced age, may have also self-excluded from the study.

Clinical Implications

Clinicians may want to consider the 3 dimensions of symptoms as the current study found a differing rank order when specifically asking about frequency, severity and distress. Modification of symptom inquiry may yield different results, as in the current study. These differing results may lead providers to alternative treatments. Put in order of F/S/D For example, a patient whose most distressing symptom is “fear of worsening” could be offered data about the common, stable, non-progressive course of the illness. Cognitive behavioral therapies, such as decreasing catastrophic thinking, could also be employed. Reports of fatigue frequency, for example, could encourage clinicians to prescribe time-based pacing activities and fatigue management rest and exercise protocols. Reports of pain or sleep disturbance severity could yield targeted pharmacologic intervention.

Clinical implications for managing low function argues toward exercise interventions and understanding other factors associated with low physical function in other disease processes. Physical and occupational therapy, pacing for fatigue, and devices to support movement to minimize pain are all areas that are impacted by the relationship between symptoms and physical function (Rooks, Dan 2007; Busch 2008; Jones et al., 2007).

Areas for Future Research

Plans to conduct a secondary analysis of existing data not represented in the aims of the current study include accounting for BMI and medications. For example, several factors correlated with symptoms and poor physical function in older adults were accounted for in the current study. Greater extremes of body mass index (BMI), either high or low, are correlated with lower physical function and increased dependence in ADLs in older adults (Bennett et al., 2002; Galanos, Pieper, Cornoni-Huntley, Bales, & Fillenbaum, 1994). Longitudinal studies have found that increased BMI over time in older adult women increase the risk of chronic health conditions and lower physical function than those that maintain their BMI over time (Coakley et al., 1998). Higher levels of BMI are found in the majority of those with FM in the US, with positive correlation between high BMI, increasing age, and lower physical function (Yunus, Arslan, & Aldag, 2002). High BMI is also correlated with increased levels of pain severity (Aoyagi et al., 2002; Evers Larsson & Mattsson, 2001; Orvieto, Rand, Lev, Wiener, & Nehama, 1994).

Increased numbers of medications used in older adult populations is correlated with increased frequency of symptoms such as fatigue, pain, and depression (Given, Given, Azzouz, Kozachik, & Stommel, 2001; Herrick et al., 2004; Liao & Ferrell, 2000; Tsai, Wei, Lin, & Chien, 2005). Further analysis could be conducted to examine the contribution of the type and number of medications as they relate to physical function. For example, common FM medications such as opioids for pain, hypnotics for sleep, and tricyclic antidepressants for mood are known to be associated with dizziness, and dizziness was a significant predictor of physical function in this model. However, side effects of these medications are known to decline with long-term use. Therefore the medication regimen will need to be further evaluated as a contributor to physical function.

Another direction for future research could include replicating the study in a larger sample consisting exclusively of adults over the age of 65. this would give researchers a first opportunity to examine not only the young-old in the range of 65-74 years of age, but the middle old, and especially old-old age groups. Focusing exclusively on adults over 65 would enhance the likelihood of identifying comorbid conditions. Questionnaires other than the CCI might be employed in the future, particularly those that measure comorbidities known to be high in FM.

Additionally, future research is needed to confirm self-report physical function measures of the LLFDI with standardized objective laboratory tests of physical function. For example, researchers might employ the Short Performance Physical Battery, the 6-

min walk test, and other objective measures of physical function. These objective findings would be correlated with LLFDI self-report measure. This future study could objectively test all persons in the sample or randomly selected sub-groups.

A final direction for future research is to develop and test an intervention to decrease fatigue, anxitety, stiffness, dizziness and pain in an effort to enhance physical function. This intervention could include both pharmacologic and non-pharmacologic independent variables. For example, exercise and cognitive behavioral therapy could be tested in conjunction with symptom-specific medications to determine if an interaction effect exists between pharmacologic and non-pharmacologic interventions. If a multiple-arm trial is not feasible, a prospective controlled trial of a combination of therapies versus a wait-listed control would nonetheless provide useful data regarding how to improve physical function in FM.

Summary

Although much has been discovered in the understanding of the pathophysiology and treatment of fibromyalgia and the expression of symptoms in this syndrome, there remain significant gaps in the literature and in our understanding of the effect of aging and comorbidity on physical function in this population. These gaps require further investigation as our population continues to age. Much information is still needed to best understand comorbidities associated with aging in those with FM and the influence of aging on symptoms in fibromyalgia.

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Arthritis and Rheumatic Diseases

OHSU
Where Healing, Teaching and Discovery Come Together
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We are writing this letter because you have been seen as a patient at the OHSU fibromyalgia clinic or have expressed an interest in participating in our fibromyalgia research studies. We would like to invite you to participate in our latest research study, “The Relationship Between Fibromyalgia Symptoms and Physical Function in Middle-Aged and Older Adults.” The study will investigate the impact of fibromyalgia symptoms on physical functioning. You will be asked to complete and return one set of questionnaires that are included in this package.

To participate in this study you must have fibromyalgia, be over the age of 50, be English speaking, and have experienced at least one symptom in addition to pain over the last seven days (such as fatigue, poor sleep, headaches, poor mood, concentration problems). Both men and women are invited to participate. All personal identifying information will be removed from your questionnaires and your confidentiality will be maintained.

If you believe you qualify for the study, please complete the enclosed study questionnaires, and return the questionnaires along with the raffle ticket in the addressed stamped envelope. The raffle ticket will enter you into a drawing for one of three available gift certificates for $100, $50, or $25 to a local grocery store or a fibromyalgia exercise DVD as a token of our gratitude for your participation.

If you choose not to participate, your relationship with our clinic and research center will not be affected in any way. We thank you in advance for your cooperation in helping us learn more about how to best treat fibromyalgia.

Sincerely,

Kim Dupree Jones PhD Casey Shillam

Kim Dupree Jones PhD, FNP
Fibromyalgia Researcher and Nurse Practitioner
eIRB #: 3418

Casey Shillam RN, MSN
OHSU PhD Candidate

Department of Medicine (OP09), The Oregon Health & Science University
3181 SW Sam Jackson Park Road, Portland OR, 97239
Tel. 503-494-5888 Email. bennetro@ohsu.edu

OREGON HEALTH & SCIENCE UNIVERSITY

Information Sheet

TITLE: The Relationship between Fibromyalgia Symptoms and Physical Function in Middle-Aged and Older Adults

PRINCIPAL INVESTIGATOR:	Kim Dupree Jones, PhD, FNP (503) 494-3837
CO-INVESTIGATORS:	Casey R. Shillam, RN, MSN (503) 913-2972 Gail Houck, PhD, RN, PMHNP (503) 494-3825 Lois Miller, PhD, RN (503) 494-2123 Kerri Winters, PhD (503) 494-0813
STUDY CONTACT:	Fibromyalgia Research Line (503) 494-3811

PURPOSE:

You have been invited to be in this research study because you have been seen as a patient at the OHSU Fibromyalgia Clinic or you have expressed interest in participating in the clinic's fibromyalgia research studies. The purpose of this study is to learn more about the impact of fibromyalgia symptoms on physical functioning in middle-aged and older adults. Two hundred people with fibromyalgia will be enrolled in the study at OHSU.

PROCEDURES:

This study consists of a one-time mailed survey that is sent to your home with an addressed, stamped return envelope. You will be asked to complete and return the one set of questionnaires, expected to take approximately 45 to 60 minutes to complete. There is no requirement to go to OHSU, as this study is to be completed through the mail, only.

To participate in this study you must have fibromyalgia, be over the age of 50, be English speaking, and have experienced at least one symptom in addition to pain over the last seven days. We ask that you have access to a telephone for follow-up only. It is not expected that everyone will require telephone follow-up, but this will be necessary only in cases to clear up any remaining questions.

If you have any questions regarding this study now or in the future, contact Casey Shillam, RN, MSN at (503) 494-3811.

RISKS AND DISCOMFORTS:

Some of the questionnaires may seem very personal or embarrassing. They may upset you. You may refuse to answer any of the questions that you do not wish to answer. If the questions make you very upset, we will help you to find a counselor.

BENEFITS:

You may or may not personally benefit from being in this study. However, by serving as a subject, you may help us learn how to benefit patients in the future.

ALTERNATIVES:

You may choose not to participate in this study at all.

CONFIDENTIALITY AND PRIVACY OF YOUR PROTECTED HEALTH INFORMATION:

Your information will be anonymous. Research records may be reviewed and copied by: the OHSU Institutional Review Board and the Office for Human Research Protection. We will not use your name or your identity for publication or publicity purposes.

The persons who are authorized to use and disclose this information are all the investigators listed on page one of this Information Sheet, other OHSU staff who are participating in the conduct of this study, and the OHSU Institutional Review Board.

The persons who are authorized to receive this information are the Office for Human Research Protections (OHRP) and any federal or other governmental agencies as required for their research oversight.

We may continue to use and disclose protected health information that we collect from you in this study indefinitely.

While this study is still in progress, you may not be given access to medical information about you that is related to the study until after the research is complete. After the study is completed and the results have been analyzed, you will be permitted access to any medical information collected about you in the study.

You have the right to revoke this authorization and can withdraw your permission for us to use your information for this research by sending a written request to the Principal Investigator listed on page one of the research consent form. If you do send a letter to the Principal Investigator, the use and disclosure of your protected health information will stop as of the date she receives your request. However, the Principal Investigator is allowed to use and disclose information collected before the date of the letter or collected in good faith before your letter arrives. Revoking this authorization will not affect your health care or your relationship with OHSU.

The information about you that is used or disclosed in this study may be re-disclosed and no longer protected under federal law.

Description of the information to be used or disclosed and the purposes of the requested use or disclosure:

Health Information *(Check as applicable)*	Purpose(s) *(Enter corresponding letter(s) from Purpose Categories)*
☒ Your complete existing health record	a,b,c,e
THE FOLLOWING CHECKED ITEM(S) WILL BE GENERATED/COLLECTED DURING THE COURSE OF THIS STUDY:	
☐ History and physical examinations	
Reports: ☐ Laboratory ☐ Operative ☐ Discharge ☐ Progress	
☐ Bioelectric Output (e.g., EEG, EKG)	
☒ Questionnaires	a,b,c,e
☐ Blood specimens	
☐ Urine, stool	

Purpose Categories

a. To learn more about the condition/disease being studied
b. To facilitate treatment, payment, and operations related to the study
c. To comply with federal or other governmental agency regulations
d. For teaching purposes
e. Other To improve health care for persons with fibromyalgia; to analyze research results, to determine eligibility, to complete research obligations in this study, to perform quality assessments related to research at OHSU.

COSTS:

You will not be charged for taking part in this study. You will not be paid for participating in this study. You will receive a raffle ticket in your questionnaire mailing to be returned with the study information. Return of the ticket with your questionnaires will enter you into a drawing for one of three available gift certificates for $100, $50, or $25 to a local grocery store as a token of our gratitude for your participation.

PARTICIPATION:

If you have any questions regarding your rights as a research subject, you may contact the OHSU Research Integrity Office at (503) 494-7887.

You do not have to join this or any research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join or withdraw early from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled.

Your health care provider may be one of the investigators of this research study, and as an investigator is interested in both your clinical welfare and in the conduct of this study. You do not have to be in any research study offered by your physician.

The participation of OHSU students or employees in OHSU research is voluntary and you are free to choose not to serve as a research subject in this protocol for any reason. If you do elect to participate in this study, you may withdraw from the study at any time without affecting your relationship with OHSU, the investigator, the investigator’s department, or your grade in any course.

We will give you a copy of this form.

ID #:________ Date:_________

Symptom Checklist for Fibromyalgia

We have listed symptoms that people with fibromyalgia may have below. Read each carefully. If you have had the symptom during the *past week*, mark "YES" and let us know how OFTEN you had it, how SEVERE it was usually, and how much it DISTRESSED or BOTHERED you by circling the appropriate number. If you DID NOT HAVE the symptom, mark "NO".

During the past week, did you have any of the following symptoms?	NO	YES	If YES How OFTEN did you have it?				If YES How SEVERE was it usually?				If YES How much did it DISTRESS or BOTHER you?				
			Rarely	Occasionally	Frequently	Almost Constantly	Slight	Moderate	Severe	Very Severe	Not at all	A little bit	Somewhat	Quite a bit	Very much
1. Pain	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
2. Feeling anxious	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
3. Skin tenderness	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
4. Difficulty falling asleep	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
5. Easily angered	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
6. Stiffness	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
7. Accident Prone	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
8. Swelling in hands, legs, feet, and/or ankles	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
9. Feeling sad or depressed	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
10. Forgetfulness	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
11. Difficulty staying asleep	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
12. Inability to enjoy life	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
13. Restless legs	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
14. Dizziness	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
15. Irritable bladder	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
16. Muscle spasms	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4

ID #:________

			If YES How OFTEN did you have it?				If YES How SEVERE was it usually?				If YES How much did it DISTRESS or BOTHER you?				
During the past week, did you have any of the following symptoms?	NO	YES	Rarely	Occasionally	Frequently	Almost Constantly	Slight	Moderate	Severe	Very Severe	Not at all	A little bit	Somewhat	Quite a bit	Very much
17. Pelvic pain	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
18. Fatigue/ Lack of energy	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
19. Irritable bowel	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
20. Headache/Migraine	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
21. Cold Hands and/or Feet	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
22. Not feeling rested after sleeping	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
23. Feel like a burden to others	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
24. Concentration problems	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
25. Sensitivity to light, sound, and/or smell	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
26. Easy bruising	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
27. Fear of symptoms worsening	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
28. Falling easily / Balance problems	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
29. Sweating / Feeling Hot	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
Are there any other symptoms you have had in the past week that we did not ask you? (Please list below)															
28. ____________________	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
29. ____________________	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4
30. ____________________	0	1	1	2	3	4	1	2	3	4	0	1	2	3	4

What are your 3 most troublesome symptoms? (Please list below)
31. _________________________________
32. _________________________________
33. _________________________________

ID #:________ Date:_________

Comorbidity Questionnaire

We have listed some common medical conditions below. Read each carefully and mark the appropriate response for your medical history.

1. Myocardial infarction:

Have you ever had a heart attack?	No _______	Yes_______
Do you have unstable or severe angina?	No _______	Yes_______

2. Congestive heart failure:

Have you ever been treated for heart failure? (You may have been short of breath and the doctor may have told you that you had fluid in your lungs or that your heart was not pumping well.)	No _______	Yes_______

3. Peripheral vascular disease:

Have you had an operation to unclog or bypass the arteries in your legs?	No _______	Yes_______
Have you ever been diagnosed with intermittent claudication?	No _______	Yes_______

4. Neurological Diseases:

Cerebrovascular accident:

Have you had a stroke, cerebrovascular accident, blood clot or bleeding in the brain, or transient ischemic attack (TIA)?	No _______	Yes_______

Hemiplegia:

Do you have difficulty moving an arm or leg as a result of the stroke or cerebrovascular accident?	No _______	Yes_______

Parkinson’s Disease:

Have you been diagnosed with Parkinson’s Disease?	No _______	Yes_______

Multiple Sclerosis:

Have you been diagnosed with Multiple Sclerosis?	No _______	Yes_______

ID #:________ Date:_________

5. Chronic obstructive pulmonary disease:

Do you have asthma?	No _______	Yes_______
If yes, do you take medicines for your asthma?	No _______	
With flare-ups of asthma only		Yes_______
I take medicines regularly, even when I'm not having a flare-up		Yes_______
Do you have emphysema, chronic bronchitis, or chronic obstructive lung disease?	No _______	Yes_______
If yes, do you take medicines for your lung disease?	No _______	
Only with flare-ups		Yes_______
I take medicines regularly, even when I'm not having a flare-up		Yes_______

6. Ulcer disease:

Do you have stomach ulcers, or peptic ulcer disease?	No _______	Yes_______
If yes, has this condition been diagnosed by endoscopy (where a doctor looks into your stomach through a scope) or an upper GI or barium swallow study (where you swallow chalky dye and then x-rays are taken)?	No _______	Yes_______

7. Diabetes:

Do you have diabetes (high blood sugar)?	No _______	Yes_______
Yes, treated by medications taken by mouth		Yes_______
Yes, treated by insulin injections		Yes_______

Has the diabetes caused any of the following problems:

Problems with your kidneys	No _______	Yes_______
Problems with your eyes, treated by an ophthalmologist	No _______	Yes_______
Diabetic or peripheral neuropathy	No _______	Yes_______

ID #:________ Date:_________

8. Renal:

Have you ever had the following problems with your kidneys:

Poor kidney function (blood tests show high creatinine) No _______ Yes_______

Have used hemodialysis or peritoneal dialysis No _______ Yes_______

Have received kidney transplantation No _______ Yes_______

9. Connective tissue disease:

Do you have rheumatic arthritis? No _______ Yes_______

If Yes:

Do you take regular medicine for rheumatic arthritis? (do not count osteoarthritis) No _______ Yes_______

What areas are affected by rheumatic arthritis? ____

____

Do you have Lupus (systemic lupus erythematosus)? No _______ Yes_______

Do you have Polymyalgia Rheumatica? No _______ Yes_______

10. Dementia, liver disease, leukemia, lymphoma, tumor, metastases, AIDS:

Do you have any of the following conditions?

Alzheimer s Disease, or another form of dementia? No _______ Yes_______

Cirrhosis, or serious liver damage? No _______ Yes_______

AIDS No _______ Yes_______

Leukemia or polycythemia vera? No _______ Yes_______

Lymphoma? No _______ Yes_______

Cancer, other than skin cancer, leukemia, or lymphoma? No _______ Yes_______

If Yes:

Has the cancer spread, or metastasized to other parts of your body? No _______ Yes_______

If the cancer has NOT metastasized, was the cancer first treated less than 5 years ago? No _______ Yes_______

ID #:________ Date:_________

11. Osteoarthritis:

Do you have osteoarthritis?	No _______	Yes_______
If Yes: Do you take medications for it regularly?	No _______	Yes_______

What areas are affected by osteoarthritis arthritis? ____

____

12. Thyroid:

Do you have a problem with your thyroid?	No _______	Yes_______
If yes, is it hypothyroid?	No _______	Yes_______

13. Hearing Problems:

Can you only hear shouted words, or do you have difficulty hearing in crowded places, or do you often depend on reading lips? Answer yes if ***any*** of these is true.	No _______	Yes_______

14. Vision Problems:

Can you only see outlines of objects and people, or do you need help in cooking, eating, dressing, bathing or going to the toilet ***because you have trouble seeing***? Answer yes if ***any*** of these is true.	No _______	Yes_______

15. Urinary Problems:

Do you frequently lose urine, to the extent that it keeps you from going out or engaging in activities at home that you would like to do?	No _______	Yes_______
Do you have an indwelling urinary catheter, urinary condom, or do you wear a heavy pad to catch urine? Do ***not*** count light pads, such as panty liners.	No _______	Yes_______

1903

PLEASE USE BLACK INK PEN

Date: ☐☐ / ☐☐ / ☐☐
(month) (day) (year)

Subject's Initials : ________________

Study Subject #: ☐☐☐☐

Study Name: ________________________________

Protocol #: ________________________________

PI: ________________________________

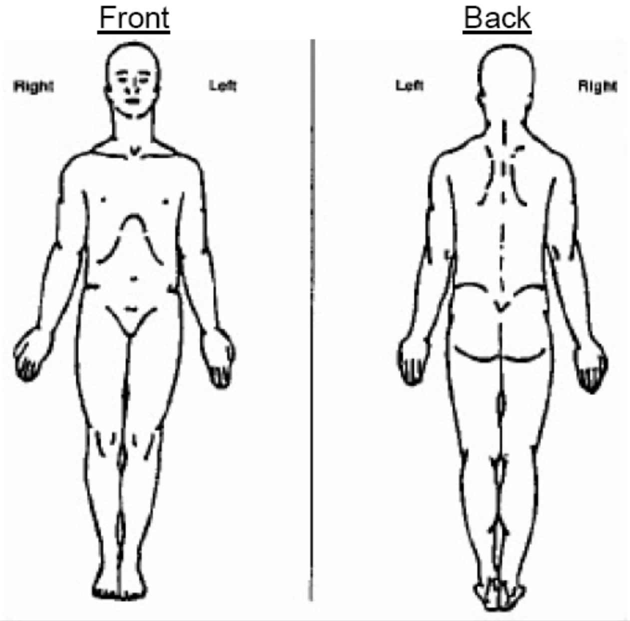
Revision: 07/01/05

Brief Pain Inventory (Short Form)

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?

☐ Yes ☐ No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by marking the box beside the number that best describes your pain at its worst in the last 24 hours.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Pain — Pain As Bad As You Can Imagine

4. Please rate your pain by marking the box beside the number that best describes your pain at its least in the last 24 hours.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Pain — Pain As Bad As You Can Imagine

5. Please rate your pain by marking the box beside the number that best describes your pain on the average.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Pain — Pain As Bad As You Can Imagine

6. Please rate your pain by marking the box beside the number that tells how much pain you have right now.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Pain — Pain As Bad As You Can Imagine

1903

Date: ☐☐ / ☐☐ / ☐☐
(month) (day) (year)

Subject's Initials : ________________

Study Subject #: ☐☐☐☐

Study Name: ______________________________

Protocol #: ______________________________

PI: ______________________________

Revision: 07/01/05

PLEASE USE
BLACK INK PEN

7. What treatments or medications are you receiving for your pain?

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please mark the box below the percentage that most shows how much relief you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
No Relief										Complete Relief

9. Mark the box beside the number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10
Does Not Interfere — Completely Interferes

B. Mood

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10
Does Not Interfere — Completely Interferes

C. Walking ability

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10
Does Not Interfere — Completely Interferes

D. Normal Work (includes both work outside the home and housework)

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10
Does Not Interfere — Completely Interferes

E. Relations with other people

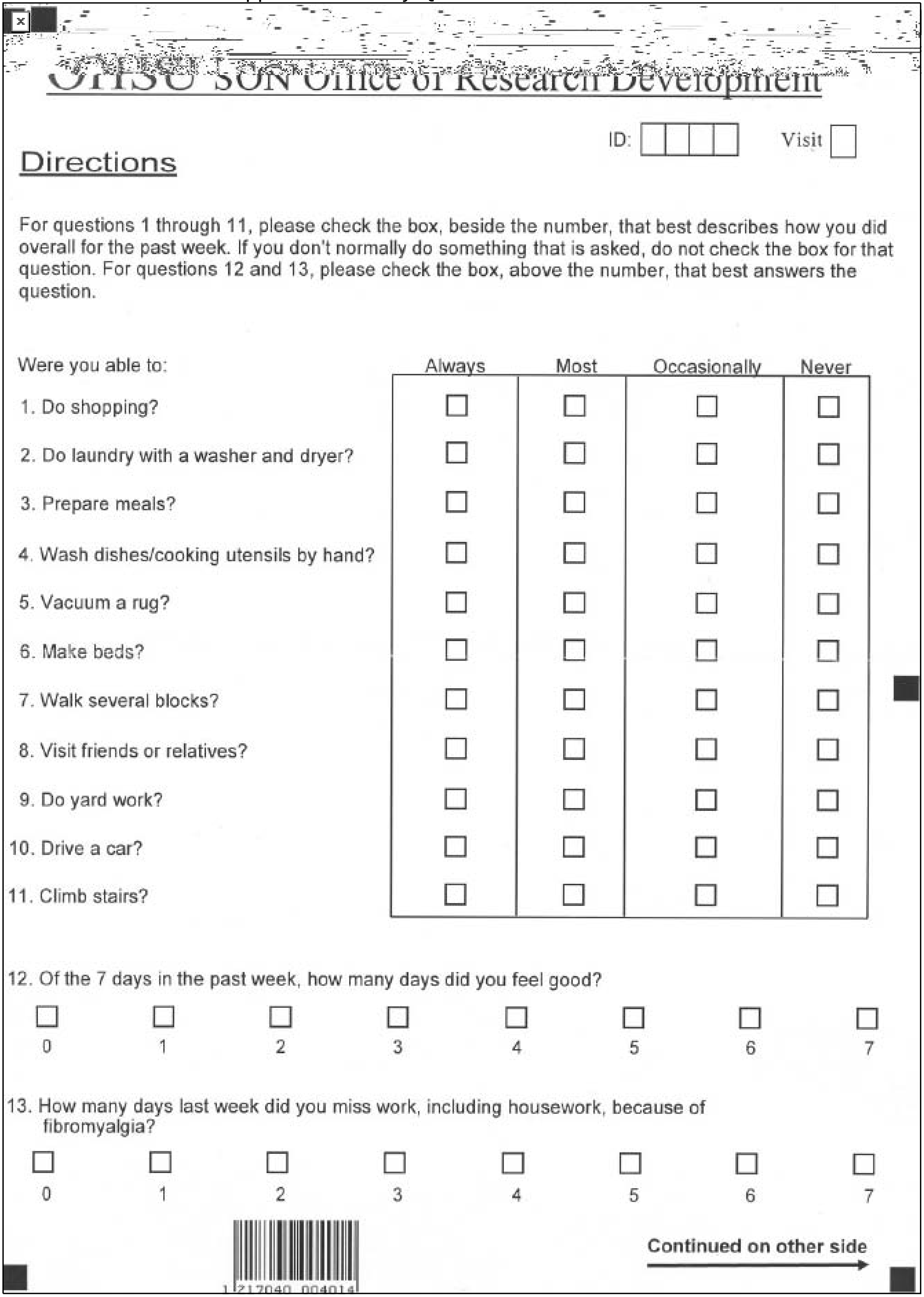
☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10
Does Not Interfere — Completely Interferes

F. Sleep

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10
Does Not Interfere — Completely Interferes

G. Enjoyment of life

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10
Does Not Interfere — Completely Interferes



OHSU SON Office of Research Development

ID: ☐☐☐☐ Visit ☐

Directions

For questions 1 through 11, please check the box, beside the number, that best describes how you did overall for the past week. If you don't normally do something that is asked, do not check the box for that question. For questions 12 and 13, please check the box, above the number, that best answers the question.

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

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

☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7

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

☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7

Continued on other side →

Late Life
Function and
Disability Instrument

Late Life FDI: Function component

BOSTON
UNIVERSITY
SARGENT
College *of* Health
and Rehabilitation
SCIENCES

Co-Authors:

Alan Jette, Ph.D., MPH, PT   Stephen Haley, Ph.D., PT

Roybal Center for the Enhancement of Late-Life Function
Sargent College for Health and Rehabilitation Sciences
Boston University

This research to develop this instrument was supported by
The National Institutes for Health's
National Institute on Aging
Grant No. AG11669

Contents

INSTRUCTIONS FOR FUNCTION QUESTIONS:

In this following section, I will ask you about your ability to do specific activities as part of your daily routines. I am interested in your *sense of your ability* to do it on a typical day. It is not important that you actually do the activity on a daily basis. In fact, I may mention some activities that you don't do at all. You can still answer these questions by assessing how difficult you think they would be for you to do on an average day.

Factors that influence the level of difficulty you have may include: pain, fatigue, fear, weakness, soreness, ailments, health conditions, or disabilities.

I want to know how difficult the activity would be for you to do without the help of someone else, and without the use of a cane, walker or any other assistive walking device (or wheelchair or scooter).

Interviewer personal note:
For the Function items, using fixed support is acceptable (e.g. holding onto furniture, walls), unless otherwise specified in the item.

[Show visual aid to interviewee]

Please choose from these answers:

None
A little
Some
Quite a lot
Cannot do

Let's begin…

Function Questions

How much difficulty do you have….? (Remember this is without the help of someone else and without the use of any assistive walking device.)	None	A little	Some	Quite a lot	Cannot do
F1. Unscrewing the lid off a previously unopened jar without using any devices	5	4	3	2	1
F2. Going up & down a flight of stairs inside, using a handrail	5	4	3	2	1
F3. Putting on and taking off long pants (including managing fasteners)	5	4	3	2	1
F4. Running 1/2 mile or more	5	4	3	2	1
F5. Using common utensils for preparing meals (e.g., can opener, potato peeler, or sharp knife)	5	4	3	2	1
F6. Holding a full glass of water in one hand	5	4	3	2	1
F7. Walking a mile, taking rests as necessary	5	4	3	2	1
F8. Going up & down a flight of stairs outside, without using a handrail	5	4	3	2	1
F9. Running a short distance, such as to catch a bus	5	4	3	2	1
F10. Reaching overhead while standing, as if to pull a light cord	5	4	3	2	1
F11. Sitting down in and standing up from a low, soft couch	5	4	3	2	1
F12. Putting on and taking off a coat or jacket	5	4	3	2	1
F13. Reaching behind your back as if to put a belt through a belt loop	5	4	3	2	1
F14. Stepping up and down from a curb	5	4	3	2	1
F15. Opening a heavy, outside door	5	4	3	2	1
F16. Rip open a package of snack food (e.g. cellophane wrapping on crackers) using only your hands	5	4	3	2	1
F17. Pouring from a large pitcher	5	4	3	2	1
F18. Getting into and out of a car/taxi (sedan)	5	4	3	2	1

Function Questions, continued

How much difficulty do you have….? (Remember this is without the help of someone else and without the use of any assistive walking device.)	None	A little	Some	Quite a lot	Cannot do
F19. Hiking a couple of miles on uneven surfaces, including hills	5	4	3	2	1
F20. Going up and down 3 flights of stairs inside, using a handrail	5	4	3	2	1
F21. Picking up a kitchen chair and moving it, in order to clean	5	4	3	2	1
F22. Using a step stool to reach into a high cabinet	5	4	3	2	1
F23. Making a bed, including spreading and tucking in bed sheets	5	4	3	2	1
F24. Carrying something in both arms while climbing a flight of stairs (e.g. laundry basket)	5	4	3	2	1
F25. Bending over from a standing position to pick up a piece of clothing from the floor	5	4	3	2	1
F26. Walking around one floor of your home, taking into consideration thresholds, doors, furniture, and a variety of floor coverings	5	4	3	2	1
F27. Getting up from the floor (as if you were laying on the ground)	5	4	3	2	1
F28. Washing dishes, pots, and utensils by hand while standing at sink	5	4	3	2	1
F29. Walking several blocks	5	4	3	2	1
F30. Taking a 1 mile, brisk walk without stopping to rest	5	4	3	2	1
F31. Stepping on and off a bus	5	4	3	2	1
F32. Walking on a slippery surface outdoors	5	4	3	2	1

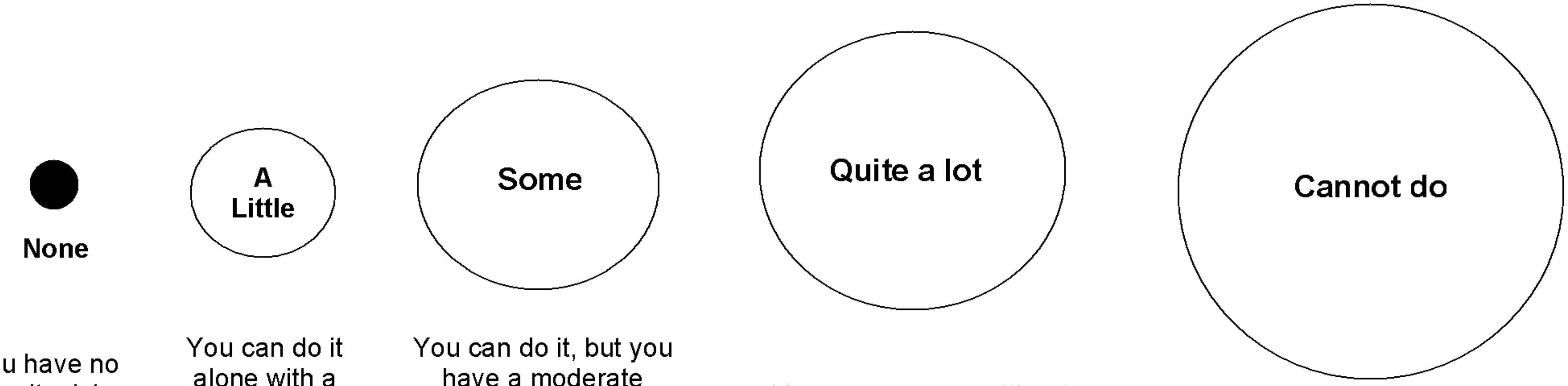
Function Questions
For those who use walking devices

The following are questions only for people using canes, walkers, or other walking devices.

When you use your cane, walker, or other walking device, how much difficulty do you have…?	None	A little	Some	Quite a lot	Cannot do
FD7. Walking a mile, taking rests as necessary	5	4	3	2	1
FD8. Going up & down a flight of stairs outside, without using a handrail	5	4	3	2	1
FD14. Stepping up and down from a curb	5	4	3	2	1
FD15. Opening a heavy, outside door	5	4	3	2	1
FD26. Walking around one floor of your home, taking into consideration thresholds, doors, furniture, and a variety of floor coverings	5	4	3	2	1
FD29. Walking several blocks	5	4	3	2	1
FD30. Taking a 1 mile, brisk walk without stopping to rest	5	4	3	2	1
FD32. Walking on a slippery surface, outdoors	5	4	3	2	1

FUNCTION VISUAL AID #1

Currently, how much difficulty do you have in doing the activity without the help of someone else, and without the use of a cane, walker or any other assistive walking device?



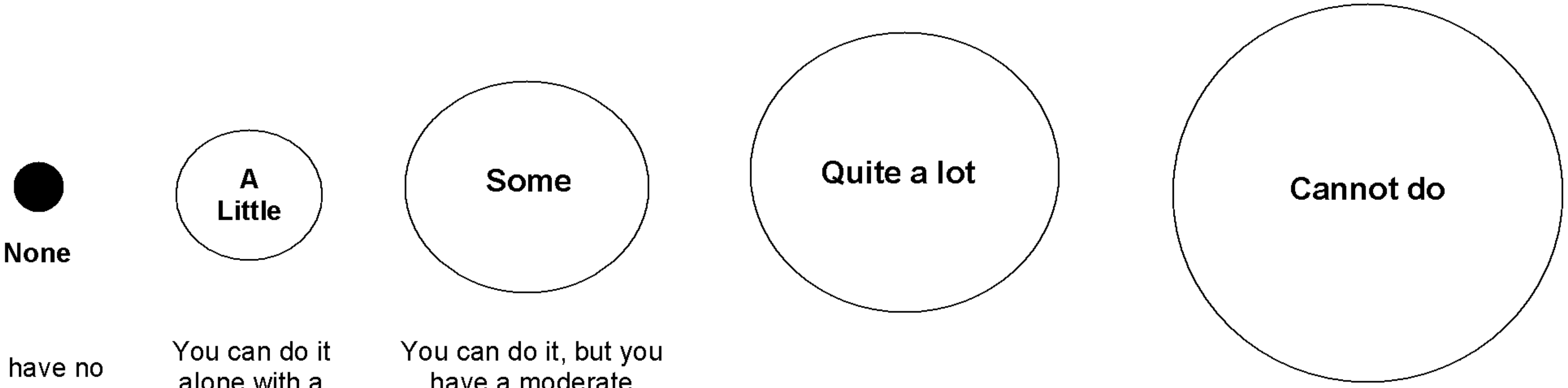
None	A Little	Some	Quite a lot	Cannot do
You have no difficulty doing The activity alone	You can do it alone with a little bit of difficulty	You can do it, but you have a moderate amount of difficulty doing it alone	You can manage without help, but you have quite a lot of difficulty doing it	It is so difficult, that you cannot do it unless you have help

Factors that may influence your level of difficulty:

Pain
Fatigue
Fear
Soreness
Ailments
Disabilities

FUNCTION VISUAL AID #2 **(For users of canes or walkers only)**

Currently, how much difficulty do you have in doing the activity when you use your cane, walker, or any other assistive walking device?



None	A Little	Some	Quite a lot	Cannot do
You have no difficulty doing The activity alone	You can do it alone with a little bit of difficulty	You can do it, but you have a moderate amount of difficulty doing it alone	You can manage without help, but you have quite a lot of difficulty doing it	It is so difficult, that you cannot do it unless you have help

Factors that may influence your level of difficulty:

- Pain
- Fatigue
- Fear
- Soreness
- Ailments
- Disabilities