DOES FIBROMYALGIA RESOLVE WITH FUNCTIONAL RESTORATION TREATMENT IN CHRONIC DISABLING OCCUPATIONAL MUSCULOSKELETAL DISORDERS? PREVALENCE AND TREATMENT RESPONSIVENESS

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MEREDITH M HARTZELL

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ABSTRACT

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Meredith M. Hartzell, M.S.

The University of Texas at Arlington, 2012

Supervising Professor: Robert J. Gatchel

Fibromyalgia (FM), a musculoskeletal syndrome involving widespread pain and tenderness to palpation, is considered stable and chronic, with few researchers evaluating diagnosis loss at post-treatment. FM patients (N = 117) entered functional restoration (FR) treatment, and 41% lost ACR 1990 diagnostic criteria for FM at post-treatment. Patients that lost the diagnosis (LFM group; n = 48) differed from patients who retained the diagnosis (RFM group; n = 69) on psychosocial measures of depressive symptoms, pain intensity, health-related quality of life, and disability at post-treatment, but were similar to the lumbar only comparison group (n = 87). LFM patients physically functioned better than RFM patients and changed more pre to post-treatment on self-reported disability measures, though lumbar only patients typically had better physical functioning. Both FM groups had significantly lower work retention rates than the lumbar only group one year post-treatment. Overall, FR is highly efficacious in treating FM.

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INTRODUCTION

1.1 Chronic Pain

Chronic pain, defined as pain that lasts for three or more months, is a major problem worldwide. The World Health Organization estimates that 20% of individuals have some form of chronic pain (D. C. Turk & Swanson, 2007), and pain may account for up to 80% of all physician visits (R. J. Gatchel, Peng, Peters, Fuchs, & Turk, 2007). More specifically, musculoskeletal pain from overuse injuries affects 33% of adults and accounts for 29% of lost workdays (International Association for the Study of Pain, 2009b), and has become such a large issue that the International Association for the Study of Pain (IASP) declared 2009-2010 as the Global Year against Musculoskeletal Pain.

The annual cost of productive time lost due to musculoskeletal pain problems was estimated to be $41.7 billion in 2002 (International Association for the Study of Pain, 2009a). In addition, $85 billion is spent on accurately diagnosing pain each year (Wallace, 2005), and $100 billion is spent on total disability costs in the U.S. (Loeser, 2006). The annual total for direct and indirect costs of chronic pain may be as high as $294.5 billion per year (National Academics of Sciences and Institute of Medicine, 2001).

Many Americans suffering from chronic musculoskeletal pain were injured at work. The Department of Labor reported 34 cases of musculoskeletal disorders per 10,000 full-time workers in 2010, which increased 4% from 2009. Musculoskeletal disorders accounted for 29% of all workplace injuries and illnesses requiring time off from work in 2010, and soreness and pain accounted for 11% of total cases (Bureau of Labor Statistics, U.S. Department of Labor,

2011). It is estimated that the costs associated with lost work days and compensation for occupational musculoskeletal disorders range from $13 billion to $20 billion per year (R. J. Gatchel & Mayer, 2000).

1.2 Treatment of Chronic Pain

The first line of treatment for musculoskeletal injury is primary care, which takes place in the acute injury phase. Primary rehabilitation's main goals are pain control and preparing the body for proper healing. Therapy includes medications such as acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs), muscle relaxants, or the use of opioids (as a last resort). In addition, physical agents such as ultrasound, heat, cold, or electrical simulation may be used in the short term. If patients do not respond to primary rehabilitation, or if the injury is severe enough, patients proceed to secondary rehabilitation. Secondary care is used in the postacute phase of injury and the goals of secondary rehabilitation include: prevention of physical deconditioning, medication habituation, and adverse psychological reactions; mobilization and strengthening of the injured area; and restoration of function once initial pain symptoms have subsided. Therapy on the secondary care level consists primarily of physical therapy, though psychosocial interventions, surgery, and multidisciplinary care may be useful for a subset of patients.

Tertiary rehabilitation is only necessary in a minority of patients (10%) (T. G. Mayer & Polatin, 2000), as it is reserved for patients with chronic injuries whom did not respond favorably to primary and secondary rehabilitation and for which surgical options are exhausted or unacceptable. Two types of tertiary rehabilitation are available: palliative pain management and multidisciplinary rehabilitation. Palliative pain management focuses on pain reduction, usually through the use of narcotics, and helps patients accept a non-functional lifestyle; the goal of palliative care is not to rehabilitate the patient to a functional state. Multidisciplinary approaches are used to address the multitude of physical, psychosocial, and socioeconomic barriers to recovery. One of the most frequent barriers to rehabilitation at the tertiary level is physical

deconditioning. Deconditioning happens when inactivity and disuse of the injured body part leads to a general loss of body functional performance, which becomes progressively worse as the amount of disuse and immobilization increases (T. G. Mayer & Polatin, 2000). The effects of deconditioning includes stiff, hypomobile joints, muscle atrophy, loss of endurance, tightening of connective tissues, inhibition of neural outflow, loss of cardiovascular fitness, and increased muscle spasms (T. G. Mayer & Gatchel, 1988).

It is essential that tertiary rehabilitation programs include quantification of physical functioning, psychosocial assessment, and address the influences of the disability system. Without these three components, it is difficult to effectively rehabilitate patients (T. G. Mayer & Press, 2003; T. G. Mayer, Gatchel, Porter, & Theodore; T. G. Mayer & Polatin, 2000).

1.3 Functional Restoration Treatment

One of the most effective tertiary rehabilitation programs is Functional Restoration (FR). FR treatment is an intensive interdisciplinary rehabilitation program based on a sports medicine approach that emphasizes return of patient function and productivity rather than pain reduction as its primary goal. FR is a biopsychosocial treatment consisting of a medically-supervised, quantitatively-directed exercise progression combined with a multi-modal disability management program (MDMP). The components of MDMP include cognitive-behavioral therapy, stress management/biofeedback training, education, and vocational reintegration (T. G. Mayer & Gatchel, 1988).

FR treatment is highly efficacious. Of the 3, 500 patients who have entered the Productive Rehabilitation Institute in Dallas for Ergonomics (PRIDE) clinic (a FR treatment program), since the clinic's opening, almost all have returned to work, with more than half of them returning to the same employer (Kolata, 2004). More recently, the work return rate for the years 2004-2008 averaged 93%, and work retention rates averaged 84% (Productive Rehabilitation Institute of Dallas for Ergonomics, 2011).

FR, however, has not been evaluated closely as a treatment for the musculoskeletal syndrome Fibromyalgia (FM). In a recent study in a chronic disabling occupational musculoskeletal disorder (CDOMD) population, 23% of patients met criteria for FM, which is significantly higher than population averages of 2% (United States Census Bureau, 2010). FM patients demonstrated worse one-year post-treatment socioeconomic outcomes, including work return, compared to non-FM and chronic widespread pain (CWP) patients (Howard et al., 2010). Given the high prevalence rates of FM in this subgroup of patients, it is important to fully understand the syndrome of FM.

1.4 Fibromyalgia

1.4.1 Diagnosis

The American College of Rheumatology (ACR) diagnostic criteria for FM has 2 components: a) presence of chronic widespread pain (CWP); and b) the presence of at least 11/18 tender points with a manual tender point assessment (F. Wolfe et al., 1990); see Figure 1.1 for tender point locations). CWP is defined as pain above and below the waist, on the left and right side of the body, with at least one point along the axial skeleton. This pain must be present for at least 3 months.

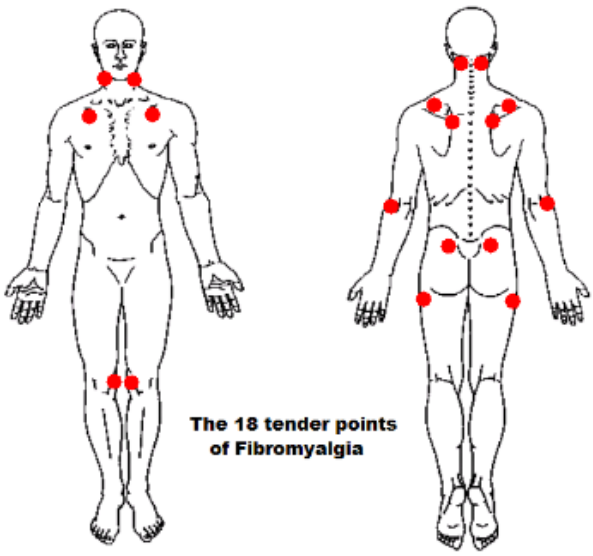

Figure 1.1 Locations of Fibromyalgia Tender Points

1.4.2 Prevalence Rate and Estimated Costs

Six million people in the United States have been diagnosed with FM, and it is estimated that these patients saw an average of four doctors before official diagnosis (Wallace, 2005). Though those diagnosed with Fibromyalgia make up approximately 2% of the population (United States Census Bureau, 2010), Fibromyalgia patients directly and indirectly cost the United States between $12 and $20 billion dollars annually (Wallace, 2005) (Jones, Hoffman, & Adams, 2008). Health costs may be high partly because patients may repeatedly visit their primary care physician with a wide array of symptoms before an official diagnosis is made (Hughes, Martinez, Myon, Taïeb, & Wessely, 2006). One study found that FM patients used health care resources twice as much as matched controls (25 visits versus 12; Hughes et al., 2006).

1.4.3 Symptoms and Comorbidities

Many other symptoms frequently co-exist with FM, though they are not part of the official diagnostic criteria. Symptoms include: fatigue (Carville et al., 2008), morning stiffness (Hughes et al., 2006), numbness, feelings of weakness (D. A. Marcus, 2009), lightheadedness, dizziness, dysmenorrhea (Giamberardino, 2008), swelling, paraesthesia, catastrophizing, non-restorative sleep (K. Mannerkorpi & Iversen, 2003), and cognitive complaints, such as poor memory and an inability to concentrate (Pridmore, 2002; Schwartz & Thompson, 2003).

In addition, FM patients often experience a number of other comorbid physical conditions, which include, but are not limited to: irritable bowel syndrome (IBS; Kurland, Coyle, Winkler, & Zable, 2006), Temporomandibular joint disorder (Balasubramaniam et al., 2007), Raynaud's syndrome (D. A. Marcus, 2009), and chronic tension headaches or migraines (D. A. Marcus, Bernstein, & Rudy, 2005). Recent literature suggests that these disorders are tied together through the same neurosensory mechanism of central sensitization (CS; M. B. Yunus, 2007a; M. B. Yunus, 2007b; M. B. Yunus, 2005; Kindler, Bennett, & Jones, 2011). The CS model suggests that physical trauma and/or sustained pain causes dysregulation and hyper-excitability of the Central Nervous System, resulting in amplified pain responses (hyperalgesia; (Giamberardino, 2008), expansion of pain receptive fields (Kindler et al., 2011), and pain experiences with normally non-painful stimuli such as a light touch (allodynia). Many other common symptoms overlap as well, such as pain, poor sleep, fatigue, and psychosocial factors such as anxiety, depression, and stress (M. B. Yunus, 2008). Because of the high number of overlapping symptoms and comorbidities, these disorders have been grouped together under the title of "Central Sensitivity Syndromes" (CSS; M. B. Yunus, 2008). Evidence for central sensitization has been found in FM: studies show decreased pain thresholds in FM patients to electrical, chemical, or thermal stimulation in comparison to normal controls (Dessein, Shipton, Stanwix, & Joffe, 2000; Giamberardino, 2008; Kindler et al., 2011).

In addition to an increased number of physical diagnoses, Fibromyalgia patients also experience greater psychosocial symptoms, including depression, anxiety, a history of psychological trauma such as sexual or emotional abuse (Abeles, Pillinger, Solitar, & Abeles, 2007), elevated stress/distress levels (Schwartz & Thompson, 2003; Aaron et al., 1996), and a higher number of Axis I and Axis II disorders as diagnosed by the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM IV; American Psychiatric Association, 1994). It is estimated that 25% of FM patients have a mental disorder (Pridmore, 2002). Between 26% and 71% of FM patients suffer from major depression or another depressive disorder (Bradley & Alberts, 1999; Epstein et al., 1999; Giesecke et al., 2003; Kurland et al., 2006). Those that have comorbid depression had 50% greater health care costs (Robinson, Theodore, Wilson, Waldo, & Turk, 2010). As well, 71% of FM patients report anxiety (Arnold, Crofford, Martin, Young, & Sharma, 2007). More than half of FM patients may suffer from symptoms of post-traumatic stress disorder (PTSD; Sherman, Turk, & Okifuji, 2000) or are diagnosed with PTSD under DSM IV criteria (H. Cohen et al., 2002).

1.4.4 Disability

Fibromyalgia patients also experience high levels of disability. As an example of how severe the pain and disability components of FM can be, research suggests that 37% of FM patients were aggravated by working at the computer and 27% by prolonged sitting (Waylonis, Ronan, & Gordon, 1994), both of which are activities considered light duties in a normal range of motion. It is reported that 74% of FM patients have reduced their usual activities due to pain and 58% reportedly spent at least 1 day in bed in the last two weeks because of health symptoms (D. A. Marcus, 2009).

Of those diagnosed with Fibromyalgia, it is estimated that 25% of patients receive some form of disability payment (F. Wolfe et al., 1997), and another 30% of FM patients chose shorter working hours or less demanding work in order to maintain employment (Giamberardino, 2008), because they felt they could not fulfill their original work duties.

One possible explanation for why FM patients experience high levels of disability was proposed by Kim Jones: the Negative Physical Exertion Cycle. In this theory, FM patients physically exert themselves, which leads to increased pain and fatigue, which then maintains or increases their fear of exertion. The patient then decreases physical activity levels, which leads to deconditioning, which then both increases the patient's disability levels as well as increases the amount of pain and fatigue the patient will have the next time he or she attempts physical activity (Jones et al., 2008). This theory is validated by the estimate that FM patients are 20% to 30% weaker than their peers and are physically unfit (Bennett et al., 1989; Simms, 1996).

1.4.5 Treatment

Treatment of FM is not standardized; a multitude of treatments exist (Adams & Sim, 2005), perhaps because symptoms that present outside of the official diagnostic criteria are so diverse. However, not all treatments have been evaluated rigorously and/or proven efficacious. It is well known that FM patients are particularly motivated to reduce their pain (D. A. Marcus, 2009), and as a result, they may be more willing to attempt a wide variety of treatments, even when there is little evidence to support the treatment. For instance, FM patients rely on a wide range of complementary and alternative (CAM) therapies, such as energy therapy, body awareness therapy (Adams & Sim, 2005), yoga, diet (Lemstra & Olszynski, 2005), vitamins/minerals, or massage (D. A. Marcus, 2009; Lemstra & Olszynski, 2005). This trend is only exacerbated by the wide variety of FM self-help books available (Friedberg, 2006); (Matallana & Bradley, 2009; Starlanyl & Copeland, 2001); often, these popular books are not written by a clinician but by FM "survivors" and state only anecdotal evidence for treatment and even inaccurate information (Starlanyl & Copeland, 2001).

There is a lack of standardization in treatment and a few high-quality studies (Carville et al., 2008; Lemstra & Olszynski, 2005; K. Mannerkorpi & Iversen, 2003) even for therapies that are more well-known and have a large literature base. Counseling (often cognitive-behavioral therapy; (Williams, 2005), stress management (Kaplan, Goldenberg, & Galvin-Nadeau, 1993),

biofeedback (Schwartz & Thompson, 2003), educational interventions (Williams, 2005), pharmacotherapy for pain, depression, or anxiety (Schwartz & Thompson, 2003; D. C. Turk, Okifuji, Sinclair, & Starz, 1998), and exercise are all widely accepted treatment for FM, but execution of these treatments is diverse and produces mixed results. While treatments such as biofeedback may be useful in combination therapy, there is no firm support for relaxation therapy when used alone (Schwartz & Thompson, 2003).

For example, exercise therapy can take the form of ergometer cycling (McCain, Bell, Mai, & Halliday, 1988), dance (Mengshoel, Kommaes, & Forre, 1992), walking (Buckolow et al., 1992), strength training (Jones, Burckhardt, & Clark, 2002), or aquatic exercise (K. Mannerkorpi, Nyberg, Ahlmén, & Ekdahl, 2000). Yet the majority of these programs produce only mild to moderate reductions in pain intensity and increases in aerobic capacity, flexibility, gait, self-selected walking speed (Tiidus, Pierrynowski, & Dawson, 2002), or other physical measures. One of the potential problems with exercise interventions is that patients may not adhere to exercise treatment because they suffer high levels of exercise-induced pain (van Santen et al., 2002; Meyer & Lemley, 2003; Jones et al., 2008; K. Mannerkorpi & Iversen, 2003). Without the proper education of a FR program, in which both patients and clinicians understand that pain does not necessarily mean harm, and that pain may actually increase during the process of an effective rehabilitation program, patients will never achieve the physical gains necessary to significantly decrease disability and perhaps lose the diagnosis of Fibromyalgia. The assumption that painful activity should be avoided is endorsed even by professional organizations such as the American College of Sports Medicine (ACSM), which recommends exercise for FM patients be aerobic in nature only, with no strength training, of only low to moderate intensity, and with little or no impact (Meyer & Lemley, 2003).

Multidisciplinary programs (Lemstra & Olszynski, 2005; (D. C. Turk et al., 1998) that use some combination of the therapies described above are recommended by the European League Against Rheumatism (EULAR) and other panels of experts, but research in

multidisciplinary treatment is plagued by the same methodological issues of small sample sizes (D. C. Turk et al., 1998), lack of adequate control groups (Carville et al., 2008; Lemstra & Olszynski, 2005) and a lack of objective outcomes. Programs may evaluate subjective outcomes, such as quality of life, pain intensity, or treatment satisfaction, but most are not focused on objective measures of rehabilitation efficacy, such as the number of tender points patients have (Nichols & Glenn, 1994; Hävermark & Langius-Eklöf, 2006; Creamer, Singh, Hochberg, & Berman, 2000; Gowans, deHeuck, Voss, & Richardson, 1999). This may be because FM is considered a stable and chronic diagnosis that is unlikely to resolve at post-treatment (F. Wolfe et al., 1997; Horizon & Weisman, 2005; Felson & Goldenberg, 1986; Hughes et al., 2006).

Three studies do examine pre-to-post changes in tender points and thus whether or not FM patients lost or retained the FM diagnosis at post-treatment. The first examines a population of educated, employed female FM patients in a community pain clinic undergoing six months of interdisciplinary rehabilitation, including stress management classes, exercise classes, behavioral modification, counseling and pharmacotherapy for depression, and trigger point injections. At post-treatment, 70.2% of patients lost the diagnosis (Bennett et al., 1996).

The second study examined the prevalence of FM in a predominantly female whiplash population (Robinson et al., 2010). After six weeks of CBT to reduce fear of movement, 63.3% of Fibromyalgia patients lost the diagnosis, though 8% of participants actually *developed* FM during that time period (leading credence to the idea that FM is a transient diagnosis). The third study, conducted in Britain, reported 30% of patients lose the diagnosis of FM after participation in either an exercise or relaxation program held in an outpatient rheumatology clinic (Richards & Scott, 2002).

Given the success rates of these three programs, it is assumed that other, more rigorous interventions would have similar rates of recovery for FM patients. FR has the potential to be particularly efficacious.

1.5 Purpose of the Current Study

The purpose of the current study was fourfold. First, this study examined the prevalence rates of Fibromyalgia within a CDOMD population, which were expected to be considerably higher (Howard et al., 2010; Aaron et al., 1996) than general population averages of 2% (United States Census Bureau, 2010). Second, this study examined the stability of the FM construct. Patients were evaluated for FM under the ACR 1990 diagnostic criteria (F. Wolfe et al., 1990), using both the components of CWP and ≥ 11/18 tender points, at pre and post-treatment. It was hypothesized that a significant percentage of patients would no longer meet criteria for FM at post-treatment. Third, this study determined the effectiveness of FR for treating patients with Fibromyalgia, using both subjective psychosocial measures, such as self-reported pain intensity, disability, and depressive symptoms, and objective one-year socioeconomic measures such as work return and work retention. Lastly, this study characterized FM patients in a CDOMD population by splitting them into two groups, those who lost and those who retained the diagnosis of FM at post-treatment, and compared each group to a lumbar only comparison group in regards to psychosocial factors, clinical diagnoses of Axis I and II disorders, and socioeconomic outcomes. These comparisons allowed researchers to better understand the differences between patients who recover from FM and patients who don't.

CHAPTER 2

METHODS

2.1 Participants

Patients referred to a regional interdisciplinary Functional Restoration (FR) rehabilitation center consented to the collection of information for treatment management and clinical research purposes. Because the information was collected as part of the standard medical record, the study was granted an exemption from review by the Institutional Review Board.

Patients were eligible for treatment if a minimum of 3 months had passed between the date of injury and treatment, if their primary or secondary care options had been unsuccessful, if they were suffering from severe pain and functional limitations, and if communicated in English or Spanish. Patients signed a Health Insurance Portability and Accountability Act (HIPAA) authorization before beginning the program. Patients did not receive payment or reward for participation in this study.

As seen in Figure 2.1, the overall sample consisted of 1059 patients CDOMD patients from the years 2005-2006 and 2010-2012 who were referred to FR treatment. Of those, 147 (14%) were diagnosed at pre-treatment for Fibromyalgia under the ACR 1990 criteria (F. Wolfe et al., 1990). It is important to note that while these patients did have FM, it was not the ailment for which the patients were referred for functional restoration treatment; all patients had a worker's compensation injury. Thirty FM patients (18%) failed to complete the treatment program, however, which left a total sample size of 117 FM patients (of which the overwhelming majority (84%) had spinal injuries). Fibromyalgia patients were further broken down into subgroups by diagnosis change at post-treatment: patients who lost the FM diagnosis (LFM group, n = 48) and patients who retained the FM diagnosis (RFM group, n = 69).

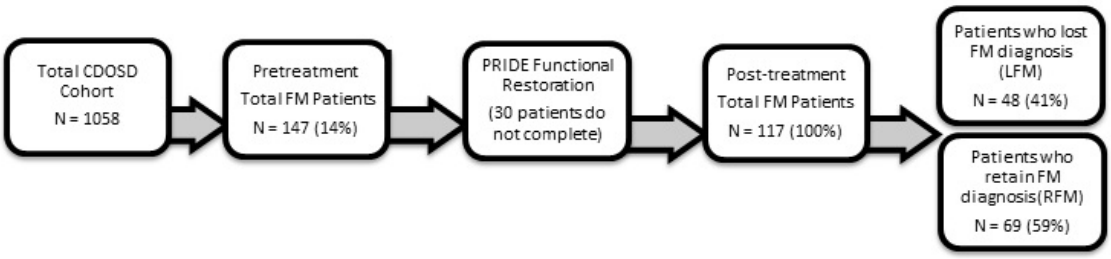

Figure 2.1 Number and Percentage of Patients who Retained and Lost the Fibromyalgia (FM) Diagnosis Post-treatment

In addition to the FM patients, a consecutive sample of lumbar patients, with no other additional injured body parts and no CWP or FM, from the years 2005-2006 (n =87) served as a comparison group. A group of lumbar only patients were chosen as a comparison group because patients with lumbar injuries are “typical” of this chronic pain population and generally have few other complicating factors.

Comparisons between the lumbar only group and both FM groups showed no differences in demographic data on age, area of injury, ethnicity, length of disability, number of injuries, or case type, as seen in Table 2.1. However, FM patients were more likely to be female. Female gender is a known risk factor for FM (Howard et al., 2010; J. McBeth, 2005;D. A. Marcus, 2009; International Association for the Study of Pain, 2010; Meyer & Lemley, 2003).

Table 2.1 Pretreatment Demographics for RFM, LFM, and Lumbar Only Patients

Variable	RFM	LFM	Lumbar Only	F/ χ^2 value	*p* value	Effect Size
Area of Injury, n (%)				7.67	.22	
lumbar only	2 (3%)	2 (4%)	N/A			
cervical only	6 (9%)	11 (23%)				
extremity only	10 (15%)	6 (13%)				
multiple spinal	13 (19%)	10 (21%)				
spinal plus additional musculoskeletal areas	35 (52%)	16 (34%)				
other	1 (2%)	2 (4%)				
Gender, n (% male)	30 (45%)	24 (51%)	62 (65%)	7.16	.01	.18
Age, mean (SD)	49.7 (8.8)	47.6 (9.8)	46.56	2.05	.13	
Ethnicity, n (%)				9.16	.32	
Caucasian	26 (39%)	21 (48%)	55 (60%)			
African American	23 (35%)	11 (25%)	15 (17%)			
Hispanic	16 (24%)	11 (25%)	20 (22%)			
Asian	1 (2%)	1 (2%)	1 (1%)			
Length of Disability in Months, mean (SD)	25.9 (27.7)	25.5 (33.1)	28.0 (35.3)	.12	.89	
Compensable Injuries, n (%)						
1 injury	15 (22%)	14 (30%)	N/A	.93	.29	
More than 1 injury	52 (78%)	32 (70%)				

2.2 Materials and Measures

2.2.1 Assessment of Fibromyalgia and Chronic Widespread Pain

2.2.1.1 Dallas Pain Drawing Grid Assessment

On the first day of treatment, patients were assessed for chronic widespread pain using the Dallas Pain Drawing Grid Assessment (Ransford, Cairns, & Mooney, 1976). This measure consisted of a single worksheet with two empty, sexless outlines of a human on it, one portraying the front side and marked “front,” the other portraying the back side and marked “back.” Patients were asked to mark the location of their pain within seven days on the outlines. An example of the Dallas Pain Drawing is shown in Figure 2.2. CWP was defined as a combination of pain above and below the waist, on the left and right side of the body, and including the axial skeleton (F. Wolfe et al., 1990).

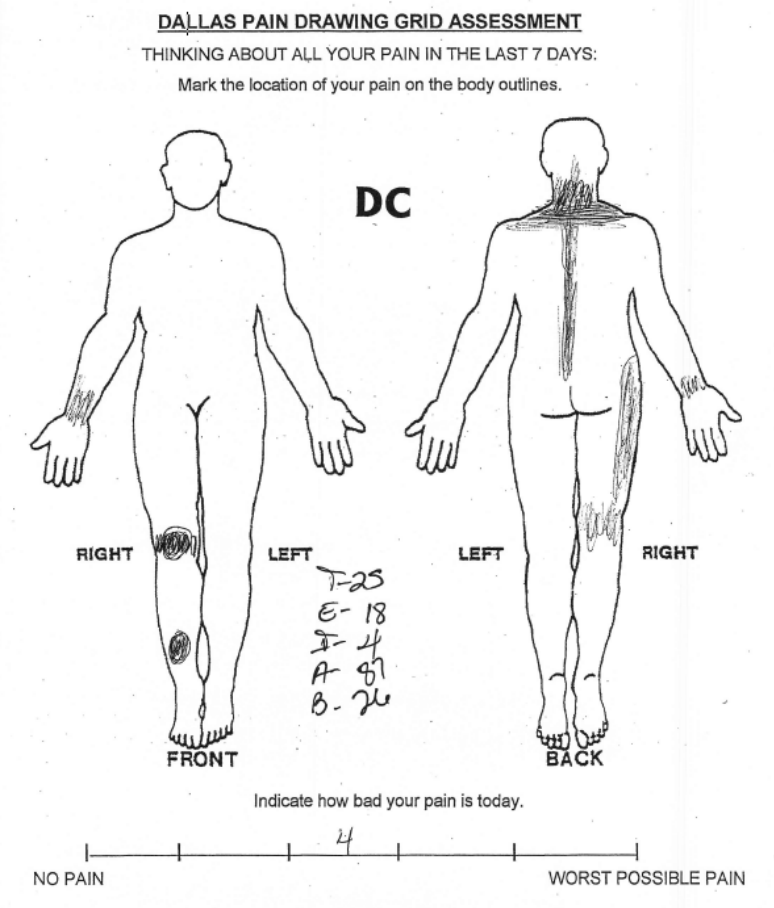

Figure 2.2 Example of a Patient with Chronic Widespread Pain (CWP) as assessed by the Dallas Pain Drawing Grid Assessment

2.2.1.2 Manual Tender Point Scale (MTPS)

If a patient was positive for chronic widespread pain, he or she was then assessed for FM using the MTPS (Sinclair, Starz, & Turk, ND), in which an examiner digitally palpitated the patient in 18 different areas of the body at 4kg of pressure. For consistency, examiners were asked to use the thumb pad of the dominant hand and to increase pressure every second from 1kg to 4kg. Please refer to Figure 1.1 for a pictorial representation of the tender points. The MTPS takes 5-7 minutes to complete (Schwartz & Thompson, 2003). Patients were diagnosed

with Fibromyalgia under the 1990 American College of Rheumatology (ACR) Criteria, which requires that patients must (1) have CWP and (2) be positive for at least 11 of 18 tender points when digitally palpitated at 4 kg of pressure (F. Wolfe et al., 1990).

2.2.2 Assessment of Physical Functioning

Assessment of physical functioning provided an objective measure of a patient's abilities at the beginning of FR and, as the patient continues through the program, it is used to measure his or her progress. Physical functioning assessments also showed the degree of effort used to perform physical tasks. When suboptimal effort was identified, with no medical reason, it alerted the clinical team that additional psychosocial barriers to functional recovery may be present. In addition, it is important to assess physical functioning because deficits are predictive and associated with disability (Polatin & Mayer, 1992).

Two different assessments of physical functioning were used: a Quantified Physical Evaluation (QFE) was used for patients from 2005-2006, and a Functional Capacity Evaluation (FCE) was used for 2010-2012 patients. All physical measurement scores were converted to percent normal by dividing the raw score by a normative score unless otherwise indicated below. Normative scores were calculated taking into account age and gender, and are based on a series of studies on normative samples (T. G. Mayer, 2000; Smith, Mayer, Gatchel, & Becker, 1985; Kishino et al., 1985; T. Mayer, Gatchel, Betancur, & Bovasso, 1995; T. Mayer, Gatchel, Keeley, Mayer, & Richling, 1994; T. G. Mayer, Gatchel, Keeley, & Mayer, 1993). Tables of normative scores can be found in Table 2.2 for 2005-2006 patients and Table 2.3 for 2010-2012 patients.

Table 2.2 Physical Measure Normative Scores for 2005-2006 Patients

Gender	**Male**				**Female**			
Age groups	**18-29**	**30-44**	**45-59**	**60-99**	**18-29**	**30-44**	**45-59**	**60-99**
Physical Measures:								
Floor to Waist Isokinetic Lift	120	120	108	96	90	90	81	72
Waist to Shoulder Isokinetic Lift	48	48	43	38	32	32	29	26
Trunk Extension	144	144	130	115	110	110	99	88
Floor to Waist PILE	45	45	41	36	40	40	36	32
Waist to Shoulder PILE	34	34	31	27	28	28	25	22

Table 2.3 Physical Measure Normative Scores for 2010-2012 Patients

Gender	**Male**				**Female**			
Age groups	**18-29**	**30-44**	**45-59**	**60-99**	**18-29**	**30-44**	**45-59**	**60-99**
Physical Measures:								
Floor to Waist Isokinetic Lift	94	94	85	75	62	62	56	50
Waist to Shoulder Isokinetic Lift	73	73	66	58	37	37	33	30
Trunk Extension	140	140	126	112	97	97	87	78
Floor to Waist PILE	45	45	41	36	40	40	36	32
Waist to Shoulder PILE	34	34	31	27	28	28	25	22

2.2.2.1 Progressive Isoinertial Lifting Evaluation (PILE)

The PILE task was a measure of lifting capacity with no restriction of activity (unlike the isokinetic tasks described below), which allows both lifting strength and agility to be measured, leading to a better true measure of lifting capacity. During this task, the patient lifted weights in a plastic box from floor to waist height (FW; 0-30 inches) and from waist to shoulder height (WS; 30-54 inches). Patients were not aware of the amount of weight in the box, though in reality, women began with a 5 pound load and men begin with a ten pound load, with the initial weight added every twenty second period. Each 20 second period had 4 lifting cycles in it, which consisted of 2 lifting movements to return to the starting point; for example, floor to waist, then waist to floor. The test ended when one of three endpoints is achieved: a) psychophysical endpoint: pain or fatigue b) aerobic end point: achievement of 85% maximum heart rate (determined by age calculations) or c) safety end point: achievement of 45-50% of body weight lifted (T. G. Mayer et al., 1988; T. G. Mayer, Barnes et al., 1988; Polatin & Mayer, 1992). The maximum final force from FW and WS was recorded, and the raw data was converted to percent normal.

In order to calculate percent normal data, patients were first assigned an ideal weight value based on height and gender. Ideal weights are listed in Table 2.4. If a patient's actual body weight is less than or equal to the ideal body weight, then the adjusted body weight value was the patient's actual body weight, since the data normalization process is skewed by overweight but not underweight values. If the patient's actual body weight was greater than the ideal body weight, however, the adjusted body weight value was the ideal body weight value. Normative scores were then calculated by dividing the final force by the adjusted body weight, multiplying by 100, and then dividing by a normative value that took into account age and gender (T. G. Mayer et al., 1988). Normative values were shown in Tables 2.2 and 2.3. PILE scores have shown high responsiveness to FR treatment, with patients often exhibiting normal or supernormal physical capacity at post-treatment (T. G. Mayer, Barnes et al., 1988).

Table 2.4 Ideal Weights Used to Calculate PILE Scores

Female		Male	
Height (in)	**Weight (lbs)**	**Height (in)**	**Weight (lb)**
58	111	62	144
59	114	63	147
60	117	64	150
61	120	65	154
62	124	66	157
63	126	67	162
64	129	68	167
65	134	69	171
66	137	70	175
67	141	71	180
68	145	72	185
69	149	73	190
70	154	74	195
71	159	75	200
72	163	76	205

If the patient used only submaximal effort, their final heart rate was relatively low and there was a large discrepancy between the target heart rate and final. This can be validated against the results from the aerobic capacity test, thus allowing identification of patients with submaximal effort.

2.2.2.2 Range of Motion (ROM)

True total lumbar ROM measurements were used in this study. In order to obtain them, the two-inclinometer technique was used. An inclinometer is a circular fluid-filled disc with a weighted gravity pendulum that remains oriented in the vertical direction. The first inclinometer was aligned over the sacrum, and the second in the sagittal plane. The trunk was held in the neutral position while the inclinometers “zero out,” and then the patient was asked to flex forward. The upper inclinometer measures gross lumbar flexion, while the lower inclinometer gives hip flexion. True lumbar flexion was calculated by subtracting the hip flexion measurement (lower inclinometer) from the gross flexion measurement (upper inclinometer). The same procedure took place when the patient is asked to extend backward, with the reading of hip extension subtracted from gross lumbar extension to calculate true lumbar extension. The

scores of true lumbar extension and true lumbar flexion were then summed to create a total true lumbar ROM score. True total lumbar ROM data was then converted into a percent normal score using normal scores of 95 degrees for 2005-2006 patients and 85 degrees for 2010-2012 patients. Norm scores were not adjusted by age or gender for true total lumbar ROM. Validation on normative subjects and ROM test reliability showed favorable results (J. Keeley et al., 1986).

Effort on the ROM task can be assessed by measuring the maximal supine straight leg raise (SLR) bilaterally. The SLR measurement should be very close to hip motion, and if the SLR exceeds total hip motion by more than 10 degrees, then the patient exerted suboptimal effort on the lumbar ROM task (Polatin & Mayer, 1992). Please note that true lumbar range of motion data was only collected on patients that had a compensable lumbar injury.

2.2.2.3 Isokinetic Liftask

Isokinetic lift tasks holds speed and acceleration constant so that torque or force becomes the only tested variable, allowing for easy calculation of individual differences (Polatin & Mayer, 1992). For 2005-2006 patients, the Cybex Liftask (Cybex Inc.) machine was used. The Cybex Liftask consisted of a standing platform with foot placement grids and a lifting handle on a cable attached to a dynamometer (J. Keeley, 1991). Patients were instructed to bend and lift with safe maximal effort (Kishino et al., 1985). Force to body weight ratios were measured for waist to shoulder (WS) and floor to waist (FW) liftasks at 18 inches per second. On the 2010-2012 data, the Biodex System 4 Lift Attachment (Biodex Medical Systems) was used. Testing took place at 20 inches per second and was measured in force to body weight (Biodex Medical Systems). This machine was demonstrated to be a valid measure of isokinetic torque (Drouin, Valovich-mcLeod, Shultz, Gansneder, & Perrin, 2004).

2.2.2.4 Trunk Strength

Trunk strength is measured isokinetically in peak torque to body weight, and as in the isokinetic lift task, speed and ROM are fixed in order to measure torque or force (J. Keeley, 1991). For 2005-2006 patients, the Cybex Isokinetic Torso Extension/Flexion (TEF) machine

(Cybex Inc.) was used. This machine has shown good reliability in normative samples (Smith et al., 1985). ROM was limited with stabilization across the chest, at the pelvis, and above and below the knees. The test began at a posturally neutral position and then peak torque for the extension task at sixty degrees per second was measured. The flexion and extension range allowed was from 0 degrees to 80 degrees, though actual range of motion in patients usually was from 0-50 degrees (Smith et al., 1985). For 2010-2012 patients, the Biodex System 3 Back Attachment machine (Biodex Medical Systems) measured trunk strength for the extension at 60 degrees per second. Patients were stabilized with a belt along the upper thigh and pelvis, and with a lumbosacral pad that maintains pelvic tilt (J. Keeley, 1991). Isokinetic trunk strength (extension) was measured at sixty degrees per second. Please note this variable was only collected if patients had a compensable lumbar injury.

2.2.2.5 Maximum Aerobic Capacity (VO_2 max)

Aerobic capacity was included in the assessment of physical functioning because it provided a good measure of overall physical fitness and how deconditioned a patient is. Aerobic capacity, in the form of VO_2 max, was calculated indirectly through a submaximal bicycle ergometer test. Patients completed 2-4 3-minute stages until their heart rate was at least 80 beats per minute for two consecutive stages, although 85% of their age-related heart-rate maximum was the ideal goal. The first test began with a 25-watt resistance, then heart rate was measured, and then the second test began with resistance between 50 and 100 watts. Tests were invalid if the patient was unable to pedal at the required speed to produce torque or if the patient could not complete at least two stages of pedaling. While a high percentage of patient tests were invalid at pre, this was most likely due to psychosocial variables such as fear-avoidance rather than actual physical inability (Protas et al., 2004).

2.2.3 Medical Case Management Evaluation

Demographic and socioeconomic outcome data were collected by the case management and nursing departments. Relevant demographic information collected included

age, ethnicity, length of disability, area(s) of injury, gender, and information about pre-treatment surgeries. Outcome data included information collected about disability compensation, income, job demand, and work status.

2.2.4 Psychosocial Intake Evaluation

After the patient was accepted into the program, he or she underwent an initial Mental Health Evaluation (MHE). A packet of self-report questionnaires included assessment of psychosocial measures of assessing pain, perceived disability, health-related quality of life, and depressive symptoms were collected at pre and post-treatment.

2.2.4.1 Perceived Pain Intensity

Patients marked their pain intensity on a 10mm visual analog scale (VAS) line, with the anchor points of “no pain” and “worst possible pain.” Pain intensity was scored by measuring the distance from the “no pain” endpoint to the patients marking. The VAS is usually easily understood and is useful in measuring subjective pain (Jensen, Karoly, & Braver, 1986). It has moderate to high test-retest reliability depending on the literacy level of the patient (α = .71-.94) and has demonstrated high correlations with other pain rating styles (r = .71-.78) (Gillian, Mian, Kendzerska, & French, 2011).

2.2.4.2 Million Visual Analog Scale (MVAS)

The MVAS measured the effect of pain and disability on activities of daily living. Examples of items included: “does your pain interfere with walking?” and “how much have you had to change your home or work place activities because of pain?” Responses to the 15 items were scored on a six point VAS and the total score ranged from 0, indicating no functional disability, to 150, indicating total functional disability (Million, Hall, Nilsen, Baker, & Jayson, 1982). Levels of disability included mild disability (0-39), moderate disability (40-84), and severe disability (>85). While little is known of the MVAS’s psychometric properties outside of its original validation study (Million et al., 1982), it is easy to use, and demonstrated good relation to non-completion status and one year socioeconomic outcomes, and thus can be useful in

identifying particularly at-risk patients (C. Anagnostis, Mayer, Gatchel, & Proctor, 2003). The MVAS shows a high degree of reproducibility, with α = .97 for intraobserver reproducibility and α = .92 for interobserver reproducibility (Million, Hall, Nilsen, Baker, & Jayson, 1982).

2.2.4.3 Patient Disability Questionnaire (PDQ)

The PDQ was a measure of functional status and was designed for use in a CDOMD population, rather than just for low back pain populations, as the MVAS and Oswestry Disability Index were. In addition, the PDQ was designed to understand the biopsychosocial aspects of disability (C. Anagnostis, Gatchel, & Mayer, 2004). Sample items included: “Are there emotional problems caused by your pain that interfere with your family, social, or work activities?” and “Does your pain interfere with personal care (such as bathing, dressing, etc.)?” Responses to 15 items were scored on a 10cm VAS scale, and total scores ranged from zero, indicating optimal functioning, to 150, indicating total disability. The PDQ can also be broken down into two components: functional status and psychosocial status. The PDQ is responsive to meaningful clinical change, corresponds with psychosocial and socioeconomic outcomes, and demonstrates high construct-related validity. The reliability coefficient was .98 for the PDQ, and inter-rater reliability was α = .96 (C. Anagnostis et al., 2004; R. J. Gatchel, Mayer, & Theodore, 2006).

2.2.4.4 Oswestry Disability Index (ODI)

While the ODI is one of the oldest and most frequently studied disability questionnaires (Fairbank & Pynsent, 2000), and demonstrates excellent psychometric properties, it had several limitations, such as the inability to distinguish low-scoring patients (floor effect) and its narrow focus on only low back pain (R. J. Gatchel et al., 2006). The ODI was made up of ten sections asking about functional limitations due to pain. Each section had a series of six possible responses, each describing a greater degree of functional difficulty than the previous response, and patients were asked to mark one box that applied to him or her in each section. The total score (max 50) is doubled and then expressed as a percentage. Established ranges on the ODI

were as follows: minimal disability (0-20%), moderate disability (20-40%), severe disability (40-60%), crippled (60-80%), and bed-bound or exaggerating (80-100%) (Fairbank, Couper, Davies, & O'Brien, 1980). The correlational coefficient for test-retest reliability was r = .99 for the tests given on the same day (Fairbank, Couper, Davies, & O'Brien, 1980). but dropped to r = .83 if tested within four days (Fairbank & Pynsent, 2000)

2.2.4.5 Medical Outcome Study 36-item Short-form Health Survey (SF-36)

The SF-36 was a measure of health-related quality of life. It is a representation of multidimensional health concepts (McHorney, Ware, & Raczek, 1993). The SF-36 has eight subscales (physical functioning, role limitations, social functioning, mental health, general health perceptions, bodily pain, and vitality) that were condensed into two summary scales: the Mental Component Scale and the Physical Component Scale. The SF-36 has demonstrated high reliability and content, criterion, and construct validity, with high reliability coefficients of α = .80 or more for each of the subscales (both test-retest and internal consistency) (McHorney et al., 1993; R. J. Gatchel, Mayer, Dersh, Robinson, & Polatin, 1999). The SF-36 has also shown good relation to socioeconomic outcomes (R. J. Gatchel, Mayer, Dersh, Robinson, & Polatin, 1999). However, it is less useful for showing individual responsiveness (R. J. Gatchel, Polatin, Mayer, Robinson, & Dersh, 1998). A higher score on the components off Mental and Physical Health reflect better self-reported health.

2.2.4.6 Beck Depression Inventory (BDI)

The BDI (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961) measured depressive symptoms and is frequently used as a screener in pain centers, though it may overestimate depressive symptoms because of the similarity between somatic symptoms of depression and physical symptoms of chronic pain (Wesley, Gatchel, Garofalo, & Polatin, 1999). The BDI consisted of 21 items scaled on a 0-3 point scale, with zero indicating the depressive symptom is not present and three indicating that the symptom is severe. Total scores ranged from 0-63, with cut-offs of no depression (0-9), mild to moderate depression (10-18), moderate to severe

depression (19-29), and severe depression (>30). The BDI has shown high internal consistency, moderate stability, and high criterion, concurrent, construct, and discriminate validity, with α scores ranging from .76-.95 in one meta-analysis (Beck, Steer, & Garbin, 1988).

2.2.4.7 Hamilton Rating Scale for Depression (HRSD)

The HRSD was a structured clinical interview designed to measure depressive symptoms over a short period of time. A total of 21 depressive symptoms were assessed, with ratings on either a five-point scale, with categories of: absent (0), doubtful or trivial (1), mild (2), moderate (3), and severe (4), or on a three-point scale, with categories of: absent (0), doubtful or mild (1), and obvious, distinct, or severe (2) (Hamilton, 1967). It is commonly used and demonstrates high validity, internal consistency, and inter-rater reliability. One meta-analysis showed a pooled alpha coefficient of .79 and pooled inter-rater and test-retest reliability of r = .93 and r =. 94 respectively (Trajković et al., 2011).

2.2.4.8 Psychosocial Clinical Interview

The clinical interview, conducted by a qualified clinician, integrated the above self-report measures with a personal patient assessment. The patient was assessed for symptoms of depression, anxiety, stress, and psychiatric disorders (as diagnosed in the DSM-IV; American Psychiatric Association, 1994), as well as assessed on his or her home and family life and presence of social support. The psychologist also determined patient motivation for recovery, including financial disincentives for return to work, secondary gain issues, and malingering symptoms (Gatchel, 1991).

2.2.5 Structured One-year Follow-up Interview

Socioeconomically-relevant outcomes were assessed one-year after discharge in a structured interview. These outcomes included: work return, which assessed if the patient has gone back to work at any point in the year following discharge, work retention, which assessed whether the patient was still working at the time of one-year follow up, excessive health care utilization, as measured by the number of visits made to providers in excess of standard follow-

up visits since discharge, and the number of new injuries and new surgeries within one-year after discharge. While the interview itself was subjective, these outcomes were independently verified through employers, the worker's compensation system, and insurance carriers and thus were objective outcomes for responsiveness to FR treatment (T. G. Mayer & Polatin, 2000).

2.3 Procedure

FR was an interdisciplinary rehabilitation program that adopts a sports medicine approach and was based on the biopsychosocial model, which views dysfunction and occupational illness as a complex interaction of biological, psychological, and social variables (D. C. Turk, 1996; R. J. Gatchel et al., 2007). The primary goal of FR was to restore function and reduce disability in a CDOMD population, rather than eliminate pain, though decreases in pain are often a by-product of FR. FR addressed the psychological, physical, financial, legal, and work-related complications that act as barriers to recovery in the chronic pain patient. Treatment was guided by a physician, who served as the medical director, with nurses serving as an extension of the physician. In addition, patients participated in physical therapy, occupational therapy, group stretching, and a multi-modal disability management program, which included individual and group counseling using a cognitive-behavioral therapy (CBT) approach, stress management techniques, biofeedback, educational sessions on the nature of pain, stress, and disability, and vocational reintegration (done by a case manager). FR treatment was interdisciplinary rather than multidisciplinary because all clinicians were housed in the same building and had direct communication with each other (Deschner & Polatin, 2000).

There were three major phases to FR rehabilitation. The first phase focused on the barriers to recovery and disability education, which was guided by a psychology staff member. The psychology staff also began treating any underlying psychopathology, with counseling and/or pharmacotherapy. In addition, stretching and ROM increase goals were emphasized by the physical therapy (PT) and occupational therapy (OT) staff. Within the initial phase, baseline physical function assessments and an initial occupational assessment and interview took place.

Frequent assessments of physical and psychosocial functioning helped maintain program objectivity and provided patients with feedback on how treatment progressed.

Phase II of FR was he intensive rehabilitation phase. It focused on the enhancement of strength, endurance, and aerobic capacity, using an individualized graded exercise plan. PT and OT played the largest part in Phase II, with psychology staff assisting to help decrease barriers to recovery and medication reliance. The primary goal of OT is not to focus on the injured body part specifically, as PT does, but instead to coordinate whole body movement to hone job skills and activities of daily living (ADLs). FCEs were regularly performed to show objective improvement.

The third phase of FR was follow-up. In this phase, the patient is gradually "weaned" off of the FR program. Emphasis was placed on continuing exercise regimens at home and the upcoming return to work. A recurrence of symptom magnification, non-compliance, and regression often takes place during this phase due to patient's anxiety about the future, so the counseling and case manager team involvement was crucial during Phase III (T. G. Mayer & Gatchel, 1988; Deschner & Polatin, 2000; T. G. Mayer & Polatin, 2000).

2.4 Analytic Plan

Mixed model Analyses of Variance (ANOVAs) were used to compare the LFM, RFM, and lumbar only groups for continuous variables. While it was proposed that mixed model Analyses of Covariance (ANCOVAs) be used in the case of any demographic differences, the only significant demographic difference, gender, did not significantly correlate with any of the physical or psychosocial variables used for analysis. Post-hoc tests for continuous variables were computed using the Bonferroni correction for multiple comparisons. Effect size for all continuous variables was partial eta-squared (η^2). Due to the large number of two-level factorial designs, the Holm Step-down procedure was initially used to determine the need for adjusted *p*-values (Holm, Mark, & Adolfsson, 2005), but no significant differences were found between the Holm *p* values and the unadjusted *p* values, so the unadjusted ones were reported.

Independent Chi-Square tests (χ^2) were used for categorical variables to compare the LFM, RFM, and lumbar only groups, with standardized residuals indicating a significant difference between groups. Effect size for categorical variables was Cohen's W (J. Cohen, 1992).

Sequential logistic regression analysis was performed in order to find the demographic, physical, and/or psychosocial factors that best predicted whether a patient lost or retained the FM diagnosis. The variables used in the logistic regression model were those found significant during the mixed model ANOVA post-hocs. The first block contained the physical variables of the percent zero PILE WS, PILE FW, WS Isokinetic lift, and total ROM score. The second block contained the psychiatric variables of MDD, substance abuse, opioid dependence, and pain disorder. In order to assess the addition of each block of variables associated with FM diagnosis loss/retention, a Pearson chi-square statistic was used. Significance for the logistic regression analysis was set at $p = .05$.

A power analysis conducted with G*Power 3.1 (Faul, Erdfelder, Lang, & Buchner, 2007; Faul, Erdfelder, Buchner, & Lang, 2009) yielded a minimum of 35 patients per group in order to detect a medium effect size; these requirements were fulfilled.

CHAPTER 3

RESULTS

3.1 Assessment of FM, CWP, and Tender Point Count at Post-Treatment

All FM completers (N = 117) were re-assessed for FM under the ACR 1990 diagnostic criteria (F. Wolfe et al., 1990) at discharge from the FR program. Patients who retained the diagnosis (n = 69) maintained > 11 tender points and the presence of CWP, while 48 (41%) patients no longer met diagnostic criteria (Figure 2.1).Of those who lost the diagnostic criteria, 24 (50%) had < 11 tender points, but still reported CWP. Of the remaining 24, 17 (35%) had < 11 tender points and no CWP, and 7 (15%) had no CWP but > 11 tender points. A repeated measures ANOVA revealed a greater decrease in mean number of tender points for the LFM group [M (change) = -7.0, SE (change) = .49], than for the RFM group, [M (change) =-.9), SE (change)], F (1,91) = 93.80, $p < .001$, partial $\eta^2 = .45$.

3.2 Assessment of Psychosocial Differences

3.2.1 Pain Intensity

Mixed-model analyses of variance (ANOVAs) were computed for pain intensity, which showed that there was a significant main effect of time from pre to post treatment, F (1, 188) = 103.35, $p < .001$, partial $\eta^2 = .36$, and a significant main effect for the groups of LFM, RFM, an lumbar only, F 2, 188) = 4.06, $p = .02$, partial $\eta^2 = .04$, but no interaction effect between time and the patient groups of LFM, RFM, and lumbar only, F (2, 188) = .44, $p = .64$, partial $\eta^2 = .01$. Post hoc analysis of time revealed that all groups showed a significant decrease in pain intensity from pre to post-treatment. Post hoc analysis of group differences showed marginally significant differences between the RFM and lumbar only groups at both pre and post treatment ($p = .09$). Means and standard deviations are shown in Table 3.1.

Table 3.1 Psychosocial Variable Means and Standard Deviations

Variable, mean (SD)	RFM		LFM		Lumbar Only	
	Pre	Post	Pre	Post	Pre	Post
MVAS	105.0 (25.1)	84.4 (29.9)	102.4 (25.6)	64.4 (32.9)	103.5 (18.5)	67.7 (28.3)
BDI	23.9 (11.6)	18.2 (13.4)	23.3 (12.9)	13.2 (9.4)	19.5 (10.2)	9.8 (7.7)
ODI	46.4 (21.1)	39.0 (18.7)	44.0 (18.2)	27.9 (16.2)	48.0 (15.6)	29.9 (13.7)
PDQ	107.4 (25.7)	84.8 (31.9)	104.6 (23.0)	68.4 (34.4)	102.6 (23.7)	69.2 (27.4)
MHS	33.7 (14.5)	35.9 (20.5)	34.8 (14.7)	42.4 (18.8)	40.3 (9.4)	48.0 (10.4)
PHS	26.1 (11.8)	27.0 (15.5)	27.2 (10.4)	30.7 (13.8)	27.4 (9.7)	35.5 (7.6)
Pain Intensity	7.5 (2.0)	5.6 (3.3)	7.1 (1.9)	4.7 (2.2)	6.9 (1.7)	4.7 (2.3)
HRSD	15.2 (12.2)	6.9 (9.0)	12.8 (14.2)	4.7 (9.7)	18.0 (6.0)	8.9 (4.8)

3.2.2 Disability Measures

3.2.2.1 MVAS

There were overall significant main effects for time, F (1, 184) = 165.28, p < .001, partial η^2 = .47, and for patient group, F (2, 184) = 4.70, p = .01, partial η^2 = .05, as well as a significant interaction effect between time and patient group, F (2, 184) = 5.29, p = .01, partial η^2 = .05. Post hoc analysis for the main effect of time revealed that all three groups showed significant decreases on the self-reported disability measure of the MVAS. Post hoc analysis for the main effect of group showed that while there were no significant differences between the LFM, RFM, and lumbar only groups at pre-treatment, the RFM group had significantly more self-reported disability than the LFM and lumbar only groups (p < .01). Examination of the interaction effect showed that while all patients improved from pre to post, the RFM group had a smaller decrease in self-reported disability than the other two groups.

3.2.2.2 PDQ

There was a significant main effect for time, F (1, 186) = 173.17, p < .001, partial η^2 = .48, as well as a significant main effect for patient group, F (2, 186) = 3.13, p = .05, partial η^2 = .03. There was also a significant interaction effect between time and group, F (2, 186) = 3.13, p = .05, partial η^2 = .03. Post hoc analysis revealed that all groups showed significant improvement from pre to post-treatment on self-reported disability as measured by the PDQ, and that the RFM group showed the least amount of mean change, as seen above with the MVAS. While there were no significant differences between the LFM, RFM, and lumbar only groups at pre-treatment, at post-treatment, the RFM group had significantly more self-reported disability than both the LFM (p = .02) and the lumbar only (p = .01) groups.

3.2.2.3 ODI

There was a significant main effect of time, F (1, 178) = 90.02, p < .001, partial η^2 = .34, but not a significant main effect for group, F (2, 178) = 2.79, p = .06, partial η^2 = .03. The interaction effect between time and group was, however, significant, F (2, 178) = 5.56, p = .01,

partial η^2 = .06. Post hoc analysis revealed that all patients significantly decreased their self-reported disability as measured by the ODI from pre to post-treatment, and that the RFM patients showed the least amount of change from pre to post when compared to the LFM and lumbar only group.

3.2.3 Health-related Quality of Life

3.2.3.1 SF-36 Mental Health Summary (MHS)

There were significant main effects for both time, F (1, 175) = 25.27, p < .001, partial η^2 = .13, and for patient group, F (2, 175) = 9.84, p < .001, partial η^2 = .10, but no significant interaction between time and patient group, F (2, 175) = 2.62, p = .08, partial η^2 = .03. Analysis of main effect post hocs revealed that the LFM and lumbar only groups (p < .001) showed a significant increase in mental health-related quality of life improvement on the MHS, but the RFM group did not (p = .25). Additionally, at pre-treatment, the RFM had a significantly lower score on the MHS when compared to the lumbar only group (p < .01), and this remained at post-treatment (p < .001).

3.2.3.2 SF-36 Physical Health Summary (PHS)

There was a significant main effect for both time, F (1, 175) = 16.08, p < .001, partial η^2 = .08, and patient group, F (2, 175) = 6.09, p = .01, partial η^2 = .07. There was also a significant interaction effect between time and patient group, F (2, 175) = 4.43, p = .01, partial η^2 = .05. Post hoc analyses revealed that while the lumbar only group significantly improved their physical health-related quality of life score from pre to post treatment (p < .001), neither the LFM nor the RFM group did so (p = .08 and p = .56; respectively). Though there were no significant differences between the RFM, LFM, and lumbar only groups at pre-treatment, at post-treatment, the RFM group had significantly lower physical health-related quality of life as measured by the PHS than the lumbar only group (p < .001).

3.2.4 Depressive Symptoms

3.2.4.1 BDI

There were significant main effects for both time, F (1, 187) = 91.87, p < .001, partial η^2 = 33, and group, F (2. 187) = 9.09, p < .001, partial η^2 = .09, but there was no significant interaction effect, F (2, 187) = 2.73, p = .07, partial η^2 = .03. Post hoc analysis revealed that all three groups of LFM, RFM, and lumbar only showed significant improvements in self-reported depressive symptoms, as measured by the BDI, from pre to post-treatment. At pre-treatment, there were no significant differences between the three groups, but at post-treatment, the RFM group had significantly more depressive symptoms than both the LFM (p = .05) and lumbar only (p < .001) groups.

3.2.4.2 HRSD

There was a significant main effect for time, F (1, 119) = 123.94, p < .001, partial η^2 = .5, as well as for group, F (2, 119) = 3.27, p = .04, partial η^2 = .05, though there was no significant interaction effect between time and group, F (2, 119) = .18, p = .83, partial η^2 = .00. Post hoc analyses revealed that all three groups showed significant improvement from pre to post-treatment in the number of self-reported depressive symptoms, as measured by the HRSD. Additionally, while there were no differences between the LFM, RFM, and lumbar only groups at pre-treatment, the lumbar only group had significantly fewer depressive symptoms than the LFM group at post-treatment (p = .05).

3.3 Assessment of Physical differences – Mixed Model ANOVAs

Due to the disproportionate number of patients with missing data due to invalid testing (n=82), maximum aerobic capacity was not included in any analyses. Aerobic testing was considered invalid if: a) the patient could not complete the test due to fear; b) the patient was on medications such as beta-blockers that prevent the patient from physically exerting the heart muscles; c) the patient could not pedal fast enough to create resistance; d) the patient could not complete at least 2 stages of pedaling with a heart rate greater than 80 beats per minute (bpm).

However, the remainder of the physical variables were calculated as percent normal as discussed in Chapter 2 and analyzed using mixed model ANOVAs, as seen in section 3.2. The means and standard deviations for each variable are shown in Table 3.2.

Table 3.2 Physical Variable Means and Standard Deviations

Variable, mean (SD)	RFM		LFM		Lumbar Only	
	Pre	Post	Pre	Post	Pre	Post
PILE WS	21.7 (25.0)	56.7 (30.7)	19.6 (18.5)	68.0 (31.1)	34.7 (25.6)	84.9 (23.5)
PILE FW	15.9 (22.4)	60.8 (33.6)	14.6 (15.0)	74.0 (31.7)	20.4 (21.6)	90.4 (30.5)
Isokinetic WS	27.9 (32.4)	75.1 (36.0)	37.4 (34.0)	90.5 (40.4)	N/A	N/A
Isokinetic FW	21.0 (30.7)	77.3 (96.0)	21.6 (23.9)	77.1 (31.5)	29.4 (32.8)	85.9 (30.6)
Isokinetic Trunk Strength	11.2 (19.7)	48.7 (70.3)	5.3 (11.9)	60.9 (25.3)	11.0 (17.7)	54.1 (21.8)
Total Lumbar ROM	73.4 (44.3)	130.8 (42.2)	73.9 (40.5)	135.6 (48.0)	89.6 (41.6)	156.5 (33.0)

3.3.1 Lifting Capacity

3.3.1.1 PILE WS

There was a significant main effect of both time, F (1, 170) = 454.10, p < .001, partial η^2 = .73, and patient group, F (2, 170) = 15.49, p < .001, partial η^2 = .15. There was also a significant interaction effect between the two variables, F (2, 170) = 5.94, p < .01, partial η^2 = .07. Post hoc analysis of the time variable showed that all variables showed significant improvements of the PILE WS lift task from pre to post-treatment, but that the RFM group showed significantly less change from pre to post-treatment. Additionally, post hoc analysis of the grouping variable showed that both FM groups had significantly lower scores on the PILE WS than the lumbar only group at pre-treatment (p < .01), and at post-treatment (p < .01).

3.3.1.2 PILE FW

There was a significant main effect for time, F (1, 168) = 598.00, p < .001, partial η^2 = .78, as well as a main effect for patient group, F (2, 168) = 10.02, p < .001, partial η^2 = .11. There was also a significant interaction effect between the two variables of time and patient group, F (2, 168) = 11.57, p < .001, partial η^2 = .12. Post hoc analysis of the time variable showed that all three patient groups increased their scores on the PILE FW lift task, though the RFM group showed less change from pre to post-treatment than both the LFM and the lumbar only group. Examination of the group difference post hocs showed that while there were no significant differences in the PILE FW lift task at pre-treatment, at post-treatment, the lumbar only group had significantly higher scores than the LFM group (p = .03) and the RFM group (p < .001).

3.3.1.3 Isokinetic WS Lift

There was a significant main effect for time, F (1, 80) = 16.87, p < .001, partial η^2 = .17, but not a significant effect for patient group, F (2, 80) = 1.84, p = .17, partial η^2 = .05. There was not a significant interaction effect between the two variables either, F (2, 80) = .59, p = *.56,* partial η^2 = .02. Post hoc analyses of the time variable revealed that both FM groups showed

significant improvement on the Isokinetic WS lift task from pre to post-treatment ($p < .001$). Lumbar only patients were not included in this analysis because the Isokinetic WS lift is only required of patients with an upper extremity or cervical injury.

3.3.1.4 Isokinetic FW Lift

There was a significant main effect for time, F (1, 153) = 135.00, $p < .001$, partial η^2 = .47, but a non-significant main effect for patient group, F (2, 153) = .97, p = .38, partial η^2 = .01. Neither was there a significant interaction effect between these two variables, F (2, 153) = .00, p = .99, partial η^2 = .00. Examination of post hocs for time showed that all three groups of LFM, RFM, and lumbar only patients showed significant increase in the Isokinetic FW lift task score from pre to post-treatment ($p < .001$).

3.3.2 Isokinetic Trunk Strength

There as a significant main effect for time, F (1, 145) = 171.9, $p < .001$, partial η^2 = .54, but not a significant main effect for patient group, F (2, 145) = .17, p = .17, partial η^2 = .00. There was also not a significant interaction effect between the two variables, F (2, 145) = 1.92, p = .15, partial η^2 = .03. Post hoc analysis of the time variable showed that all three patient groups showed significant improvement from pre to post-treatment on the Isokinetic Trunk Strength measure ($p < .001$).

3.3.3 Total Lumbar ROM

There was a significant main effect for time, F (1, 162) = 415.17, $p < .001$, partial η^2 = .72, as well as for the variable of patient group, F (2, 162) = 6.24, $p < .01$, partial η^2 = .07. However, there was no significant interaction effect between the two variables, F (2, 162) = 1.14, p = .32, partial η^2 = .01. Post hoc analysis of the time variable showed that all groups showed significant improvement from pre to post-treatment. Post hoc analysis of patient group differences revealed that while there were no significant differences between the LFM, RFM, and lumbar only groups at pre-treatment, at post-treatment, the lumbar only group had a

significantly higher total lumbar ROM score than bot the LFM (p = .04) and the RFM group (p = .001).

3.4 Assessment of Physical Differences – Percent Zero Analysis

Since few physical measures were significant at pre-treatment, a percent zero analysis was conducted. Variables were dichotomized into two groups: a score of zero at pre-treatment (indicating the patient could not complete the test or was not willing to attempt the test) or any other score. Results are depicted in Table 3.3. The RFM group was significantly more likely to score a zero on the WS PILE at pre-treatment than both the LFM group and the lumbar only group (z = 5.4), and the LFM group was significantly more likely to score a zero than the lumbar only group, z = -3.2. While not significant (p < .07), the same pattern held for the FW PILE scores, with the RFM group more likely to score a zero than both the LFM and the lumbar only group.

Table 3.3. Percent Zero Analysis of Physical Variables at Pre-treatment

Variable, n (% 0)	LFM	RFM	Lumbar Only	X^2	p value	Effect Size
PILE WS	8 (17%)	21 (31%)	10 (11%)	11.33	.003	.23
PILE FW	17 (36%)	30 (45%)	26 (27%)	5.28	.07	.16
Isokinetic WS	9 (19%)	21 (31%)	0 (0%)	32.50	< .001	.39
Isokinetic FW	16 (34%)	30 (45%)	30 (32%)	3.10	.21	.12
Trunk Extension	22 (47%)	31 (46%)	47 (50%)	.19	.91	.03
Total ROM	0 (0%)	0 (0%)	0 (0%)	N/A	N/A	N/A

On the WS Isokinetic lift, no lumbar patients scored a zero, which was significantly fewer patients than both the RFM and the LFM group, z = -5.4. The RFM group was also significantly less likely to score at zero than the LFM group, z = 4.8. All patients completed the ROM task. No other differences were found in percent zero analysis of physical measures at pre-treatment.

Since pre-treatment percent zero analysis of physical measures yield several significant findings, the same analysis was also run at post-treatment. Very few differences remained between the three groups at post-treatment, since most patients no longer scored a zero on their physical tests at post-treatment as they did at pre-treatment. Of note is the fact that no one scored a zero on the Isokinetic WS lift task and on the total ROM task in any of the three groups, and that the only group to have a zero on the PILE WS, PILE FW, and Isokinetic FW lift task was the RFM, though this was not significant due to the low n. The RFM group was significantly more likely to score at zero on the Isokinetic trunk strength measure at post-treatment (z = 3.6) as well. Results of the post-treatment percent zero analysis can be seen in Table 3.4.

Table 3.4 Percent Zero Analysis of Physical Variables at Post-treatment

Variable	LFM	RFM	Lumbar Only	X^2 value	*p* value	Effect Size
PILE WS, n (% 0)	0 (0%)	1 (2%)	0 (0%)	2.13	.35	.10
PILE FW, n (% 0)	0 (0%)	1 (2%)	0 (0%)	2.13	.35	.10
Isokinetic WS, n (% 0)	0 (0%)	0 (0%)	0 (0%)	N/A	N/A	N/A
Isokinetic FW, n (% 0)	0 (0%)	1 (2%)	0 (0%)	2.13	.35	.10
Trunk Extension, n (% 0)	0 (0%)	6 (9%)	0 (0%)	13.09	.001	.25
Total ROM, n (% 0)	0 (0%)	0 (0%)	0 (0%)	N/A	N/A	N/A

3.5 Assessment of Psychiatric Disorder Differences

All DSM IV diagnoses (American Psychiatric Association, 1994) were recorded by the clinician during the Psychosocial Clinical Interview. However, the only diagnoses analyzed here are the Axis I disorders of Major Depressive Disorder (MDD), Bipolar Disorder, Generalized Anxiety Disorder (GAD), Substance Abuse, Opiate Dependence, Pain Disorder, and a created variable that combines all of the anxiety disorders together (any anxiety disorder). Frequencies among the LFM, RFM, and lumbar only groups were significantly different on several Axis I disorders (Table 3.5). Lumbar only patients were significantly less likely to be diagnosed with Major Depressive Disorder (MDD) than both FM groups, z = -2.5. The RFM group was

significantly less likely to be diagnosed with substance abuse than the LFM and lumbar only groups (z = -2.5), and they were also significantly less likely to be dependent on opioids, z =-2.4. However, the RFM group was significantly more likely to be diagnosed with Pain Disorder, z = 1.4.

Among the Axis II personality disorders, no significant differences existed between the LFM, RFM, and lumbar only groups, even when the personality disorders were grouped into clusters (Table 3.6). While the number of patients diagnosed with these disorders is low, and thus *p* value is expected to be low, the effect size for the analysis of Axis II personality disorder differences was also very small (the largest being .15).

Table 3.5 Prevalence of Axis I Psychiatric Disorders

Variable	LFM	RFM	Lumbar Only	X^2 Value	*p* Value	Effect Size
Major Depressive Disorder, n (%)	28 (60%)	37 (55%)	38 (40%)	6.21	.05	.17
Bipolar Disorder, n (%)	1 (2%)	0 (0%)	0 (0%)	3.46	.18	.13
Generalized Anxiety Disorder, n (%)	10 (21%)	18 (27%)	20 (21%)	.85	.65	.06
Substance Abuse, n (%)	7 (15%)	2 (3%)	14 (15%)	6.48	.04	.18
Opiate Dependence, n (%)	6 (13%)	2 (3%)	14 (15%)	6.08	.05	.17
Any Anxiety Disorder, n (%)	16 (34%)	23 (34%)	24 (25%)	1.97	.37	.10
Pain Disorder, n (%)	29 (62%)	45 (67%)	36 (38%)	14.98	.001	.27

Table 3.6 Prevalence of Axis II Psychiatric Disorders

Variable	LFM	RFM	Lumbar Only	X^2 Value	*p* value	Effect Size
Any Cluster A Disorder (n, % yes)	2 (2%)	7 (10%)	7 (7%)	2.88	.24	.12
Cluster A Personality Disorders (n, % yes)						
Paranoid	1 (2%)	6 (9%)	5 (5%)	2.45	.29	.11
Schizoid	1 (0%)	1 (2%)	1 (1%)	.67	.72	.06
Schizotypal	0 (0%)	0 (0%)	1 (1%)	1.21	.55	.08
Any Cluster B Disorder (n, % yes)	7 (15%)	10 (15%)	15 (16%)	.22	.90	.03
Cluster B Personality Disorders (n, % yes)						
Antisocial	0 (0%)	2 (3%)	0 (0%)	4.28	.11	.14
Borderline	4 (9%)	3 (5%)	5 (5%)	.90	.64	.07
Histrionic	1 (2%)	0 (0%)	3 (3%)	2.10	.35	.10
Narcissistic	2 (4%)	5 (8%)	7 (7%)	.58	.75	.05
Any Cluster C Disorder (n, % yes)	3 (6%)	7 (10%)	11 (12%)	.96	.62	.07
Cluster C Personality Disorders (n, % yes)						
Avoidant	0%)	0 (0%)	0 (0%)	N/A	N/A	N/A
Dependent	1 (2%)	0 (0%)	4 (4%)	3.00	.22	.12
Obsessive-Compulsive	2 (4%)	7 (10%)	7 (7%)	1.52	.47	.09

3.6 One-year Outcome Differences

One-year outcomes are presented in Table 3.7. Outcomes were significantly different among the three groups on measures of work retention (p = .03, W = .02), with the lumbar only group having the highest work retention rate (82%), and the LFM and RFM groups having similarly low retention rates (59% and 60%, respectively). Work return was marginally significantly different among the three groups (p = .07). There were no significant differences among any of the three groups in health care utilization or the number of new surgeries and injuries at one year after discharge.

Table 3.7 Comparison of One-year Outcome Measures Between LFM, RFM, and Lumbar Only Groups

Variable	RFM	LFM	Lumbar Only	F/ χ^2 value	*p* value	Effect Size
Return-to-Work, n (% yes)	27 (77%)	21 (72%)	64 (89%)	4.74	.07	.02
Work Retention, n (% yes)	21 (60%)	17 (59%)	58 (82%)	8.17	.03	
Health Care Utilization, n (% yes)	7 (18%)	4 (13%)	10 (14%)	.54	.73	
Surgery on Original Injury n (% yes)	2 (5%)	1 (3%)	5 (7%)	.48	.81	
New Injury n (% yes)	1 (3%)	0 (0%)	0 (0%)	2.59	.26	
Number of Treatment Seeking Visits, mean (SD)	2.4 (7.2)	1.5 (5.6)	.9 (3.8)	.95	.39	

3.7 Prediction of LFM and RFM Designation

A sequential logistic regression analysis was used to predict whether patients would lose or retain the FM diagnosis at post-treatment based upon the significant or marginally significant demographic, psychosocial, psychiatric, and physical variables in the MANOVAs at pre-treatment. The model contained two blocks: the first with the significant physical variables of the percent zero PILE WS, PILE FW, WS Isokinetic lift, and total ROM score; the second the significant psychiatric variables of MDD, substance abuse, opioid dependence, and pain disorder.

Block one (physical variables) did not significantly contribute to prediction of the LFM and RFM designation, χ^2 (4, N = 84) = 3.23, p = .52. Block two (psychiatric disorders) was found to be a marginally significant predictor of LFM and RFM designation at post-treatment, χ^2 (3, N = 84) = 7.52, p = .06. Even with the addition of block two, however, the overall model does not significantly predict which patients will lose or retain the diagnosis of Fibromyalgia at post-treatment, χ^2 (7, N = 84) = 10.77, p = .15. Table 3.8, shows the final step of the sequential regression analysis, with all variables at the final block. Please note that according to the Wald criteria, substance abuse is the only variable to significantly predict LFM and RFM designation.

Binary logistic regression analysis was run a second time, using only substance abuse as a predictor of FM status at post-treatment. Results showed that substance abuse was a significant predictor of LFM and RFM designation, χ^2 (1, N = 114) = 5.43, p = .02. The null model had a 59% chance of correctly classifying cases to either the LFM or RFM group. When substance abuse was included, the chance of correctly classifying cases was increased to 63%, which is a 4% increase from the null model (chance). General guidelines for classification accuracy indicate that a good predictor should improve the classification accuracy by 25% or more. Including substance abuse accounted for 6% of the variance in this model, Nagelkerke R^2 = .06, indicating poor model fit. Table 3.9 shows the regression coefficient, standard error, Wald

statistic, and odds ratio for binary logistic regression model with only substance abuse as a predictor.

Table 3.8 Sequential Logistic Regression Analysis for Prediction of LFM and RFM Designation – All Variables at Final Block

Variable	B	SE	Wald	*p*	Exp B
Percent Zeros: PILE WS	1.15	.76	2.31	.13	3.16
Percent Zeros: PILE FW	-.20	.65	.09	.77	.82
Percent Zeros: Isokinetic WS	.39	.68	.32	.57	1.47
Total ROM	-.00	.01	.17	.68	1.0
MDD	.87	.57	2.34	.13	2.39
Substance Abuse	2.20	.10	4.90	.03	9.05
Pain Disorder	-.94	.64	2.14	.14	.39
Constant	-1.36	.85	2.55	.11	.26

Table 3.9 Logistic Regression Analysis for Prediction of LFM and RFM Designation – Substance Abuse Only

Variable	B	SE	Wald	*p*	Exp B
Substance Abuse	1.74	.83	4.42	.04	5.69

CHAPTER 4

DISCUSSION

The overarching goal of the present study was to examine Fibromyalgia in the context of a functional restoration program developed for patients with CDOMD. In particular, this study examined the prevalence rates of FM, the stability of the FM diagnosis from pre to post-treatment, the effectiveness of treating FM with tertiary rehabilitation such as FR, and the characteristics of two groups of FM patients: those who lost the diagnosis of FM at post-treatment and those who retained the diagnosis at post-treatment.

4.1 Assessment of FM, CWP, and Tender Point Count at Post-Treatment

After completion of the FR program, nearly half (41%) of patients no longer met the ACR 1990 diagnostic criteria from FM (F. Wolfe et al., 1990). The majority of the patients (50%) who lost the FM diagnosis at post-treatment did so by decreasing the number of tender points to < 11 while still reporting CWP, though a substantial percentage (35%) had neither the required number of tender points nor the presence of widespread pain. As expected, patients who lost the diagnosis (LFM group) had a significant change in tender point number from pre to post-treatment, but those who retained the FM diagnosis (RFM group) did not.

Few studies (Bennett et al., 1996; Robinson et al., 2010; Richards & Scott, 2002) have evaluated the change in tender point count and thus the loss or retention of the FM diagnosis after treatment intervention, most likely because FM is considered a chronic and stable condition that patients do not recover from. However, results from these three studies indicated that between 30% and 70% of patients no longer met diagnostic criteria for FM at post-treatment, and the results from the current study are consistent with those findings, especially since patients in the current study underwent FR treatment, which is a highly rigorous treatment program for the most severely disabled. While it is tempting to say that the LFM patients were

"cured," these findings must be interpreted with caution. The 1990 ACR diagnostic criteria (F. Wolfe et al., 1990) for FM, used in this study, while intended to be as objective as possible, may pose limitations. Several authors have pointed out that tender point counts in FM populations may be somewhat transient and easily influenced by stressors and other psychosocial factors, such as anxiety, depression, and fatigue (J. McBeth, MacFarlane, Benjamin, Morris, & Silman, 1999; Maquet, Croisier, Demoulin, & Crielaard, 2004; Croft et al., 1996; F. Wolfe, 1997). In fact, the ACR has recently adopted alternative criteria for FM, which eliminates manual tender point evaluations, and accounts for other symptoms within the diagnostic criteria, including fatigue, unrefreshed sleep, and cognitive problems (F. Wolfe et al., 2010).

4.2 Assessment of Psychosocial Differences

Very few psychosocial pre-treatment differences existed between the LFM, RFM, and lumbar only groups. The RFM group exhibited higher pain intensity and a lower mental-health related quality of life, but no other psychosocial differences were detected. These findings are not surprising, and that FM patients are known to have high pain intensity. In addition, FM is part of a larger group of diagnoses called Central Sensitivity Syndromes (CSSs), in which one of the central hallmarks of a CSS is hyperalgesia and allodynia (M. B. Yunus, 2008). Additionally, extremely high pain intensity has been linked to poor treatment program outcomes, which the RFM group exhibits (McGeary, Mayer, & Gatchel, 2006).

Generally, the RFM group had worse psychosocial outcomes at post-treatment when compared to either the LFM or the lumbar only groups. The RFM group showed significantly more depressive symptoms and less health-related quality of life than the lumbar only group and significantly more pain intensity than both the lumbar only and the LFM groups. The RFM group also exhibited significantly higher scores on disability measures than both the lumbar only and the LFM groups. Of note is the fact that the LFM group was statistically similar to the lumbar only group on all psychosocial post-treatment measures, and even had higher raw scores on the disability measures of the MVAS and the ODI. This is indicative of the success of

the FR program, since the 41% of patients who no longer met diagnostic criteria for FM at post-treatment are now as recovered as patients suffering only from a lumbar injury.

The pattern of the above findings at post-treatment, depicting increased health-related quality of life, and decreased depressive symptoms, pain intensity, and self-reported disability is typical of patients undergoing a functional restoration treatment program (C. Anagnostis, Mayer, Gatchel, & Proctor, 2003; C. Anagnostis et al., 2004; R. J. Gatchel et al., 2006).

The RFM group's lack of recovery is not unexpected. First, as stated in the introduction section, FM patients are well-known to be severely disabled (Giamberardino, 2008; D. A. Marcus, 2009; Waylonis et al., 1994), with up to 25% of patients receiving some form of disability payment (F. Wolfe et al., 1997). Therefore, while the LFM group significantly increased their overall functioning, the RFM group's behavior remained consistent with the general clinical picture of FM, especially since it is estimated that between 26% and 71% of FM patients have a depressive disorder (Bradley & Alberts, 1999; Epstein et al., 1999; Giesecke et al., 2003; Kurland et al., 2006; Hudson, Goldenberg, Pope, Keck, & Schlesinger, 1992).

Second, a previous study by our group on FM that did not dichotomize patients into subgroups found that all FM patients had more depressive symptoms, more pain intensity, more self-reported disability, as seen in the MVAS and PDQ disability assessments, and less health-related quality of life, as assessed by the SF-36 Physical and Mental Health summaries (Howard et al., 2010). Other studies have also found low health-related quality of life in FM patients (Verbunt, Pernot, & Smeets, 2008).

All three groups showed significant pre to post improvements on all psychosocial measures, including the BDI, all three measures of perceived disability (MVAS, PDQ, and ODI), perceived pain intensity, and both the mental and physical health components of the SF-36. However, significantly greater mean change from pre to post-treatment was exhibited in the lumbar only group and the LFM group as opposed to the RFM group on all three disability measures, and there was significantly more mean change on the SF-36 Physical and Mental

Health Summaries n the lumbar only group than in the RFM group. There were no differences in the amount of mean change for the remainder of the psychosocial variables.

4.3 Assessment of Physical Differences

At pre-treatment, lumbar only patients scored significantly higher on the WS PILE than both FM groups. Lumbar only patients were also less likely to score zeros on the WS PILE, perhaps because this was not the area in which they sustained major injury. The LFM group was significantly less likely to score a zero on the WS Isokinetic lift than the RFM group. All patients completed the ROM task, which is not surprising, given that the task does not have a heavy physical demand level and that bending, while potentially frightening or difficult for the most disabled patient, does not present the same physical and psychosocial difficulties lifting does.

While studies have shown that poor cardiovascular fitness may be linked to decreased physical performance in patients with low back pain (Cady, Bischoff, O'Connell, Thomas, & Allan, 1979; Schmidt, 1985), this study was unable to include an aerobic capacity measurement due to the high proportion of patients whose aerobic capacity testing was invalid. This finding is consistent with another study done by our group on aerobic capacity, although the number of patients with an invalid aerobic test is lower, perhaps because testing was performed on a typical CDOMD population and not on a FM population with significant psychosocial distress and high levels of disability (Protas et al., 2004).

While several studies have evaluated the physical capacity of FM in terms of aerobic functioning (McCain et al., 1988; Buckolow et al., 1992; K. Mannerkorpi et al., 2000), only a few have evaluated strength training, and even fewer reported results of the physical tests (Jones et al., 2002; Häkkinen, Häkkinen, Hannonen, & Alen, 2001). It is assumed that the FM patients were relatively weak at pre-treatment, given the estimate that FM patients are 20-30% weaker than their peers (Bennett et al., 1989; Simms, 1996) and are estimated to have a 59% reduction in voluntary muscle contraction (C. M. Henriksson, Liedberg, & Gerdle, 2005).

There were also a multitude of physical differences at post-treatment between the lumbar only, LFM, and RFM groups. The lumbar only group scored significantly higher on both the PILE WS and PILE FW, as well as had a larger range of motion, than both of the Fibromyalgia groups. While the LFM group was not statistically similar to the lumbar only group on all physical measures, as it was for the psychosocial measures, the LFM group still was physically more similar to the lumbar only group than to the RFM group. Again, this is indicative of recovery; studies have shown that lumbar patients perform as well, or sometimes better than, a normative sample on physical capacity measures at post-treatment (Curtis, Mayer, & Gatchel, 1994).

It is interesting to note that percent zero analysis, while a lucrative analysis at pre-treatment, yielded few significant results at post-treatment. This was due to the fact that there were no zeros scored in any group on the Isokinetic WS lift task, and the total lumbar ROM task, and that only one zero was scored, in the RFM group only, for the physical measures of PILE WS, PILE FW, and the FW Isokinetic lift task. While this finding was not significant due to the low sample size, it remains an interesting finding. Only on the trunk strength measure was the RFM group significantly more likely to score a zero at post-treatment than both the LFM and lumbar only groups. The lack of patients scoring zeros at post-treatment indicates psychosocial recovery, since the psychosocial barriers (such as fear or secondary gain) to task completion were removed. In addition, patients complete the same battery of physical tasks periodically throughout the program, and effort continually increases from pre to post treatment (Brady, Mayer, & Gatchel, 1994).

Few studies have evaluated the physical differences between FM patients and the general population. However, minimal to moderate strength improvements have been noted after exercise programs in FM patients (Gusi, Tomas-Carus, Häkkinen, Häkkinen, & Ortega-Alonso, 2006; Häkkinen et al., 2001; Jones et al., 2002).

All three groups showed significant change on all physical functioning measures from pre to post-treatment, indicating a positive effect of the FR treatment program. This finding is consistent with other literature on function capacity testing in functional restoration (T. G. Mayer et al., 1986; T. Mayer, Tabor, Bovasso, & Gatchel, 1994; Brady et al., 1994; Curtis et al., 1994). The lumbar only group showed a significantly greater amount of change from pre to post-treatment than both FM groups, however, on both PILEs. There were no other significant differences between the three groups on pre to post change.

Results of this analysis show that while LFM patients may be psychosocially similar to lumbar only patients, the LFM group still lacks the physical functioning gains that would completely equate them with the lumbar only group. Although, given FM patients' reputation for being physically unfit for even basic activities of daily living tasks (Waylonis et al., 1994; C. Henriksson & Liedberg, 2000), the fact that LFM patients show up to a 57 point increase on measures of physical functioning is encouraging, even if they do not completely match pace with the lumbar only group.

4.4 Assessment of Psychiatric Disorder Differences

Examination of Axis I and Axis II disorders at pre-treatment showed that lumbar only patients were significantly less likely to be diagnosed with MDD, which is expected, given the high prevalence of depression among FM (Bradley & Alberts, 1999; Epstein et al., 1999; Giesecke et al., 2003; Kurland et al., 2006) and CWP (T. G. Mayer, Towns, Neblett, Theodore, & Gatchel, 2008) patients. Also expected was the fact that RFM patients were significantly more likely to be diagnosed with pain disorder than both the LFM and lumbar only groups, which goes along with their higher pain intensity ratings at pre-treatment. FM patients have been found to be more likely to have somatization disorder (Aaron et al., 1996), which is in the same category (somatoform disorders) as pain disorder, and somatization in general has been found to predict the onset of CWP (J. McBeth, Macfarlane, Benjamin, & Silman, 2001). FM has also been intermittently classified as a medically unexplained illness (MUI; Johnson, 2008), and the

presence of MUIs is highly linked to somatization. Literature also indicates that after development of a work-related injury, CDOMD patients are more likely to be diagnosed with MDD and pain disorder (Dersh et al., 2007), and FM patients are the most problematic of CDOMD patients.

RFM patients were significantly less likely to be diagnosed with substance abuse and to be dependent on opioids. While initially this seems counterintuitive, Marcus states that FM patients may be more motivated to improve than other chronic pain populations, and this may explain their lack of substance abuse/opiate dependence (D. A. Marcus, 2009). These results may also be explained by a difference in the way substance abuse and opiate dependence is being diagnosed in the clinic. Recently, the clinicians ask only if the patient is using his or her medication as prescribed, and if the answer is yes, than the patient does not meet criteria for opiate dependence, even if the patient would meet DSM IV diagnostic criteria (American Psychiatric Association, 1994). Since all of the lumbar only patients came from 2005-2006, when substance abuse and opiate dependence were still being evaluated only by strict DSM IV criteria, this may account for the reason why the FM groups have significantly lower substance abuse and opiate dependence.

There were no significant differences between any of the three groups on the Axis II personality disorders, even when the personality disorders were grouped into clusters. While one can easily imagine that FM patients would have a higher percentage of personality disorders than the general population, no studies are known to the author in which this finding has been confirmed (T. G. Mayer et al., 2008), thus the results of this study are in line with recent literature.

4.5 Assessment of One-year Outcome Differences

There was relatively little difference between the LFM, RFM, and lumbar only groups on one-year outcomes; the only significant difference was in work retention, with the lumbar only group significantly more likely than both FM groups to retain work after returning back to it.

These findings were not unexpected given the results of a previous FM study showing poor work return and work retention rates, with female FM patients exhibiting especially low work retention rates. It was, however, the researcher's fervent hope that once FM patients were split into the LFM and RFM designation, the RFM group would be found to have significantly lower work return and work retention rates, thus explaining why all FM patients had such poor work outcomes. This begs the question, though: why did LFM patients have such good psychosocial and physical outcomes at post-treatment, and yet not maintain those gains at one-year? Perhaps these findings in themselves support the notion of FM as a transient diagnosis; patients may exhibit many signs of recovery while actively in a program, but find it relatively easy to slip back into the disability role without extra supervision or after stressful life events. Certainly, as discussed above, the diagnostic criteria itself can be influenced by such things (Croft et al., 1996; J. McBeth et al., 1999; F. Wolfe, 1997). Perhaps an examination of outcomes at three or six months would be lucrative in understanding the differences between FM groups and the lumbar only group on socioeconomic outcomes.

Surprisingly, there were no significant differences between any of the three groups on health care utilization, the number of new surgeries, or the number of new injuries. It is well known that FM patients have a high rate of health-care utilization (Hughes et al., 2006), and the lack of this finding may speak to the efficacy of the FR treatment program. There was also no significant difference on the percentage of patients who had returned to work in the one year after discharge; this may be due to the fact that many FM patients continue working with modifications, such as reducing the number of hours worked or changing work hours to start later in the day, taking short breaks during the work day, and working from home (C. M. Henriksson et al., 2005). In fact, this phenomenon is so common that the U.S. Department of Labor's Job Accommodation Network (JAN) put together a special bulletin on how employers can accommodate employees with FM (Loy, U.S. Department of Labor's Office of Disabilty Employment Policy, & Job Accommodation Network, 2011).

Work return and work retention are also influenced by many other factors. For instance, psychological distress, fear-avoidance (Dersh et al., 2007), difficulty securing a job after post-treatment (T. G. Mayer, Gatchel, & Prescott, 2002), presence of somatization (Campello, Weiser, Nordin, & Hiebert, 2006), higher self-report scores on pain (McGeary et al., 2006), a history of early childhood abuse (McMahon, Gatchel, Polatin, & Mayer, 1997), pre-treatment surgery (T. Mayer et al., 1998) and demographic factors such as age, gender, and marital status (Brede, 2011) must all be considered.

4.6 Prediction of LFM and RFM Designation

A sequential logistic regression analysis was done using all significant variables from the multivariate analyses in order to predict which patients would lose or retain the FM diagnosis at post-treatment. However, very few differences between the three groups were present at pre-treatment, and even fewer existed solely between the LFM and RFM groups. Logistic regression analysis revealed that the single significant predictor of LFM/RFM designation was substance abuse, which was an extremely weak predictor, with only 4% increase in prediction from chance and accounting for only 6% of the variance. This lack of significant predictors most likely speaks to the lack of physical and psychosocial differences at pre-treatment. The question thus remains: what happens during FR treatment to distinguish these patients? Perhaps there may be differences at pre-treatment that are not measured in this particular FR program, such as coping style (D. C. Turk, Okifuji, Sinclair, & Starz, 1996; Walen, Cronan, Serber, Groessl, & Oliver, 2002), affect (Zautra, Johnson, & Davis, 2005), stress levels (Aaron et al., 1996; Schwartz & Thompson, 2003; Johnson, 2008; Kivimäki et al., 2004), childhood trauma (Abeles et al., 2007; Goldberg & Goldstein, 2000), or other unidentified factors.

4.7 Conclusions on FR Treatment for Fibromyalgia Patients

Functional Restoration, while proven highly efficacious for CDOMD populations (Kolata, 2004; Productive Rehabilitation Institute of Dallas for Ergonomics, 2011), has not been

evaluated for use with such a specialized population as FM until recently (Howard et al., 2010; Hartzell et al., 2012). Results show that with FR treatment, 41% of FM patients lose the FM 1990 ACR diagnostic criteria at post-treatment, which is astounding. Researchers consider FM a stable, chronic disorder and frequently do not evaluate patients for tender point count (and loss of diagnosis) at post-treatment. In addition to losing the diagnosis, this group of patients also showed significant psychosocial improvement at post-treatment, to the extent that they were statistically indistinguishable from lumbar only patients. These patients also showed significant improvement in measures of physical functioning at post-treatment, which is impressive considering the severe levels of disability FM patients are known for. Overall, results indicate that FM patients benefit from FR and therefore FR treatment is recommended for rehabilitation of FM patients in the future.

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BIOGRAPHICAL INFORMATION

Meredith Hartzell is a second year graduate student and graduate teaching assistant at the University of Texas at Arlington. She is currently working on research regarding Fibromyalgia, validation of the Central Sensitization Index (CSI), the use of pain drawings to assess non-organic pain, and assessment of the Patient Health Questionnaire Somatization Scale for use in a CDOMD population.

Meredith received her Bachelor of Arts in Psychology from the State University of New York, College at Oneonta in 2010.