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Perceived contributing factors, locus of control and self-efficacy in patients with fibromyalgia syndrome (FMS)

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A Thesis

Entitled

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By

Sara L. Holl

Submitted to the Graduate Faculty as partial fulfillment of the

Requirements for the Masters of Science in Pharmaceutical Science Degree in Pharmacy

Health Care Administration

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The University of Toledo

August, 2011

An Abstract of

Perceived Contributing Factors, Locus of Control and Self Efficacy in Patients with

Fibromyalgia Syndrome (FMS)

by

Sara L. Holl

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May 2011

Health care providers should have a better understanding of how a fibromyalgia patient perceives their illness in order to tailor interventions specific to the patient's biological and psychosocial needs. A cross-sectional, exploratory study design was used to evaluate the perceived contributing factors, locus of control and self-efficacy of 267 female fibromyalgia patients via an online survey. The most frequent perceived contributing factors were stress/worry, overwork and accident or injury. Participants tended to have a more internal locus of control and lower levels of self-efficacy. Respondents with an internal locus of control were more confident in performing skills necessary to manage their fibromyalgia compared to those respondents with an external locus of control. The internal reliability and validity of the survey instrument was acceptable. Healthcare professionals can use this survey to assess fibromyalgia patients' beliefs about their illness and their ability to effectively participate in self-management techniques.

Acknowledgements

This thesis would not have been possible without the love and support of my parents and my fiancé, Mike. I will never be able to thank you enough and I will be forever grateful. Earning a Master's degree has been a very important personal goal, and I would not have achieved it without you.

I would also like to thank my major advisor, Dr. Sharrel Pinto, and my committee members, Dr. VarunVaidya and Dr. Curtis Black. You have all been very supportive and I appreciate all of the guidance you have given me along the way. Additionally, I would like to thank the faculty, staff, and my fellow colleagues at the University of Toledo for all of your assistance and support.

Contents

List of Tables

Chapter 1

Introduction

Interest in fibromyalgia (FM) has risen in recent years due to the increase in prevalence of this condition. Still, very little is known about the etiology of fibromyalgia and the common characteristics of the patients that suffer from it. Classified by the American College of Rheumatology merely as a syndrome consisting of widespread chronic pain for at least 3 months and pain in at least 11 of 18 tender points, it is often difficult to diagnose.[1] Patients experience a variety of additional symptoms including fatigue and disturbed sleep patterns, anxiety or depression, and sensitivity to light and temperature.[2]

Experts have not been able to determine a definitive cause for fibromyalgia as of yet. A limited amount of studies have been conducted to explore possible contributing factors. The most commonly explored factor is the link between those who have experienced some type of physical trauma. Those people who have sustained a musculoskeletal injury, such as whiplash or other soft tissue trauma to the neck or spine,

have been found to develop FM at a higher rate.[3-6] Closely related to this hypothesis is the idea that high levels of stress, such as traumatic childhood experiences or post-traumatic stress disorder, leads to the development of FM.[7,8] Sleep disorders have also been correlated with the possible onset of fibromyalgia.[9,10] Patients with FM have also been linked with hormonal deficiencies and perturbations in certain studies, specifically sex hormones and those related to the neuroendocrine system.[11-14] Conflicting evidence has been found concerning genetic influences on the development of fibromyalgia. Some studies have concluded that there is a link, while others have not.[15] Interestingly, some studies have looked at the connection between women who have silicone breast implants and the prevalence of FM.[16,17] Breast cancer is also of interest due to its high prevalence in females and its onset frequently being related to imbalances in sex hormones. These studies all have limited sample sizes and populations, and often arrive at inconclusive results. More studies are needed to make solid conclusions as to what additional factors lead to the development of FM.

Demographic factors may play a large role in the development of FM. However, little is known about the universal demographic characteristics of patients with FM so it is difficult to make any definite connections. It has been found that approximately 90% of FM cases in the United States occur in women.[18] One study found that FM was slightly more prevalent in Caucasian women when compared to African American women.[19] Additionally, some research has found that full-time employment is beneficial to fibromyalgia patients while other studies argue that working full-time aggravates fibromyalgia symptoms.[20-22] Of the few studies that have looked at demographic

correlations, most have not been able to find any significant relationships among variables such as age or race.[23-25] This may be due to the small sample sizes of many of these studies.

Convincing and supported information concerning FM patients will help make this disease easier to diagnose and can ultimately lead to universal acceptance of FM as a legitimate medical condition. If factors leading to the development of FM can be identified, then ways in which to prevent FM can be addressed.

Health care providers should have an understanding of how a fibromyalgia patient perceives their illness in order to tailor interventions specific to the patient's biological and psychosocial needs. A considerable amount of evidence has suggested that patient-physician agreement about patients' concerns is associated with improved health outcomes, increased patient satisfaction, and adherence to treatment recommendations.[26-34] Most fibromyalgia patients visit several physicians through the process of obtaining an accurate diagnosis, as some physicians likely dismissed their concerns or considered them to be hypochondriacal.[35] These occurrences often perpetuate the mistrust of physicians. Additionally, compliance with complex fibromyalgia self-management therapy regimens tends to be low, particularly if there is poor patient-physician concordance with respect to treatment.[35] Physicians must be aware of the correlation between fibromyalgia patients' illness perceptions and the effect it has over personal and treatment control in order to make the most appropriate treatment recommendations and provide the highest quality care.

Health care providers must find ways to better understand fibromyalgia patients' behaviors in order to make appropriate changes and further optimize treatment therapies. One way to do this is through the use of health behavior theory, which can help researchers and physicians to better comprehend and explain patient behaviors.[36] This is particularly vital to the success of self-management of patients with chronic diseases, such as fibromyalgia. Bandura's social cognitive theory illustrates how human behavior can be interpreted and predicted through a person's beliefs by means of measuring self-efficacy expectations and outcomes expectations (i.e. locus of control).[37]

When studying outcome and self-efficacy expectations for medication management, health professionals can educate and socially support patients. Consistent with Bandura's social cognitive theory, health care providers (such as physicians and pharmacists) may act as role models and present avenues to help patients master specific behaviors.[36] Positive reinforcement given by a health professional will likely lead to improved patient outcome and self-efficacy expectations. The social cognitive theory states that, among other factors, an individual's social environment influences their behavior.[37] Part of a person's social environment is the social support they receive from others, which can include social, physical or emotional assistance from health professionals by way of interpersonal interactions focused on the concern for the patient. Health care professionals can serve in a social support role and have the ability to positively influence the patients' outcome and self-efficacy expectations for medication management as well as self-management practices.

4

1.1   Need for Research

There is a need for a study that examines characteristics of FM patients on a larger scale. To date, virtually all studies conducted have only been able to examine a small, concentrated group of patients and generalizability is limited. Furthermore, many studies have been done in countries other than the U.S. which, again, can lend itself to reduced generalizability for American patients.

Patients' illness perceptions may play a large role in choices regarding treatment since a majority of care for a chronic disease, such as fibromyalgia, is managed by the individual.[10] While this ideal has been examined in other chronic illness groups, very little research has been published to date on this topic in the fibromyalgia population.[38] More studies need to be done concerning fibromyalgia patients' illness perceptions in relation to health behaviors.

Specifically, there is a lack of studies addressing fibromyalgia patients' behaviors according to health behavior theory in a large patient population. This gap in the literature can be filled by the results of this study.

1.2   Significance

This study would draw on patients from all areas of the United States and collect information on an array of factors to determine prevalence. This study hopes to gain

information on not only the factors that have been identified thus far, but will elicit responses from patients as to any other factors that may have contributed to the development of their condition. Presently, patients have not been asked for their own opinion as to the factors that they feel may have contributed most to their disease. The studies up until now have only focused on one specific patient population and a singular possible factor. Eliciting direct responses from a wide variety of patients with different experiences and in various settings will allow the researchers to gather the most common factors that link all of the patient population. Discovery of any possible new factors can serve as a starting point for future research.

Similarly, there is much to gain from identifying demographic factors that are common amongst FM patients. These factors may help to identify specific populations of people who may be at a higher risk for developing FM. Considering the degree of uncertainty concerning this disease state and its epidemiology, the information collected from this study would be of great help to the scientific and medical community.

Patients with fibromyalgia struggle daily with justifying the legitimacy of an illness with many non-visible symptoms, such as pain and fatigue.[39] Studies have reported that female fibromyalgia patients experience a great deal of stress due to the disagreement between how they perceive their illness and the lack of objective findings to support the existence and severity of their condition.[40] Feelings of rejection and confusion often prevent them from handling their illness constructively.[40] This study will highlight the importance of health care providers' social support and hopefully encourage

them to empathize with their fibromyalgia patients in an effort to improve patients'

illness perceptions. Improved illness perceptions will likely lead to improved outcomes

and a better quality of life for the patients.[41]

One of the most significant applications of the results of this study is that

physicians can generalize information of perceived contributing factors, locus of control

and self-efficacy to better approach and understand their fibromyalgia patients.

Currently, very little is known about the characteristics, beliefs and behaviors of "typical"

fibromyalgia patients. Health care professionals can use the results reported in this study

to make assumptions about the female fibromyalgia patient population in the United

States, due to the larger sample size and wide geographic area from which it was drawn.

Improved therapy regimens may also result from this information.Physicians may

be able to categorize fibromyalgia patients based on their locus of control and

self-efficacy and can better assess their willingness and future success with disease

self-management. Medication therapy management (MTM) programs can be designed

for fibromyalgia patients to include interventions aimed at improving patients'

self-efficacy and addressing locus of control. These tailored interventions can increase

the degree of fibromyalgia patients' internal control and empower them to make better

choices regarding their therapy. Fibromyalgia patients may develop more confidence and

become more active in managing their disease, leading to improved health outcomes and

enhanced quality of life.

1.3   Goal

To discover common characteristics and behaviors of female fibromyalgia

patients in the United States.

1.4   Objectives

1) To describe the patient population and demographic characteristics.

2) To describe the perceived contributing factors of fibromyalgia infemale

   fibromyalgia patients.

3) To describe the locus of control in female fibromyalgia patients.

4) To describe the self-efficacy in female fibromyalgia patients.

5) Develop a reliable and valid survey instrument to measure perceived

   contributing factors, locus of control, and self-efficacy in female fibromyalgia

   patients.

Chapter 2

Literature Review

This chapter provides an overview of the literature related to the study. It is divided into the following sections: 1) Fibromyalgia Syndrome; 2) Etiology and Pathophysiology of Fibromyalgia; 3) Diagnosis of Fibromyalgia; 4) Prevalence of Fibromyalgia in the United States/Demographic Characteristics; 5) Treatment Options for Fibromyalgia; 6) Possible Contributing Factors to the Development of Fibromyalgia; 7) Illness Perceptions in Fibromyalgia Patients; 8) Treatment Satisfaction in Fibromyalgia Patients; & 9) Theoretical Framework.

2.1.   Fibromyalgia Syndrome

Fibromyalgia syndrome (FM or FMS) is an idiopathic, multisystem, chronic condition. It is distinguished by an array of symptoms, including diffuse widespread musculoskeletal pain, poor sleep, fatigue, mood disorders, paresthesias, and cognitive

difficulties, as well as other associated indicators.[26]Currently, no formal system or laboratory test exists for the clinical diagnosis of this condition. The American College of Rheumatology provided criteria for the classification of FM in 1990 and is still used today.[1]A patient must have a history of widespread pain for at least three months. Widespread pain is defined as pain in the left side of the body, pain in the right side of the body, pain above and below the waist, presence of axial skeletal pain, shoulder and buttock pain, and lower back pain. Also, a patient with fibromyalgia must experience pain in at least 11 out of 18 tender point sites located at various points on the body. Tender points are defined as specific places on the muscle that elicit a feeling of sensitivity when pressure is applied (normally 4 kg). The pain is confined to the tender point; it does not trigger pain anywhere else on the body. If a patient meets both of these criteria, they are considered to have fibromyalgia.[1]

In 1904, Sir William Gowers first used the term "fibrositis" to describe a painful condition of the muscles which he believed was due to inflammation. Years later, studies done by Smythe and Moldofsky found that the diffuse tenderness that patients experienced was not due to inflammation of the muscle nor fibrous tissue.[27] Consequently, the term for the condition was changed from fibrositis to fibromyalgia in 1976.[2,4] The term "fibromyalgia" comes from the Latin roots "fibro" (connective tissue), "my" (muscles), "al" (pain), and "gia" (condition of).[26]

Over the years, fibromyalgia has progressively been acknowledged as one of most common causes for chronic widespread pain, most commonly in women. However, this syndrome is still poorly understood due to its unknown etiology.[2,26]

2.2   Etiology and Pathophysiology of Fibromyalgia

Review of the literature uncovers many theories associated with the possible etiology of FM. However, the exact cause of this condition has not been proven as of now. It is likely that the true etiology of FM is complex and caused by the combination of multiple syndromes.[2,26,28] Some of the most commonly identified factors that perhaps play a role in the pathophysiology of FM will be discussed here.

Many studies provide support for the relationship between stress and altered activity in both the sympathetic nervous system and the hypothalamic-pituitary-adrenal (HPA) axis.[26,29] Studies have found that patients with fibromyalgia often have significant dysregulation of the HPA axis.[29] This HPA axis dysfunction leads to disturbances in the stress/adaptation response in FM patients.   Patients with a poorly regulating HPA axis have many hormonal imbalances, including elevated basal levels of adrenocortical trophic hormone (ACTH) and follicle-stimulating hormone as well as decreased levels of insulin-like growth factor 1 (IGF-1), growth hormone, estrogen, cortisol, and thyroid hormones. Reduced levels of the acetic acid 5-hydroxyindole (5-HT), which has an effect on peripheral and central pain processing, may also contribute to HPA axis abnormalities.[29] While it has yet to be found whether these neurohormones are

fundamental to or secondary causes of the pathogenesis of fibromyalgia, many of these hormones have an influence on the body's ability to perceive pain and can likely be related to FM pain.[26]

Elevated levels of cerebrospinal fluid substance P, an excitatory neurotransmitter, are found in more than 80% of patients with fibromyalgia. Substance P contributes to the transmission of pain impulses from peripheral receptors to the central nervous system. Elevated levels of substance P are associated with increased sensitivity of nerves to pain and heighten the body's pain awareness.[26] High concentrations of substance P in patients with FM may be related to reduced 5-HT levels. This combination leads to a decreased in presynaptic inhibition of pain-related primary afferent neurons.[29]Increased levels of substance P have been positively correlated with more severe sleep disturbance.[30]

Low serotonin levels may be the most widely recognized biochemical abnormality connected with fibromyalgia syndrome. Researchers have focused on serotonin levels mostly for its involvement in both stage 4 sleep and pain modulation.[26] Low serotonin levels are also believed to contribute to depression, sleep disturbances, anxiety, pain, and impaired smooth muscle function.[31] About 30% of patients with FM are also diagnosed with a depression, which could be a result of decreased serotonin levels.[32] Serotonin levels in the central nervous system may be estimated indirectly by way of low levels of tryptophan and 5-HT.[33]

Numerous theories revolve around the idea that FM is somehow related to sleep quality. Studies utilizing electroencephalographs (ECG) have shown that fibromyalgia patients lose deep sleep, which is often referred to as stage 4.[33] Stage 4 sleep is theorized to be vital to nervous system functioning and conditions that interfere with stage 4 sleep (such as anxiety or pain), can cause or worsen existing circumstances. One example is growth hormone, which is produced during stage 4 sleep. Low levels of growth hormone are often found in FM patients. Growth hormone is involved in tissue repair; therefore, low levels of growth hormone could be caused from lack of stage 4 sleep and contribute to diffuse tissue pain.[26]

Due to the elusiveness of fibromyalgia's etiology and pathophysiology, diagnosis of this syndrome is very difficult and often controversial.

2.3   Diagnosis of Fibromyalgia

Even though FM has become more prevalent in recent years, it still remains highly under-diagnosed and inadequately treated. The only clinical diagnostic criteria that is universally accepted for fibromyalgia comes from the American College of Rheumatology (ACR).[1]Most often, physicians must perform a differential diagnosis to rule out the possibility of a patient having one of the many other diseases that overlap with or mimic fibromyalgia. Similar conditions include polymyalgia rheumatic, hypothyroidism, chronic fatigue syndrome, and myofascial pain syndrome. Patients should also be evaluated for the possibility of an endocrine disease, neurologic disorder,

psychiatric disorder, or sleep disorder. Physicians should also be aware of the other overlapping conditions associated with FM, such as irritable bowel syndrome, interstitial cystitis, metabolic and inflammatory myopathies, rheumatoid arthritis, systemic lupus erythematosus (SLE), and osteoarthritis.[2,26]

Physicians do not use ACR criteria alone to diagnose patients with FM and not all patients who meet the ACR criteria necessarily have FM. There are many clinical markers that are associated with fibromyalgia and physicians will look for the presence of certain symptoms in addition to meeting ACR criteria.[34] There are three key features that are present in nearly every patient diagnosed with fibromyalgia syndrome: widespread musculoskeletal pain, fatigue, and sleep disturbance.[2]Paresthesias, cognitive dysfunction (such as short term memory loss), mood disturbances, and headaches are often found in most FM patients. Waxing and waning of presenting symptoms is fairly common. Fibromyalgia symptoms are exacerbated by humid and cold weather, physical or mental stress, and poor sleep. Moderate physical activity, adequate sleep, relaxation, and warm and dry weather have been known to improve symptoms.[2]

Due to the fact that there are currently no diagnostic studies to confirm the diagnosis of fibromyalgia, other methods must be used. Most often this involves a multistep approach including a comprehensive physical examination and history, rheumatology and neurology workup, and a psychiatric evaluation.[35]There are no laboratory abnormalities or blood tests that can confirm the diagnosis of fibromyalgia. However, laboratory tests are still very useful for ruling out the possibility of the patient

having another condition. Another helpful tool is the Fibromyalgia Impact Questionnaire (FIQ), a validated survey instrument meant to measure the wide range of FM-related symptoms and monitor a patient's response to therapy. Numerous studies have shown that FM patients can be distinguished from patients who may have another similar condition by their scores on the FIQ.[42]

2.4   Prevalence of Fibromyalgia in the United States/Demographic Characteristics

Presently, nearly 6 million Americans (2-4% of the general population) in the United States are affected by fibromyalgia. The majority of FM cases are seen in women, with the estimate falling between 80-90%.[43] FM is most commonly diagnosed in middle-aged women, ranging from ages 40-75, and is often menopausal.[26,44] Fibromyalgia syndrome occurs in 5-6% of adult patients attending general medical and family practice clinics. This statistic increases to 10-20% of adults who are seeing a rheumatologist, making it one of the most frequent diagnoses in office-based rheumatology practices.[29]

Little else is known about fibromyalgia patients in terms of common demographic factors. Of the few studies that have looked at demographic correlations, most have not been able to find any significant relationships among variables such as income, education, age or race.[23-25] One study found that FM was slightly more prevalent in Caucasian women compared to African American women.[19] Some studies show that

fibromyalgia is more common in patients who have a family member with fibromyalgia.[45] There is also often a high prevalence of pain syndromes, sleep disorders, and mood disorders in these families. This suggests a possible role of genetic and environmental factors in the development of fibromyalgia.[46]

2.5   Treatment Options for Fibromyalgia

Currently, the need for successful pharmacotherapy for fibromyalgia syndrome is not being met. Due to the inability to categorize a specific cause for FM, research has shifted its focus to symptom management as opposed to etiology.[47] Because symptoms often fluctuate in severity, treatment for fibromyalgia is approached from a chronic illness standpoint instead of management of a single episode.[47] Regardless of the form of treatment, all therapies have the common goals of controlling severe pain, improving sleep and increasing daily functioning.[26,29]

The most successful treatments for fibromyalgia fall under the category of central nervous system agents. These forms of drugs affect numerous neurochemicals (such as substance P, serotonin, and norepinephrine) that have a wide variety of functions in the spinal cord and brain. These functions include modulation of pain sensation and tolerance.[42] Antidepressants, specifically tricyclic antidepressants (TCA), have the widest amount of support and proven efficacy in treatment of FM symptoms.[26, 48-51]The most common TCA that is prescribed for fibromyalgia patients is amitriptyline (Elavil). TCAs work by blocking the reuptake of norepinephrine and serotonin in the body. This can

help treat a patient's pain, fatigue, and sleep disturbances as well as promote a sense of well-being.[26] Tricyclic antidepressants were found to be better than a placebo in two meta-analyses in the treatment of FM and were found to be more effective than the placebo for all clinical outcomes.[48] A study by Winfield found that approximately one third of patients experienced moderate short-term improvements in pain, disturbed sleep, patient and physician assessments, physical status, psychological status, and capacity of activities of daily living.[52] Most physicians will start FM patients on low doses of TCA and gradually increase the dose over time due to its anticholinergic side effects and possible weight gain.[2]

Selective serotonin reuptake inhibitors (SSRIs) have also shown modest evidence for efficacy. A notable study done by Arnold et al.[53] found that female patients with FM who took fluoxetine (Prozac) improved their total scores on the Fibromyalgia Impact Questionnaire (FIQ), as well as subscores for pain, fatigue, and depression compared to the control group. However, pain in tender points and total myalgic scores were not significantly improved and there were no differences in the measures of mood disturbances between the two groups.[53] Published studies supporting the use of SSRIs are limited, yet clinical experience sustains the notion that SSRI's should be tried in patients with FM.[54] While they are not viewed as effective as TCAs for analgesic purposes, SSRI's can be used for depression associated with fibromyalgia.[26]

While generally not effective as single-acting agents, muscle relaxants given in combination with a TCA or SSRI may alleviate some symptoms of FM.[26] Recently, a

meta-analysis validated the efficacy of cyclobenzaprine (Flexeril) in patients with fibromyalgia.[55] Cyclobenzaprine is structurally similar to tricyclic antidepressants and is shown to be most effective in improving sleep and reducing pain.[55] The American Pain Society sponsored clinical practice guidelines, entitled *Management of Fibromyalgia Syndrome*, which support the use of cyclobenzaprine and state there is strong evidence for efficacy.[56]

In 2007, the FDA approved pregabalin (Lyrica) for the treatment of fibromyalgia, making it the first drug approved specifically for fibromyalgia patients.[57]Pregabalin (PGB) is a second-generation anticonvulsant that binds to and modulates voltage-gated calcium channels. PGB diminishes the release of neurotransmitters, including norepinephrine and substance P, by reducing calcium influx at nerve terminals. While the exact mechanism is not understood, this is assumed to be the basis for the drug's anticonvulsant as well as analgesic properties.[58] A meta-analyses of randomized controlled trials examining the effects of FM symptoms treated with pregabalin, it was found that there was strong evidence for pain reduction, improved sleep, and improved health-related quality of life. A reduction in fatigue and anxiety were also observed, but were not substantial.[58]

Other classes of drugs have shown little to no proven efficacy in the treatment of fibromyalgia. Randomized clinical trials have shown some evidence for the effectiveness of duloxetine (Cymbalta), a serotonin/neorepinephrine reuptake inhibitor (SNRI), and tramadol (Ultram), a centrally acting synthetic analgesic drug.[2, 48-51] No strong evidence

for efficacy has been found for opioids, corticosteroids, nonsteroidal anti-inflammatory drugs, and thyroid hormones.[58]

In addition to prescription medication, other alternative therapies are often recommended in the treatment of fibromyalgia syndrome. The most highly recommended non-pharmacologic treatment is exercise.[2, 26,29,48]Exercise programs have been found to improve pain, physical function, and psychological status.[2, 48] However, patients often have difficulties in maintaining a regular exercise schedule due to pain and fatigue associated with FM.[2] Many studies have found that some form of psychological therapy, particularly Cognitive Behavioral Therapy (CBT), is also an effective form of treatment. Several longitudinal randomized controlled trials found improved function and decreased pain severity in FM patients participating in CBT.[59-62] Other trials have noted improvements in patients practicing meditation, relaxation, and stress management.[63] Types of complementary and alternative medications (CAM) such as acupuncture, massage therapy, hypnotherapy, chiropractic therapy, and EMG biofeedback have been used by FM patients.[2,26,48] Patient education is often emphasized as essential in the treatment of fibromyalgia. The more patients understand about their condition, the easier it will be for them to take on a more active role in their treatment and can develop self-management plans.[2]A multidisciplinary approach is often taken when it comes to fibromyalgia treatment. A combination of exercise, cognitive behavioral therapy, and patient education along with pharmacotherapy would result in an optimal treatment program.[2,48]

2.6   Possible Contributing Factors to Fibromyalgia

Experts have not been able to determine a definitive cause for fibromyalgia as of yet. A limited amount of studies have been conducted to explore possible factors. The most commonly explored factor is the link between those who have experienced some type of physical trauma. Those people who have sustained a musculoskeletal injury, such as whiplash or other soft tissue trauma to the neck or spine, have been found to develop FM at a higher rate.[3-6]Closely related to this hypothesis is the idea that high levels of stress, such as traumatic childhood experiences or post-traumatic stress disorder, leads to the development of FM.[7,8] Sleep disorders have also been correlated with the possible onset of fibromyalgia.[9,10]Patients with FM have also been linked with hormonal deficiencies and perturbations in certain studies.[11-14]Questionable evidence has been found regarding genetic influences on the development of fibromyalgia.[15] Research has also examined the association between women who have silicone breast implants and the prevalence of FM.[16,17]

Demographic factors may play a large role in the development of FM. However, little is known about the universal demographic characteristics of patients with FM so it is difficult to make any definite connections. It has been found that approximately 90% of FM cases in the United States occur in women.[18]Female patients are generally more at risk for pain syndromes due to increased pain sensitivity compared to males. Women apparently lack certain pain-inhibitory mechanisms that men do not. Also, reproductive hormones have been found to influence central pain-modulatory mechanisms.[2]One study

20

found that FM was slightly more prevalent in Caucasian women when compared to African American women.[19] A single study found that women with a lower education level were more likely to develop fibromyalgia.[25] Inconclusive results have been found concerning whether employment has a positive or negative effect on FM patients.[20-22]

Of the few studies that have looked at demographic correlations, most have not been able to find any significant relationships among variables such as income, education, age, or race.[23-25] This may be due to the small sample sizes of many of these studies. A better understanding of common demographic factors of FM patients may help to identify at-risk populations.

2.7   Illness Perceptions in Fibromyalgia Patients

Patients with fibromyalgia struggle daily with justifying the legitimacy of an illness with many non-visible symptoms, such as pain and fatigue.[39] Studies have reported that female fibromyalgia patients experience a great deal of stress due to the disagreement between how they perceive their illness and the lack of objective findings.[40] Feelings of rejection and confusion often prevent them from handling their illness constructively.[2]

Patients' illness perceptions are believed to influence coping responses to an illness. This theory is demonstrated in Leventhal's common sense self-regulation model (CSSRM) of illness representations.[64] The model proposes that patients construct their

own illness representations to help them rationalize their experience and provide a foundation for their coping response. Leventhal's CSSRM consists of five core components of patients' representations including beliefs about the etiology of the illness (cause), its symptoms and labels (identity), personal consequences of the illness (consequences), the expected duration (timeline), and the expectation that the individual or healthcare provider can control or influence the outcome of the illness (controllability). These dimensions may explain the selection of coping strategies and adherence to treatment.[64]

Recently, illness perceptions and cognitions have been acknowledged for their importance in the ability to control musculoskeletal conditions, including fibromyalgia, where catastrophizing is common.[65] A number of studies have indicated that patients with catastrophizing illness perceptions experience more pain, feel more disabled by their pain, experience more psychological distress, and have unfavorable pain treatment outcomes.[66-70] One particular study conducted by Nielson and Jenson found that fibromyalgia patients with more positive illness perceptions, such as believing to have control over pain and not viewing themselves as disabled by their pain, showed better treatment outcomes compared to those patients with negative illness perceptions.[70] Patients' illness perceptions may play a large role in choices regarding treatment since a majority of care for a chronic disease, such as fibromyalgia, is managed by the individual.[10] While this ideal has been examined in other chronic illness groups, very little research has been published to date on this topic in the fibromyalgia population.[10]

More studies need to be done concerning fibromyalgia patients' illness perceptions in the in relation to health behaviors and quality of life outcomes.

2.8   Locus of Control and Self-Efficacy

The construct locus of control originated from the social learning theory developed by Julian Rotter in 1966.[71] Social learning theory is based on the ideal that personality represents an interaction of the individual with their environment. Rotter proposed that, in order to understand behavior, one must take into account both the individual (in terms of life experiences) and the stimuli present in their environment. There are four main components present in Rotter's social learning theory: behavioral potential, expectancy, reinforcement value and the psychological situation. The most well-known construct within the social learning theory is locus of control. Locus of control, in relation to the social learning theory, refers to the concept of generalized expectancies for control of reinforcement. A more general definition describes locus of control as a person's belief about what causes the good or bad results in his/her life.

2.9   Theoretical Framework

Leventhal's common sense self-regulation model postulates that patients' illness perceptions play a significant role in how they cope with their illness and influence the choices that patients make concerning treatment. Therefore, the factors that fibromyalgia patients feel contributed most to the development of their fibromyalgia likely influence

how much control they believe they have over their condition (*i.e.*outcome expectations or locus of control). While it was important in this study to examine the outcome expectations of participants (locus of control), it was equally important to measure the confidence that the participants have in themselves to sufficiently perform the tasks necessary to produce the positive outcomes (self-efficacy). The social cognitive theory states that changes in a person's behavior will only occur when a person believes that outcomes are dependent upon their actions and, furthermore, that they believe they can adequately perform the action(s) necessary to produce the desired outcome. Based on these theoretical ideals, it is important for healthcare professionals to understand how a fibromyalgia patient's perceived contributing factors can influence how much control they feel they have over their disease and, furthermore, how much control a patient feels they have over their condition can influence the amount of confidence they have in performing the skills necessary to manage their fibromyalgia.

Figure 2.9 Theoretical Framework
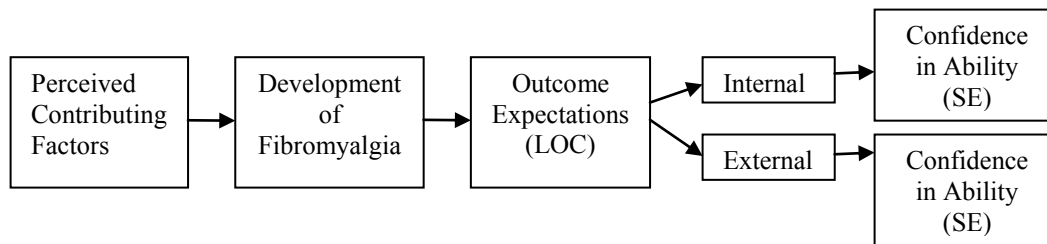
Fibromyalgia syndrome is a condition in need of extensive research in order to better understand not only the disease itself, but those patients who are diagnosed with it. Patients are anxious to find a cause for FM in order to validate the disease they suffer from and take appropriate steps towards possible prevention techniques for others. This

study will utilize this unique and determined patient population to do just that. Identifying possible causes and demographic characteristics common to FM patients and then linking them to the prevalence of symptoms will demonstrate universal patterns found across the nation. Information from this study can serve as a platform for many future studies seeking to better understand and provide evidence to support fibromyalgia patients.

Chapter 3

Methodology

       This chapter provides a detailed description of the methodology used to conduct this study. It is divided into the following sections: 1) Sample Selection; 2) Study Design; 3) Study Variables; 4) Survey Instrumentation; 5) Data Collection and Entry; 6) Sample Size; 7) Data Analysis. Approval from the Institutional Review Board (IRB) is needed because human subject participation is required. Approval will be obtained from the IRB at the University of Toledo.

3.1   Sample Selection

       The participants used for this study were female patients who were at least 18 years of age and had been diagnosed with fibromyalgia. Patients were selected from the 383 U.S. located fibromyalgia support groups from 48 states found on the National Fibromyalgia Association (NFA) website. NFA is the largest non-profit organization in the United States. The NFA works to provide support to patients with fibromyalgia. Over fifty individuals comprise its board of

directors, medical advisory board and staff. All hold professional degrees in their respective fields (i.e. MDs, PhDs). For the purposes of this study, the leaders of the individual support groups were contacted via email. A standard, detailed cover letter was sent explaining the study and emphasis was placed how important their contribution would be. The leaders who expressed that their support group would be interested in participating were sent links to the survey. The survey, consisting of a previously validated survey instrument, gathered information on the perceived possible causes of fibromyalgia, the patients' perceived personal control over their condition, as well as their perceived treatment control.

This patient population of NFA support group members was chosen because members of the association voluntarily become part of the support groups because it helped provide the support and motivation to overcome the debilitating nature of this condition. The principal investigator believed that these members would be actively interested in this study since it pertained directly to the groups' common interest (i.e. fibromyalgia).

3.2   Study Design

A cross-sectional, exploratory study design was used.

3.3   Study Variables

Variables included in this study consisted of demographic factors of the fibromyalgia patients (age, race, education, employment and state of residence) and the possible contributing factors of fibromyalgia. The 2nd objective involved the variable of common possible contributing factors of fibromyalgia*, which was defined based on results of a literature review and items already included in a previously validated survey instrument (Revised Illness Perception Questionnaire). Additional variables consisted of patients' scores on a locus of control scale and a self-efficacy scale that satisfied the 3rd, 4th, and 5thobjectives. Patients' locus of control are presented in the form of three subscales (internal, chance, and powerful others) and were calculated from the responses to the 18-item Multi-Dimensional Health Locus of Control (MHLC) scale. Patients' self-efficacy were calculated from the responses to 6 items on the Stanford Self-Efficacy for Managing Chronic Disease survey instrument.

Operational definition:*Researchers define "contributing factors" as any factors which lead patients to believe they developed fibromyalgia.

3.4   Survey Instrumentation

The Revised Illness Perception Questionnaire (IPQ-R) was developed to provide a quantitative assessment of the five components of the illness representations from Leventhal's common sense self-regulation model.[72] The IPQ-R also contains sections that gather information about patients' perceived causes of their condition and severity of symptoms using a 5-point Likert scale. For this study, the investigators used the 18-

itemsection on perceived contributing factors of the condition. Furthermore, the researchersclassified the perceived contributing factors as either internal or external according to Rotter's theory of locus of control. In this way, the perceived contributing factors could be compared to the scores on the Multi-Dimensional Health Locus of Control (MHLC) scale. The authors of the IPQ-R created the instrument so that it could be easily adapted to many disease states by replacing the generic phrase "my illness" with the condition of the patient population of interest. The IPQ-R has been previously used in the fibromyalgia patient population (referred to as the IPQ-R-FM) with successful results.[65]

The Multi-Dimensional Health Locus of Control (MHLC) Scale is one of the most widely used measures of health-related beliefs.[73] In this study, Form C of this survey was used, which is designed to measure "condition-specific" locus of control in patients with an existing medical condition. As with the IPQ-R-FM, the word "condition" could be replaced by "fibromyalgia". The MHLC scale calculates scores for four independent subscales of internal factors, external factors, and the extent to which powerful others and doctors affect patients' locus of control. The authors of the MHLC scale designed the subscales to be independent of one another and advise researchers that they do not have to calculate all four subscales for a study if it does not apply[73]; therefore, it would be acceptable to only calculate the scores for only those subscales which directly apply to the study. The scale consists of 18 Likert scale items, each item ranging from 1 (strongly disagree) to 6 (strongly agree). These scores are reported on a continuous scale and were calculated as the sum of the values selected for each item. Higher scores

indicate a more internal LOC while a lower score indicates a more external LOC. It is

important to note that there is no definitive cut-off to classify a patient as "external" or

"internal" and the author strongly advises against attempting to do so. The difference

between internal or external locus of control is a false dichotomy, in that a person does

not exhibit either an internal or external locus of control for all beliefs in their lives.

Rather, it is on a situational basis. This study sought to measure patients' general locus

of control as it relates to their beliefs concerning their fibromyalgia. The MHLC scale has

been validated for use in many disease states. Various versions of the MHLC scale have

been used in a small number of studies involving fibromyalgia patients. However, they

were all conducted in countries outside of the United States. One such study reported

that FMS patients tended to be more external when compared to rheumatoid arthritis

patients, but the sample size was small (n = 31).[74]

The Stanford Self-Efficacy for Managing Chronic Disease scale was used to

measure self-efficacy.[75] It is a 6-item instrument that measures several domains common

to many chronic diseases, including symptom control, role function, emotional

functioning and communicating with physicians. Each item is rated on a scale from 1-10,

with one being "not at all confident" and 10 being "totally confident". The score for each

item is the number selected for each item. The score for the scale is the mean of the six

items, with higher scores indicating a higher degree of self-efficacy. To date, this survey

instrument has not been used in the fibromyalgia patient population. However, it has

been validated in many other chronic disease states.[75] The authors of the instrument

encourage the use of the instrument in any chronic disease state by changing the term "disease" to the specific condition of the population under study.

In addition to the questions from the IPQ-R-FM, MHLC and Stanford Self-Efficacy for Managing Chronic Disease Scale, the respondents were asked to answer demographic questions about themselves pertaining to gender, age, race, education, employment and state of residence. These variables were measured to provide a better idea of what the fibromyalgia population of the United States looks like.

Appendix A contains the full version of the fibromyalgia survey used in this study.

3.5   Data Collection and Entry

Leaders from the 47 U.S. support groups of the National Fibromyalgia Association were contacted via email to ascertain if their groups had an interest in participating in the survey study. Their contact information was listed on the National Fibromyalgia Association website. The researchers believed that gaining a prior commitment from the leaders of the groups would ensure a higher response rate of all members, as the leader was asked to encourage all members to fill out the survey. The members would also know when the survey would be sent, so there would be less chance that the survey would be overlooked or deleted as they would be expecting it.

For the purposes of this study, the leaders of the individual support groups were contacted via email. A standard, detailed cover letter was sent explaining the study and emphasis was placed on how important their contribution will be (see Appendix B). In order to get a clearer idea of the total number of participants the researchers will have access to in the population, the leaders of the support groups were asked to reply to the email with answers to the following questions:

1) *How many total members does your support group currently have?*

2) *How many female fibromyalgia patients (formally diagnosed by a health professinal and 18+ years of age) do you have in your support group?*

3) *Would all interested members of the support group have access to the Internet in order to take an online survey?*

4) *As leader, do you have a list of all members' current email addresses?*

The leaders were also informed that they would receive the link to the online survey via email and could then forward on the link to the rest of the interested members in the support group. This way, the privacy of all members of the support group would be protected.

After receiving replies from all reachable (some email addresses of the group leaders were no longer valid so the message was undeliverable) and interested support groups, the researcher tallied up the reported amount of people who fit the inclusion criteria to calculate an estimated population size. By using the estimated population size, a more accurate sample size was calculated.

Since an email format was used for this survey, one cannot be sure that the correct person is answering the survey. Therefore, the investigator included qualification questions in the survey that the respondent must correctly answer before proceeding with the survey. Previous to beginning the survey, the respondents were asked to confirm that they were an adult, female fibromyalgia patient that has been clinically diagnosed by a physician. If they answered positively, they were allowed to continue with the survey. If not, a message would appear thanking them for their time and no survey was given.

The survey was created using Survey Monkey software. Data was collected using this program and was then formatted in an Excel spreadsheet. This data was imported into Statistical Package for the Social Sciences (SPSS) ver. 17 for analyses.

3.6 Sample Size

The sample size used for this study was determined from a commonly used sample size table.[76]The alpha value was set at .05 with a confidence level of 95%. Of the 383 support groups listed on the NFA website that could be reached, 69 groups replied with interest in the study. According to the estimates given by group leaders, there was a total of 5,307 members in these support groups and 4,827 (90.9%) were adult females clinically diagnosed by physicians. The minimum sample size needed was 357 respondents out of a total estimated population of 5,000 (rounded up to 5,000 for the purposes of the sample size chart).

3.7   Data Analysis

For statistical analysis, collected data was entered into Statistical Package for the Social Science (SPSS version 17.0). Descriptive statistics were calculated to satisfy objectives 1-4. A series of principal component Varimax rotation factor analyses and Pearson correlations run using convergent/ discrimination principal were performed to satisfy the 5th objective.

Chapter Four

Results

 This chapter provides a detailed description of the results of this study. It is divided into the following sections: 1) Response Rate; 2) Participant Characteristics; 3) Perceived Contributing Factors; 4) Locus of Control; 5) Self Efficacy; 6) Relationship Between Locus of Control and Self-Efficacy; and 7) Reliability and Validity of Survey Instrument.

4.1 Response Rate

 The estimated population for this study was 4,827 adult female support group members who had been formally diagnosed with fibromyalgia by a physician. The survey was sent to the leaders of the 69 support groups and they were each asked to send a reply email to the researcher to inform them of how many members they sent the survey to. Eleven response emails were received. The total number of support group participants that were sent the survey (according to the response emails) was 1,132. The

number of participants to complete the survey was 267. Therefore, the response rate was

23.6% for this survey. A survey was considered complete if the respondent correctly

answered the qualifying questions, answered any part of the perceived contributing

factors section, and answered all parts of the locus of control and self-efficacy sections.

4.2   Participant Characteristics

The general characteristics of those who participated in the study are shown in

Table 4.1. The mean (± S.D.) age of respondents was 52 ± 11.1 years and the majority of

participants described themselves as Caucasian. Most had at least some college

education and nearly 30% earned a Bachelor's degree. At the time of the survey, 41.2%

of the participants were unemployed and claimed a household income of less than

$100,000 per year (82.9%).   Most of the participants reside in the southern United States,

which was defined as the states of Texas, Oklahoma, Arkansas, Louisiana, Mississippi,

Alabama, Tennessee, Kentucky, West Virginia, Maryland, Washington D.C., Virginia,

North Carolina, South Carolina, Georgia, and Florida. About three-fourths of

participants were currently taking prescription medications for the management of their

fibromyalgia.

Table 4.1

Participant Characteristics

Characteristic	
Age(mean ± S.D.)	52.0 ± 11.1
Race/Ethnicity	
Caucasian	90.4% (206)
African American	3.1% (7)
Hispanic	3.1% (7)
Other	3.4% (8)
Highest Level of Education	
High school or equivalent	9.2% (210)
Some college	40.8% (93)
Bachelor's degree	28.9% (66)
Master's or professional degree	21.1% (48)
Employment Status	
Currently unemployed	41.2% (94)
Employed part time (less than 40 hrs/week)	15.8% (36)
Employed full time (> 40 hrs/week)	23.7% (54)
Homemaker	19.3% (44)
Average Household Income	
Under $10,000	4.3% (9)
$10,000 – 39,999	32.9% (79)
$40,000 – 99,999	45.7% (96)
$100,000 – 150,000	12.9% (27)
Over $150,000	4.3% (9)
Geographic Location	
Midwest	14.5% (33)
Northeast	21.9% (51)
South	54.8% (125)
West	7.8% (18)
Are you currently taking any prescription medications for your fibromyalgia?	
Yes	73.5% (166)
No	26.5% (60)

4.3   Perceived Contributing Factors

Participants agreed that internal factors of stress or worry (55.4%) and overwork (41.5%) and the external factor of accident or injury (37.2%) contributed to the onset of their fibromyalgia. Participants were more likely to disagree that external factors contributed to the development of their fibromyalgia; a majority of participants felt that their fibromyalgia was not a result of their diet or eating habits (51.7%), chance or bad luck (72.8%), poor medical care in their past (75.3%), aging (65.9%), alcohol (91.4%), smoking (88.7%), menopause (70.3%), breast cancer (87.7%), or breast implants (89.2%). Participants did notthink that they themselves were a contributing factor to the onset of their disease; participants did not feel that internal factors, such as their own behavior (64.5%), mental attitude (64.5%), or their emotional state (33.9%) were a possible cause of their fibromyalgia. Table 4.2 shows the frequency of perceived contributing factors reported by the participants.

Table 4.2

Frequency of Perceived Contributing Factors

Perceived Contributing Factor (I or E)	% Agree (N)	% Not Sure (N)	% Disagree (N)
Stress or worry (I)	**55.4 (133)**	26.3 (63)	18.3 (44)
My own behavior (I)	8.7 (20)	23.1 (54)	**64.5 (151)**
My mental attitude (I)	12.4 (29)	23.1 (54)	**64.5 (151)**
Family problems or worries caused by my illness (I)	27.7 (65)	24.7 (58)	**47.7 (112)**
My emotional state (I)	33.5 (79)	32.6 (77)	**33.9 (80)**
Overwork (I)	**41.5 (98)**	27.1 (64)	31.4 (74)
Hereditary (E)	30.0 (71)	**40.1 (95)**	30.0 (71)
A germ or virus (E)	30.8 (72)	**39.7 (93)**	29.5 (69)
Diet or eating habits (E)	15.9 (37)	32.3 (75)	**51.7 (120)**
Accident or injury (E)	**37.2 (87)**	26.9 (63)	35.9 (84)
Chance or bad luck (E)	9.5 (22)	17.7 (41)	**72.8 (169)**
Poor medical care In my past (E)	6.5 (15)	18.2 (42)	**75.3 (174)**
Pollution in my environment (E)	15.3 (36)	**46.4 (109)**	38.3 (90)
Aging (E)	11.6 (27)	22.4 (52)	**65.9 (153)**
Alcohol (E)	1.7 (4)	6.9 (16)	**91.4 (213)**
Smoking (E)	1.7 (4)	9.5 (22)	**88.7 (205)**
Menopause (E)	9.2 (21)	20.5 (47)	**70.3 (161)**
Known hormonal Imbalance (E)	22.7 (53)	30.0 (70)	**47.2 (110)**
Breast cancer (E)	0.4 (1)	9.9 (23)	**89.7 (208)**
Breast implants (E)	0.9 (2)	9.9 (23)	**89.2 (207)**
Sleep disorder (E)	29.7 (70)	31.8 (75)	**38.6 (91)**

Numbers in bold indicate the most frequent response
I = Internal factor
E = External factor

Participants were also asked to rank the top three factors they felt contributed most to the onset of their fibromyalgia but it is shown as the most popular 3 answers (Table 4.3). The most frequent response was a tie between the internal factor of "stress or worry" and the external factor of "hereditary". Participants also believed that the external factors of "accident or injury" and "germ or virus" were the most likely to have contributed to their disease.

Table 4.3

Ranked Perceived Contributing Factors

Perceived Contributing Factor	N
1) Stress or worry	106
1) Hereditary	106
2) Accident or injury	83
3) Germ or virus	73

Participants were encouraged to provide any additional factors that they felt possibly contributed to the development of their fibromyalgia that were not listed as an option in the survey. Most all of the responses were health-related, including past autoimmune diseases, neurological disorders, and thyroid issues. However, some participants also attributed their fibromyalgia to physical and emotional abuse they have experienced throughout their lifetime. Appendix C contains a list of the most common perceived contributing factors that were provided by respondents.

4.4   Locus of Control

Table 4.4 shows the participants' scores on theMulti-Dimensional Health Locus

of Control (MHLC) Scale. The scores reveal that participants tend to be more internal

when dealing with their fibromyalgia. This indicates that patients likely believe they are

more in control of their fibromyalgia and would be more willing to participate in

self-management exercises. Additionally, participants in this survey scored a mean

($\pm$ S.D.) of 15.8 $\pm$ 5.38 and 8.6 $\pm$ 3.67 on the subscales of Powerful Others and Doctors,

respectively. These results show that participants may potentially be influenced by

physicians and other trusted healthcare professionals, such as pharmacists. This indicates

that members of the healthcare team would have an opportunity to encourage

fibromyalgia patients to take an active role in their healthcare and could act as an

effective source of support and encouragement to patients.

Table 4.4

Locus of Control Scores (Multi-Dimensional Health Locus of Control [MHLC] Scale)

Subscale	Mean Score $\pm$ S.D.
Internal[a]	18.3 $\pm$ 6.41
Chance[a]	14.7 $\pm$ 6.68
Powerful Others[a]	15.8 $\pm$ 5.38
Doctors[b]	8.6 $\pm$ 3.67

a-   Mean score can range from 6 – 36; higher scores indicate a stronger affinity for that type of locus of control

b-   Mean score can range from 3-18; higher scores indicate that doctors have stronger influence over patient's condition

4.5   Self-Efficacy

Table 4.5 shows the participants' scores on the Stanford Self-Efficacy for Managing Chronic Disease scale. Participants had an overall mean (± S.D.) score of 4.60 ± 2.21, indicating that participants have a relatively low level of self-efficacy concerning the management of their disease. Participants had the lowest amount of self-efficacy for the domain of fatigue (3.69 ± 2.56) and had the highest amount of self-efficacy for the domain of doing things other than taking medications to manage their fibromyalgia (6.25 ± 2.81). Scores were also higher for the domain of performing different tasks and activities to manage fibromyalgia (5.23 ± 2.76).

Table 4.5

Self-Efficacy Scores (Stanford Self-Efficacy for Managing Chronic Disease Scale)

Question	Mean Score ± S.D.
Fatigue	3.69 ± 2.56
Physical discomfort or pain	3.72 ± 2.53
Emotional distress	4.33 ± 2.64
Other symptoms or health problems	4.35 ± 2.61
Perform different tasks and activities to manage FM	5.23 ± 2.76
Do things other than taking medication	6.25 ± 2.81
Overall Score	4.60 ± 2.21

*Mean score for each item and mean overall score can range from 1-10; higher scores indicate a higher level of self-efficacy

4.6   Relationship Between Locus of Control and Self-Efficacy

To further understand the interrelationships between locus of control and self-efficacy in this population, respondents were classified as having an internal or external locus of control and scores were examined on each of the items on the Stanford

Self-Efficacy for Managing Chronic Disease Scale to determine which items respondents

felt the most and least confident in performing. For the purposes of this study, each

respondent's type of locus of control (i.e. internal or external) was determined by the

highest average locus of control score. Furthermore, Pearson correlations were

performed to determine if there were any significant relationships between the scores on

the locus of control scales and the scores of each item on the self-efficacy scale.

Table 4.6 shows the relationship between internal locus of control and

self-efficacy. Respondents with an internal locus of control scored highest on the

self-efficacy item of doing things other than taking medications to manage their

fibromyalgia and scored lowest on the self-efficacy item of doing things to control their

fatigue associated with their condition. Additionally, correlations between internal locus

of control scores and all six items on the Stanford Self-Efficacy for Managing Chronic

Disease Scale were found to be significant at the p<0.01 level.

Table 4.6   Relationship Between Internal Locus of Control and Self-Efficacy

Question	Mean Score ± S.D.	P value
Fatigue	4.23 ± 2.64	0.274**
Physical discomfort or pain	4.27 ± 2.59	0.291**
Emotional distress	4.69 ± 2.70	0.254**
Other symptoms or health problems	4.73 ± 2.54	0.341**
Perform different tasks and activities to manage FM	6.06 ± 2.72	0.397**
Do things other than taking medication	7.04 ± 2.59	0.354**

Mean score for each item can range from 1-10; higher scores indicate a higher level of self-efficacy

** = Significant at p<0.01

Table 4.7 shows the relationship between external locus of control and self-efficacy. Respondents with an external locus of control scored highest on the self-efficacy item of doing things other than taking medications to manage their fibromyalgia and scored lowest on the self-efficacy item of doing things to control the pain associated with their condition. No correlations between external locus of control scores and scores on the six items of the self-efficacy scale were found to be significant.

Furthermore, respondents with an external locus of control had lower average scores on all six items of the self-efficacy scales compared to the scores for respondents with an internal locus of control. This indicates that respondents with an internal locus of control tended to feel more confident in performing the skills necessary to manage their fibromyalgia than those respondents with an external locus of control.

Table 4.7   Relationship Between External Locus of Control and Self-Efficacy

Question	Mean Score ± S.D.	P value
Fatigue	3.05 ± 2.41	0.353
Physical discomfort or pain	2.92 ± 2.27	0.983
Emotional distress	3.88 ± 2.46	0.829
Other symptoms or health problems	3.72 ± 2.59	0.807
Perform different tasks and activities to manage FM	4.27 ± 2.40	0.520
Do things other than taking medication	5.31 ± 2.68	0.719

Mean score for each item can range from 1-10; higher scores indicate a higher level of self-efficacy

4.7   Reliability and Validity of Survey Instrument

In order to assess the internal reliability of the survey used in this study, coefficients of reliability were calculated individually for each of the three subscales

44

included in the fibromyalgia survey as well as for the survey as a whole (all three subscales combined). The Cronbach's alpha value for perceived contributing factors, locus of control and self-efficacy were 0.83, 0.75 and 0.91, respectively. The combined Cronbach's alpha value for the survey as a whole was .779. To be considered a reliable scale, an acceptable Cronbach's alpha value is ≥ 0.7[77]; therefore, the fibromyalgia survey used in this study has satisfactory internal reliability.

Evidence for face validity of the survey instrument was found through a review of the survey instrument by research colleagues. Additionally, a pilot test was conducted using pharmacy healthcare administration graduate students as participants.

A series of principal components factor analyses with Varimax rotation was performed on the responses of the fibromyalgia survey. First, a factor analysis was conducted on the responses from the locus of control scale only. A 4-factor solution accounting for 55.78% of the variance was optimal using the Scree criterion. The items loaded onto the four factors of internal, external, powerful others, and doctors that the scale was designed to measure.[73] A factor analysis was also conducted on the responses from the self-efficacy scale only. A 1-factor solution accounting for 69.31% of the variance was optimal using the Scree criterion. The items loaded onto the single factor of self-efficacy, which was the only intended factor to be measured in the Stanford Self-Efficacy for Managing Chronic Disease Scale.[75] Finally, a factor analysis was conducted on the responses from the locus of control scale and self-efficacy scale together. A 5-factor solution accounting for 59.57% of the variance was optimal using

the Scree criterion. The items loaded onto the five factors of internal, external, powerful

others, doctors, and self-efficacy. Based on the series of factor analyses, the survey

instrument used in this study was determined to be adequately measuring the factors that

were intended to be measured (internal and external locus of control and self-efficacy)

and, therefore, the instrument is considered to be valid.

Chapter Five

Discussion

This chapter provides a discussion of the results of this study. It is divided into the following sections: 1) Discussion; 2) Limitations; and 3) Future Research.

5.1   Discussion

Results support the internal reliability of the fibromyalgia survey used in this study to measure perceived contributing factors, locus of control, and self-efficacy of fibromyalgia patients participating in a support group. All three subscales as well as the survey as a whole presented acceptable Cronbach's alpha values. This corroborates with the previously established reliability of the IPQ-R-FM and MHLC scale in the fibromyalgia patient population. Furthermore, this was the first study, to the best of the researcher's knowledge, to use the Stanford Self-Efficacy for Managing Chronic Disease scale in the fibromyalgia patient population. Internal validity for this scale was

previously supported for other chronic disease states, but this is the first study to test reliability in the fibromyalgia patient population. While validity of the three separate surveys has been previously established, the researchers wished to test validity of the survey instrument as a whole. Face validity was tested through assessment by fellow pharmacy administration colleagues and performing a pilot test with pharmacy administration graduate students. To further test the validity of the survey instrument as a whole, a series of factor analyses was performed on the responses from this survey. Overall, the survey instrument used in this study was found to be valid and accurately measured the factors of internal and external locus of control and self-efficacy. This result was very encouraging and indicates that this survey would be acceptable to use in future studies.

The final estimated response rate for this survey was 23.6%, with a total of 267 participants. Previous surveys of female fibromyalgia patients have not been able to make many generalizations regarding common demographic factors. Participants in this survey tended to be middle-aged women (52 ± 11.1 years), which is similar to the results of other studies.[26,44] The majority of the participants in this study were Caucasian, supporting the results of a previous study which found that fibromyalgia was more prevalent in Caucasian women versus African American women.[19] Very few studies have been able to establish significant relationships between fibromyalgia and other demographic variables, such as income, education, or employment. This study found that participants tended to be educated, with a majority having at least some college education and over a quarter had earned a Bachelor's degree. Participants could also be categorized

socioeconomically as middle-class; 45.7% of participants claimed a household income of $40,000-99,999 per year. While this study did not examine the direct relationship between employment status and severity of symptoms, it is interesting to note that nearly half of the participants were unemployed at the time the survey was taken. Studies have found conflicting results concerning employment and fibromyalgia, as some have found that working full-time exacerbates symptoms and other studies have found that full-time workers claim better management of symptoms.[20-22]This factor needs to be further explored in future studies. The majority of participants were taking a prescription medication to manage their fibromyalgia.

Results of the responses from the survey revealed that the most common perceived contributing factors were stress or worry and overwork. These factors were both categorized in this study as internal factors, as participants can be in control of how they let stress or overwork affect them personally. These emotional factors have been commonly linked to fibromyalgia and have been cited as reasons for the onset of fibromyalgia in other studies.[7-9]Physicians should be aware of the role that stress and overwork play in the patient's view of their disease and willingness to actively participate in treatment.A number of studies have indicated that patients with catastrophizing illness perceptions experience more psychological distress which can lead to unfavorable pain treatment outcomes.[66-70]Healthcare professionals should seek to provide an outlet for patients to cope with the emotional symptoms of their fibromyalgia in addition to any prescription medications they may prescribe. One particular study found that fibromyalgia patients with more positive illness perceptions, such as believing to have

control over pain and not viewing themselves as disabled by their pain, showed better treatment outcomes compared to those patients with negative illness perceptions.[70] Patients' perceptions concerning the causes of their disease may play a large role in choices regarding treatment since a majority of care for a chronic disease, such as fibromyalgia, is managed by the individual.[10]Patients who feel that their fibromyalgia was caused an internal factor they can control, such as stress, can be comforted by the knowledge that there are treatment options, both in terms of pharmacotherapy and cognitive behavior therapy, available for them.

Additionally, a majority of participants did not feel that external factors were a main cause of their fibromyalgia. This result is promising because it would likely be more difficult to encourage and support a fibromyalgia patient who believes that their fibromyalgia was due to a cause outside of their control, such as pure chance or bad luck. The most common perceived contributing factors that were categorized as external were accident or injury and genetics (*i.e.* hereditary). While a link between accidents and injury and the prevalence of fibromyalgia has been established[3-6], any relationship between genetics and fibromyalgia has yet to confirmed.[15,45,46]

Physicians must seek to better understand patients' perceived contributing causes, as these beliefs are of particular importance to their involvement in treatment. The objective of many self-management programs is to help patients understand and reframe their beliefs and expectations about their disease.[48-50] It is possible that these programs

will be more effective to those fibromyalgia patients who attribute the cause of their disease to an internal factor.

Another purpose of this survey was seeking to gather any additional perceived contributing causes that had not been explored in any fibromyalgia surveys to date. This was giving participants the opportunity to provide any additional factors that they felt contributed to their onset of their fibromyalgia that was not included in this survey. The participants in this study provided additional causes that were mostly related to their health history, such as past autoimmune diseases, neurological disorders, and thyroid disorders. All of these additional factors have been explored in other studies involving fibromyalgia patients or patients with chronic widespread pain.[11-14] Other causes related to physical or emotional abuse the participant had experienced at some point in their lifetime. These factors have also been associated with the onset of fibromyalgia and examined in previous studies.[3-9] While no new perceived contributing factors were mentioned in this study, the practice of eliciting responses from fibromyalgia patients should still be included in future studies until a definitive cause for this disease is confirmed.

Participants in this study tended to have an internal locus of control. This differs from other studies, which have found that patients with FMS selected from a clinical setting are more likely to have an external locus of control.[74,78] This often tends to be the case in patients who experience chronic pain, due to the lack of control they feel they have over their condition which leads them to choose ineffective coping strategies.

51

Because participants of this study were members of fibromyalgia support groups, they may feel more empowered and motivated to more effectively manage their disease because they have a network of people that understand their condition and can sympathize with one another. They also can share advice as to what therapies and coping strategies work best for them and can serve as support and encouragement to other members of the group. It is important to note that participants scored on the lower end of the scale for Doctors (8.6 ± 3.67 out of a possible score of 18), indicating that they are not heavily influenced by the opinions of their physicians. Fibromyalgia patients often have difficulty articulating their symptoms clearly and effectively convincing physicians of the severity of their condition. This can breed feelings of mistrust and helplessness when dealing with health professionals, leading to a heightened sense of lack of control when managing their disease.[79,80] It has been found that many members of the healthcare team lack the proper knowledge to effectively deal with a fibromyalgia patient's pain symptoms.[81] Members of the healthcare team need to become more focused on finding ways to better empathize with patients suffering from fibromyalgia in order to gain their trust. This will improve the patient-professional relationship by fostering trust, thereby increasing the amount of positive influence the healthcare professional has over the patient's self-management choices.

It was important in this study to examine both the outcome expectations of participants (locus of control), and also to measure the confidence that the participants have in themselves to sufficiently perform the tasks necessary to produce the positive outcomes (self-efficacy). The social cognitive theory states that changes in a person's

behavior will only occur when a person believes that outcomes are dependent upon their actions and, furthermore, that they believe they can adequately perform the action(s) necessary to produce the desired outcome.[82] While it is promising that participants in this study have a more internal locus of control, their scores on the self-efficacy scale were still rather low (overall mean score of 4.60 ± 2.21 out of a possible 10). Although participants believe that performing the correct actions will produce positive outcomes, they are lacking the confidence necessary to effectively perform the tasks that will improve the self-management of their disease. The social cognitive theory further states that an individual's social environment influences their behavior.[82] Consistent with theory, health care providers, such as physicians and pharmacists, can serve in a social support role in their patients' environment. Health professionals can become role models by helping their patients to perform specific behaviors relevant to their self-management and also provide positive reinforcement. A patient's self-efficacy can be improved through the physical and emotional assistance that they receive from members of the healthcare team in the form of personal exchanges focused on the concern for the other.[83] Healthcare professionals need to find ways of determining fibromyalgia patients' self-efficacy levels, such as administering a survey such as this in the clinical setting, in order to better understand and enable patients with this condition.

One of the most important objectives of this study was to better understand some of the common characteristics of female fibromyalgia patients in the United States and how healthcare professionals can apply that to their interactions with patients. By assessing a patient's locus of control and self-efficacy, one can have a better idea of how

willing a patient is going to be to make behavior changes and can also gauge the possible

success of health interventions based on the patient's confidence to perform the tasks

necessary to make behavior changes. Based on ideas from the social cognitive theory,

patients can have lower or higher levels of self-efficacy paired with a more internal or

external locus of control. Once the locus of control and self-efficacy of a patient are

determined, generalizations can be made regarding the level of support a patient needs to

succeed in his/her self-management and what types of health behavior interventions

would be most appropriate. Figure 1 illustrates the four "categories" that a fibromyalgia

patient could fall under depending on their personal locus of control and self-efficacy

regarding their disease.

Figure 5-1. LOC and SE Matrix for Fibromyalgia Patients
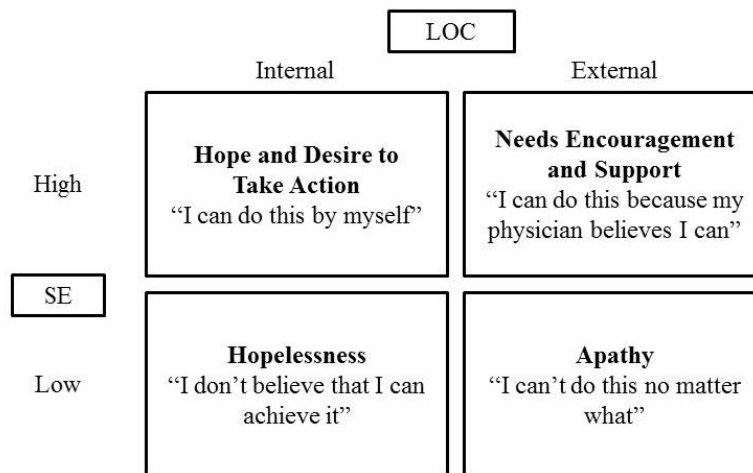
This matrix, based on ideals from Bandura's social cognitive theory[84,85], shows

how the different levels of locus of control and self-efficacy form the thoughts and

actions of fibromyalgia patients. A more internal locus of control paired with low levels

54

of self-efficacy can cause a patient to have reduced self-worth and create a sense of hopelessness because they believe that they cannot achieve their self-management goals. A patient with a more external locus of control paired and higher levels of self-efficacy may protest health interventions because they do not believe it will lead to a positive outcome. These patients will need more support and encouragement from their social environment, such as family, friends, and healthcare professionals. Negative outcome expectancies (external locus of control) and lower levels of self-efficacy tend to be apathetic and resigned from self-management efforts because they do not believe in the therapy nor themselves. These patients would be particularly difficult to influence and healthcare professionals need to be even more empathetic to gain trust from these patients. It should be a goal of health professionals to get all patients to the level of "hope and desire to take action", where the patient has both a positive outcome expectancy (internal locus of control) and a high degree of confidence in themselves to make the necessary behavior changes (high self-efficacy). Participants in this study tended to have an internal locus of control and lower levels of self-efficacy concerning the self-management of their fibromyalgia. This puts them into a category of "hopelessness", due to their high outcome expectancy but lack of belief in their ability to perform the proper tasks for self-management of their condition. This should indicate to physicians that they should attempt to demonstrate certain self-management techniques and provide patients with additional social support. Pharmacists can provide fibromyalgia patients with additional knowledge about their prescription medications and give them advice on how to become more adherent to their medications and receive the maximum pharmacological benefit.

Members of the healthcare team, such as physicians, can use the survey developed in this study to administer to their patients in a clinical setting. Physicians can calculate the results for locus of control and self-efficacy and easily categorize patients based on the locus of control and self-efficacy matrix for fibromyalgia patients (see Figure 5-1). This will give healthcare professionals a better idea of how to approach their patients and can indicate how much assistance and encouragement a patient may require from them.

5.2   Limitations

This study design has limitations that should be mentioned. First, the sample size was not large enough to reach the statistical power needed. Therefore, this study can only be adequately generalized to female fibromyalgia patients in support groups and may not fairly represent all female fibromyalgia patients in the United States.

The choice to use an online survey posed several challenges. One of the biggest challenges with online surveys is participants' access to the internet. The researcher asked each of the support group leaders to estimate how many of their members had access to the internet prior to distributing the surveys. Nearly all group leaders replied that a majority of their members had internet access and also indicated that emails and online socials groups served as main sources of communication amongst members. These responses supported the decision to use an online format for the survey. Dissemination of the survey relied heavily on the support group leaders and, therefore, was not under direct control of the researcher. Additionally, many of the emails could

have been sent to a "junk folder" or deleted by the recipients. The support group leaders were contacted several times in order to gain prior commitment to the survey. The group leaders personally distributed the surveys in order to protect the privacy of the group members, and also in hopes that more members would complete the survey since it was sent to them from the support group leaders whom they know and trust.

It is also possible that selection bias occurred. All participants were part of a fibromyalgia support group. Therefore, their responses may differ from fibromyalgia patients in other settings. Furthermore, out of a possible 1,132 fibromyalgia support group members who received the survey, 267 participants completed the survey. Those members who decided to participate in the survey may differ from those who did not. However, it was not possible in this study to compare characteristics of respondents to non-respondents.

5.3   Future Research

This study serves as a preliminary step to future fibromyalgia research. More testing is needed to support the external reliability and validity of the survey used in this study. In particular, this survey should be applied in a clinical setting, as results may be different than those who are in support groups and likely receiving a higher level of reinforcement from others. Furthermore, this survey should be tested for feasibility of use in a clinical setting. Studies should be conducted to obtain the opinions of

physicians, pharmacists and other healthcare professionals regarding the usefulness and practicality of this survey to better understand their fibromyalgia patients.

Future research can also be conducted to determine which interventions positively impact locus of control and self-efficacy of fibromyalgia patients. Bandura's social cognitive theory suggests that successful experiences in symptom management, pain control and daily function will produce the greatest changes in self-efficacy beliefs.[37]Therefore, interventions should focus on developing effective coping skills and also include ways to incorporate these skills in the patients' daily environment.[86]

Chapter Six

Conclusions

6.1   Conclusions

The most frequent perceived contributing factors for the onset of fibromyalgia

were the internal factor of stress/worry or overwork and the external factor of accident or

injury. Female fibromyalgia patients in support groups tend to have a more internal locus

of control and relatively lower levels of self-efficacy. Respondents with an internal locus

of control were more confident in performing skills necessary to manage their

fibromyalgia compared to those respondents with an external locus of control. Both

respondents with an internal and external locus of control felt most confident that they

could do something other than taking medications to manage their fibromyalgia.

Respondents with an internal locus of control felt least confident that they could do

something to manage fatigue associated with their condition while respondents with an

external locus of control were least confident that they could control the pain associated with the condition.

The internal reliability and validity of the survey instrument was acceptable; the reliability and validity of the survey suggests that it would be acceptable to use in other settings, such as a clinical setting, in future studies. Healthcare professionals, such as physicians and pharmacists, can use this survey to assess fibromyalgia patients' beliefs about their illness and their ability to effectively participate in self-management techniques. This survey can serve as a tool to improve the professional-patient relationship by fostering understanding and empathy, as well as assisting health professionals in choosing effective self-management interventions dependent upon a patients' locus of control and level of self-efficacy.

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Appendix A

Fibromyalgia Survey

Hello,

As part of a graduate thesis study, a survey has been developed to gather information on fibromyalgia patients' views on the perceived possible causes of their condition, as well as their beliefs over the controllability of their condition and self-efficacy.

The survey will take approximately 10-15 minutes to complete. While participation is voluntary, you answers are highly valued and will help others to better understand fibromyalgia syndrome and the people who suffer from it. Please answer all questions. The questions are meant to measure your beliefs about fibromyalgia, so there are no right or wrong answers. All information will be kept confidential.

Thank you for your participation!

Section 2. Qualifying Questions

1. Are you a female?
   □ Yes
   □ No

2. Are you at least 18 years of age?
   □ Yes
   □ No

3. Were you clinically diagnosed with fibromyalgia by a physician or specialist?
   □ Yes
   □ No

<u>Section 3. Perceived Contributing Factors of Fibromyalgia</u>

We are interested in what you consider may have been the cause of your illness. As people are very different, there is no correct answer for this question. We are most interested in your own views about the factors that caused your illness rather than what others, including doctors or family, may have suggested to you.

Below is a list of possible causes for your illness. Please indicate whether you agree, disagree or are unsure that they were causes for you by checking the appropriate box.

1. Please indicate how much you agree or disagree that the following were causes of fibromyalgia for you:

	Agree	Not Sure	Disagree
Stress or worry	□	□	□
Hereditary (i.e. it runs in my family)	□	□	□
A germ or virus	□	□	□
Diet or eating habits	□	□	□
Chance or bad luck	□	□	□
Poor medical care in my past	□	□	□
Pollution in my environment	□	□	□
My own behavior	□	□	□
My mental attitude (i.e. thinking about life negatively)	□	□	□
Family problems or worries caused by my illness	□	□	□
Overwork	□	□	□

	Agree	Not Sure	Disagree
My emotional state (i.e. feeling down, lonely, anxious, sad)	☐	☐	☐
Aging	☐	☐	☐
Alcohol	☐	☐	☐
Smoking	☐	☐	☐
Accident or injury (including motor vehicle collision)	☐	☐	☐
Menopause	☐	☐	☐
Known hormonal imbalance	☐	☐	☐
Breast cancer	☐	☐	☐
Breast implants	☐	☐	☐
Sleep disorder (i.e. insomnia, sleep apnea, etc.)	☐	☐	☐

Section 4. Perceived Contributing Factors to Fibromyalgia

In the boxes below, please list in rank-order (from most important to least important) the three most important factors that you believe caused your illness. You may use any of the items listed on the previous page, but also feel free to add any additional ideas of your own.

1. The most important causes for me are:
   1._____
   2._____
   3._____

Section 5. Beliefs about Your Fibromyalgia (Locus of Control)

Each item below is a belief statement about your fibromyalgia. For each item, please select the response that reflects the extent to which you agree or disagree with that statement. Please make sure that you answer EVERY item.   This is a measure of your personal beliefs, so there are no right or wrong answers.

1. Please indicate the extent to which you agree or disagree with each of the following statements:

	Strongly Disagree	Moderately Disagree	Slightly Disagree	Slightly Agree	Moderately Agree	Strongly Agree
If my fibromyalgia worsens, it is my own behavior which determines how soon I will feel better again.	□	□	□	□	□	□
As to my fibromyalgia, what will be will be.	□	□	□	□	□	□
If I see my doctor regularly, I am less likely to have problems with my fibromyalgia.	□	□	□	□	□	□
Most things that affect my fibromyalgia happen to me by chance.	□	□	□	□	□	□
Whenever my fibromyalgia worsens, I should consult a medically trained professional.	□	□	□	□	□	□
I am directly responsible for my fibromyalgia getting worse or better.	□	□	□	□	□	□
Other people play a big role in whether my fibromyalgia improves, stays the same, or gets worse.	□	□	□	□	□	□
Whatever goes wrong with my fibromyalgia is my own fault.	□	□	□	□	□	□
Luck plays a big part in determining how my fibromyalgia improves.	□	□	□	□	□	□

	Strongly Disagree	Moderately Disagree	Slightly Disagree	Slightly Agree	Moderately Agree	Strongly Agree
In order for my fibromyalgia to improve, it is up to other people to see that the right things happen.	□	□	□	□	□	□
Whatever improvement occurs with my fibromyalgia is largely a matter of good fortune.	□	□	□	□	□	□
The main thing which affects my fibromyalgia is what I do myself.	□	□	□	□	□	□
I deserve the credit when my fibromyalgia improves and the blame when it gets worse.	□	□	□	□	□	□
Following doctor's orders to the letter is the best way to prevent my fibromyalgia from getting anyworse.	□	□	□	□	□	□
If my fibromyalgia worsens, it's a matter of fate.	□	□	□	□	□	□
If I am lucky, my fibromyalgia willget better.	□	□	□	□	□	□
If my fibromyalgia takes a turn for the worst, it is because I have notbeen taking proper care of myself.	□	□	□	□	□	□
The type of help I receive from otherpeople determines how soon my condition approves.	□	□	□	□	□	□

Section 6. Managing Your Fibromyalgia (Self-Efficacy)

We would like to know how confident you are in doing certain activities related to your fibromyalgia. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time.

1. Please choose the number that corresponds to your confidence that you can perform the tasks regularly at the present time.

	Not at all Confident		Somewhat Confident		Totally Confident					
	1	2	3	4	5	6	7	8	9	10
How confident are you that you can keep the fatigue caused by your fibromyalgia from interfering with the things you want to do?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
How confident are you that you can keep the physical discomfort or pain of your fibromyalgia from interfering with the things you want to do?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
How confident are you that you can keep the emotional distress caused by your fibromyalgia from interfering with the things you want to do?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
How confident are you that you can keep any other symptoms or health problems you have from interfering with the things you want to do?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

	Not at all Confident				Somewhat Confident					Totally Confident
	1	2	3	4	5	6	7	8	9	10
How confident are you that you can do the different tasks and activities needed to manage your fibromyalgia so as to reduce your need to see a doctor?	□	□	□	□	□	□	□	□	□	□
How confident are you that you can do things other than just taking medication to reduce how much your fibromyalgia affects your everyday life?	□	□	□	□	□	□	□	□	□	□

Section 7. Respondent Characteristics

Please answer a few questions about yourself. Your responses will help us better understand common characteristics of female fibromyalgia patients. All information you provide will be kept confidential.

1. Age _____

2. Race/Ethnicity
    □ Caucasian
    □ African American
    □ Hispanic
    □ Asian/Pacific Islander
    □ Other (please specify) _____

3. Highest level of education

    □ Grammar school
    □ High school or equivalent
    □ Some college
    □ Bachelor's degree
    □ Master's or professional degree

4. Employment status

    □ Currently unemployed
    □ Employed part-time (less than 40 hours per week)
    □ Employed full-time (40 or more hours per week)
    □ Homemaker

5. Are you currently taking any prescription medications for your fibromyalgia?

    □ Yes
    □ No

6. Average household income _____

7. Current state of residence _____

77

<u>Section 8. Thank You!</u>

Thank you very much for taking the time to complete my survey! Your participation has helped to further the knowledge about fibromyalgia and the unique patients who suffer from it.

Appendix B

Email Cover Letters

Initial Email:

Dear Fibromyalgia Support Group Leaders of (insert state),

Hello, my name is Sara Holl and I am a Master's student at the University of Toledo (Toledo, OH) in the Pharmacy Healthcare Administration program. I am currently working on my thesis project and would greatly appreciate input from yourself and other members of your support group. The focus of my thesis study is to gather information on fibromyalgia patients' views on the perceived effectiveness, satisfaction and adherence to their medication therapy. Additionally, I want to collect information on the possible causes of the condition.

Very few studies have examined perceived effectiveness, satisfaction and adherence to medication with fibromyalgia patients. These three factors are highly correlated with quality of life and can provide medical professionals with a clearer idea of how to tailor future interventions to best serve this unique patient population. Convincing and supported information concerning fibromyalgia patients will help make this syndrome easier to diagnose and can ultimately lead to universal acceptance of fibromyalgia as a legitimate medical condition.

This subject matter is very close to my heart because my mother is diagnosed with fibromyalgia and I have seen firsthand the pain it has caused her. I feel that my thesis study is the best way to help her and potentially thousands of others who share this condition.

I am hoping that you and the other members of your support group will be interested in participating in this study. The study is in the early stages and I am looking for female fibromyalgia patients who would be interested in taking a short online survey. I will be sending out a mass survey to members of NFA support groups across the nation and would love for your group to participate.

As leader of your support group, I have a few preliminary questions that I need answered to get a better idea of my sample population (if you are not sure, estimate to the best of your ability). Please take a minute and reply to this email with answers to the following questions:

How many total members does your support group currently have? _____

How many female fibromyalgia patients (diagnosed by a health professional and 18+ years old) do you have in your support group? _____

Would all interested members of the support group have access to the Internet in order to take an online survey? _____

As leader, do you have a list of all members' current email addresses? _____
If you are the leader of multiple groups, please answer these questions for each group

Please share this with the other members of your support group and respond to this e-mail by Wednesday, November 11th if you are interested in being a part of this project. Feel free to contact me with any questions. I look forward to your response!

  Sincerely,
    Sara Holl

Reply:

Thank you for your interest in my thesis study! I will be in contact with you in the next few weeks to inform you when the survey will be sent out. As the contact person, I can send you the link to the survey and you can forward it on to all interested members. That way, you can protect the privacy of your members. I really appreciate your participation.

  Sincerely,
    Sara Holl

Survey Email:

Dear Participant,

You are invited to participate in the research project entitled "Perceived Contributing Factors, Locus of Control and Self-Efficacy of Female Fibromyalgia Patients", which is being conducted at the University of Toledo under the direction of Sara Holl (student investigator) and Dr. Sharrel Pinto (faculty advisor). You were contacted a few months ago regarding your interest in taking an online survey regarding your beliefs about fibromyalgia for my thesis. We would greatly appreciate input from yourself and other members of your support group.

The following link will take you to the survey. It is designed to take approximately 10-15 minutes to complete. There are very minimal risks to participating in this study. The researchers will make every effort to prevent anyone who is not on the research team from knowing that you provided this information or what the information is. All responses will be anonymous and information will be kept confidential. In order to preserve confidentiality, no personal information will be collected for this survey.

The only direct benefit to you if you participate in this research may be that you will learn about how pharmacy healthcare administration experiments are run and may learn more about patients' beliefs about fibromyalgia. Others may benefit by learning about the results of this research. Your refusal to participate in this study will involve no penalty or loss of benefits to which you are otherwise entitled. In addition, you may discontinue participation at any time without any penalty or loss of benefits.

Please forward this link on to all members who are interested in participating. We will send the results of the survey to the group leaders who can share the information with their members. We appreciate your participation.

All group leaders: please respond to this email with the approximate amount of members you forwarded the survey on to and/or if you posted the link on a webpage. You could also CC: me to the email you forward on to your group members if that would be easier. This will help to calculate an accurate response rate. I appreciate it!

Before you decide to accept this invitation to take part in this study, you may ask any questions that you might have. If you have any questions at any time before, during or after your participation you should contact Sara Holl at sara.holl@rockets.utoledo.edu. If you have questions beyond those answered by the research team or your rights as a research subject or research-related injuries, please feel free to contact Dr. Jeffrey Busch, research compliance coordinator at (419) 530-2844.

By completing the survey, you are providing your informed consent to participate in this research project.

Please click here to take the survey. Thank you!

Appendix C

Perceived Contributing Factors Provided by Respondents

Examples of Perceived Contributing Factors Provided By Respondents

- Neurological issues
- Lyme disease
- Bacteria or virus
- Epstein Barr
- Total hysterectomy
- Family history
- Abuse during childhood
- Eating habits
- Lupus
- Childbirth
- Stress from taking care of an ill family member
- Childhood trauma
- Brain disorder
- Severe infection
- Spondylitis
- Anxiety
- Arthritis
- Tuberculosis
- Rheumatic fever
- Domestic violence
- Sexual abuse
- Complications following a surgery
- Chronic stress
- Depression
- Hashimoto's thyroiditis
- Hypoglycemia
- Environmental toxins
- Changes in the weather/temperature