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# Self-Reported Quality of Life, Treatment Effectiveness, Attitudes and Perceptions of Fibromyalgia Patients

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# SELF-REPORTED QUALITY OF LIFE, TREATMENT EFFECTIVENESS, ATTITUDES AND PERCEPTIONS OF FIBROMYALGIA PATIENTS

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ABSTRACT

SELF-REPORTED QUALITY OF LIFE, TREATMENT EFFECTIVENESS, ATTITUDES AND PERCEPTIONS OF FIBROMYALGIA PATIENTS

By

Carroline P. Lobo

December 2013

Thesis supervised by Dr. Andrea Pfalzgraf

**OBJECTIVES:** To assess FMS patients' quality of life (QoL) and pain based on: patient perceptions of physicians' attitudes, trust in physicians, invalidation, treatment type, and demographics.

**METHODS:** An on-line survey was conducted via the National Fibromyalgia and Chronic Pain Association. Descriptive and inferential statistics were performed.

**OUTCOMES:** The survey resulted in 670 (70.5%) usable responses. Invalidation, use of complementary and alternative medicine (CAM), income, age, and education were significant predictors of QoL. Trust in physician, income, education, and number of referrals were significant predictors of pain. Use of CAM only was associated with lower pain, while use of pharmacologic medications and CAM was associated with higher QoL.

**CONCLUSIONS:** Invalidation and trust in physicians may impact pain and QoL in FMS. The use of CAM or CAM with medications may improve pain and QoL.

**KEYWORDS**: Fibromyalgia, Invalidation, Complementary and Alternative Medicine, Quality of Life, Pain.

*To*

*My parents,*

*Cyril and Gretta Lobo*

*&*

*my loving sister*

*Sheryl*

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## LIST OF ABBREVIATIONS

FMS – Fibromyalgia Syndrome

QoL – Quality of Life

CAM – Complementary and Alternative Medicine

NFMCPA – National Fibromyalgia and Chronic Pain Association

# CHAPTER ONE: INTRODUCTION

Chapter one provides an introduction for the thesis project. A statement of the research problem and the theoretical framework follow. The chapter concludes with a discussion of the significance of the project and the specific research objectives of the study.

## BACKGROUND

Fibromyalgia syndrome (FMS) is a chronic non-inflammatory pain disorder which has garnered increased attention in the recent years. Primarily characterized by widespread pain [1], FMS patients tend to experience a multitude of co-morbid conditions. These can include fatigue, sleep disturbance, morning stiffness, headache, irritable bowel syndrome (IBS), rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), and various psychological conditions, including anxiety and depression [2-4]. Originally considered a disorder of muscular inflammation, it was termed 'fibrositis' by Sir William Gowers in 1904 [5]. FMS, however, started receiving more attention in 1987 when the American Medical Association (AMA) identified it as a probable cause of disability [6]. Later in 1990 the American College of Rheumatology (ACR) established the tender point and widespread pain criteria for classification of patients in epidemiological and research studies [4]. FMS patients are reported as the most common group of patients seen by rheumatologists [6, 7].

The worldwide prevalence of FMS has been estimated to range from 0.5% to 5% with a 7 times higher prevalence in women [7, 8]. Approximately, 2 to 6 % of the population in the U.S. is impacted by FMS [8, 9]. There is very little information about other demographic characteristics of this population. Studies utilizing non-probability sampling techniques or data from hospital and outpatient population suggest that the age range of FMS patients is usually between 45-64 years [10-12]. Currently, there is no epidemiological data on the distribution of FMS across different races. A study examining hospital discharge records in the U.S. from 1997 to 2007 found the majority of

FMS patients were White, while only 5.8% were Black and 3.8% were Hispanic [10]. The economic burden associated with this disorder has been found to be enormous with societal expenditures estimated for the U.S. to be $ 12-14 billion per year [13]. Health related quality of life is considerably compromised in FMS patients. A study comparing the quality of life (QoL) of FMS patients to those with other disorders like RA, osteoarthritis, chronic obstructive pulmonary disorder, and insulin dependent diabetes mellitus, reported that FMS patients had the lowest scores across various QoL domains [14].

## STATEMENT OF THE RESEARCH PROBLEM

Nearly 23 years after the establishment of the first diagnostic criteria [4], FMS is still a highly misunderstood disorder. The four important factors contributing to poor recognition and poor understanding of this disorder are: *unknown etiology*, *symptom overlap, symptom heterogeneity*, and *lack of objective markers* to confirm a diagnosis.

Despite tremendous research in the past few years, the etiology of FMS is unclear. Several studies have attempted to explain the possible contributing factors, but no definite cause has been established**.** Clauw and Chrousos [15] proposed an etiologic model to explain the possible pathogenesis. They suggested that FMS may have a genetic component which may be initially latent. Certain triggering events may result in activation of the latent genetic factors, which in turn may change activity of the central and autonomic nervous systems, resulting in a wide array of symptoms [15]. Altered neuroendocrine levels including substance P, serotonin, and norepinephrine coupled with altered activity of the hypothalamic-pituitary axis may be responsible for changes in

activity of the central nervous system [16]. Factors such as motor vehicle accidents, whiplash injury, or neck and spine injury have been considered to be possible triggers of FMS [17-19]. Mistreatment in childhood (ex. abuse or neglect) and physical factors including persistent work-related stress have also been postulated as contributing factors [20].

FMS may co-occur with several rheumatologic conditions. Approximately, 25 to 61% patients with SLE, up to 57% patients with RA, 27 % patients with IBS, 24% patients with psoriatic arthritis, and 9% patients with Bechet's disease have reported concurrent FMS [21-23]. Non-rheumatologic conditions can co-occur with FMS. These conditions include: hypertension, diabetes, coronary artery disease, sleep apnea, and migraine [24, 25]. Additionally, FMS has been reported in patients with Hepatitis C [26].

Symptom heterogeneity is common in FMS. Some researchers have attempted to categorize FMS patients according to symptoms. For instance, De souza JB *et al*. [27] reported two subgroups differing on the levels of psychological distress: 1) FMS Type I characterized by high levels of pain, fatigue, and stiffness, but low levels of anxiety, depression, and morning tiredness, and 2) FMS Type II characterized by high levels of pain, fatigue, and stiffness, but also high levels of anxiety, depression, and morning tiredness. Both groups, however, had hyperalgesic responses to pain. Loevinger *et al.* [28] reported four subgroups that differed on physiological and psychological profiles and history of child abuse. All subgroups met the tender point diagnostic criteria. The first subgroup reported irregular physiologic levels of cortisol and history of childhood abuse and the highest levels of pain, fatigue, and disability. The second subgroup had irregular immunologic, metabolic, and neuroendocrine functions and also reported

psychological distress, high pain, and disability. The third subgroup had normal physiological status but reported intermediate levels of pain. The fourth subgroup had only low levels of psychological distress and pain. It thus appears that pain is a common characteristic across individuals, but the associated co-morbid conditions may vary. This non-uniformity of symptoms poses a challenge not only in diagnosis, but also in designing adequate treatment strategies.

In 1990, the ACR established the "tender point criteria" which required pain on digital palpation in at least 11 of 18 tender points defined by ACR [4]. Research indicates, however, that patients with less than 11 tender points may also have FMS and that patient with more than 11 tender points may not get diagnosed. [29]. Accurate identification of tender points requires a clinician's expertise. Some physicians lack belief in the 1990 ACR criteria, and others do not rely on the ACR criteria for diagnosis [29, 30]. Interestingly, some physicians have reported using the ACR criteria only to avoid being viewed as "inefficient" by patients [30]. There are no specific laboratory tests to help identify FMS. However, tests like, rheumatoid factor (for RA), thyroid tests (for hypothyroidism), anti-nuclear anti-bodies (for SLE), erythrocyte sedimentation rate (for CFS, polymyalgia rheumatic, and other inflammatory disorders) are utilized to rule out the possibility of other illnesses [3].

Diagnosis and management of this disorder is a challenge for both patients and physicians. The symptoms of FMS are not necessarily visible. Patients have a normal physical appearance. Symptoms are non-uniformly present across individuals. Additionally, there is high prevalence of co-morbidities. Due to these complications, patients are often unable to effectively communicate and therefore validate their

symptoms to health care professionals [31, 32]. The tender-point diagnostic criteria have not proven to be completely effective and there are no other physiologic markers to aid in diagnosis. For these reasons, many health care professionals believe that FMS may not be a true disorder [30, 33]. Non endorsement of FMS by the medical fraternity is a debatable issue [34, 35]. Physicians and other health care professionals have reported disbelief, discomfort, lack of confidence in diagnosing, and lack of confidence in treating the illness. The discordance between the attitudes of physicians and patients is very evident in scientific literature and will be elaborated in the next two sections.

*HEALTH CARE PROFESSIONALS' PERCEPTIONS OF FMS*

Some members of the medical community view FMS as a "wastebasket diagnosis" or simply a label for chronic pain with no definite underlying cause [34, 36]. An important factor contributing to physicians' distrust appears to be the conflicting nature of symptoms and patients' outward appearance. Physicians have reported being suspicious of patients' symptom severity, and consequently some physicians have reported FMS patients as being "exaggerators" [30, 31, 33, 37]. Due to a lack of supportive diagnostic findings, the cause of symptom experiences may be perceived to be psychological in nature [31, 33]. Past studies have reported the difficulty, confusion, and helplessness of general physicians and rheumatologists in accepting individuals with FMS as patients [30, 35]. The scientific literature has documented that physicians have attempted to "avoid" these patients [30]. Physicians have admitted referring FMS patients to rheumatologists who, in turn, may refer them other providers such as FMS education teams [30].

The discomfort of the medical fraternity with the disorder was apparent in a Norwegian survey (2008) for prestige rank ordering of 38 diseases by physicians and medical students [38]. Respondents were asked to rank a list of disorders based on their comfort in treating patients with these disorders. FMS was assigned the lowest rank and was listed below AIDS, schizophrenia, depressive and anxiety neurosis [38]. According to the study, the factors associated with the low ranking of FMS were disease-specific features such as invisibility of symptoms, subjectivity in diagnosis, chronicity of the disorder, high prevalence in women, uncertainty regarding treatment effectiveness, and

severe pain. Respondents in this survey admitted adhering to the medical literature rather than working collaboratively with patients to understand the illness [38]. Some of the survey respondents also expressed concerns over lack of medical training regarding diagnosis and treatment of this disorder [38].

The issues of disease legitimacy and discordance among patients and physicians have been investigated. A 2010 study assessed the perceptions of FMS by the medical community and patients [39]. Thirty five percent (n=189) of the general practitioners surveyed were not confident diagnosing the disorder [39]. Another 30% reported a lack of knowledge regarding treatment options [39]. The majority (76%, n=139) of general practitioners and specialists (64%, n=139) reported FMS patients as 'time-consuming' and 'frustrating' [39]. In the same study, a focus group of FMS patients (n=18) reported thoughts and feelings including: avoidance from physicians, lack of treatment efficacy, disbelief, and apathy [39].

In summary, some studies indicate that physicians perceive FMS patients as psychologically stressing, non-co-operative, and unwilling to accept their situation. Factors related to FMS, including: subjectivity of illness description, difficulty in diagnosis, a normal physical appearance of patients, and poor efficacy of treatments may lead physicians to feel uncomfortable and in some cases "frustrated" in attempting to treat patients with FMS [33]. The subjective nature of this disorder has raised issues regarding the legitimacy of FMS [31, 33, 39] Additionally, many physicians have developed negative attitudes, cynicism, and skepticism toward these patients. Inadequate understanding, lack of knowledge, and lack of objective laboratory findings have led some medical professionals to doubt the seriousness and in some cases lack empathy

toward FMS patients [30, 39]. These attitudes of health care professionals may lead to poor support of FMS patients [31, 40]. The next section will discuss how FMS patients perceive health care professionals.

*PATIENT PERCEPTIONS OF HEALTH CARE PROFESSIONALS*

According to a survey of FMS patients (n=132) conducted by Bernard *et al.* [41], approximately 30.3% FMS patients reported seeking recognition of their disorder from health care professionals [41]. More than 50% of the respondents placed importance on understanding and patient listening from health care professionals versus simply prescribing medications [41].

As stated above, there is a poor correlation between patients' outward appearance and symptoms [33, 37]. This may play a crucial role in the development of suspicion and disbelief towards FMS patients [33]. Helplessness, frustration, and dissatisfaction have been reported by patients when health care professionals did not believe their symptom descriptions [31]. Patients have reported experiencing a change in doctor's attitude toward them when no physical or physiological explanations for their symptoms are found [31, 40]. In addition, patients have reported limited time during consultations and multiple referrals which may indicate that at least some health care professionals have a dismissive attitude. Some patients have developed the opinion that physicians have little knowledge of the disorder [42]. An important component of the physician-patient interaction appears to be the shared-decision making where patients are provided an opportunity to actively participate in the process of care [43]. Unfortunately, FMS patients have reported an absence of collaborative approach in the treatment [42].

Patients perceive inadequate support from health care professionals as one of the barriers to effective management of FMS symptoms [44].

Another important facet of this problem is the stigma associated with the disorder. Patients have reported being labeled as psychological or malingerers, with their moral characters being questioned [31, 44]. The multitude of patient experiences like lack of recognition, stigmatization, embarrassment, frustration, lack of support, skepticism, and cynicism have been defined by Kool *et al*. [45] as '*Invalidation*'. Patients may now face a risk of getting absorbed into 'Fibroism' or 'Culture of Fibromyalgia'. In other words, they believe there is no solution for fibromyalgia other than coping with the symptoms [46]. Inadequate understanding and poor health care support can impact patients on physical, emotional, social, and economic levels [32]. Lack of agreement between physicians and patients regarding the disorder has been reported to contribute to patient-stress and frustration [37, 40, 42].

Howell [47] developed a theoretical model for explaining the impact of chronic non-malignant pain on the daily life of women with pain. The model consists of four phases:

1) Healthy phase 1-Pain takes over*:* This phase is characterized by onset of chronic pain, continuous search for diagnosis and cure, but the experience of decreased ability to perform usual, daily activities.

2) Illness-Filling life with despair*:* This phase is characterized by increased self-doubt because no cure had been found for the pain. Patients in this phase may blame themselves for experiencing pain. Moreover, patients in this phase can experience negative responses and invalidation of their symptoms from others.

3) Healthy phase 2-Filling life with new hope: This phase is characterized by the self-acceptance of pain and by validation from others. In addition, patients begin to adapt to life with pain.

4) Healthy phase 3-Fulfilling life with pain: This phase indicates progression toward good health. Patients in this phase are aware of pain, but focus more on daily life activities.

Howell's model suggests that, patients experiencing pain can progress through the various healthy phases (Healthy phases 1, 2, and 3) provided pain is validated by the self and others. Transition through the healthy phases enables patients to accept challenges of living with pain. Contrarily, frequent invalidating patterns can cause patients to revert to the 'Illness' phase which in turn can result in negative health outcomes [47].

A review of the literature indicates that the invalidation of symptom experiences in FMS is an important issue. Invalidation may contribute to discord in the physician-patient relationship [31, 39]. According to Howell's model, invalidation is an important contributor to poor health outcomes in FMS patients [47]. Therefore, the goal of this study is to investigate the relationships between patient perceptions of physician attitudes, patient experiences of invalidation, patients' trust in physicians, socio-demographic and the patient reported health outcomes of QoL and pain in FMS patients.

## NEED FOR RESEARCH AND SIGNIFICANCE

Scientific literature reveals conflicting patient-physician interactions. The negative typifying of FMS patients was described in the studies above. Experiences of many FMS patients with health care professionals are reportedly quite negative [31, 39,

40]. This may be opposite to the recognition, understanding, individualized treatment, and care this disorder may require [30-32, 39, 40, 42]. It is, therefore, important to gain insight into the experiences of FMS patients, and investigate the impact on QoL and pain. Most studies assessing physician-patient interactions have been conducted in a small sample of FMS patients and have been qualitative (semi-structured interviews, focus groups) in nature. There are very few studies that explain patient perceptions of health care professionals in larger populations with FMS. Moreover, most of these studies have been conducted outside the U.S. [31, 33, 37, 39, 40, 44, 45]. The impact of invalidation from health care professionals on health outcomes (QoL and pain) have not been quantitatively assessed in any of the above-mentioned studies. This would be the first study to quantitatively assess the impact of health care professionals' attitudes on health outcomes of patients with FMS in the U.S.

Patient experiences with health care professionals may impact treatment choices provided and associated effectiveness. The support provided by the physicians may be reflective of the type of treatment provided. Few studies have reported treatment patterns for FMS patients. This study will help understand current treatment strategies for patients with FMS. Clinical trials have recommended an interdisciplinary treatment approach to provide relief from symptoms. This study will help understand if patients are being prescribed only medications or only complementary and alternative medicine or both. The phenomenon of Invalidation has been recently described in a Dutch population and factor analysis revealed the two domains, described as 'Lack of Understanding' and 'Discounting'. Thus, this is also the first study to assess the structure of 'Invalidation' in the U.S. population.

The Institute of Medicine Report (2011) identifies negative outlook toward pain on the part of physicians as being a barrier to providing quality care [48]. The reports calls for a 'cultural transformation' in the treatment of pain patients with an emphasis on developing a patient-centered treatment approach characterized by a trusting physician-patient relationship. The results of this study may help provide clinicians, researchers, and policy makers with the information on developing newer strategies for effective treatment of patients with FMS.

## GOALS

The overall aim of this study is to assess self-reported patient perceptions of health care providers, treatment effectiveness, QOL, and pain levels. The theoretical framework for this study can be seen in Figure 1. The specific objectives are described below.

## OBJECTIVES

1. *Objective 1: To determine factor structure and internal consistency of the 'Patient perceptions of physician attitudes' scale.*
2. *Objective 2: To determine factor structure and internal consistency of the standardized scales used in the survey.*

   More specifically,

   - *Objective 2a: To determine factor structure and internal consistency of the Trust in Physician Scale in a sample of patients with FMS.*
   - *Objective 2b: To determine factor structure and internal consistency of the Illness Invalidation Inventory in a sample of FMS patients.*
   - *Objective 2c: To determine factor structure and internal consistency of the Quality of Life Scale-16 in a sample of FMS patients.*
3. *Objective 3: To predict self-reported quality of life and pain levels (current) of FMS patients based on patient perceptions of physician attitudes, patients' trust in physicians, patient perceptions of medical professionals, treatment effectiveness, and demographics.*

More specifically,

- *Objective 3a: To predict self-reported quality of life of FMS patients based on patient perceptions of physician attitudes, patients' trust in physicians, patient perceptions of medical professionals, treatment effectiveness, and demographics.*
- *Objective 3b: To predict self-reported pain levels (current) of FMS patients based on patient perceptions of physician attitudes, patients' trust in physicians, patient perceptions of medical professionals, treatment effectiveness, and demographics.*

4. *Objective 4: To determine trends in the utilization of current treatments for FMS.*

   More specifically,

   - *Objective 4a: To determine trends in the utilization of pharmacologic treatments for FMS.*
   - *Objective 4b: To determine trends in the utilization of non-pharmacologic treatments for FMS.*

5. *Objective 5: To assess differences in the self-reported quality of life and pain (current) of FMS patients based on type of treatment.*

   More specifically,

   - *Objective 5a: To assess differences in the self-reported quality of life of FMS patients who utilized pharmacologic treatments alone, non-pharmacologic treatments alone, and those utilizing both pharmacologic and non-pharmacologic treatments.*

- *Objective 5b: To assess differences in the self-reported pain (current) of patients of FMS patients who utilized pharmacologic treatments alone, non-pharmacologic treatments alone, and those utilizing both pharmacologic and non-pharmacologic treatments*

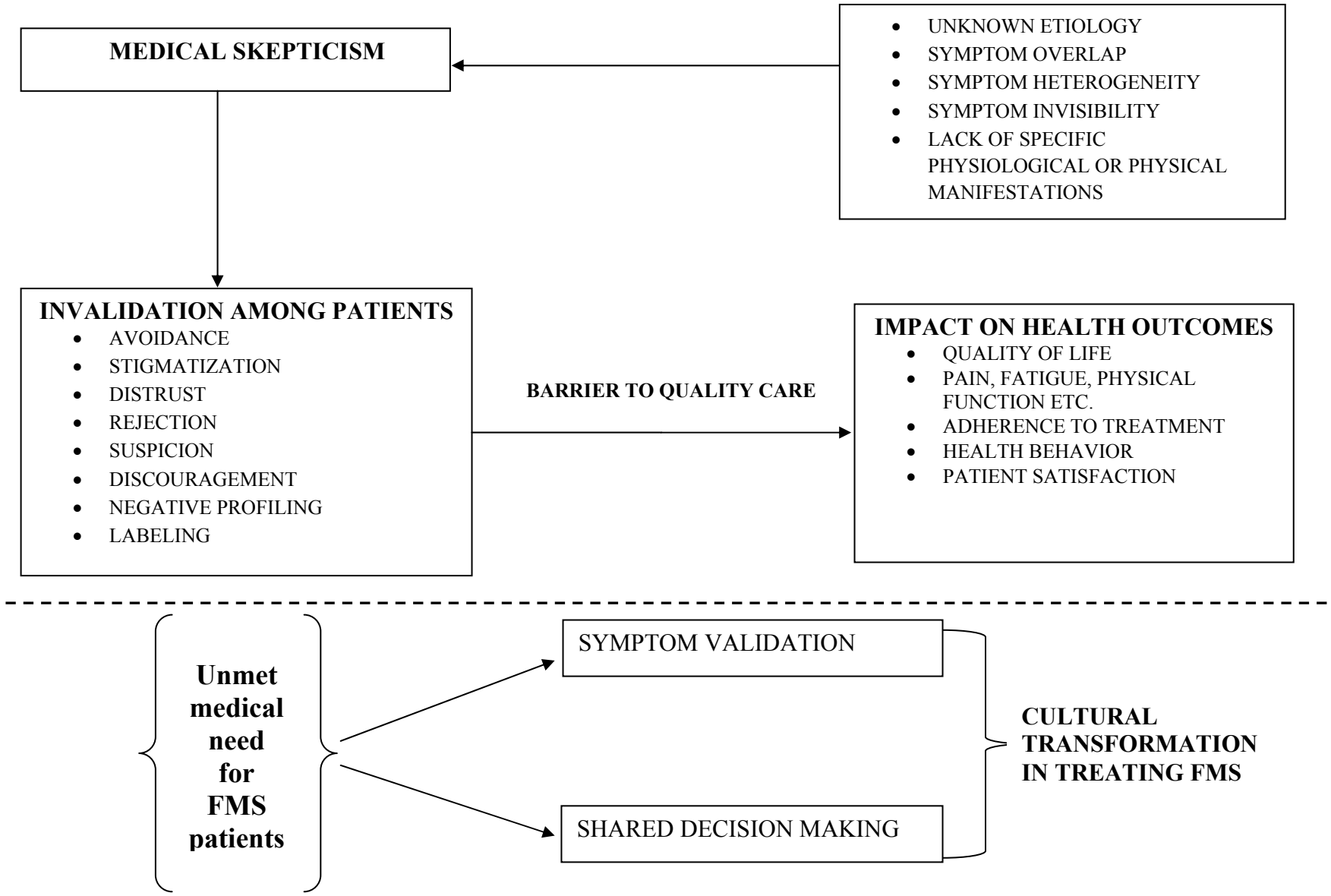
6. *Objective 6: To assess differences in the self-reported quality of life and pain levels of FMS patients based on type of pharmacologic treatments.*

   More specifically,

   - *Objective 6a: To assess differences in the self-reported quality of life of FMS patients based on type of pharmacologic treatments.*
   - *Objective 6b: To assess differences in the self-reported pain levels of FMS patients based on type of pharmacologic treatments.*

**Figure 1. Theoretical framework of the research problem:**

Impact of medical skepticism on health outcomes in Fibromyalgia Syndrome



# CHAPTER TWO: LITERATURE REVIEW

Chapter two discusses the details of fibromyalgia syndrome (FMS). The chapter begins with a brief discussion of the history of the disorder. This is followed by a discussion of the etiology, pathophysiology, associated risk factors, epidemiology, and diagnosis of FMS. Next, both pharmacological and non-pharmacological treatment options are described. The chapter ends with a discussion of the impact of FMS on quality of life of patients.

## HISTORICAL BACKGROUND AND NOMENCLATURE

In the eighteenth century, FMS was considered to be a form of non-articular or muscular rheumatism. Some researchers explained FMS symptoms to be a result of inflammation of the connective tissues. Other researchers believed FMS was an outcome of muscular tissue proliferation. Sir William Gowers followed the school of thought that FMS was the result of an inflammatory process and called the disorder 'Fibrositis' in 1904 [5]. Over the years, research studies failed to find an inflammatory pathological process. In 1976, Smythe and Moldofsky [49] reported that the tenderness was not due to inflammation of muscular tissues [49].The name was changed from 'fibrositis' to 'fibromyalgia syndrome' [50]. The term has Latin roots: 'fibro'-'connective', 'my'-muscle, algia-pain [49]. Despite the fact that people have been impacted by FMS for centuries, the disorder gained clinical recognition only two and a half decades ago. In 1987, the American Medical Association identified it as a potential cause of disability [6]. In 1990 the American College of Rheumatology (ACR) established the tender point and widespread pain criteria for research and epidemiologic studies [4]. Later, it was also certified as a 'legitimate' disorder by the World Health Organization and the National Institute of Health [6].

FMS lacks well-defined and measurable objective physiological markers. Physicians have to rely on patients' subjective description of the symptom experiences. Hence, it is classified as an 'illness' rather than a 'disease' [51].

## ETIOLOGY

Despite tremendous research conducted in the past three decades, the etiology of FMS still remains unclear; however, numerous mechanisms have been postulated.

In a normal pain transmission process as explained by Bradley [18], the A-δ- and C-nerve fibers in skin or muscle tissues transmit ascending pain signals via the dorsal horns of the spinal cord to the brain. This pain signal is moderated by the release of substance P and excitatory amino acids (EAA) (ex. glutamate) which bind to the post synaptic receptors and transmit the pain signal via the pain transmission spinal neurons that project into the brain. Contrarily, pain inhibitory mechanisms also occur via the descending system moderated by the release of neurotransmitters including norepinephrine (NE), serotonin, and endorphins. Continuous pain signals cause a cascade of reactions mediating the constant release of substance P and EAA. Additionally, enhanced excitation of the pain transmission neurons occurs via glial cells to release nitric oxide, which in turn increases the release of substance P and EAA. Glia cells aid the release of prostaglandins and cytokines which further contribute to the neuronal excitability [18].

Abnormal pain control mechanisms have been observed in FMS patients. The source of sensory input is unclear, however, central augmentation of the pain response has been postulated [52]. FMS patients have been found to have a 50 % higher sensitivity to pain than healthy individuals [53]. Reduced cerebrospinal fluid levels of serotonin have been reported suggesting irregularity in the descending pain inhibitory mechanisms [54]. Additionally, hyperactive hypothalamic-pituitary axis (HPA) and significantly higher cortisol levels have been reported in FMS patients. The levels of cortisol have

been found to have significant correlations with morning pain [55, 56]. The autonomic nervous system also plays a role in the mediation of stress and pain. Decreased vasoconstriction, orthostatic hypotension, and reduced heart rate are observed in FMS patients and have been attributed to the alterations in the autonomic nervous system [57-59]. It is uncertain if sleep disturbance is a cause or an outcome of FMS. Poor sleep quality and worsened pain symptoms have been reported in FMS patients [60]. Polysomnographic studies have reported disturbed α-δ wave sleep patterns, which may interfere with the production of the growth hormone (GH) and insulin like growth factor-1 (IGF-1) important in muscle repair [61, 62]. Impaired muscle healing is reported to play a role in irregular and continuous transmission of pain impulses [63].

**RISK FACTORS**

The causative factors that are believed to play a role in the development of FMS can be classified as physical, emotional, physiological or genetic. Trauma due to accidents, and work related stress are examples of physical risk factors. A study investigating the incidence of FMS following traumatic events found that approximately 61% of patients experienced the onset of FMS-like symptoms after motor vehicle accidents and 12.5% reported FMS symptoms after work-related injury [64]. Of those patients reporting FMS symptoms, 83.5% fulfilled the ACR criterion of 11 or more tender points [64]. Specifically, trauma to the neck has been associated with FMS. A study conducted in Israel found people to have a 10 times higher risk of developing FMS within a year of neck injury as compared to those with fractures in the lower part of the body, $p = 0.001$ [65]. Persistent stress is believed to cause alterations in the

hypothalamus which leads to reduced activity of the HPA [66]. A life-style dominated by 'workaholism' has been believed to induce changes in the functioning of the HPA [67]. Emotional risk factors such as mistreatment in childhood (ex. abuse or abandonment), has been found to be associated with the development of pain and FMS related symptoms in adulthood [20]. Examples of physiologic risk factors include increased cortisol levels in women with FMS which have been found to be associated with morning pain [55]. It is not clear if disrupted sleep is a causative factor in the development of FMS, but a long-term follow up study by Mork and Nielsen [68] demonstrated that women with more sleep problems had a greater chance of developing FMS as compared to those with fewer or no sleep problems.

Genetic influences have also been postulated as contributing to FMS. A study investigating prevalence of FMS in the children of 20 women with FMS reported that 16 (28%) of 58 children met the ACR diagnostic criteria for FMS. Another study attempted to investigate the prevalence of FMS among the first-degree relatives of patients with FMS. Thirty four (6.4%) of 533 first-degree relatives met the ACR diagnostic criteria [69]. Low blood serotonin levels (which may interfere with pain inhibitory mechanisms) have been reported in the siblings of FMS patients [70].

## EPIDEMIOLOGY

The worldwide prevalence of fibromyalgia has been estimated to range from 0.5% to 5% [7]. One of the early studies on the prevalence of FMS in the United States (U.S) was conducted by Wolfe *et al* [8] . This study reported the overall prevalence to be 2%-5% and the prevalence was found to increase with age. This study was conducted in the

early 1990's in a population that was 88% white. Current estimates may be different. It was estimated that 5 million people in the U S had FMS in 2005 [71]. However, this study used the prevalence ratio from a 1993 study and adjusted it to the 2005 population of the U.S. as reported by the Census Bureau [71]. With respect to gender, women are seven times more likely to have FMS than men [8]. Weir *et al.* [2] reported an age adjusted incidence of 11.28 per 1000 person-years for females and 6.88 per 1000 person-years for males [2]. Unfortunately, there is very little information on the epidemiological characteristics of FMS.

## DIAGNOSIS & SYMPTOM HETEROGENEITY

Diagnosis of fibromyalgia can be complicated and confusing. The average time from symptom onset to diagnosis ranges from 2.3 to 8 years [72, 73]. Accurate diagnosis and timely treatment can help improve quality of life. This may also reduce the direct economic costs (ex. numerous physician referrals) the indirect costs (ex. loss in work productivity, travel expenses to clinics). These costs associated with FMS can contribute to the enormous socio-economic burden. Health care utilization has actually been found to decrease in FMS patients after diagnosis [74].

In 1990, the ACR established the tender point and widespread pain criteria for diagnosing FMS for research purposes. These criteria have also been applied to clinical settings. The first criterion involves the history of widespread body pain for at least 3 months in all four body quadrants [4]. The second criterion is pain on digital palpation of 4kg force in at least 11 of 18 tender points as defined by the ACR. The 1990 ACR criteria has a sensitivity of 88.4% and specificity of 81.1% [4]. However, research indicates that

FMS patients may have less than 11 tender points and that the cut-off of 11 (out of 18 tender points) may not be accurate [29]. The multi-symptom nature of fibromyalgia was not considered by 1990 ACR criteria. Hence, new and more simplistic diagnostic criteria were established in 2010 and provide an alternative means of diagnosis. Diagnosis can now be ascertained on the basis of the following three criteria [75]:

1) Widespread pain index (WPI) and a symptom severity (SS) scale scores as follows:

a) WPI $\geq$ 7 AND SS $\geq$ 5 OR

b) WPI 3– 6 AND SS $\geq$ 9

2) Presence of other symptoms for at least 3 months.

3) Absence of other disorder that could explain the pain.

The more recent diagnostic criteria (2010) include essential components such as assessment of patient history in addition to the assessment of hallmark FMS symptoms (ex. fatigue, sleep disturbance, and cognitive dysfunction).

There are no specific laboratory tests to help identify FMS. Other tests, however, including thyroid tests (for hypothyroidism), rheumatoid factor (for Rheumatoid Arthritis), anti-nuclear anti-bodies (for Systemic Lupus Erythematosus), erythrocyte sedimentation rate (for Chronic Fatigue Syndrome, polymyalgia rheumatic, and other inflammatory disorders) are utilized to rule out the presence of other illnesses [3]. Symptom heterogeneity is very common in patients with FMS. While some patients may present with symptoms of psychological distress, others may present with more physical symptoms, such as fatigue or irritable bowel syndrome. Many FMS patients have co-morbid conditions [1]. Depression, anxiety, headache, and irritable bowel syndrome are 2.1 to 7 times more likely to be present in FMS patients [2]. Validated disease-specific

instruments including the Revised Fibromyalgia Impact Questionnaire, Fibro Fatigue Scale, Combined Index of Severity in Fibromyalgia, Fibromyalgia Assessment Status are available to assess the severity of co-morbid disorders.

## TREATMENT OPTIONS

The treatment of FMS is oriented toward achieving symptom relief Guidelines suggest a multi-modal approach that incorporates both pharmacological and non-pharmacological techniques along with patient education for effective symptom management [76]. The American Pain Society (APS) and the Association of the Scientific Societies in Germany (AWMF) recommend aerobic exercise (AE), cognitive behavioral therapy (CBT), and amitriptyline for first-line therapy. Contrarily, the European League Against Rheumatism (EULAR) suggests first-line therapy constituting pharmacological agents like tramadol, amitryptyline, fluoxetine, duloxetine, milnacipran, moclobemide, pirlinodol, tropisetron, pramiprexol, and pregabalin [76]. While EULAR and AWMF do not recommend opioids, APS suggests low dose opioids may be useful and provide symptom relief. Non-steroidal anti-inflammatory agents and corticosteroids are not recommended as single treatment strategies by any set of guidelines.

### *PHARMACOLOGIC THERAPIES*

The classes of pharmacological agents used in the treatment of FMS belong to three categories: antidepressants [tricyclic agents, selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs)], muscle relaxants, and anti-epileptics, of which the former is the most extensively studied [3]. In 2007, the U.S.

Food and Drug Administration approved the first drug- pregabalin (Lyrica ®) for treatment of fibromyalgia. In the following years, two more drugs were approved – duloxetine (Cymbalta ®) and milnacipran (Savella ®) [77]. Pregabalin HCl (Lyrica ®) acts as an analgesic and anxiolytic agent in addition to its anti-epileptic properties. It binds to the $\alpha_2\delta$ subunit of calcium gated voltage channels and aids in reduction of the release of substance P and other substances like glutamate at the neuronal synapses [78]. Thus, the neurotransmission of pain is modulated contributing to its analgesic action. A 14-week randomized, double-blinded, placebo-controlled trial, for three different treatment groups based on doses of pregabalin (300 mg/d, 450 mg/d, 600 mg/d, n=750 patients) administered twice a day reported significant reduction in pain scores. Pain was measured by an 11-point numeric pain rating scale ranging from 0 (no pain) to 10 (worst possible pain). At the end of 14 weeks, the reduction in pain score as compared to the placebo was -0.71 for the 300 mg/d dose category, -0.98 for the 450 mg/d dose category, -1.00 for the 600 mg/d dose category , $p < .001$ [79]. The FREEDOM trial, a six-month, double-blind, placebo-controlled trial, evaluated the loss of therapeutic response (LTR) for pregabalin (n=279) versus placebo (n=287). The trial found that the pregabalin group had significantly longer LTR than the placebo group, $p < 0.0001$ [80]. In the placebo group, 61% lost therapeutic response as compared to 32% in the pregabalin group. However, higher discontinuation rates (17%) due to adverse events were found in the pregabalin group.

Duloxetine HCl (Cymbalta ®) is a selective serotonin-norepinephrine reuptake inhibitor. As the name suggests, it acts by blocking the neuronal reuptake of serotonin and norepinephrine. This action increases the concentrations of these neurotransmitters at

the neuronal synapses and modulates pain transmission [18]. A 12-week, double-blinded, placebo-controlled trial of duloxetine demonstrated its efficacy to reduce pain [81]. The primary end point and was measured as greater than 30% reduction in average pain severity score as measured by the Brief Pain Inventory (short form). This score represents average pain severity on a scale from 0 (no pain) to 10 (pain as bad as you can imagine) during the past 24 hours. At the end of 12 weeks, 55% (n=118, $p$ <0.001) patients receiving once daily dose of duloxetine (60 mg), and 54% (n=116, p =0.002) patients receiving and twice daily doses of duloxetine (60 mg) achieved the primary end point versus only 33% (n=120) in the placebo group. Additionally, the drug was found to be well tolerated [81]. A 15-week multicenter, randomized, double-blind, placebo-controlled trial of milnacipran demonstrated a significant reduction in pain (100 mg/d, $p$=0.03 and 200 mg/d, $p$=0.002).The discontinuation rate due to adverse events, however, was found to be 19.5% and 23.7% for 100mg/d and 200mg/d as compared to 9.5% for placebo [82].

Antidepressants have long been used in the treatment of FMS. Amitriptyline (Elavil®), a tricyclic antidepressant, is perhaps the most commonly used for FMS [3]. A meta-analysis of 35 clinical trials evaluated the efficacy of antidepressants for the treatment of FMS. The efficacy outcomes measured were Health-Related Quality of Life, pain, sleep, fatigue, and depression. For SNRIs, the effect size for pain was small and that for other end-points was not sizeable. A greater than 30% pain reduction from baseline (primary end point) was found in 40% of the patients taking SNRIs, but only 30% of the patients who were given placebo. The Relative Risk (RR) of adverse event drop out was 1.83 ($I^2$=33%). For SSRIs, 36.4% of the patients reported a greater than 30% pain reduction as compared to 20.6% of the patients on placebo (RR=1.60, $I^2$=0%). Of those

patients taking TCAs, 48.3% achieved the end point of greater than 30% pain reduction (from baseline) versus 27.8% patients using a placebo. This meta-analysis concluded by recommending amitryptyline for co-morbid sleep disturbances and duloxetine for co-morbid depression [83]. Fluoxetine (10-80 mg/d) was reported to be effective in a 12-week, double-blind trial with significant decreases in pain ($p$=0.002), fatigue ($p$=0.05), and depression ($p$=0.01) [84].

*NON-PHARMACOLOGIC THERAPIES*

APS recommends CBT and patient education as first-line non-pharmacologic treatments for FMS [85]. CBT has been reported to improve psychological characteristics associated with FMS [86]. Glombiewski *et al*. [87] conducted a meta-analysis of 30 types of psychological treatments. The psychological therapies were classified into six types as follows: a) cognitive and/or operant therapies, b) relaxation treatments (ex. biofeedback, neuro-feedback), c) educational treatments, d) behavioral operant treatments, e) mindfulness-based treatments, and f) others (ex. eye movement desensitization). The size of the treatment effects when quantified supported long-term treatments for reduction in pain. Psychological treatments were also found to be effective in improving sleep, functional status, and catastrophizing. Cognitive therapy was found to be most efficacious of all psychological treatments. The authors concluded that psychological therapies should be a major component of multimodal treatments for FMS patients.

Other non-pharmacologic treatments have demonstrated efficacy in decreasing symptom severity of FMS. Aerobic exercise (AE) has shown some efficacy in symptom

amelioration. A meta-analysis of 35 AE randomized controlled trials provided evidence for decreased pain, fatigue, depressed mood, and improved health-related QoL. Continued land-based or water-based exercise of slight to moderate intensity for two to three times a week up to at least 4 weeks was required for treatment efficacy [88]. Acupuncture is a commonly used therapy for FMS, but the evidence for its efficacy is mixed. A comprehensive systematic review of acupuncture treatments for FMS patients evaluated seven clinical trials and reported there was a small effect on pain improvement (standardized mean difference=-0.25; 95% CI=(0.49, 0.02); $p$=0.04), however, there was no improvement in pain at follow-up [89]. The review concluded that acupuncture alone was not favorable for the treatment of FMS patients.

There are limited clinical trials of CAM for FMS. More research is required for demonstrating the effectiveness CAM treatment for treating FMS patients.

## HEALTH OUTCOMES IN FIBROMYALGIA

Chronic health conditions have an impact on patient QoL. FMS was clinically defined in 1990 and since that time several studies have aimed to examine and quantify QoL in FMS patients. Burckhardt *et al.* [14] compared the QoL of patients with FMS to that of patients with RA, osteoarthritis, chronic obstructive pulmonary disease, permanent ostomies, insulin dependent diabetes mellitus, and healthy controls. FMS patients were found to have the lowest QoL values (71.5±11.8) when measured with the Quality of Life Scale–16 (QOLS-16). A similar study comparing the QoL of Swedish women with FMS, RA, and SLE using the same standardized measure (QOLS-16) found that FMS patients

had significantly lower QoL values: FMS (77.6 ± 14.2) versus RA (83.4 ± 9.6) versus SLE (86.0 ± 13.6), $p < 0.05$ [90].

The QoL studies comparing only FMS to RA patients have provided contrasting results. Birtane M *et al.* [91] found that FMS patients had significantly lower mental health scores on the Short Form (SF)-36(49.87 ± 14.77) versus RA patients (62.5 ± 12.80) [91]. The differences between other health domains including physical functioning, physical role, body pain, general health, vitality, social functioning, and emotional role were not significant. Ofluoglu *et al.* [92] compared the QoL among Turkish females with FMS and RA using the Arthritis Impact Measurement Scale II and Beck Depression Inventory. A low QoL was reported in both groups, however, a statistically significance difference was not found. Similarly, Walker *et al.* [93] compared the QoL and physical functioning among FMS and RA patients using the SF-36 and Stanford Heath Assessment Questionnaire. It was found that FMS patients had low scores (poor QoL) across all mental health domains, physical role, and social function. Da Costa *et al.* [94] utilized the SF-36 and compared QoL between women diagnosed with FMS and women diagnosed with SLE. This study found that QoL was impaired for both groups; however, FMS patients had significantly lower scores on both the physical function domain and the total physical component summary ($p < 0.001$).

Arnold *et al.* [95] conducted a focus group (n=48) to attempt to understand the impact of FMS on daily functioning. Pain and fatigue were reported to be continually present and pain was reported to impact sleep. Patients reported symptoms of depression, anxiety, and dyscognition which they believed impacted their QoL. The unpredictable nature of symptoms, inability to perform daily routine tasks, lack of social acceptance,

reduced working capacity, inability to devote time for family or activities of leisure were reported as undesirable outcomes of FMS. Cunningham and Jillings [44] conducted interviews of eight FMS patients and found that the continuous presence of symptoms and unpredictability in their severity was a common problem that patients encountered. Patients reported abandoning their former roles at family and at work. Symptom invisibility was reported and patients expressed that this caused emotional distress. Patients reported other complications including a general lack of support and the belief that their health care professionals did not take their symptoms seriously.

In summary, the review of literature reveals various uncertainties surrounding FMS with regards to etiology, risk factors, epidemiology, diagnosis, and treatments. Numerous pathogenic mechanisms and risk factors have been postulated, but not one mechanism has been confirmed. FMS diagnosis is challenging and clinical trials of treatments have demonstrated mixed efficacy. FMS patients may experience both a decrease in QoL and a lack of acknowledgement (from society and health care professionals). There is a great deal of ambiguity and uncertainty regarding FMS and this presents challenges for both health care professionals and patients. The goal of this study is to assess patients' perceptions of physician attitudes, experiences of invalidation, trust in physicians, experiences with various treatments and related health outcomes (QoL and Pain). By exploring and learning more about the patient experience perhaps more patient-centric views and treatment approaches can be established thereby improving QoL for patients diagnosed with FMS.

# CHAPTER THREE: METHODOLOGY

This chapter outlines the methodology used to conduct this study. It begins with an overview of web-based surveys, and later explains the data collection procedure used for the study. Development of the survey instrument, validation, and pilot testing are explained in detail. This chapter ends with a description of the data analyses.

## STUDY DESIGN

This study was cross-sectional and exploratory in nature and utilized web-based survey methodology for data collection.

## WEB-BASED SURVEYS: A BRIEF OVERVIEW

Web-based surveys use the internet for data collection and offer advantages of quick and easier data collection at relatively low costs. Primarily, web-based surveys are classified as probability and non-probability based surveys [96]. For probability based surveys, the researcher has a prior knowledge of a nonzero probability of sample selection. In other words, the sampling frame is known, and each person in the sampling frame has an equal probability of being selected. For non-probability based surveys, there is no prior knowledge of the sampling frame and access to the survey cannot be restricted to population of interest [96, 97]. Due to non-availability of information on the sampling frame, calculation of response rates and other survey metrics for non-probability based surveys is difficult [97]. Couper [96] sub-categorized non-probability surveys as:

a) *Web surveys as entertainment*: This sub-category refers to opinion based surveys or debates on a particular topic posted on websites, for example, opinion polls on immigration laws posted by an on-line news website. Any one is permitted to ask or respond to questions. More specifically, this sub-category represents a platform for participants to share their opinions on a given topic, rather than respond to a set of questions pre-determined by a researcher.

b) *Self-selected web surveys:* This sub-category represents those surveys where participants are 'invited' by means of advertisements. There are disadvantages to this type of survey. These include the following: respondents may complete the survey multiple times and the survey may be shared or forwarded to others who may or may not represent the target population.

c) *Volunteer panels of internet users*: Surveys in this sub-category are similar to self-selected web surveys, but access to members outside the target population is restricted. Initially, the volunteer panel is created by advertisements on internet portals. Demographic information is collected to create a large database of potential participants for future surveys. Access is permitted by means of email identifiers or password. Since, the initial data collection occurs by self-recruitment, these surveys may not truly represent the target population.

The current study best fits the category of self-selected web surveys. This survey methodology was utilized in order to get access to a larger population of patients with fibromyalgia syndrome (FMS). The survey was advertised in the February 2013 edition of the on-line newsletter of the National Fibromyalgia and Chronic Pain Association (NFMCPA). This newsletter was e-mailed to approximately 110,000 members, and interested recipients volunteered to participate in the study. No information was available on the actual number of patients with FMS within the member group. Any person who claimed to have FMS was allowed to participate. Additionally, there was no restriction on passing the survey to others, via email, or sharing it on social networking websites. The non-availability of appropriate information presented challenges in calculation of the

survey response rate. Necessary steps were taken to minimize these limitations and will be explained in the later sections of this chapter.

## INSTRUMENT DEVELOPMENT

The survey instrument consisted of five sections (Appendix A1). All the questions in this survey were voluntary and respondents were able to stop answering at any point during the survey.

### Section I: Initial Consent and Screening

a) The first section explained the purpose of the survey and asked participants for their consent. Participants providing consent were allowed to proceed through the survey. 'Thank you for your participation' message was displayed for participants not providing consent.
b) The second screening question asked: '*Do you currently have fibromyalgia?'* Those answering 'yes' were allowed to proceed through the survey, while participants answering 'no' were directed to end of survey with a 'Thank you for your participation' message.
c) Similarly, individuals less than 18 years of age were also screened out of survey participation.

### Section II: Assessment of patient perceptions of physician attitudes, patients' trust in physicians, and patients' perceptions of medical professionals.

The second section consisted of three survey instruments:

a) *Patient perceptions of physician attitudes*: This instrument was developed based on extensive review of literature with an aim to quantify the support and

acknowledgement FMS patients receive from their physicians. The instrument consists of nine items; each item is categorically measured using a five-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). The respondents were instructed to answer the items based on their interactions with any physician they saw on a more regular basis.

b) *Trust in Physician Scale*: This is a 11-item validated instrument which aims to provide a quantitative measure of the trust patients have in their physicians [98]. Each item is categorically measured using a five-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). Respondents were instructed to answer the items based on their interactions with any physician they saw on a more regular basis. This instrument has been previously tested in FMS patients [99].

c) *Patient perceptions of medical professionals:* The Illness Invalidation Inventory was utilized to measure patient perceptions of medical professionals. This instrument was developed in the Netherlands in 2011 and was intended to measure invalidation experiences of patients with FMS and other chronic pain syndromes [100]. With this instrument, invalidation is measured with respect to five sources: Spouse/Partner, Family, Medical Professionals, People at Work, and People in Social Services. The medical professionals section of this instrument was utilized in this study. This section includes eight items to assess patient perceptions and experiences of dealing with medical professionals. The responses are measured on a five-point Likert scale – 1 (never), 2 (seldom), 3 (sometimes), 4 (often), to 5 (very often). This instrument further consists of two factors which are 'Discounting' and 'Lack of Understanding'. Experiences of distrust,

admonition, rejection of one's ability to work, poor acknowledgement of fluctuations in symptoms, and offer of unusable advice to patients are represented by 'Discounting' [100]. An example of item from the scale that measures Discounting is: *Medical professionals think I am an exaggerator.* 'Lack of Understanding' measures poor recognition and comprehension of illness, and lack of emotional support from medical professionals [32]. An example of item from the scale that measures Lack of Understanding is: *Medical professionals take me seriously*. This instrument has been validated in patients with FMS and Rheumatoid Arthritis [45].

**Section III: Current treatment patterns.**

This section was designed to evaluate current treatment trends for patients with FMS. Utilization patterns of both pharmacologic and non-pharmacologic medications were collected.

a) Pharmacologic medications: Respondents were first asked if they used prescription or over-the-counter (OTC) medications for treating their symptoms of FMS.

b) Respondents answering 'yes' were provided with a list of 28 medications. The list was derived from a previous study that had asked a sample of nearly 3000 FMS patients to select the most commonly used medications from an original list of 253 medications [101]. The respondents were also asked to rate the effectiveness of prescribed medications. Respondents answering 'no' were then led to the next question on use of non-pharmacologic treatments or complementary and alternative medicine (CAM).

c) Next, all respondents were asked if they used CAM for treating their symptoms of FMS. Respondents answering 'yes' were provided with a list of commonly used CAM treatments. They were further asked to rate the effectiveness of each type of CAM treatment they utilized.

**Section IV: Quality of life and current pain levels of FMS patients.**

a) *Quality of Life Scale–16 (QOLS-16)*: This is a 16-item generic instrument which was originally designed to assess quality of life of patients with rheumatic diseases [102]. Each item is measured on a seven-point Likert scale with categories ranging from 1 (terrible), 2 (unhappy), 3 (mostly dissatisfied), 4 (mixed), 5 (mostly satisfied), 6 (pleased), and 7 (delighted). Respondents were asked to select the category that best described their satisfaction on six domains: 1) material and physical well-being, 2) relationships with other people, 3) social, community and civic activities, 4) personal development and fulfillment, 5) recreation, and 6) independence. For example, *how satisfied are you at this time with health – being physically fit and vigorous?* OR *how satisfied are you at this time with participating in active recreation?*

b) *Current Pain:* Pain was measured on an 11- point, continuous, visual analog scale ranging from 0 to 10, with 0 indicating no pain and 10 indicating worst pain.

Before including the validated instruments as a part of this study, permission was sought and obtained from the respective authors.

**Section V: Demographics and Miscellaneous Questions**

To assess socio-economic and other demographic characteristics of the respondents, questions regarding gender, race, marital status, highest level of education, age, annual

income, and current place of residence were included. In addition, questions regarding health insurance coverage of CAM therapies, and number of referrals to health care providers were included in the survey.

## INSTRUMENT VALIDATION

Validation is a process of confirming if the items of a survey instrument truly measure what they intend to measure and can be divided into four main categories: *content*, *criterion*, *construct*, and *face validity* [103].

C*ontent validity* measures the completeness of an instrument [103]. *Criterion validity* measures the degree of agreement between a new instrument and another well-established instrument or gold standard for measuring the research question [103]. *Construct validity* measures the degree of association of items of an instrument to a hypothetical construct, which is to be evaluated [103]. *Face validity* is performed after the instrument has been developed and refers to reviewing the instrument for any ambiguity in the questions or topics covered [103]. For this study, content and face validity of the survey instrument were assessed. The purpose of content validation is to ascertain whether items of an instrument include the entire range of concepts relevant to the topic of interest. For content validation, the expert opinion of two researchers in FMS was sought. The survey instrument was provided to these experts, and they independently performed a detailed analysis to evaluate the relevance of the survey components to the intended research objectives [103]. Additionally, the researchers in this study team and two other student researchers in Health Economics and Outcomes Research assessed the survey for face validity.

## DATA COLLECTION

This study utilized primary data collection methodology, which refers to data collected via face-to-face interviews, telephone, mail, or internet surveys. The National Fibromyalgia Association (NFA), NFMCPA, and the state support groups listed on the website of the NFA were initially contacted. On-line studies conducted via these organizations have reported a sample size of more than 2000 respondents [2, 12, 101]. Favorable replies were received from the president of the NFMCPA, but very few state support group leaders. Additionally, the total number of members in these support groups was very low (nearly 1000) as compared to the membership of the NFMCPA (> 75,000, at the time of initial contact with the president of the organization). The members of the NFMCPA were thus invited to participate in this study. The NFMCPA is a not for profit organization located in Logan, Utah, United States. It aims to educate patients, their families/caregivers, and government bodies about FMS and other pain conditions through research and advocacy programs.

Prior to conducting the main study, the survey instrument was pre-tested. The aim of the pre-test was to assess clarity and completeness of the survey, and participant compatibility with the questions. The state support group leaders of the NFA were contacted and agreed to forward the survey to their members. Based on an estimate from the support group leaders, a sample size of 1,000 was utilized for the pre-test which was conducted in October 2012. In addition to the original survey questions, the pre-test also asked several additional questions. The pre-test questions are included in Appendix A2. Based on the results of the pre-test, the list of medications was expanded and no other major changes were included in the main survey.

The main survey was then advertised in the electronic newsletter of the NFMCPA in February 2013. For this purpose, the president of NFMCPA was contacted via email and the study objectives were briefly explained. An e-mail list of registered members was requested. Due to member-privacy, the list of e-mail addresses of its members could not be obtained for our research purposes. However, the president agreed to advertise the survey link in their newsletter which was e-mailed to approximately 110,000 registered members. The survey was conducted via Qualtrics®, an on-line survey software which also enabled direct download into a statistical package (SPSS) for analyses.

**STUDY SUBJECTS AND RECRUITMENT**

Since the study required participation of human subjects, an approval from the Institutional Review Board at Duquesne University was obtained. For this study, participants were recruited through the on-line newsletter advertisement. The newsletter was emailed on February 5, 2013. The advertisement briefly described the importance of the study and its objectives. The survey was advertised as follows:

*Duquesne University School of Pharmacy is conducting a research project regarding Fibromyalgia. This study will focus upon self-reported quality of life, treatment effectiveness, and attitudes and perceptions of patients. This study will require that you complete a survey of approximately 30 to 45 minutes. This survey will be completely anonymous. Data will only be recorded in aggregate and no personal identification of data will be made. Your participation is essential for understanding the treatment of this disorder and will assist in making recommendations regarding more effective treatment outcomes and improving quality of life for people with Fibromyalgia.*

*Please click on the link below if you agree to complete the survey. Please note that the results of the study will be shared once the study is complete.*

*Thanks in Advance,*

*Dr. Andrea Pfalzgraf*

*Dr. Vincent Giannetti*

***Survey Link***

https://duqbusiness.qualtrics.com/SE/?SID=SV_5nkCC84OSQ3xT01

Registration for receiving digital newsletters from the NFMCPA is free for anyone willing to register for updates. Thus, the organization membership is not limited to members with FMS alone, but may include family members, caregivers, or significant others of the FMS patients. In addition, researchers or other people interested in learning more about the disorder may also sign-up as members. Therefore, to avoid sample contamination, a screening question was used at the beginning of the survey. Participants were asked if they had FMS (*Do you currently have fibromyalgia?)*, and those answering 'No' were screened out of participation in the survey. The survey also screened out patients who were less than 18 years of age. Participants, who did not meet the above discussed criteria, were automatically directed to the end of survey with a 'Thank you for your participation' message. The survey link was active for a period of approximately three weeks and was terminated on February 26, 2013.

## DATA ANALYSIS

The survey data was imported into IBM® SPSS® Statistics version 20.0 (IBM Corp., Armonk, NY). All statistical analyses were conducted via IBM® SPSS®. Data analyses included both descriptive and inferential statistics.

### RESPONSE-RATE CALCULATIONS

Due to non-availability of a well-defined sampling frame, calculation of response rates for web-based surveys is problematic. Completion rate is the most useful metric that can be calculated for non-probability based surveys [97]. Completion rate is defined as the percentage of people who start, qualify, and complete the survey [97]. The survey tool (Qualtrics®) in this study could not capture the number of people who started the survey and did not qualify. Hence, the completion rate could not be calculated. According to the officials at the NFMCPA, 890 emails (out of 110,000) bounced back and there were 950 clicks on the survey link [104]. Due to reasons of confidentiality, the NFMCPA could not provide any other estimates related to the survey.

**Table 3.1. Calculation of response rate: I) Example for response rate calculation for tradition mail surveys, and II) Response rate calculation for current study.**

| | I | II |
|---|---|---|
| | **Traditional Mail Survey** | **Current Study** |
| Original sample size | 100 | --- |
| Undeliverable surveys | 10 | 890 |
| **Effective sample size** | **90** | **950** |
| Number of surveys returned | 80 | 810 |
| Unusable surveys | 10 | 140 |
| Usable responses | 70 | 670 |
| Usable response rate (%) | 77.78 | 70.52 |

The following example explains the response rate calculation in a traditional mail survey. Suppose a mail survey was sent to 100 study participants of which 10 were undeliverable.

The effective sample size of participants would then reduce to 90. If 80 surveys were returned of which 10 were incomplete or partially filled, then the final number of surveys that can be used for analyses would reduce to 70. The response rate for this example, also called as usable response rate, can be calculated as:

$$\text{Response rate} = \frac{\text{Number of usable responses}}{\text{Effective sample size}} * 100$$

Therefore the usable response rate in this example is 77.78% (Table 3.1).

For the current study, the original sample size was not known. According to the officials at the NFMCPA, 890 emails bounced back and there were 950 clicks on the survey link. Due to reasons of confidentiality, the NFMCPA could not provide any other estimates related to our survey. Therefore, in this study the emails that bounced back were taken as a proxy for undeliverable surveys. The number of clicks was utilized as a proxy for number of surveys returned. During data cleaning, 140 surveys were found to be incomplete. Therefore, the final number of usable surveys was 670 and the usable response rate for this study was calculated to be 70.52% (Table 3.1).

DEMOGRAPHICS & FMS-RELATED CHARACTERISTICS

The demographic characteristics were assessed for all survey respondents. Specifically, mean age (years), gender, race, marital status, highest level of education, and place of residence were assessed. Descriptive statistics were calculated for the responses. Mean values were calculated for age which is a continuous variable in this study. Frequencies and percentages were calculated for the categorical demographic variables. The summary scores for all scales, namely Patient perceptions of physician

attitudes, Trust in Physician Scale, Illness Invalidation Inventory, and QOLS-16 were calculated. The total scores on all scales were continuous variables. Years since diagnosis of FMS (continuous variable), and number of referrals from health care providers (categorical variable) were calculated. More specifically, mean values and standard deviations were calculated for continuous variables, while frequencies and percentages were calculated for categorical variables.

STUDY OBJECTIVES

Each objective is stated below and is followed by a description for data analysis.

*Objective 1: To determine factor structure and internal consistency of the 'Patient perceptions of physician attitudes' scale.*

The Patient perceptions of physician attitudes scale was developed from a review of scientific literature. This scale had nine variables with each response measured on a five-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). Descriptive statistics (mean and standard deviation) were calculated to assess respondents' rating of each variable. Exploratory factor analysis was performed to determine the structure of the scale. Internal consistency reliability was assessed using Cronbach's α coefficient. For accurate factor structure when conducting factor analysis, a minimum sample size of 20 observations per variable has been suggested [105]. Therefore, to meet this objective a minimum of 20*9=180 observations was required.

*Objective 2: To determine factor structure and internal consistency of the standardized scales used in the survey.*

There were three standardized scales in the study. These were Trust in Physician Scale, Illness Invalidation Inventory, and QOLS-16. The Trust in Physician Scale and the

QOLS-16 were previously tested for factor structure in an outpatient FMS population [99, 102]. The Illness Invalidation Inventory was tested in a European population with FMS who attended an outpatient clinic for treatment. It has, however, not been tested in a U.S. FMS population [100, 106].

The sample of FMS patients in this study was different from that in the previous studies mainly because these FMS patients belonged to a self-help group. Research has indicated that active members of self-help groups tend to have high levels of symptom severity [107]. Consequently, the responses of the participants in this study may be different from the responses of participants in previous studies in whom the validation of the above mentioned scales was conducted. Therefore, the factor structure of these scales may not be the same as previous studies [99, 100, 102]. Therefore, it was important to test the factor structure of the previously validated scales, namely Trust in Physician Scale, the Illness Invalidation Inventory, and the QOLS-16. For the reasons explained above, all three validated instruments were tested for factor structure by conducting exploratory factor analysis. Internal consistency was assessed for the three validated instruments by measuring Cronbach's α coefficient.

*Objective 2a: To determine factor structure and internal consistency of the Trust in Physician Scale in a sample of patients with FMS.*

This scale had 11 items with each response measured on a five-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree) [98]. Descriptive statistics (mean and standard deviation) were calculated to assess respondents' rating of each variable. Exploratory factor analysis was conducted to analyze the structure of the scale. Eigen values and scree plot were assessed to decide on the structure of the instrument. In

addition, internal consistency of the scale was measured using Cronbach's α coefficient. As explained in objective 1, the minimum sample size to meet this objective was 20*11=220 [105].

*Objective 2b: To determine factor structure and internal consistency of the Illness Invalidation Inventory in a sample of FMS patients.*

This scale had eight items with each response measured on a five-point Likert scale ranging from 1 (never) to 5 (very often) [100]. The scale was previously shown to have two factors: Discounting (representing patient experiences of admonishing, disbelief, etc.) and Lack of Understanding (representing patient experiences of lack of support). Descriptive statistics (mean and standard deviation) were calculated to assess respondents' rating of each variable. Similar to Objective 2a, exploratory factor analysis was conducted and Eigen values and scree plot were assessed. In addition, internal consistency of the scale was measured using Cronbach's α coefficient. The minimum sample size required for this analysis was 20*8=160 [105].

*Objective 2c: To determine factor structure and internal consistency of the Quality of Life Scale-16 in a sample of FMS patients.*

This scale had 16 items with each response measured on a seven-point Likert scale – 1 (terrible), 2 (unhappy), 3 (mostly dissatisfied), 4 (mixed), 5 (mostly satisfied), 6 (pleased), and 7 (delighted) [102]. Descriptive statistics (mean and standard deviation) were calculated to assess respondents' rating of each variable. Exploratory factor analysis was conducted to analyze the structure of the scale. Eigen values and scree plot were assessed to decide on the structure of the instrument. In addition, internal consistency of

the scale was measured using Cronbach's α coefficient. To meet this objective, a minimum sample size required for the analysis was 20*16=320 [105].

*Objective 3: To predict self-reported quality of life and pain levels (current) of FMS patients based on patient perceptions of physician attitudes, patients' trust in physicians, patients' perceptions of medical professionals, treatment effectiveness, and demographics.*

The specific relationships tested for this objective are discussed below.

*Objective 3a: To predict self-reported quality of life of FMS patients based on patient perceptions of physician attitudes, patients' trust in physicians, patients' perceptions of medical professionals, treatment effectiveness, and demographics.*

Multiple regression analysis was performed to assess this objective. The summary score from QOLS-16 was the dependent variable (QoL), which is continuous in nature. Both categorical and continuous predictors were used in the model. The continuous predictors for this model were: summary scores of Patient perceptions of physician attitudes scale, Trust in Physician Scale, Discounting and Lack of understanding from the Illness Invalidation Inventory, age, and years since diagnosis. The categorical variables for this model were: Use of prescription or OTC medicine, use of CAM, number of referrals to physicians, marital status, education, and income. With 11 predictors, the minimum sample size required for this analysis was 123 as calculated with G*Power (α=0.05, power (1-β)=0.8 and effect size ($\eta^2$)=0.15) [108].

*Objective 3b: To predict self-reported pain levels (current) of FMS patients based on patient perceptions of physician attitudes, patients' trust in physicians, patients' perceptions of medical professionals, treatment effectiveness, and demographics.*

Multiple regression analysis was performed to assess this objective. The pain score from the visual analog scale was the dependent variable, which was continuous in nature. Both categorical and continuous predictors were used in the model. The continuous predictors for this model were: summary scores of Patient perceptions of physician attitudes' scale, Trust in Physician Scale, Discounting and Lack of Understanding from the Illness Invalidation Inventory, age, and years since diagnosis. The categorical variables for this model were: Use of prescription or OTC medicine, use of CAM, number of referrals to physicians, marital status, education, and income. As calculated with G*Power, a minimum sample size of 123 was required for a Type I error ($\alpha$) of 0.05, power (1-$\beta$) of 0.8 and an effect size ($\eta^2$)=0.15 [108].

*Objective 4: To determine trends in the utilization of current treatments for FMS.*

The specific relationships analyzed for this objective are discussed below.

*Objective 4a: To determine trends in the utilization of pharmacologic treatments for FMS.*

Section III of the survey first asked respondents if they used prescription or OTC medications for treating their symptoms of FMS. If they answered 'yes', they were provided with a list of 28 medications (prescription and OTC), and were asked to select the medications that were utilized. Among the selected medications, they were further asked to rate their effectiveness as follows: '*Do not currently take*', '*Very Effective*', '*Moderately Effective*', '*Not at all Effective*,', and '*Made symptoms worse*'. If the respondents answered 'no' (they did not utilize medications), they were led to the next section inquiring about the use of CAM. Descriptive statistics or frequency distributions were estimated for the prescribed medicines and the effectiveness ratings.

*Objective 4b: To determine trends in the utilization of non-pharmacologic treatments for FMS.*

Respondents were asked if they used CAM for treating their symptoms of FMS. If they answered 'yes', they were provided with a list of CAM and were asked to select the CAM treatments that they have tried. Among the selected CAMs, they were further asked to rate their effectiveness as follows: '*Do not currently take*', '*Very Effective*', '*Moderately Effective*', '*Not at all Effective*,', and '*Made symptoms worse*'. If the respondents answered 'no' to the use of CAM, they were led to the next section (Section IV: Quality Of Life Scale-16). Descriptive statistics or frequency distributions were estimated for the CAM and the effectiveness ratings.

*Objective 5: To assess differences in the self-reported quality of life and pain (current) of FMS patients based on type of treatment.*

The specific relationships tested for this objective are discussed below.

*Objective 5a: To assess differences in the self-reported quality of life of FMS patients who utilized pharmacologic treatments alone, non-pharmacologic treatments alone, and those utilizing both pharmacologic and non-pharmacologic treatments.*

One-way analysis of variance was performed to assess objective 5a. The dependent variable was QoL (summary score of the QOLS-16). The independent variable or factor was type of treatment which included three levels, namely pharmacologic medications (representing use of prescription or OTC medications only), non-pharmacologic medications (representing use of CAM treatments only), and both pharmacologic and non-pharmacologic medications (representing use of both prescription or OTC medications and CAM treatments). As calculated with G*Power, the minimum sample

size required for this analysis was 432 for a Type I error (α) of 0.05, power (1-β) of 0.8 and an effect size ($\eta^2$)=0.15 [108].

*Objective 5b: To assess differences in the self-reported pain (current) of FMS patients who utilized pharmacologic treatments alone, non-pharmacologic treatments alone, and those utilizing both pharmacologic and non-pharmacologic treatments.*

One-way analysis of variance was performed to assess objective 5b. The pain score from the visual analog scale was the dependent variable. The independent variable or factor was type of treatment which included three levels, namely pharmacologic medications (representing use of prescription or OTC medications only), non-pharmacologic medications (representing use of CAM treatments only), and both pharmacologic and non-pharmacologic medications (representing use of both prescription or OTC medications and CAM treatments). As calculated with G*Power, the minimum sample size required for this analysis was 432 for a Type I error (α) of 0.05, power (1-β) of 0.8 and an effect size ($\eta^2$)=0.15 [108].

*Objective 6: To assess differences in the self-reported quality of life and pain levels (current) of FMS patients based on type of pharmacologic treatments.*

The specific relationships for this objective are discussed below.

*Objective 6a: To assess differences in the self-reported quality of life of FMS patients based on type of pharmacologic treatments.*

A Kruskal-Wallis test was performed to assess objective 6a. The dependent variable was QoL (summary score of the QOLS-16). The independent variable was type of pharmacologic medication which included five levels, namely pain medications, antidepressants, anti-anxiety medications, anti-seizure medications, and muscle relaxants.

The sample size for the anti-anxiety, anti-seizure, muscle relaxant group was found to be less than 30. Therefore, a non-parametric test, Kruskal-Wallis was performed.

*Objective 6b: To assess differences in the self-reported pain levels (current) of FMS patients based on type of pharmacologic treatments.*

Similar to Objective 6a, a Kruskal-Wallis test was performed to assess objective 6b. The pain score from the visual analog scale was the dependent variable. The independent variable was type of pharmacologic medication which included five levels, namely pain medications, antidepressants, anti-anxiety medications, anti-seizure medications, and muscle relaxants.

# CHAPTER FOUR: RESULTS

In this chapter, the results of the survey are discussed. The results are presented in the order of the objectives stated in the data analysis section of the previous chapter on Methodology.

## RESULTS OF PRE-TEST

The pre-test was sent to three support group leaders from the National Fibromyalgia Association. The total number of members in these support groups was estimated to be nearly 1000. Sixty-eight responses were obtained in the pre-test. A majority of respondents who answered the pre-test were females (84%). The mean age of respondents was 50.8±11.27 years. Eighty-three percent of the pre-test respondents were White/Caucasian. In order to assess respondent compatibility with the survey questions, the pre-test survey included several questions in addition to the original survey questions. The pre-test questions are provided in Appendix A2. Eighty-one percent of the pre-test respondents found the survey items easy to read and understand. The mean for survey completion time was found to be 15 minutes. Based on these estimates, respondents were found to be comfortable with the length of the survey and the nature of the survey questions. The list of pharmacologic medications was expanded based on feedback from the pre-test. Three additional medications (Mobic®, Zanaflex®, and Mucinex®) that were found to be frequently utilized by FMS patients were included. No other major changes were needed based on the results of the pre-test.

## SURVEY RESPONSES

The final survey was advertised, along with a link to the survey, in the February, 2013 edition of the electronic newsletter of the National Fibromyalgia and Chronic Pain Association (NFMCPA). The newsletter was sent to approximately 110,000 members of NFMCPA (personal communication, February 26, 2013) [104]. We received responses from 810 participants. According to the estimates provided by the NFMCPA, 950 had clicked on the survey link, and there were 815 bounced emails [104]. Due to issues with

confidentiality, the NFMCPA could not provide other survey response estimates, for example, the number of network undeliverable emails, or the number of participants opening the emails. The newsletter was emailed on February 5, 2013. Toward the end of the third week, responses to the survey declined to 1 or 2 responses per day. Hence, the survey was terminated on February 26, 2013. The survey link was thus active for approximately three weeks. As explained under 'Data Analysis' section of Chapter 3, the response rate for the final survey was found to be 70.52%.

## RESULTS OF FINAL SURVEY

### DEMOGRAPHIC & FMS-RELATED CHARACTERISTICS

A vast majority (97%) of the survey respondents were females with a mean age of 54 years. With respect to the other demographics, the respondents were White/ Caucasian (93%), married with children (51%), and had received at least a college education (57%). Nearly 62% respondents were found to have an annual income of less than $50000. Approximately, 17% of the respondents indicated they resided in the Northeast, 22% were from the Midwest, 33% were from the South, and 21% resided in the West. Additionally, 7% of the survey participants indicated they lived outside the United States (U.S.) and were from Argentina, Australia, Canada, Chile, Germany, Great Britain, Italy, New Zealand, Puerto Rico, or South Africa. The respondents' demographic information is listed in Table 4.1.

**Table 4.1. Socio-demographic characteristics of survey sample.**

| | MEAN±SD | NUMBER (%) |
|---|---|---|
| **AGE (y)** | 54.08 ± 10.99 | NA |
| **GENDER** | | |
| Female | NA | 647 (96.56) |
| Male | | 20 (3.0) |
| **RACE** | NA | |
| White/Caucasian | | 620 (92.5) |
| African American | | 13(1.9) |
| Hispanic | | 16(2.4) |
| Asian | | 3(0.4) |
| Native American | | 3(0.4) |
| Pacific Islander | | 2(0.3) |
| Other | | 10(1.5) |
| **MARITAL STATUS** | NA | |
| Single, never married | | 49(7.3) |
| Married without children | | 98 (14.6) |
| Married with children | | 342(51) |
| Divorced | | 109 (16.3) |
| Separated | | 14 (2.1) |
| Widowed | | 23 (3.4) |
| Living w/ partner | | 34 (5.1) |
| **EDUCATION** | NA | |
| Less than High School | | 6 (0.9) |
| High School / GED | | 77 (11.6) |
| Some College | | 207 (31.1) |
| 2-year College Degree | | 95 (14.3) |
| 4-year College Degree | | 168 (25.3) |
| Master's Degree | | 93 (14.0) |
| Professional Doctorate Degree (JD, MD, DDS etc.) | | 19 (2.9) |
| **INCOME** | NA | |
| Less than $25,000 | | 239(35.7) |
| $25,001-$50,000 | | 173(25.8) |
| $50,001-$75,000 | | 107(16.0) |
| $75,001-$100,000 | | 55(8.2) |
| $100,001-$125,000 | | 20(3.0) |
| >$125,001 | | 41(6.0) |
| **RESIDENCE** | NA | |
| Northeast | | 111 (16.6) |
| Midwest | | 148 (22.1) |
| West | | 140 (20.9) |
| South | | 221(33.0) |
| Puerto Rico & Others | | 48 (7.18) |

**SD=standard deviation. NA= not applicable. Percentages may not add to 100% due to missing data**

Prior to calculating summary scores, all reversely worded items were recoded. Questions in a survey are reversely worded to avoid the possibility of respondents answering all questions in the same manner. For items with reverse wording, high score refers to the opposite of the construct the survey aims to measure. For example, in a survey that aims to measure satisfaction on a scale of 1 (strongly disagree) to 5 (strongly agree), the items can be worded as: a) The product was very useful, b) The product was better than the previous products, c) The product was cheaper than the other product, d) The product was not very economical. The fourth item (d) is reversely worded. While high score for the first three items indicates satisfaction, a high score for the fourth item indicates dissatisfaction. Therefore, for calculating total satisfaction, reverse scoring is done and the highest and lowest numerical values are switched. In a similar manner, all reversely worded items in the four scales used in this study were reverse scored.

Next, the summary scores on the individual scales used in the survey instrument were calculated.

*Patient perceptions of physician attitudes:* The instrument consists of nine items; each item is categorically measured using a five-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). Examples of items from this scale are: '*My doctor treats fibromyalgia as a real illness*' OR *'My doctor tries to avoid me'* (reverse scored item). Three items in this scale were reversely scored. The mean score for each individual item is provided in Table 4.2. It can be seen that the highest score was reported for '*My doctor tries to avoid me'* (4.40±0.92). This was a reversely worded item and as explained above, a high score on the item indicated the opposite of the construct being measured. Since the aim of this instrument was to measure support being received from physicians, a high

score on the item indicated that, on an average, patients disagreed with the statement. Similarly, the lowest score (3.15±1.29) was reported for '*I have experienced the frustration of my doctor while treating me*' indicating that, on an average, patients neither agreed nor disagreed with this statement. A composite score was calculated using the unweighted mean of the responses to the nine items. Missing values were replaced with the mean score. The composite score was called 'Perceived physician support'. On a scale of 9 to 45, the mean score for physician support was 34.81±7.49, indicating that the respondents experienced fairly high support from their physicians.

**Table 4.2. Mean and standard deviation of the individual scale items from the Patient perceptions of physician attitudes scale.**

| ITEMS[a,b] | MEAN | SD |
|---|---|---|
| My doctor is compassionate. | 4.02 | 1.01 |
| My doctor understands my feelings on pain. | 3.84 | 1.10 |
| My doctor admits if he does not know the answer. | 3.90 | 1.06 |
| My doctor treats fibromyalgia as a real illness. | 4.17 | 0.99 |
| My doctor takes my concerns seriously. | 4.06 | 1.02 |
| My doctor tries to avoid me.† | 4.40 | 0.92 |
| My doctor thinks my illness is mostly psychological.† | 4.08 | 1.04 |
| I have experienced the frustration of my doctor while treating me.† | 3.15 | 1.29 |
| I am satisfied with the treatment provided by my doctor. | 3.55 | 1.20 |

**a: Respondents were asked to rate their agreement with the statements in the scale.**
**b: On the 5-point Likert scale, response categories are as follows: 1= strongly disagree, 2 = disagree, 3 = neither agree nor disagree, 4 = agree, 5 = strongly agree.**
**SD = standard deviation, † = Reversely scored item.**

*Trust in Physician Scale:* The individual item responses for this scale are measured on a five-point Likert scale and vary from 1 (strongly disagree) to 5 (strongly agree). An example of item from this scale is: *'I trust my doctor so much that I always follow his/her advice.'* Or '*I doubt that my doctor cares about me as a person'* (reverse scored item). Four items on the scale were reverse scored. The mean score for each individual item is provided in Table 4.3. It can be seen that the highest score (4.23±0.97) was reported for

the last item in the scale which was reversely coded and the lowest score (2.72±1.01) was obtained on the fourth item: '*If my doctor tells me something is so, then it must be true*'. To calculate total score, the composite scores of the 11 items was first calculated by taking an unweighted mean of the responses to the 11 items. These scores were later transformed to a 0-100 scale by subtracting 1 from the mean score for each case and multiplying it by 25[98]. On a scale of 0-100, the mean trust score was 65.56±20.08.

**Table 4.3. Mean and standard deviation of individual items from Trust in Physician Scale.**

| ITEMS[a,b] | MEAN | SD |
|---|---|---|
| I doubt that my doctor really cares about me as a person.† | 4.09 | 1.11 |
| My doctor is usually considerate of my needs and puts them first. | 3.84 | 1.02 |
| I trust my doctor so much I always try to follow his/her advice. | 3.67 | 1.01 |
| If my doctor tells me something is so, then it must be true. | 2.72 | 1.01 |
| I sometimes distrust my doctor's opinion and would like a second one.† | 3.09 | 1.16 |
| I trust my doctor's judgment about my medical care. | 3.76 | 0.96 |
| I feel my doctor does not do everything he/she should about my medical care.† | 3.33 | 1.31 |
| I trust my doctor to put my medical needs above all other considerations when treating my medical problems. | 3.60 | 1.09 |
| My doctor is well qualified to manage (diagnose and treat or make an appropriate referral) medical problems like mine. | 3.85 | 1.10 |
| I trust my doctor to tell me if a mistake was made about my treatment. | 3.59 | 1.14 |
| I sometimes worry that my doctor may not keep the information we discuss totally private.† | 4.23 | 0.97 |

**a: Respondents were asked to rate their agreement with the statements in the scale.**
**b: On the 5-point Likert scale, response categories are as follows: 1= strongly disagree, 2 = disagree, 3 = neither agree nor disagree, 4 = agree, 5 = strongly agree.**
**SD = standard deviation, † = Reversely scored item.**

*Illness Invalidation Inventory:* The unweighted mean of five items from the scale represents 'Discounting' from medical professionals which measures the frequency of experiences such as distrust, admonition, rejection of one's ability to work, poor acknowledgement of fluctuations in symptoms, and offer of unusable advice to patients [100]. The remaining three items were reversed scored and their unweighted mean

represented 'Lack of Understanding' which measured frequencies of poor recognition and comprehension of illness, and lack of emotional support from medical professionals. The mean score for each individual item is provided in Table 4.4. Discounting and Lack of Understanding scores were found to be 2.64 and 2.45 respectively. According to the classifications provided by the illness invalidation inventory, the survey respondents reported to have 'sometimes' experienced 'Discounting' and 'Lack of Understanding' [100].

**Table 4.4. Mean and standard deviation of the individual items of Illness Invalidation Inventory.**

| ITEMS[a,b] | MEAN | SD |
|---|---|---|
| Medical professionals find it odd that I can do much more work on some days than other days. | 2.70 | 1.11 |
| Medical professionals think that I should be tougher. | 2.57 | 1.19 |
| Medical professionals give me unhelpful advice. | 2.76 | 1.13 |
| Medical professionals make me feel like I am an exaggerator. | 2.66 | 1.24 |
| Medical professionals think I can work more than I do. | 2.52 | 1.24 |
| Medical professionals take me seriously.† | 2.27 | 0.99 |
| Medical professionals understand the consequences of my health problems or illness.† | 2.58 | 1.09 |
| Medical professionals give me a chance to talk about what is on my mind.† | 2.53 | 1.08 |

**a: Respondents were asked to rate their frequency of experience with the statements provided.**
**b: On the 5-point Likert scale, response categories are as follows: 1= never, 2 = seldom, 3 = sometimes, 4 = often, 5 =very often.**
**SD = Standard Deviation, † = Reversely scored item.**

*Quality of Life Scale –16 (QOLS-16)*: Respondents were asked to select the category that best described their satisfaction on six domains: 1) material and physical well-being, 2) relationships with other people, 3) social, community and civic activities, 4) personal development and fulfillment, 5) recreation, and 6) independence. The mean score for each individual item is provided in Table 4.5. It can be seen that the lowest score was reported for satisfaction with health (2.73 ± 1.32) and the highest score was reported for

passive recreational activities reading, listening to music, or observing entertainment (5.25±1.42).

A composite score of 16 items in the scale was calculated by taking an unweighted mean of the responses on the 16 items. Missing items were replaced with the mean score. The mean QOLS-16 score for the general populations has been reported to be 90. For this study sample, the mean QOLS-16 score was 66.98±18.23 and was found to be consistent with scores reported for FMS populations in previous studies [14, 102].

**Table 4.5. Mean and standard deviation of individual items from the Quality of Life Scale-16.**

| ITEMS[a,b] | MEAN | SD |
|---|---|---|
| Material comforts home, food, conveniences, financial security | 4.51 | 1.61 |
| Health - being physically fit and vigorous | 2.73 | 1.32 |
| Relationships with parents, siblings & other relatives - communicating, visiting, helping | 4.37 | 1.62 |
| Having and rearing children | 5.00 | 1.72 |
| Close relationships with spouse or significant other | 4.82 | 1.86 |
| Close friends | 4.66 | 1.67 |
| Helping and encouraging others, volunteering, giving advice | 4.62 | 1.59 |
| Participating in organizations and public affairs | 3.77 | 1.60 |
| Learning - attending school, improving understanding, getting additional knowledge | 4.19 | 1.76 |
| Understanding yourself - knowing your assets and limitations - knowing what life is about | 4.83 | 1.54 |
| Work - job or in home | 3.65 | 1.81 |
| Expressing yourself creatively | 4.39 | 1.66 |
| Socializing - meeting other people, doing things, parties, etc. | 3.48 | 1.75 |
| Reading, listening to music, or observing Entertainment | 5.25 | 1.42 |
| Participating in active recreation | 3.14 | 1.64 |
| Independence, doing for yourself | 4.41 | 1.66 |

**a: Respondents were asked to rate their satisfaction with each of the items in the QOLS-16.**
**b: On the 7-point Likert scale, response categories are as follows: 1=terrible, 2=unhappy, 3 =mostly dissatisfied, 4 =mixed, 5 =mostly satisfied, 6=pleased, and 7 =delighted.**

Other characteristics: Respondents indicated a mean pain score of 6.2 on the visual analog scale. This has been classified in the literature as a "moderate pain" level [109]. Approximately, 26% of the respondents had more than 10 referrals to health care providers. The mean number of years since diagnosis was 13 and the majority (98%) of the respondents indicated they had received diagnosis from a health care provider. The disorder-related characteristics are summarized in Table 4.6.

**Table 4.6. FMS-related characteristics of survey sample**

| | MEAN ± SD | NUMBER (%) |
|---|---|---|
| **PHYSICIAN SUPPORT** | 34.81 ± 7.49 | NA |
| **TRUST IN PHYSICIAN** | 65.56 ± 20.08 | NA |
| **DISCOUNTING** | 2.64 ± 1.00 | NA |
| **LACK OF UNDERSTANDING** | 2.45 ± 0.96 | NA |
| **QUALITY OF LIFE** | 66.98 ± 18.23 | NA |
| **CURRENT PAIN** | 6.20 ± 2.27 | NA |
| **YEARS SINCE DIAGNOSIS** | 12.79 ± 8.14 | NA |
| **NUMBER OF HCP REFERRALS** | NA | |
| None | | 36 (5.4) |
| 1-5 | | 278 (41.5) |
| 6-10 | | 176 (26.3) |
| 11-15 | | 71 (10.6) |
| 16-20 | | 34 (5.1) |
| More than 20 | | 71 (10.6) |
| **NA = not applicable, HCP = health care provider**<br>**Percentages may not add to 100% due to missing data** | | |

STUDY OBJECTIVES

This section provides a brief explanation for conducting factor analysis and estimating internal consistency reliability of the four scales used in the study. There are several steps in validating a newly developed research questionnaire. Some essential steps including content and face validation were performed as described under the section 'Instrument Validation'. The next goal, therefore, was to analyze the structure of the instrument by conducting factor analysis, and perform an assessment of the internal consistency of the items in a scale.

Factor analysis is a statistical technique that helps investigate the relationships between the observed or "manifest" variables and summarize these relationships into unobservable "hypothetical constructs" or "factors" [110, 111]. Factor analysis arranges the observed variables into a smaller number of factors. For example, The Brief Pain Inventory which consists of 11 items which can be grouped into two factors: 1) Factor 1 measured severity of pain and consisted of four items. 2) Factor 2 measured interference of pain with daily functioning and consisted of seven items [112]. Factor analysis is often used in performing the construct validation of multi-item scales.

Internal consistency reliability also known as "internal validity" measures the degree to which all items in a scale measure the same concept [113]. When all scale items have high internal consistency, the summary score of that scale is a reflection of each individual item from the scale [113]. Cronbach's α coefficient is a measure of the internal consistency and it ranges from 0 to 1; values greater than 0.7 are usually indicative of a high internal validity [113].

This study had four scales, namely Patient perceptions of physician attitudes, Trust in Physician Scale, Illness Invalidation Inventory, and QOLS-16. The first scale,

Patient perceptions of physician attitudes, was developed in this study. The other three scales were standardized scales. The Trust in Physician Scale and the QOLS-16 were previously tested for factor structure in an outpatient FMS population [99, 102]. The Illness Invalidation Inventory was tested in a European population with FMS, but has not been tested in a U.S. FMS population [100, 106].

However, as explained in chapter 3, the population in this study was different than the study populations in previous studies. Respondents were not recruited through probability based sampling techniques and the study population belonged to a self-help group which may have had different levels of symptom severity than the outpatient populations in which the instruments were previously tested [107]. Assuming that the responses of these participants may be different from the general population with FMS, the factor structure of these scales was analyzed. Internal consistency reliability was also assessed for the three validated instruments by measuring Cronbach's α coefficient.

*Objective 1: To determine factor structure and internal consistency of the 'Patient perceptions of physician attitudes' scale.*

While conducting factor analysis, researchers have recommended using 20 observations per variable for accurate estimation of the factor structure [105]. In this study, 670 respondents were included in the final analyses based on completion of the survey. However, if a respondent failed to answer even a single item in a scale, the statistical package (IBM® SPSS®) automatically deleted that respondent from factor analysis. Thus, the final sample size for the factor analysis of the Patient perceptions of

physician attitudes' scale was 626, which was greater than the minimum sample size required for this analysis (The required sample size was 20*9=180).

The three essential steps in conducting a factor analysis are: 1) factor extraction, 2) factor retention, and 3) factor rotation [105]. The first step of factor extraction helps the researcher decide the number of factors that underlie a given set of variables [105]. There are various methods for conducting factor extraction; principal component analysis and principal axis factoring being the most common methods [105, 114]. Since there is little information on the relative importance of each method, the current study utilized principal axis factoring due to its robustness to assumptions of normality [105]. The next essential step is to decide how many factors to retain. There are four criteria used in the determination of factor retention:

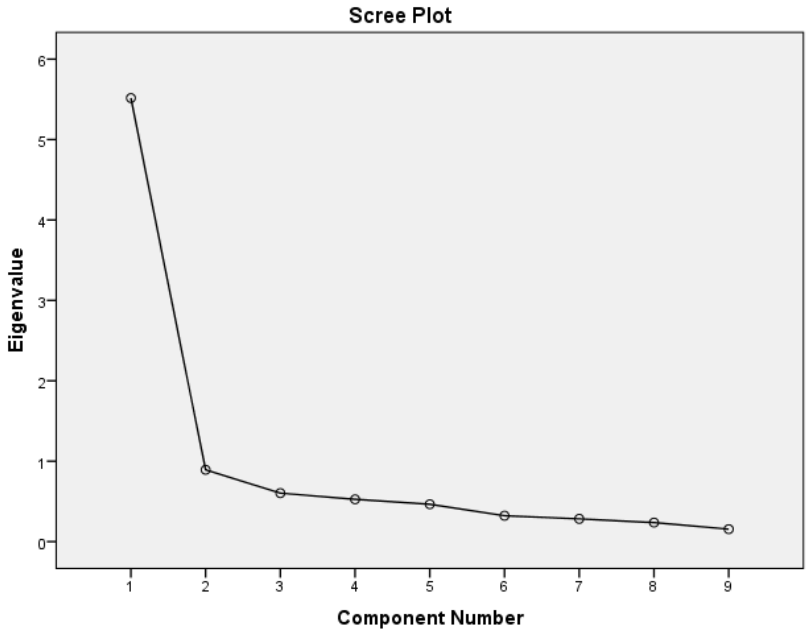
1) Kaiser criterion: This guideline suggests retaining those factors with Eigen value greater than 1 [114].
2) Scree plot: This involves a graphical analysis of Eigen values versus factor number plot. The 'natural bend' or 'breakpoint' is observed in the plot after which the curve becomes flat. The number of points above the bend represent the number of factors to be retained [114].
3) Proportion of variance: This refers to retaining factors which explain a certain amount of variance in the data. It has been criticized for its rather subjective nature [114].
4) Interpretability: This refers to examining factor loadings and identifying if they share a common conceptual basis [114].

Using the Kaiser criterion of Eigen value greater than one, there was only one identifiable factor with an Eigen value of 5.5 (Table 4.7). The scree plot also showed only one point above the breakpoint, thereby supporting the observations of the Kaiser criterion (Figure 4.1). For the proportion of variance criterion, it is suggested that factors explaining at least 10% of the variance should be retained [114]. In this analysis, there was only one factor that explained a majority (61%) of the variance (Table 4.7). All other variance proportions were less than 10%.

**Table 4.7. Eigen values and proportion of variance from the Patient perceptions of physician attitudes scale.**

| COMPONENT | EIGEN VALUES | % VARIANCE | CUMULATIVE VARIANCE |
|---|---|---|---|
| **1** | 5.52 | 61.29 | 61.29 |
| **2** | 0.89 | 9.92 | 71.21 |
| **3** | 0.60 | 6.70 | 77.92 |
| **4** | 0.51 | 5.84 | 83.76 |
| **5** | 0.47 | 5.17 | 88.92 |
| **6** | 0.32 | 3.58 | 92.50 |
| **7** | 0.28 | 3.15 | 95.64 |
| **8** | 0.24 | 2.63 | 98.27 |
| **9** | 0.16 | 1.73 | 100.00 |

**Figure 4.1. Scree plot showing one factor above the breakpoint from the Patient perceptions of physician attitudes scale.**




The third and last essential step was to conduct factor rotation. The goal of factor rotation is to make the interpretation of the data easier and meaningful. Factor rotation enables the variables with high factor loading to load on to one factor and those with low or zero loadings on to other factors [114]. There are two types of rotations: orthogonal and oblique. While orthogonal rotations assume that the factors are not correlated to each other, oblique rotation allows for factor correlation. Orthogonal rotation can further be subdivided into three types: varimax, quartimax, and equamax [105, 115]. The most commonly used method of factor rotation is the varimax rotation [105].

Varimax rotation was used for this analysis. The results of the factor rotation are shown in Table 4.8. It can be seen that all items load on to only one factor with the loadings for each factor being greater than 0.4. The table also provides values of communalities which are defined as the percent variation of each item in a given factor

[115]. Based on these observations, it can be concluded that the 'Patient perceptions of physician attitudes scale' had only one dimension.

**Table 4.8. Factor loadings and communalities ($h^2$) for 9 items from the Patient perceptions of physician attitudes scale.**

| ITEMS | $h^2$ | LOADINGS |
|---|---|---|
| My doctor is compassionate. | 0.79 | 0.89 |
| My doctor understands my feelings on pain. | 0.80 | 0.89 |
| My doctor admits if he does not know the answer. | 0.44 | 0.66 |
| My doctor treats fibromyalgia as a real illness. | 0.70 | 0.84 |
| My doctor takes my concerns seriously. | 0.79 | 0.89 |
| My doctor tries to avoid me | 0.56 | 0.75 |
| My doctor thinks my illness is mostly psychological | 0.57 | 0.74 |
| I have experienced the frustration of my doctor while treating me | 0.21 | 0.45 |
| I am satisfied with the treatment provided by my doctor. | 0.68 | 0.82 |

**$h^2$ or communalities indicate the proportion of variance explained by each item in the factor. Values above 0.3 indicate that each item in the scale shares common variance with other items. Loading indicates correlation of each item with the factor.**

The results of the reliability analysis demonstrated that the scale had a Cronbach's α value of 0.91 indicating high reliability.

*Objective 2: To determine factor structure and internal consistency of the standardized scales used in the survey.*

The specific relationships tested for this objective are discussed below.

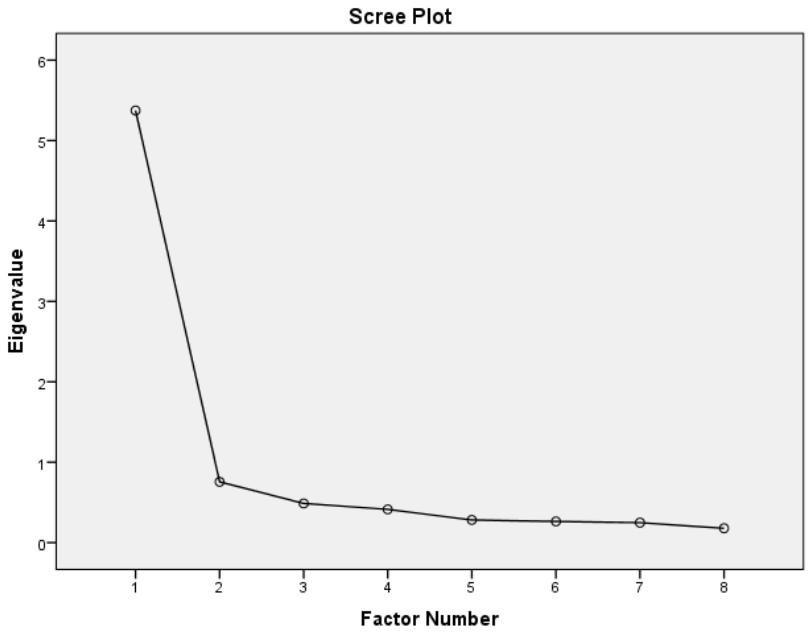
*Objective 2a: To determine factor structure and internal consistency of the Trust in Physician Scale.*

An exploratory factor analysis utilizing the same steps as explained for Objective 1 was conducted. There were 639 respondents who answered all items of the scale, thereby meeting the minimum sample size requirements (The minimum sample size required was 20*11=220). Factor extraction was performed using principal axis factoring. Next, factor retention was examined. The Kaiser criterion showed that there was one factor with an Eigen value greater than 1. The proportion of variance criterion for factor retention showed that only one factor explained 56% of the variance (Table 4.9). The scree plot also showed only one point above the main breakpoint (Figure 4.2), thereby supporting the Kaiser criterion and the proportion of variance criterion. Therefore, a decision was made to retain one factor.

**Table 4.9. Eigen values and proportion of variance from the Trust in Physician Scale.**

| COMPONENT | EIGEN VALUES | % VARIANCE | CUMULATIVE VARIANCE |
|---|---|---|---|
| **1** | 6.15 | 55.92 | 55.92 |
| **2** | 0.87 | 7.94 | 63.86 |
| **3** | 0.69 | 6.25 | 70.11 |
| **4** | 0.66 | 6.03 | 76.15 |
| **5** | 0.56 | 5.10 | 81.25 |
| **6** | 0.44 | 4.01 | 85.25 |
| **7** | 0.38 | 3.42 | 88.67 |
| **8** | 0.37 | 3.33 | 92.00 |
| **9** | 0.32 | 2.93 | 94.93 |
| **10** | 0.28 | 2.57 | 97.49 |
| **11** | 0.28 | 2.51 | 100.00 |

**Figure 4.2. Scree plot showing one factor above the breakpoint from the Trust in Physician scale.**




Varimax rotation was performed for factor rotation. All variables loaded onto one common factor as shown in Table 4.10. The internal consistency of the scale in this sample was found to be 0.91 indicating high reliability.

**Table 4.10. Factor loadings and communalities ($h^2$) for 11 items from Trust in Physician scale.**

| ITEMS | $h^2$ | LOADINGS |
|---|---|---|
| I doubt that my doctor really cares about me as a person. | 0.43 | 0.66 |
| My doctor is usually considerate of my needs and puts them first. | 0.68 | 0.83 |
| I trust my doctor so much I always try to follow his/her advice. | 0.68 | 0.82 |
| If my doctor tells me something is so, then it must be true. | 0.45 | 0.67 |
| I sometimes distrust my doctor's opinion and would like a second one. | 0.52 | 0.72 |
| I trust my doctor's judgment about my medical care. | 0.71 | 0.84 |
| I feel my doctor does not do everything he/she should about my medical care. | 0.49 | 0.70 |
| I trust my doctor to put my medical needs above all other considerations when treating my medical problems. | 0.67 | 0.72 |
| My doctor is well qualified to manage (diagnose and treat or make an appropriate referral) medical problems like mine. | 0.59 | 0.77 |
| I trust my doctor to tell me if a mistake was made about my treatment. | 0.67 | 0.82 |
| I sometimes worry that my doctor may not keep the information we discuss totally private. | 0.26 | 0.51 |

**$h^2$ or communalities indicate the proportion of variance explained by each item in the factor. Values above 0.3 indicate that each item in the scale shares common variance with other items. Loading indicates correlation of each item with the factor.**

*Objective 2b: To determine factor structure and internal consistency of the Illness Invalidation Inventory in a sample of FMS patients.*

A total of 650 respondents answered all items of the scale and were included in the analysis. This number (n=650) met the minimum sample size requirements (20*8=160) for the analysis [105]. Factor extraction was performed using principal axis factoring, and factor retention was then examined. The Kaiser criterion showed that there was only one factor with an Eigen value greater than 1, and the proportion of variance criterion showed that only one factor explained 67% of the variance (Table 4.11). The scree plot also showed only one point above the main breakpoint (Figure 4.3), thereby supporting Kaiser criterion and proportion of variance. Therefore, a decision was made to retain one factor. The factor loadings in Table 4.12 show that all items load on to only one factor. This study demonstrates that the factor structure has only one dimension. The internal consistency reliability for this scale was 0.93 indicating high reliability.

**Table 4.11. Eigen values and proportion of variance from the Illness Invalidation Inventory.**

| COMPONENT | EIGEN VALUES | % VARIANCE | CUMULATIVE VARIANCE |
|---|---|---|---|
| **1** | 5.37 | 67.17 | 97.17 |
| **2** | 0.76 | 9.45 | 76.62 |
| **3** | 0.49 | 6.08 | 82.70 |
| **4** | 0.41 | 5.17 | 87.86 |
| **5** | 0.28 | 3.52 | 91.38 |
| **6** | 0.26 | 3.29 | 94.67 |
| **7** | 0.25 | 3.10 | 97.77 |
| **8** | 0.18 | 2.23 | 100.00 |

**Figure 4.3. Scree plot showing one factor above the breakpoint from the Illness Invalidation Inventory.**

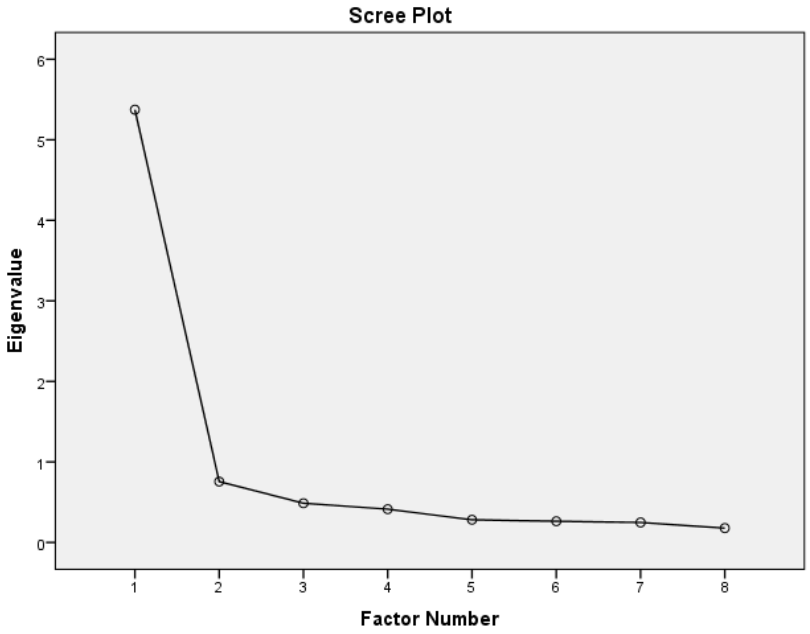


**Table 4.12. Factor loadings and communalities ($h^2$) for 8 items from the Illness Invalidation Inventory.**

| ITEMS | $h^2$ | LOADINGS |
|---|---|---|
| Medical professionals find it odd that I can do much more work on some days than other days. | 0.54 | 0.73 |
| Medical professionals think that I should be tougher. | 0.70 | 0.84 |
| Medical professionals give me unhelpful advice. | 0.64 | 0.80 |
| Medical professionals make me feel like I am an exaggerator. | 0.82 | 0.90 |
| Medical professionals think I can work more than I do. | 0.67 | 0.82 |
| Medical professionals take me seriously. | 0.73 | 0.86 |
| Medical professionals understand the consequences of my health problems or illness. | 0.65 | 0.81 |
| Medical professionals give me a chance to talk about what is on my mind. | 0.63 | 0.79 |
| **$h^2$ or communalities indicate the proportion of variance explained by each item in the factor. Values above 0.3 indicate that each item in the scale shares common variance with other items. Loading indicates correlation of each item with the factor.** | | |

*Objective 2c: To determine factor structure and internal consistency of the Quality of Life Scale-16 in a sample of FMS.*

An exploratory factor analysis was performed as explained in Objective 1 of this chapter. There were 625 respondents who answered all items of the scale and this met the minimum sample size requirements for the analysis (minimum sample size: 20*16=320).

**Table 4.13. Eigen values and proportion of variance from the Quality of Life Scale-16.**

| COMPONENT | EIGEN VALUES | % VARIANCE | CUMULATIVE VARIANCE |
|---|---|---|---|
| **1** | 7.56 | 47.23 | 47.23 |
| **2** | 1.34 | 8.39 | 55.62 |
| **3** | 1.06 | 6.35 | 61.97 |
| **4** | 0.81 | 5.03 | 67.00 |
| **5** | 0.74 | 4.65 | 71.65 |
| **6** | 0.59 | 3.70 | 75.35 |
| **7** | 0.58 | 3.64 | 78.99 |
| **8** | 0.51 | 3.16 | 82.15 |
| **9** | 0.48 | 3.02 | 85.17 |
| **10** | 0.47 | 2.96 | 88.12 |
| **11** | 0.41 | 2.55 | 90.67 |
| **12** | 0.36 | 2.25 | 92.92 |
| **13** | 0.33 | 2.09 | 95.01 |
| **14** | 0.30 | 1.87 | 96.88 |
| **15** | 0.28 | 1.72 | 98.60 |
| **16** | 0.22 | 1.40 | 100.00 |

**Figure 4.4. Scree plot showing one factor above the breakpoint from the Quality of Life Scale-16.**

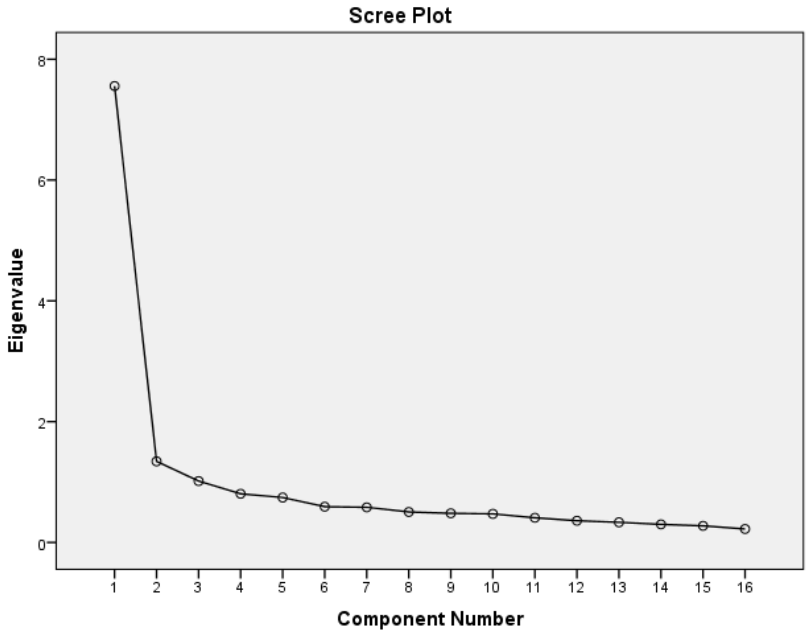



Table 4.13 shows three factors with an Eigen value greater than one. The first factor explains 47% of the variance in the data; however, the second and third factors explain only 8% and 6% of the variance respectively. Moreover, the scree plot shows only one factor (Figure 4.4). The factor loadings in Table 4.14 (Loadings 1) also show that all the 16 items had higher correlation ($r>0.6$) with the first factor. An analysis of the variance proportion explained by first factor, results of the scree plot, and results of the factor loadings suggested that the QOLS-16 had a one-dimensional factor structure in this sample of FMS patients. The internal consistency of this scale was 0.91, indicating high reliability.

**Table 4.14. Factor loadings and communalities ($h^2$) for 16 items from the Quality of Life Scale-16.**

| ITEMS | $h^2$ | LOADINGS 1 | LOADINGS 2 | LOADINGS 3 |
|---|---|---|---|---|
| Material comforts home, food, conveniences, financial security | 0.58 | 0.55 | 0.41 | 0.34 |
| Health - being physically fit and vigorous | 0.67 | 0.66 | -0.10 | 0.47 |
| Relationships with parents, siblings & other relatives-communicating, visiting, helping | 0.59 | 0.61 | 0.46 | -0.12 |
| Having and rearing children | 0.49 | 0.47 | 0.52 | 0.00 |
| Close relationships with spouse or significant other | 0.64 | 0.54 | 0.58 | -0.04 |
| Close friends | 0.64 | 0.73 | 0.16 | -0.27 |
| Helping and encouraging others, volunteering, giving advice | 0.69 | 0.75 | -0.08 | -0.36 |
| Participating in organizations and public affairs | 0.67 | 0.75 | -0.26 | -0.21 |
| Learning- attending school, improving understanding,getting additional knowledge. | 0.69 | 0.73 | -0.33 | -0.21 |
| Understanding yourself - knowing your assets and limitations - knowing what life is about | 0.57 | 0.70 | -0.05 | -0.27 |
| Work - job or in home | 0.62 | 0.75 | -0.05 | 0.23 |
| Expressing yourself creatively | 0.58 | 0.74 | -0.11 | -0.15 |
| Socializing - meeting other people, doing things, parties, etc. | 0.65 | 0.78 | -0.19 | 0.07 |
| Reading, listening to music, or observing entertainment | 0.50 | 0.71 | -0.04 | -0.05 |
| Participating in active recreation | 0.73 | 0.72 | -0.26 | 0.37 |
| Independence, doing for yourself | 0.63 | 0.72 | -0.12 | 0.29 |

**$h^2$ or communalities indicate the proportion of variance explained by each item in the factor. Values above 0.3 indicate that each item in the scale shares common variance with other items. Loading indicates correlation of each item with the factor.**

*Objective 3: To predict self-reported quality of life and self-reported pain levels (current) of FMS patients based on patient perceptions of physician attitudes, patients' trust in physicians, patients' perceptions of medical professionals, treatment effectiveness, and demographics.*

The specific relationships tested for this objective are discussed below.

*Objective 3a: To predict self-reported Quality of Life of FMS patients based on patient perceptions of physician attitudes, patients' trust in physicians, patients' perceptions of medical professionals, treatment effectiveness, and demographics.*

A multiple linear regression analysis was conducted using quality of life (QoL) as the dependent variable. The following predictors were used for this analysis.

*Continuous predictors*:

a) Summary score of the Patient perceptions of physician attitudes scale.
b) Summary score of the Trust in Physician Scale.
c) Mean score on the Illness Invalidation Inventory.
d) Age in years.
e) Years since diagnosis.

*Categorical predictors:*

Dummy coding was used for all categorical variables used in this model. The dummy coded variable in regression analyses is assigned a value of 1 if a condition is true, and 0 if it is false [116].

a) Use of prescription or over-the-counter (OTC) medication: If a respondent answered 'yes' to using prescription or OTC medication, this variable was assigned a value of 1, otherwise it was assigned a value of zero.

b) Use of complementary and alternative medicine (CAM): As explained in a), if a respondent answered 'yes' to using CAM, the variable was assigned a value of 1, otherwise it was assigned a value of zero.

c) Number of referrals to health care providers: For respondents with 10 or less referrals, this variable was assigned a value of 1; otherwise it was assigned a value of zero.

d) Marital status: If a respondent was married (with or without children) or living with a partner, the variable was assigned a value of 1, otherwise it was assigned a value of zero. Marital status in this study was considered an indicator of spousal/partner support.

e) Education: For this variable, 1 indicated having an education from at least some college; otherwise it was assigned a value of zero.

f) Income: For this variable, 1 indicated income above $50000; otherwise it was assigned a value of zero.

The normality assumption of the dependent variable was assessed using a histogram. Bivariate scatter plots were created to check for the linear relationship between each independent variable and the dependent variable. The histogram showed that the dependent variable of QoL was normally distributed. The scatter plots showed that the independent variables and the dependent variable (QoL) were linearly related. Thus, the assumptions of normality and linearity were met.

For multiple regression analysis, high correlation between the predictors may interfere with the precision of the regression estimates. The high overlap between the variables is referred to as 'multicollinearity' [117]. A bivariate correlation matrix of predictors helps identify high correlations. Another method to examine multicollinearity is the assessment of the variance inflation factor (VIF) for individual predictors [117]. The VIF is an indication of a linear relationship between the predictors and values above 10 may indicate multicollinearity [117]. For this model, bivariate correlations were conducted and it was found that summary scores of Patient perceptions of physician attitudes scale and the Trust in Physician Scale were highly correlated ($r=0.85$, $p<0.001$). To avoid issues with multicollinearity, the summary scores of only one instrument were used in the final regression analysis. It was decided to retain the Trust in Physician Scale because it is a standardized instrument. All other correlations were less than 0.6.

*Model selection:*

When there are several predictors for building a regression model, many models can be built and selection of the best model can be a tedious process. Different model selection strategies can be used for selecting the best model.

a) All possible regressions procedure: In this procedure, the number of models that can be fitted is $2^k$-1, where k is the number of predictors [118]. Once the models are fitted, each model's squared multiple correlation or $R^2$ (indicator of goodness of fit of the model), F statistic (the ratio of the mean regression sum of squares to the mean residual sum of squares), and Mean squared error (mean residual sum of squares), are evaluated to determine the model with the best fit. This procedure is guaranteed to find the model with the largest $R^2$ and lowest mean squared error.

For the analysis in this study there were 10 independent variables, thus there would be $2^{10}$ - 1 = 1023 models that could be fit, thereby making this method computationally challenging.

b) Forward selection: In this method, variables are sequentially added to an initial model containing the constant term alone. At each step, the null hypothesis that there is no change in $R^2$ is tested at $\alpha$=0.05. Variables causing the largest increase in $R^2$ are retained in the model, in order to reject the null hypothesis. The variable addition procedure stops when there are no other variables that cause a significant increase in $R^2$.

c) Backward elimination: This method begins with a model containing all predictors. Variables are then removed one at a time. At each step, variables causing the least change in $R^2$ are removed from the model. In this case, the change is $R^2$ is small enough such that the null hypothesis (no change in $R^2$) cannot be rejected. The variable removal procedure stops when there is a significant change in $R^2$ due to the removal of any variable. The $\alpha$ level for this procedure is set at 0.1 or higher [119].

d) Stepwise regression: In this method, the variables are sequentially entered in the model and those variables contributing to the variance in the model are retained. This method is a combination of forward selection and backward elimination. It is the most commonly used method for building a model [119]. Similar to the forward selection method, this procedure selects variables that cause a significant change in $R^2$. The variables are then assessed to check to determine if they meet the elimination criteria as explained in backward elimination. The significance

level for variable addition is set lower than the significance level for variable elimination [119].

This analysis was exploratory in nature. There were 11 predictors and there was no pre-existing theory to guide the order of entry into the regression model. In such scenarios, the procedure of stepwise regression is recommended [120]. The stepwise method of regression was utilized for this analysis. The commonly used significance levels for variable selection is 0.05 and that for variable removal is 0.1 [119]. Based on the stepwise regression procedure, the predictors contributing to QoL were Invalidation, use of CAM, age, marital status, and income. Normality of residuals was assessed using the histogram (Figure 4.5a) and probability plots (P-P plots) (Figure 4.5b). Figure 4.5a shows that the residuals follow a normal distribution. The straight line in the normal P-P plot in Figure 4.5b represents an ideal normal distribution. The dark line represents the residuals. It can be seen that the dark line approximately super-imposes on the straight line, thereby confirming that normal distribution of the residuals. These plots confirmed the assumption of multiple linear regression that the error terms in the model were normally distributed. Figure 4.5c shows a scatter plot of the residual versus predicted values. The residuals are randomly scattered along the center and do not show an increasing or decreasing trend as the value of the predicted variable increases, thereby indicating homogeneity of variance.

**Figure 4.5a. Histogram of residuals for final model with quality of life as the dependent variable.**

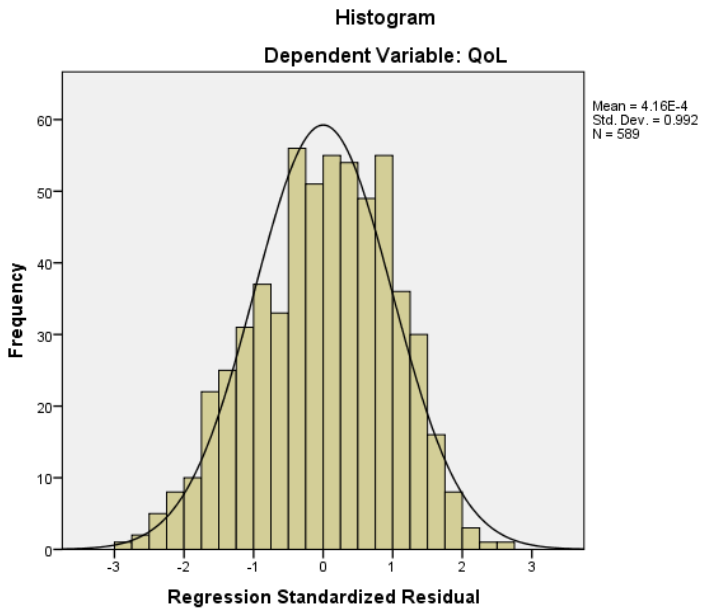
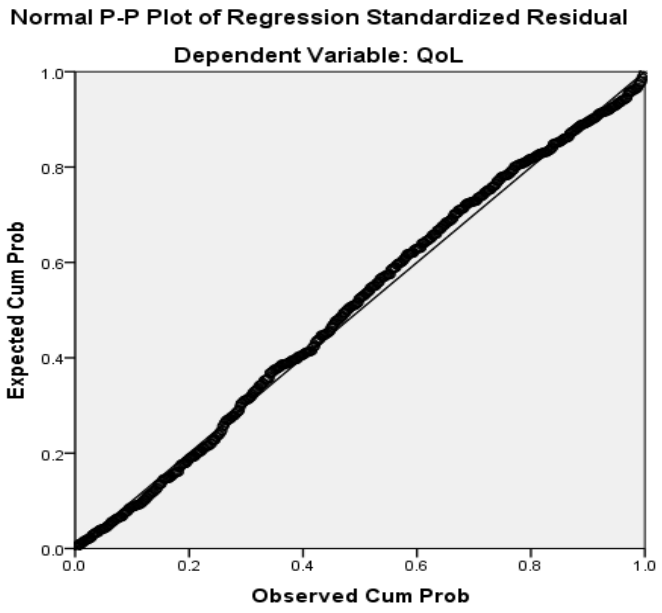



**Figure 4.5b. Normal probability plot of standardized residuals for final model with quality of life as the dependent variable.**



Mahalanobis distance was used to assess outliers and influential points were assessed using Cook's distance. Mahalanobis distance is defined as the distance between $i^{th}$ case on a predictor from the centroid of other predictors [121]. Cook's distance is defined as the sum of the squared differences in the predicted values of the dependent variable when the $i^{th}$ case is included and removed [122]. The final model was fitted excluding influential points and outliers. The final sample size for this analysis was 583 which exceeded the minimum sample size requirements. The proportion of the variance in the dependent variable that is explained by the combination of independent variables is called the coefficient of determination or squared multiple correlation ($R^2$) [117]. For the final model, $R^2$ was 22 %, F (5, 577) = 32.98, $p<0.001$. Collinearity was ruled out as the values for VIF for each predictor was less than 10. Table 4.15 displays the results of the regression analysis. The final prediction model is:

***Quality of Life = 64.10 – 5.66 (Invalidation score) + 3.16 (Use of CAM) + 0.19(Age) + 3.64 (Marital Status) + 7. 33 (Income).***

A standardized regression equation for the final model can be expressed as:

$$\textbf{Predicted } Z_{\textit{Quality of Life}} = -0.31\, Z_{\textit{Invalidation score}} + 0.09\, Z_{\textit{Use of CAM}} + 0.19\, Z_{\textit{Age}} + 0.1\, Z_{\textit{Marital Status}} + 0.21\, Z_{\textit{Income}}.$$

**Figure 4.5c. Residual versus fitted values plots for final model with quality of life as the dependent variable.**

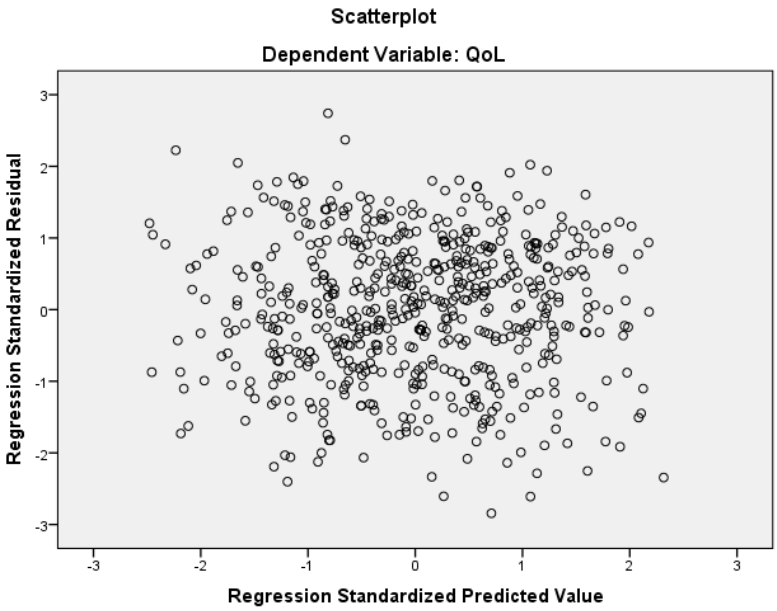


**Table 4.15. Linear regression model for quality of life as dependent variable.**

| **Regression Model** | | **B** | **Standardized coefficient (β)** | **95% CI** | | **Sig. level** |
|---|---|---|---|---|---|---|
| Variables | Levels | | | Lower Bound | Upper Bound | |
| **Intercept** | None | 64.10 | | 55.48 | 72.71 | <0.001 |
| | | | | | | |
| **Invalidation** | None | -5.66 | -0.31 | -7.06 | -4.27 | <0.001 |
| | | | | | | |
| **Age** | None | 0.19 | 0.12 | .07 | 0.302 | <0.05 |
| | | | | | | |
| **Use of CAM** | Yes | 3.16 | 0.09 | 0.57 | 5.76 | <0.05 |
| | No† | | | | | |
| | | | | | | |
| **Marital Status** | Married | 3.64 | 0.1 | 0.88 | 6.39 | <0.05 |
| | Single/Divorced/Separated/Widowed† | | | | | |
| | | | | | | |
| **Income** | $50001 and above | 7.33 | 0.21 | 4.69 | 9.96 | <0.001 |
| | Less than $50000† | | | | | |
| **N** | **R squared** | **Adjusted R squared** | **Model fit** | | | |
| | | | F | Sig. level | | |
| 583 | 0.22 | 0.216 | 32.98 | <0.0001 | | |

**Multiple linear regression analysis - stepwise method. Significance level=0.05, †=reference category, B = regression coefficient, , β = standardized regression coefficient CI=Confidence Interval, Sig. level = significance level, CAM=Complementary and Alternative Medicine.**

*Objective 3b: To predict self-reported pain levels (current) of FMS patients based on patient perceptions of physician attitudes, patients' trust in physicians, patients' perceptions of medical professionals, treatment effectiveness, and demographics.*

As explained in objective 3a, a similar multiple regression analysis was conducted with pain as the continuous dependent variable. The same predictors were used to build this model. Assumption of normality of the dependent variables was assessed and confirmed using a histogram. Bivariate scatter plots of independent variables against the dependent variable helped confirm the assumption of linearity. Next, the stepwise method of model selection was used. Trust in Physician, Number of referrals to health care providers, Income and Education were found to be significant predictors of pain. Normality of residuals was assessed using the histogram of the residuals (Figure 4.6a) and P-P plots (Figure 4.6b). Figure 4.6a shows that the residuals were normally distributed Figure 4.6b indicates that the dark line representing residuals almost super-imposed on the straight line (ideal normal distribution), thereby confirming the normal distribution of residuals. Figure 4.6c shows a scatter plot of the residual versus predicted values. This scatterplot shows a rectangular pattern which indicates that the residuals do not show any increasing or decreasing trend with an increase in the predicted values of dependent variable (pain), thereby confirming homogeneity of variance [117]. It can be seen that the residuals are randomly scattered with scores concentrated along the center. This random scatter of residuals confirmed homogeneity of variance [123].

The final sample size for this analysis was 543 which exceeded the minimum sample size requirements (as explained under 'Data Analysis' in chapter 3, the minimum

sample required was 123). Outliers and influential points were excluded, and the final model was found to explain 13% of the variance in pain levels, F (4, 538)=19.30, $p<0.001$. Collinearity was ruled out as the values for variance inflation factor for each predictor were less than 10.

Table 4.16 displays the results of the regression analysis. The final prediction model is:

***Pain = 9.18 -0.013 (Trust score) - 0.83 (Number of referrals to health care providers) - 0.78 (Income) -1.25 (Education).***

A standardized regression equation for the final model can be expressed as:

$$\textbf{Predicted } Z_{pain} = -0.12\, Z_{\text{Trust score}} - 0.17\, Z_{\text{Number of referrals to health care providers}} - 0.17\, Z_{\text{Income}} - 0.19\, Z_{\text{Education}}.$$

**Figure 4.6a. Histogram of residuals for final model with pain as the dependent variable.**

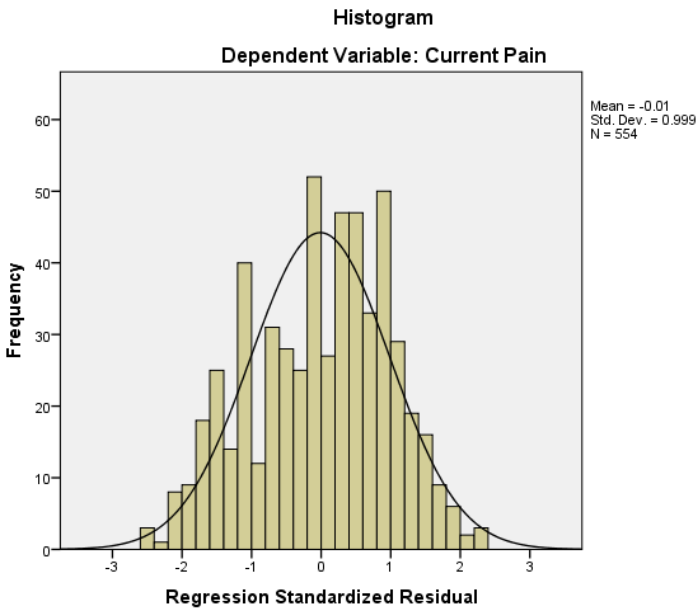



**Figure 4.6b. Normal probability plot of standardized residuals for final model with pain as the dependent variable.**

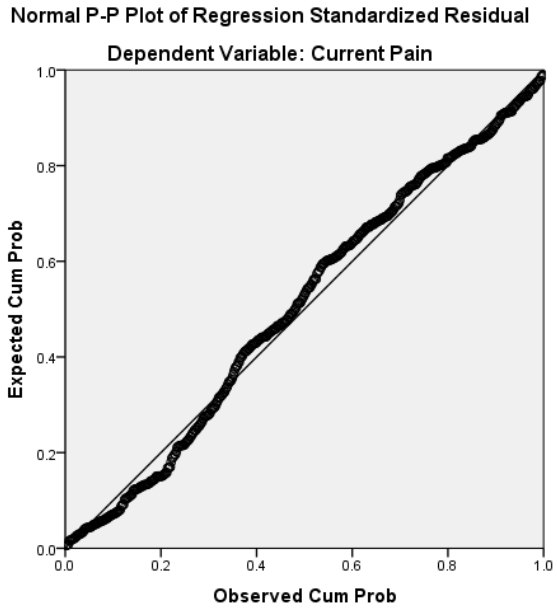


**Figure 4.6c. Residual versus fitted values plots for final model with pain as the dependent variable.**

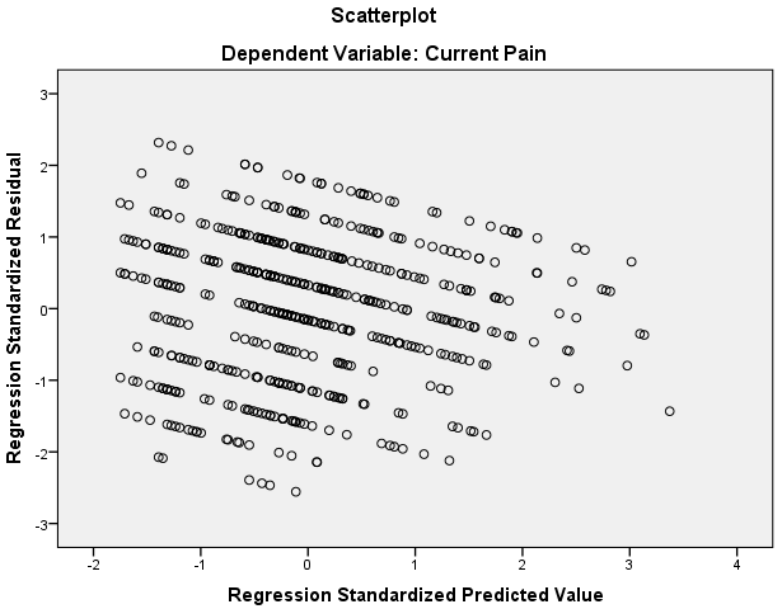


**Table 4.16. Linear regression model for current pain levels as dependent variable.**

| **Regression Model** | | **B** | **Standardized coefficient (β)** | **95% CI** | | **Sig. level** |
|---|---|---|---|---|---|---|
| Variables | Levels | | | Lower Bound | Upper Bound | |
| **Intercept** | None | 9.18 | | | | |
| | | | | | | |
| **Trust in physician** | None | -0.013 | -0.12 | -.022 | -0.01 | <0.05 |
| | | | | | | |
| **Income** | $50001 and above | -0.78 | -0.17 | -1.14 | -0.41 | <0.001 |
| | Less than $50000† | | | | | |
| | | | | | | |
| **Number of Referrals to HCP** | Less than 10 | -0.83 | -0.17 | -1.22 | -0.44 | <0.001 |
| | † Greater than 10 referrals | | | | | |
| | | | | | | |
| **Education** | At least some college education | -1.25 | -0.19 | -1.79 | -0.72 | <0.001 |
| | High School or less† | | | | | |
| **N** | **R squared** | **Adjusted R squared** | **Model fit** | | | |
| | | | **F** | **Sig. level** | | |
| 543 | 0.13 | 0.12 | 19.30 | <0.001 | | |

**Multiple linear regression analysis - stepwise method. Significance level=0.05, †=reference category, B = regression coefficient, β = standardized regression coefficient, CI= Confidence Interval, Sig. level = significance level, HCP = Health care provider.**

*Objective 4: To determine trends in the utilization of current treatments for FMS.*

The specific relationships analyzed for this objective are presented below.

*Objective 4a: To determine trends in the utilization of pharmacologic treatments for FMS.*

The majority (91%) of the survey respondents agreed to using prescription or OTC medications for treating their symptoms of FMS (Table 4.17).

**Table 4.17. Percentage of respondents using prescription or over-the-counter medications.**

| **Do you use prescription or over-the-counter medications for treating your symptoms of fibromyalgia?** | | |
|---|---|---|
| | **Frequency** | **Percent** |
| **Yes** | 608 | 90.7 |
| **No** | 60 | 9.0 |
| **Missing** | 2 | 0.3 |
| **Total** | 670 | 100 |

The most frequently prescribed medications were as follows: Flexeril® (28%) (Muscle relaxant), Cymbalta® (27%) (Antidepressant), Ultram® (26%) (Analgesic), Vicodin® (24%) (Analgesic), and Lyrica® (20%) (Anti-convulsant) (Table 4.18). Tylenol® (20%) (Analgesic) and Motrin®/Advil® (15%) (Analgesic) were the highly utilized OTC medications (Table 4.19). Most respondents using these medications rated their effectiveness as 'moderately effective': Flexeril® (61%), Cymbalta® (51%), Ultram® (56%), Vicodin® (48%), Tyenol® (61%) and Motrin® (74%). If 'other' was selected as the medication choice, an open-ended question was asked to inquire as to the type of

'other' medication used by respondents (but not provided in the list). Celexa® (2%) (Antidepressant) was the most commonly used "other" medication. Tables 4.18 and 4.19 display trends in utilization and effectiveness of each of the prescription and OTC medications.

**Table 4.18. Trends in utilization of pharmacologic treatments (prescription medicines) for treating symptoms of FMS.**

| Medicine (Brand Name USA) | Do not currently take | Very Effective | Moderately effective | Not at all effective | Made symptoms worse | Total respondents |
|---|---|---|---|---|---|---|
| **Flexeril®** | 4 | 43 | 103 | 15 | 3 | 168 |
| **Cymbalta®** | 9 | 54 | 83 | 12 | 4 | 162 |
| **Ultram®** | 11 | 41 | 89 | 13 | 4 | 158 |
| **Vicodin®** | 4 | 64 | 69 | 4 | 2 | 143 |
| **Lyrica®** | 8 | 46 | 56 | 4 | 5 | 119 |
| **Neurontin®** | 10 | 26 | 67 | 8 | 3 | 114 |
| **Ambien®** | 6 | 46 | 40 | 3 | 2 | 97 |
| **Xanax®** | 8 | 36 | 28 | 7 | 0 | 79 |
| **Elavil®** | 4 | 17 | 31 | 7 | 3 | 62 |
| **Desyrel®** | 5 | 19 | 26 | 4 | 0 | 54 |
| **Klonopin®** | 1 | 22 | 24 | 3 | 2 | 52 |
| **Zanaflex®** | 3 | 24 | 19 | 4 | 0 | 50 |
| **Wellbutrin®** | 3 | 10 | 32 | 3 | 1 | 49 |
| **Savella®** | 8 | 10 | 24 | 5 | 1 | 48 |
| **Percocet®** | 3 | 17 | 24 | 1 | 0 | 45 |
| **Prozac®** | 4 | 8 | 23 | 4 | 2 | 41 |
| **Zoloft®** | 3 | 10 | 21 | 6 | 1 | 41 |
| **Effexor®** | 6 | 9 | 21 | 4 | 0 | 40 |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Melatonex®** | 2 | 10 | 20 | 4 | 0 | 36 |
| **Mobic®** | 4 | 9 | 15 | 3 | 0 | 31 |
| **Valium®** | 3 | 6 | 10 | 0 | 1 | 20 |
| **Paxil®** | 3 | 7 | 6 | 1 | 0 | 17 |
| **Darvocet®** | 3 | 3 | 2 | 0 | 0 | 8 |
| **Other** | 4 | 99 | 129 | 16 | 1 | 249 |

**Table 4.19. Trends in utilization of pharmacologic treatments (over-the-counter medicines) for treating symptoms of FMS.**



| Medicine (Brand Name USA) | Do not currently take | Very Effective | Moderately effective | Not at all effective | Made symptoms worse | Total respondents |
|---|---|---|---|---|---|---|
| **Tylenol®** | 4 | 8 | 74 | 34 | 1 | 121 |
| **Motrin/Advil®** | 3 | 6 | 70 | 14 | 1 | 94 |
| **Naprosyn®/ Aleve®** | 1 | 6 | 49 | 11 | 1 | 68 |
| **Mucinex®** | 2 | 14 | 13 | 9 | 0 | 38 |
| **Ecotrin®** | 3 | 1 | 7 | 7 | 0 | 18 |

*Objective 4b: To determine trends in the utilization of non-pharmacologic treatments for FMS.*

**Table 4.20. Percentage of respondents using nonpharmacologic or complementary and alternative medicine.**

| Do you use complementary and alternative medicine for treating your symptoms of fibromyalgia? | | |
|---|---|---|
| | **Frequency** | **Percent** |
| **Yes** | 441 | 65.8 |
| **No** | 224 | 33.4 |
| **Missing** | 5 | 0.7 |
| **Total** | 665 | 99.3 |

Approximately, 66% of the survey respondents used CAM (Table 4.20). Vitamin supplements (59%), Massage Therapy (54%), Meditation (43%), and Aerobic exercise (41%) were the CAM treatments that were most commonly utilized. Approximately 56% of respondents using vitamin supplements found it to be moderately effective. Among those using massage therapy, 46% rated it to be very effective while 36% found it to be moderately effective. Most (55%) respondents using meditation rated it as moderately effective. Aerobic exercise was rated moderately effective by 42% respondents, while 30% respondents reported that aerobic exercise made their symptoms worse. Table 4.21 displays the effectiveness ratings of CAM treatments.

Nine percent of those who used massage therapy and 30% of those who used aerobic exercise reported that their symptoms worsened due to the use of the respective CAM treatments. Among the 'other' category of CAM, yoga/tai chi/light stretching exercise (10%) and chiropractic treatment (9%) were commonly used. Respondents were

asked about their relative preference for using prescription medicines versus CAM. Additionally, respondents were also asked, if they used CAM treatments without their physician's advice, their preference for CAM, and health insurance coverage for CAM. The results showed that 41% respondents (n=441) preferred CAM over prescription or OTC medications. Approximately, 74% respondents (n=445) indicated they utilized CAM treatments without their physician's recommendation. Approximately 49% respondents did not have health insurance coverage for CAM, while 25% respondents indicated their health insurance partially covered CAM treatments.

**Table 4.21. Trends in utilization of complementary and alternative medicines for treating symptoms of FMS.**

| Type of Therapy | Do not currently take | Very Effective | Moderately effective | Not at all effective | Made symptoms worse | n |
|---|---|---|---|---|---|---|
| **Vitamin Supplements** | 12 | 75 | 224 | 86 | 1 | 398 |
| **Massage Therapy** | 16 | 167 | 129 | 18 | 32 | 362 |
| **Meditation** | 12 | 72 | 159 | 47 | 1 | 291 |
| **Aerobic Exercise** | 24 | 41 | 115 | 15 | 82 | 277 |
| **Acupuncture** | 33 | 51 | 67 | 49 | 8 | 208 |
| **Spa Therapy** | 23 | 62 | 86 | 28 | 2 | 201 |
| **Herbal Medicine** | 20 | 29 | 120 | 54 | 3 | 226 |
| **Cognitive Behavioral Treatment** | 18 | 31 | 82 | 41 | 2 | 174 |
| **Other** | 20 | 86 | 71 | 15 | 3 | 195 |

**n= total respondents**

*Objective 5: To assess differences in the self-reported quality of life and pain (current) of FMS patients based on type of treatment.*

The specific relationships tested for this objective are discussed below.

*Objective 5a: To assess differences in the self-reported quality of life of FMS patients who utilized pharmacologic treatments alone, non-pharmacologic treatments alone, and those utilizing both pharmacologic and non-pharmacologic treatments.*

*Objective 5b: To assess differences in the self-reported pain (current) of FMS patients who utilized pharmacologic treatments alone, non-pharmacologic treatments alone, and those utilizing both pharmacologic and non-pharmacologic treatments.*

To achieve objectives 5a and 5b, a new variable was created. Those respondents who answered 'yes' to the use of prescription or OTC medicines and 'no' to the use of CAM were coded as '1'. Thus, the value of 1 indicated the use of pharmacologic treatments alone. Respondents answering 'no' to the use of prescription or OTC medicines and 'yes' to the use of CAM were coded as '2'. Thus, the value of 2 indicated the use of CAM or non-pharmacologic treatments alone. Similarly, respondents answering 'yes' to the use of prescription or OTC medicines and 'yes' to the use of CAM were coded as '3'. Thus, the value of 3 indicated the use of both pharmacologic and non-pharmacologic treatments.

Next, a one-way analysis of variance was conducted to determine if there was a significant difference in the health outcomes of QoL and pain levels of those who used pharmacologic treatments alone (prescription and OTC) versus those who used CAM alone versus those who utilized both pharmacologic treatments and CAM

**Table 4.22. Descriptive statistics for types of treatments.**

| **Type of therapy** | | **Outcomes (SD)** | |
|---|---|---|---|
| | | QoL | Current Pain |
| Pharmacologic only | | 63.71(18.10) | 6.55 (2.14) |
| | n | 202 | 187 |
| Non Pharmacologic only | | 70.03 (19.38) | 5.50 (2.63) |
| | n | 38 | 32 |
| Both Pharmacologic and Non Pharmacologic only | | 68.25 (17.92) | 6.08 (2.27) |
| | n | 401 | 365 |
| **Total (n)** | | 641 | 584 |
| **SD = standard deviation, QoL = quality of life** | | | |

*Null Hypothesis 5a: There is no difference in the quality of life of respondents using pharmacologic treatments, non- pharmacologic treatments, or both pharmacologic treatments and non-pharmacologic treatments.*

As explained under 'Data Analysis' in Chapter 3, the minimum sample size required for this analysis is 432 for a Type I error ($\alpha$) of 0.05, power ($1-\beta$) of 0.8 and an effect size ($\eta^2$) of 0.15 [108]. Table 4.22 shows that the total sample size for this analysis was 641, thereby exceeding the minimum sample size requirement. The dependent variable of QoL was found to be normally distributed. Levene's test was used to assess homogeneity of variances among the three groups. Tables 4.23 and 4.24 display the results of the one-way analysis of variance. For testing null hypothesis 5a, there were 202 respondents who used pharmacologic treatment only, 38 respondents who used non-pharmacologic

treatments/CAM only, and 401 respondents who used both type of treatments. The power for this analysis was 99% as calculated with G*Power version 3.1.5[108]. The significance level for this test was set at 0.05. For assessing variance between the groups, Levene's test (null hypothesis that the group variances are equal) was conducted. The significance level for Levene's statistic was found to be 0.056 which indicated that the variances between the groups were not significantly different and thus the assumption for homogeneity of variances was met. The results show that there was a statistically significant difference in the QoL of respondents using the three types of treatment strategies, F (2,638) = 4.84, $p$ = 0.008, effect size ($\eta^2$=0.15).

**Table 4.23. Results of one-way analysis of variance for mean differences in quality of life of FMS patients using pharmacologic therapy alone, non-pharmacologic therapy alone, and both pharmacologic and non-pharmacologic therapies.**

| | Sum of Squares | df | Mean Square | F | Sig. |
|---|---|---|---|---|---|
| **Between Groups** | 3156.81 | 2 | 1578.405 | 4.84 | .008 |
| **Within Groups** | 208264.18 | 638 | 326.433 | | |
| **Total** | 211420.98 | 640 | | | |
| **Dependent variable=quality of life, Sig.=significance level set at 0.05** | | | | | |

Post-hoc tests were conducted using the Bonferroni method. The post-hoc tests revealed that respondents using both types of treatment had a significantly higher QoL versus those using pharmacologic treatment alone, $p$= 0.011.

**Table 4.24. Results of post-hoc tests (Bonferroni Method) for mean differences in quality of life of FMS patients using pharmacologic therapy alone, non-pharmacologic therapy alone, and both pharmacologic and non-pharmacologic therapies.**

| Group (I) | Group (J) | Group (I-J) | Mean Difference | Sig. level | 95% CI | |
|---|---|---|---|---|---|---|
| | | | | | LB | UB |
| **1** | 2 | -6.320 | 3.195 | 0.145 | -13.99 | 1.35 |
| | 3 | -4.539* | 1.559 | 0.011 | -8.28 | -.80 |
| **2** | 1 | 6.320 | 3.195 | 0.145 | -1.35 | 13.99 |
| | 3 | 1.782 | 3.067 | 1.000 | -5.58 | 9.14 |
| **3** | 1 | 4.539* | 1.559 | 0.011 | .80 | 8.28 |
| | 2 | -1.782 | 3.067 | 1.000 | -9.14 | 5.58 |

**Group 1=pharmacologic, Group 2=non-pharmacolgic, Group 3=both pharmacologic and non-pharmacologic therapies. * indicates mean differences significant at the 0.05 level, LB=Lower Bound, UB=Upper Bound**

*Null Hypothesis 5b: There is no difference in the pain levels (current) of respondents using pharmacologic treatments, non-pharmacologic treatments, or both pharmacologic treatments and non- pharmacologic treatments.*

As calculated with G*Power, the minimum sample size required for this analysis is 432 for a Type I error (α) of 0.05, power (1-β) of 0.8 and an effect size ($\eta^2$) of 0.15 [108]. Table 4.22 shows that the total sample size for this analysis was 584, thereby exceeding the minimum sample size requirement. The dependent variable of pain was found to be normally distributed. For testing null hypothesis 5b, there were 187 respondents who used pharmacologic treatment only, 32 respondents who used non-pharmacologic treatments/CAM only, and 365 respondents who used both type of treatments. The power for this analysis was 99% as calculated with G*Power version 3.1.5 [124]. The

significance level for this test was set at 0.05. Levene's test (null hypothesis of equal variance between groups) was used to assess homogeneity of variances between the three groups. The significance level for Levene's test was found to be 0.831 which indicated that the variances between the groups were not significantly different and thus the assumption for homogeneity of variances was met. Tables 4.25 and 4.26 display the results of the one-way analysis of variance. The results show that there was a statistically significant difference in the current pain of respondents using the three types of treatment strategies, F (2, 581)=5.06, $p$=0.014.

**Table 4.25. Results of one-way analysis of variance for mean differences in current pain levels of FMS patients using pharmacologic therapy alone, non-pharmacologic therapy alone, and both pharmacologic and non-pharmacologic therapies.**

| | Sum of Squares | df | Mean Square | F | Sig. |
|---|---|---|---|---|---|
| **Between Groups** | 43.30 | 2 | 21.65 | 4.28 | .014 |
| **Within Groups** | 2939.06 | 581 | 5.06 | | |
| **Total** | 2982.35 | 583 | | | |

**Dependent variable=Current pain levels, Sig.=significance level set at 0.05**

Post-hoc tests were conducted using the Bonferroni method. The post-hoc tests revealed that respondents using only non-pharmacologic treatment had significantly lower pain levels versus those using pharmacologic treatment alone, $p$ = 0.046.

**Table 4.26. Results of post-hoc tests (Bonferroni Method) for mean differences in current pain levels of FMS patients using pharmacologic therapy alone, non-pharmacologic therapy alone, and both pharmacologic and non-pharmacologic therapies.**

| Group (I) | Group (J) | Group (I-J) | Mean Difference | Sig. level | 95% CI | |
|---|---|---|---|---|---|---|
| | | | | | LB | UB |
| **1** | 2 | 1.045* | .430 | .046 | .01 | 2.08 |
| | 3 | .466 | .202 | .065 | -.02 | .95 |
| **2** | 1 | -1.045* | .430 | .046 | -2.08 | -.01 |
| | 3 | -.579 | .415 | .488 | -1.58 | .42 |
| **3** | 1 | -.466 | .202 | .065 | -.95 | .02 |
| | 2 | .579 | .415 | .488 | -.42 | 1.58 |

**Group 1=pharmacologic, Group 2=non-pharmacologic, Group 3=both pharmacologic and non-pharmacologic therapies. * indicates mean differences significant at the 0.05 level, LB=Lower Bound, UB=Upper Bound**

*Objective 6: To assess differences in the self-reported quality of life and pain levels (current) of FMS patients based on type of pharmacologic treatments.*

The specific relationships tested for this objective are discussed below.

*Objective 6a: To assess differences in the self-reported quality of life of FMS patients based on type of pharmacologic treatments.*

To achieve objective 6, a new variable was created to categorize respondents who utilized a specific class of pharmacologic medication. The medication list provided in the survey covered five classes of drugs: Pain medications (prescription and OTC), Anti-

depressants, Anti-Anxiety, Muscle Relaxants, and Anti-Seizure. The new variable categorized respondents such that they utilized only one type of drug and thus belonged to only one category. As shown in Table 4.27, the sample size for users of anti-anxiety, muscle relaxants, and anti-seizure medications was less than 30. Based on the central limit theorem, the dependent variable in these categories may not be normally distributed [119]. Hence, a non-parametric test, Kruskal-Wallis was conducted to evaluate this objective.

*Null Hypothesis 6a: There is no difference in the median self-reported quality of life of respondents using pain medications (prescription and OTC), anti-depressants, anti-anxiety, muscle relaxants, and anti-seizure medications.*

**Table 4.27**. **Frequency of medications by pharmacologic class.**

| Type of medication class | N | Percent |
|---|---|---|
| Pain medication | 36 | 27.27 |
| Antidepressants | 59 | 44.70 |
| Anti-anxiety | 7 | 5.30 |
| Muscle relaxants | 11 | 8.34 |
| Anti-seizure | 19 | 14.39 |
| **TOTAL** | 132 | 100 |

There was, however, no difference in the median self-reported QoL of respondents by medication type, $\chi^2$=3.26, p=0.515 (Table 4.28).

**Table: 4.28. Results of Kruskal-Wallis test for analyzing differences in median quality of life based on type of medication class.**

| Type of medication class | N | Median rank (QoL) |
|---|---|---|
| Pain medication | 36 | 77.33 |
| Antidepressants | 59 | 63.44 |
| Anti-anxiety | 11 | 58.14 |
| Muscle relaxants | 19 | 58.18 |
| Anti-seizure | 7 | 72.29 |
| Total | 132 | |
| $\chi^2$=3.26, p=0.515 | | |
| **Dependent variable = quality of life (QoL)** | | |

*Objective 6b: To assess differences in the self-reported pain levels (current) of FMS patients based on type of pharmacologic treatments.*

As explained in objective 6a, a Kruskal-Wallis test was conducted to achieve this objective.

*Null Hypothesis 6b: There is no difference in the median self-reported pain of respondents using pain medications (prescription and OTC), anti-depressants, anti-anxiety, muscle relaxants, and anti-seizure medications.*

**Table: 4.29. Results of Kruskal-Wallis test for analyzing differences in median pain levels based on type of medication class.**

| Type of medication class | n | Median rank for pain |
|---|---|---|
| Pain medication | 34 | 65.65 |
| Antidepressants | 54 | 58.02 |
| Anti-anxiety | 11 | 68.36 |
| Muscle relaxants | 18 | 68.00 |
| Anti-seizure | 7 | 58.43 |
| Total | 124 | |
| $\chi^2$=1.40, p=0.845 | | |
| **Dependent variable = current pain levels** | | |

There was no statistically significant difference in the median self-reported pain levels of respondents utilizing different types of medication, $\chi^2$=1.40, p=0.845 (Table 4.29)

# CHAPTER FIVE: DISCUSSION AND CONCLUSIONS

The discussions and conclusions of this study are presented in chapter five. The study findings are discussed in context of current scientific literature. This chapter also presents the study limitations, future directions, and conclusions.

One goal of this study was to predict self-reported quality of life (QoL) and pain levels of patients with fibromyalgia syndrome (FMS) based on patient perceptions of physician attitudes, trust in physicians, patients' perceptions of medical professionals, treatment-effectiveness, and various demographic variables. The study also evaluated the differences in QoL and pain levels of FMS patients based on types of treatments used. The key finding in this study suggested that physician attitudes of distrust, suspicion, lack of support and acknowledgement toward FMS, collectively termed as 'Invalidation', have a significant impact on QoL. It was also demonstrated that trust in physician was an important predictor of pain. The findings also suggest that CAM treatments may have a beneficial effect in reducing pain. Combination treatment (the use of both prescriptions medicine and CAM treatments) may be beneficial in improving QoL of FMS patients.

A non-probability convenience sample of FMS patients, who were members of the National Fibromyalgia and Chronic Pain Association (NFMCPA), responded to an on-line survey developed for this study. The survey was conducted for a period of approximately three weeks and 810 responses were received. However, 140 surveys could not be used for data analysis due to incomplete data. Thus, the final survey sample size was 670 and the usable response rate was 71%. The type of survey conducted in this study is classified as 'self-selected web survey', where access to survey cannot be restricted. Therefore, the sampling frame could not be defined for this study. Initial screening questions allowed only adults with FMS to proceed through the survey.

A majority of the respondents in this study were predominantly females (97%), White/Caucasian (93%) and had received at least a 2 year college education (57%). These findings are consistent with previous reports that White people with higher education

tend to use the internet more frequently [125]. Moreover, these demographics also support previous studies which suggest that women tend to be active seekers of on-line health information [125, 126]. The demographic characteristics closely matched those in previous studies that used both probability and non-probability sampling techniques for conducting surveys in FMS patients [11, 101, 127]. The characteristics of FMS such as moderate pain and low QoL were in agreement with previous findings for this population [102, 127]. However, the average time since diagnosis (13 years) was nearly twice as high as those reported by previous studies [100, 127]. Nearly 26.3% of the respondents in this study reported being referred more than 10 times to various health care providers.

A new instrument was developed to explore and quantify the problem of patient perceptions of poor recognition of FMS among health care professionals, and to quantify the support and acknowledgement FMS patients receive from their physicians. This instrument was called 'Patient perceptions of physician attitudes' and consisted of 9 items that were measured on a five-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). Exploratory factor analysis confirmed that all nine items of the instrument measured one construct which was then termed as 'perceived physician support'. Since the instrument had only one construct, all nine items were summed together to provide one composite score. This composite score ranged from 9 to 45 with a higher score indicating greater support from physicians. The content and face validity of the scale was conducted during the survey validation process. High internal consistency with a Cronbach's $\alpha$=0.91 demonstrated that all items in the scale were correlated and that the scale had high reliability. Further, the summary score of this scale had high correlations with that of the Trust in Physician Scale (Pearson product moment

correlation, r=0.86) which has been previously tested in the FMS population [99]. The high correlations with a previously validated instrument confirmed the convergent validity (degree of agreement between a new scale and a previously established and validated instrument) of this scale [128]. Thus, a valid and reliable instrument to measure perceived physician support for patients with FMS was developed through this study.

Three validated instruments were used to measure the objectives of this study. These were the Trust in Physician Scale, Illness Invalidation Inventory, and QOLS-16 [98, 100, 102]. An exploratory factor analysis was conducted to evaluate the factor structure of the three instruments. Consistent with previous findings, the Trust in Physician Scale demonstrated a one-dimensional structure that explained 67% of the factor variance with Cronbach's $\alpha$=0.91 [99]. However, the factor analysis of the QOLS-16 and the Illness Invalidation Inventory revealed results that were different from those in previous studies. QOLS-16 showed a one-factor structure that explained 47% of the factor variance with all item loadings greater than 0.4. A previous study on people with chronic illnesses (rheumatoid arthritis, osteoarthritis, lupus, chronic obstructive pulmonary disease, post-ostomy surgery, and FMS) had demonstrated a three-factor solution with the three factors defined by: 1) Relationships and Well-Being, 2) Health and Functioning, and 3) Personal, Social, and Community commitment [129]. Despite the three-factor solution, the QOLS-16 is scored by taking an unweighted mean of the 16 scale items. The internal consistency of QOLS-16 was found to be 0.92 and was similar to previous studies [102].

The Illness Invalidation Inventory was previously tested on an outpatient population with FMS and rheumatoid arthritis. Results of the factor analysis revealed a

two-factor solution, namely Discounting and Lack of Understanding [100]. Discounting represented the unweighted mean of the five items in the scale. The present study, however, revealed a one-factor solution (67% factor variance) with all variable loadings greater than 0.4. The one-factor solution indicated that all items measured the same construct. This new construct was named 'Invalidation' and was scored by taking the unweighted mean of all eight items in the scale.

This was the first study to quantify the relationship between measures of trust in physician, experiences of invalidation and health outcomes such as QoL and pain in FMS patients. A multiple linear regression model using stepwise regression was conducted to explore this relationship. The predictors in the model consisted of the summary scores of the Trust in Physician Scale, Illness Invalidation Inventory, characteristics such as time since diagnosis, number of physician referrals, use of prescription or OTC medications, use of CAM, and demographic characteristics of age, marital status, education, and income. Since the variables of perceived physician support (summary score of the Patient perceptions of physician attitudes scale) and trust in physician (summary score of the Trust in Physician Scale) correlated highly with each other (Pearson product moment correlation, r=0.86), only one summary measure was used to reduce redundancy and to avoid multicollinearity. The study findings revealed that invalidation, use of CAM, age, marital status, and income together had a significant impact on QoL. Despite controlling for demographic variables of age, marital status and income, invalidation had a significant impact on QoL. These findings are in agreement with previous studies showing that invalidation is detrimental to health outcomes in FMS patients [31, 37, 40, 42, 44]. The model in this study explained 22% of the variation in QoL. Similarly,

another regression model with the same predictors was explored to identify the impact of these predictors on pain. It was shown that trust in physician, number of referrals to health care providers, income, and education together had a significant impact on pain. After controlling for demographic factors, the model showed that higher trust in physician reduced pain. This may be attributed to a placebo effect of trust, where reduced pain is an outcome of patients believing that their physician is contributing to health improvement. There was a direct relationship between number of referrals and pain. Respondents with more than 10 referrals were found to have higher pain than those with 10 or less referrals. While invalidation was related to lower QoL in this study, it was not shown to impact pain. This study measured QoL with respect to six domains: 1) material and physical well-being, 2) relationships with other people, 3) social, community and civic activities, 4) personal development and fulfillment, 5) recreation, and 6) independence. Constant invalidation of symptoms from health care professionals may impact self-development, relationships with others, and interaction with society which are essential aspects of quality of life. Results showed that more than 50% of the study population used CAM. Similarly, the study also found CAM treatments to be effective in improving pain. Therefore, experiences of invalidation may not have impacted pain.

Qualitative studies in the past have reported that patients turn to CAM when they do not find required help from health care providers [33, 42]. In this study, nearly 51% respondents to this survey reported utilizing CAM without their physician's recommendation. Meditation, vitamin supplements, and massage therapy were the most commonly utilized CAM therapies reported. In addition, respondents also mentioned using chiropractic and hot water therapies. All therapies were rated by respondents as

moderately effective in treating symptoms of FMS. This study demonstrated that CAM therapies were associated with reduced pain as compared to prescription medicines. However, people using prescription medicines and CAM therapies had significantly better QoL than those using either of the two strategies alone. More than half of the survey respondents were utilizing CAM therapies without their physician's recommendation, and CAM therapies were associated with reduced pain. . This finding would suggest that better education of physicians regarding CAM and more frequent communication with patients could be beneficial in FMS symptom management.

## LIMITATIONS

One limitation of this study is the use of a non-probability sampling technique for recruiting respondents which presented problems with defining the sampling frame. There was no control on restricting the survey to a defined sample or on passing the survey to others. Approximately 5% (n=670) respondents in this study reported receiving the survey through social networking websites, emails from family/friends or personal blogs. The design issues of non-probability sampling techniques also present problems of coverage error and non-response bias. Only respondents with internet access and could respond to this survey, thus representing coverage error. Non-response bias occurs when the characteristic of early respondents to a survey differ from those of the non-respondents. It can be estimated by comparing demographic and attitudinal characteristics of early respondents to late respondents (serving as a proxy for non-respondents) or by sending a follow-up survey to non- respondents. Non-response bias could not be estimated for this study as the majority (91%) of survey respondents had

completed the survey in the first week of posting. Also, sending another survey was not feasible as email addresses of the respondents were not known. Thus, it was not possible to identify the respondents who answered the survey when it was first emailed and differentiate their characteristics from those who did not respond.

A majority of the respondents (98%) reported to have been diagnosed by a health care professional. It was not known if they were formally diagnosed with criteria developed by the American College of Rheumatology (2010) [75]. Due to the concerns of respondent burden, the survey did not incorporate the formal FMS diagnostic criteria to ascertain that the respondents did indeed have FMS. The survey did not specify questions regarding specific health care professionals and it was therefore not possible to contrast results based on various categories of health care professionals. The data on all measures were self-reported. Also, this study may be more representative of educated, White/Caucasian, married females who were registered with the NFMCPA, and had agreed to have been diagnosed by a health care professional. However, as explained in the beginning of this chapter, the demographics and clinical characteristics of this study closely match with those in previous studies (both web and non-web surveys) that have attempted to obtain a nationally representative sample of FMS patients [11, 101, 127].

## STUDY STRENGTHS & FUTURE RESEARCH

A new instrument called the 'Patient perceptions of physician attitudes' was developed to measure perceived physician support and was shown to be reliable and valid. This scale is specific to FMS and should be further tested in a more representative sample for future research purposes. The psychometric characteristics (validity and

reliability) of the Trust in Physician scale were confirmed in an on-line population of FMS. Previous studies in a European population with FMS have reported a two-factor solution (Discounting and Lack of Understanding) for the Illness Invalidation Inventory. The scale was tested for the first time in an American population with FMS and was shown to consist of only one factor with Discounting and Lack of Understanding highly correlating with each other. Future studies need to be conducted in a more representative sample to confirm the factor structure.

This was the first study to quantitatively demonstrate the impact of invalidation and trust on the QoL and pain in a more robust U.S population. The two multivariate models explained a small percentage of variation in outcomes of QoL and pain. Other variables including co-morbidities, insurance status may help improve these models in future studies. Invalidation was only measured with respect to medical professionals. Future research should explore relationships between health outcomes and invalidation from personal (spouse, family) and other professional resources.

## CONCLUSIONS

Acknowledgement of FMS and trust in physicians are psychosocial factors that significantly impact QoL and pain in people with FMS. Data from the current study supports previous literature that validation of symptom experiences is essential in effective symptom management and achieving improved outcomes in FMS patients. This study demonstrated that prescription medicines alone may not provide a beneficial effect for treating FMS. Different classes of pharmacological medicines also may not provide improvement in QoL or pain. Complementary and alternative medicine may be more

effective in reducing pain and use of both prescription medicines and complementary and alternative treatment strategies together may be useful in improving QoL. Though the results may not be generalizable, this study demonstrated that invalidation and trust in physicians are associated with health outcomes in FMS patients. These factors should receive more attention in treatment outcome studies and should be considered by health professionals in the treatment of FMS patients. Future studies in a more representative population may help confirm these findings.

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## APPENDIX A1: SURVEY INSTRUMENT USED FOR STUDY.

**Self-Reported Quality of Life, Treatment –Effectiveness, Attitudes and Perceptions of Fibromyalgia Patients**

A thesis study in partial fulfillment for the requirements of the MS in Pharmacy Administration degree at Duquesne University, Pittsburgh, PA

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**Purpose:** You are being asked to participate in a research project that seeks to investigate the self-reported quality of life, treatment-effectiveness, and attitudes and perceptions of fibromyalgia patients. By participating in this project, you will be required to answer a short survey questionnaire. This survey will take approximately 30 to 45 minutes of your time.

**Risks and Benefits:** There are no risks greater than those encountered in everyday life. For the most part, the questions you are being asked are questions you have probably been asked in the past. If, however, you feel uncomfortable answering any of the questions, please feel free to stop the survey. Although there may be no direct benefit to you, by participating in this survey you are helping researchers better understand patients with fibromyalgia.

**Compensation**: There is no compensation, but participation in this project will require no monetary cost to you. Your input, however, is essential in determining the self-reported quality of life, treatment-effectiveness, and attitudes and perceptions.

**Confidentiality:** This survey is anonymous. Your name will never appear on this survey, and no identity will be made in the data analysis. Please note that all responses will be kept confidential and data will be analyzed in aggregate form. Qualtrics has SAS 70 Certification and meets the privacy requirements for health care records imposed by the Health Insurance Portability and Accountability Act (HIPAA). All Qualtrics accounts are hidden behind passwords and all data is password protected. The data will remain on the Qualtrics server for one year. Following completion of the survey, the data collected will be downloaded and stored on a password protected computer until the data analysis is complete. Only the researchers will have access to this password protected data.

**Right to Withdraw:** You are under no obligation to participate in this study. You are free to withdraw your consent to participate at any time.
**Voluntary Consent:** I understand if I have any questions regarding this survey or research project I may contact Dr. Pfalzgraf, Ms. Lobo, or Dr. Joe Kush (Chair of the Institutional Review Board at Duquesne University) at kush@duq.edu.

Browser Meta Info
Browser
Version
Operating System
Screen Resolution
Flash Version
Java Support
User Agent

**Section I**

1. I have read, understood, and printed a copy of, the above consent form and desire of my own free will to participate in this study. By clicking "Yes" and pressing next at the bottom of this page, I am providing my consent to participate in this survey.

- Yes
- No

If No Is Selected, Then Skip To End of Survey

2. Do you currently have fibromyalgia?

- Yes
- No

If No Is Selected, Then Skip To End of Survey

3. Are you 18 years of age or older?

- Yes
- No

If No Is Selected, Then Skip To End of Survey

1. Please indicate approximately how many years ago you were diagnosed with fibromyalgia?

   OPEN ENDED QUESTION

2. Were you diagnosed by a health care professional?

- Yes
- No

Answer If Were you diagnosed by a health care professional? No Is Selected

3. If you were not diagnosed by a health care professional, how were your symptoms of fibromyalgia diagnosed?

   OPEN ENDED QUESTION

## Section II

1. Please indicate how much you Agree or Disagree to the following statements. For the purposes of this survey, the term 'Doctor' refers to any physician you see most regularly. The statements in this section refer to only ONE doctor.

| | Strongly Disagree | Disagree | Neither Agree nor Disagree | Agree | Strongly Agree |
|---|---|---|---|---|---|
| My doctor is compassionate. | • | • | • | • | • |
| My doctor understands my feelings on pain. | • | • | • | • | • |
| My doctor admits if he does not know the answer. | • | • | • | • | • |
| My doctor treats fibromyalgia as a real illness. | • | • | • | • | • |
| My doctor thinks my illness is mostly psychological. | • | • | • | • | • |
| My doctor takes my concerns seriously. | • | • | • | • | • |
| My doctor tries to avoid me. | • | • | • | • | • |
| I have experienced the frustration of my doctor while treating me. | • | • | • | • | • |
| I am satisfied with the treatment provided by my doctor. | • | • | • | • | • |

2. Please indicate how much you Agree or Disagree to the following statements. For the purposes of this survey, the term 'Doctor' refers to any physician you see most regularly. The statements in this section refer to only ONE doctor.

| | **Strongly Disagree** | **Disagree** | **Neither Agree nor Disagree** | **Agree** | **Strongly Agree** |
|---|---|---|---|---|---|
| I doubt that my doctor really cares about me as a person. | • | • | • | • | • |
| My doctor is usually considerate of my needs and puts them first. | • | • | • | • | • |
| I trust my doctor so much I always try to follow his/her advice. | • | • | • | • | • |
| If my doctor tells me something is so, then it must be true. | • | • | • | • | • |
| I sometimes distrust my doctor's opinions and would like a second one. | • | • | • | • | • |
| I trust my doctor's judgment about my medical care. | • | • | • | • | • |
| I feel my doctor does not do everything he/she should about my medical care. | • | • | • | • | • |
| I trust my doctor to put my medical needs above all other considerations when treating my medical problems. | • | • | • | • | • |
| My doctor is well qualified to manage (diagnose and treat or make an appropriate referral) medical problems like mine. | • | • | • | • | • |
| I trust my doctor to tell me if a mistake was made about my treatment. | • | • | • | • | • |
| I sometimes worry that my doctor may not keep the information we discuss totally private. | • | • | • | • | • |

3. Please answer the following questions based on your interactions with medical professionals. For Example, your primary care physician, medical specialist, physical therapist, and other medical professionals. (Do not include your employer's company physician).

| | Never | Seldom | Sometimes | Often | Very Often |
|---|---|---|---|---|---|
| Medical professionals find it odd that I can do much more on some days than other days. | • | • | • | • | • |
| Medical professionals make me feel like I am an exaggerator. | • | • | • | • | • |
| Medical professionals think I can work more than I do. | • | • | • | • | • |
| Medical professionals give me unhelpful advice. | • | • | • | • | • |
| Medical professionals think that I should be tougher. | • | • | • | • | • |
| Medical professionals take me seriously. | • | • | • | • | • |
| Medical professionals understand the consequences of my health problems or illness. | • | • | • | • | • |
| Medical professionals give me the chance to talk about what is on my mind. | • | • | • | • | • |

## Section III

1. Do you use prescription or over-the-counter medications for treating your symptoms of fibromyalgia?

- Yes
- No

If No Is Selected, Then Skip To Section III, question 6.

2. Please select ALL medications that are currently prescribed for your symptoms of fibromyalgia.

| | Prescribed | Not Prescribed |
|---|---|---|
| | | |
| LYRICA (Pregabalin) | • | • |
| CYMBALTA (Duloxetine HCl) | • | • |
| SAVELLA (Milnacipran HCl) | • | • |
| PROZAC (Fluoxetine) | • | • |
| ZOLOFT (Sertraline) | • | • |
| ELAVIL (Amitryptyline) | • | • |
| PAXIL (Paroxetine) | • | • |
| EFFEXOR (Venlafaxine) | • | • |
| NEURONTIN (Gabapentin) | • | • |
| ULTRAM (Tramadol) | • | • |
| ULTRACET (Tramadol - Acetaminophen) | • | • |
| FLEXERIL (Cyclobenzaprine) | • | • |
| TYLENOL (Acetaminophen) | • | • |
| MOTRIN / ADVIL (Ibuprofen) | • | • |
| NAPROSYN / ALEVE (Naproxen) | • | • |
| ECOTRIN (Aspirin) | • | • |
| CELEBREX (Celecoxib) | • | • |
| TYLENOL 2 / 3 / 4 (Codeine + Acetaminophen) | • | • |
| VICODIN (Hyrdocodone + Acetaminophen) | • | • |
| DARVOCET (Propoxyphen + Acetaminophen) | • | • |
| AMBIEN (Zolpidem) | • | • |
| WELLBUTRIN (Buproprion) | • | • |
| DESYREL (Trazadone) | • | • |
| XANAX (Aprazolam) | • | • |
| PERCOCET / ROXICET (Oxycodone + Acetaminophen) | • | • |
| MELATONEX (Melatonin) | • | • |
| VALIUM (Diazepam) | • | • |
| KLONOPIN (Clonazepam) | • | • |
| ZANAFLEX (Tizanidine) | • | • |
| MOBIC (Meloxicam) | • | • |
| MUCINEX/TUSSIN (Guaifenesin) | • | • |
| OTHER | • | • |

3. How effective, overall, are your medications for your symptoms of FMS?

| | Do not currently take | Very Effective | Moderately Effective | Not at all effective | Made symptoms worse |
|---|---|---|---|---|---|
| LYRICA (Pregabalin) | • | • | • | • | • |
| CYMBALTA (Duloxetine HCl) | • | • | • | • | • |
| SAVELLA (Milnacipran HCl) | • | • | • | • | • |
| PROZAC (Fluoxetine) | • | • | • | • | • |
| ZOLOFT (Sertraline) | • | • | • | • | • |
| ELAVIL (Amitryptyline) | • | • | • | • | • |
| PAXIL (Paroxetine) | • | • | • | • | • |
| EFFEXOR (Venlafaxine) | • | • | • | • | • |
| NEURONTIN (Gabapentin) | • | • | • | • | • |
| ULTRAM (Tramadol) | • | • | • | • | • |
| ULTRACET (Tramadol - Acetaminophen) | • | • | • | • | • |
| FLEXERIL (Cyclobenzaprine) | • | • | • | • | • |
| TYLENOL (Acetaminophen) | • | • | • | • | • |
| MOTRIN / ADVIL (Ibuprofen) | • | • | • | • | • |
| NAPROSYN / ALEVE (Naproxen) | • | • | • | • | • |
| ECOTRIN (Aspirin) | • | • | • | • | • |
| CELEBREX (Celecoxib) | • | • | • | • | • |
| TYLENOL 2 / 3 / 4 (Codeine + Acetaminophen) | • | • | • | • | • |
| VICODIN (Hyrdocodone + Acetaminophen) | • | • | • | • | • |
| DARVOCET (Propoxyphen + Acetaminophen) | • | • | • | • | • |
| AMBIEN (Zolpidem) | • | • | • | • | • |
| WELLBUTRIN (Buproprion) | • | • | • | • | • |
| DESYREL (Trazadone) | • | • | • | • | • |
| XANAX (Aprazolam) | • | • | • | • | • |
| PERCOCET / ROXICET (Oxycodone + Acetaminophen) | • | • | • | • | • |
| MELATONEX (Melatonin) | • | • | • | • | • |
| VALIUM (Diazepam) | • | • | • | • | • |
| KLONOPIN | • | • | • | • | • |

| | | | | | |
|---|---|---|---|---|---|
| (Clonazepam) | | | | | |
| ZANAFLEX (Tizanidine) | • | • | • | • | • |
| MOBIC (Meloxicam) | • | • | • | • | • |
| MUCINEX/TUSSIN (Guaifenesin) | • | • | • | • | • |
| OTHER | • | • | • | • | • |

4. Please provide the names of the other medications that were prescribed but not covered by the above question.

OPEN ENDED QUESTION

5. Please provide the names of the medications you have taken in the past and briefly explain the reasons for discontinuation.

OPEN ENDED QUESTION

The next few questions ask about your use of complementary and alternative medicine. For the purposes of this survey, complementary and alternative medicine includes all treatments other than medications.

6. Do you use complementary and alternative medicines for treating your symptoms of fibromyalgia?

- Yes
- No

If No Is Selected, Then Skip To Section IV

7. Do you use both medications and complementary and alternative medicines for treating your symptoms of fibromyalgia?

- Yes
- No

8. Please select ALL complementary and alternative medications that you have recently tried for your symptoms of fibromyalgia.

| | I have tried | I have not tried |
|---|---|---|
| AEROBIC EXERCISE | • | • |
| COGNITIVE BEHAVIORAL TREATMENT | • | • |
| ACUPUNCTURE | • | • |
| SPA THERAPY | • | • |
| MEDITATION | • | • |
| HOMEOPATHY | • | • |
| MASSAGE THERAPY | • | • |
| HERBAL MEDICINE | • | • |
| VITAMIN SUPPLEMENTS | • | • |
| OTHER | • | • |

9. How effective, overall, are your complementary and alternative medications for your symptoms of fibromyalgia?

| | Do not currently take | Very Effective | Moderately Effective | Not at all effective | Made symptoms worse |
|---|---|---|---|---|---|
| AEROBIC EXERCISE | • | • | • | • | • |
| COGNITIVE BEHAVIORAL TREATMENT | • | • | • | • | • |
| ACUPUNCTURE | • | • | • | • | • |
| SPA THERAPY | • | • | • | • | • |
| MEDITATION | • | • | • | • | • |
| HOMEOPATHY | • | • | • | • | • |
| MASSAGE THERAPY | • | • | • | • | • |
| HERBAL MEDICINE | • | • | • | • | • |
| VITAMIN SUPPLEMENTS | • | • | • | • | • |
| OTHER | • | • | • | • | • |

10. Please provide the names of the other complementary and alternative treatments that were prescribed but not covered by the above question.

OPEN ENDED QUESTION

11. How many of your physicians have recommended complementary and alternative medicine in addition to medications?

OPEN ENDED QUESTION

12. Did you use complementary and alternative medicine for achieving relief from your symptoms without your physician's recommendation?

- Yes
- No

13. Do you prefer complementary and alternative medicine for relief from pain over medications?

- Yes
- No

14. Do you prefer BOTH medications and complementary and alternative medicine for relief from pain?

- Yes
- No

**Section IV**

1. On a scale of 0 to 10, with 0 indicating no pain and 10 indicating worst pain, what was the level of pain you experienced when you first sought medical help for your fibromyalgia symptoms?

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

2. On a scale of 0 to 10, with 0 indicating no pain and 10 indicating worst pain, what is the level of pain you currently experience?

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

3. Please read each item and select the option that best describes how satisfied you are at this time. Please answer each item even if you do not currently participate in an activity or have a relationship. You can be satisfied or dissatisfied with not

doing the activity or having the relationship. In this case, you have to rate how satisfied or dissatisfied you are with lack of the activity.

| | Terrible | Unhappy | Mostly Dissatisfied | Mixed | Mostly Satisfied | Pleased | Delighted |
|---|---|---|---|---|---|---|---|
| Material comforts home, food, conveniences, financial security. | • | • | • | • | • | • | • |
| Health - being physically fit and vigorous. | • | • | • | • | • | • | • |
| Relationships with parents, siblings & other relatives-communicating, visiting, helping. | • | • | • | • | • | • | • |
| Having and rearing children. | • | • | • | • | • | • | • |
| Close relationships with spouse or significant other. | • | • | • | • | • | • | • |
| Close friends. | • | • | • | • | • | • | • |
| Helping and encouraging others, volunteering, giving advice. | • | • | • | • | • | • | • |
| Participating in organizations and public affairs . | • | • | • | • | • | • | • |
| Learning- attending school, improving understanding, getting additional knowledge . | • | • | • | • | • | • | • |
| Understanding yourself - knowing your assets and limitations - knowing what life is about. | • | • | • | • | • | • | • |
| Work - job or in home. | • | • | • | • | • | • | • |
| Expressing yourself creatively. | • | • | • | • | • | • | • |
| Socializing - meeting other people, doing things, parties, etc. | • | • | • | • | • | • | • |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Reading, listening to music, or observing entertainment. | • | • | • | • | • | • | • |
| Participating in active recreation. | • | • | • | • | • | • | • |
| Independence, doing for yourself. | • | • | • | • | • | • | • |

**Section V**

1. What is your gender?

- Male
- Female

2. What is your race?

- White/Caucasian
- African American
- Hispanic
- Asian
- Native American
- Pacific Islander
- Other

3. What is your current status?

- Single, never married
- Married without children
- Married with children
- Divorced
- Separated
- Widowed
- Living w/ partner

4. What is the highest level of education you have completed?

- Less than High School
- High School / GED
- Some College
- 2-year College Degree
- 4-year College Degree
- Master's Degree
- Professional Doctorate Degree (JD, MD, DDS etc.)

5. What is your current age?

OPEN ENDED QUESTION

6. Where do you currently reside?

- Alabama
- Alaska
- Arizona
- Arkansas
- California
- Colorado
- Connecticut
- Delaware
- District of Columbia
- Florida
- Georgia
- Hawaii
- Idaho
- Illinois
- Indiana
- Iowa
- Kansas
- Kentucky
- Louisiana
- Maine
- Maryland
- Massachusetts
- Michigan
- Minnesota
- Mississippi
- Missouri
- Montana
- Nebraska
- Nevada
- New Hampshire
- New Jersey
- New Mexico
- New York
- North Carolina
- North Dakota
- Ohio

- Oklahoma
- Oregon
- Pennsylvania
- Puerto Rico
- Rhode Island
- South Carolina
- South Dakota
- Tennessee
- Texas
- Utah
- Vermont
- Virginia
- Washington
- West Virginia
- Wisconsin
- Wyoming
- Canada
- Puerto Rico
- Australia
- Great Britain
- Other

7. What is your annual salary (including bonuses and commissions) in U.S. dollars?

- $0 - $25,000
- $25,001 - $50,000
- $50,001 - $75,000
- $75,001 - $100,000
- $100,001 - $125,000
- $125,001 - $150,000
- $150,001 - $175,000
- $175,001 - $200,000
- $200,001+

8. Does your health insurance cover visits for any complementary and alternative medicine you are currently using?

- Yes, offers complete coverage
- Yes, offers partial coverage
- No
- I am uninsured
- I do not use complementary and alternative medicine.

9. Please indicate the number of times you were referred to other health care professionals during the course of your illness.

- 1-5
- 6-10
- 11-15
- 16-20
- More than 20
- None

10. Please indicate how you found the link to this survey:

- The National Fibromyalgia and Chronic Pain Association newsletter.
- Other (Please indicate how you found the link) _____

11. Thank you for completing the survey. Your responses are very valuable, and your participation in this survey is much appreciated. If you have any additional comments on your experience with fibromyalgia, please mention in the textbox provided. Thank you once again!

OPEN ENDED QUESTION

**APPENDIX A2: ADDITIONAL QUESTIONS USED AT END OF SURVEY IN THE PRE-TEST TO ASSESS PARTICIPANT COMPATIBILITY AND SURVEY CLARITY.**

1. Would you recommend this survey to your family or friends who suffer from fibromyalgia?

- Yes
- No

If no, could you explain the reason?

OPEN ENDED QUESTION

2. Did you find the items easy to read and understand?

- Yes
- No

3. Did you find any of the wordings confusing?

- Yes
- No

4. Which section, if any, did you find most difficult to answer and why?

OPEN ENDED QUESTION

5. Approximately how many minutes did you take to answer the survey?

OPEN ENDED QUESTION

6. Do you have any other suggestions for improving the survey?

OPEN ENDED QUESTION