A Randomized Controlled Trial of Muscle Strengthening Versus Flexibility Training in Fibromyalgia

by

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ABSTRACT

Although resistance training has long been accepted as a means for developing and maintaining muscular strength and mass, it has only recently been recognized as a factor to promote health in chronic disease states. *Purpose:* The purpose of this study was to determine the effectiveness of a muscle strengthening program as compared to a stretching program in women with fibromyalgia syndrome (FM). *Methods:* Sixty-eight women with FM ages 28-59 (mean 48) years were randomly assigned to a 12-week, twice weekly exercise program consisting of either muscle strengthening (treatment) or stretching (control). A certified exercise instructor taught both classes. Progressive muscle strengthening exercises were specifically designed to minimize post exercise soreness. For example, exercises were kept near the midline of the body and provided several seconds delay between contractions. The control group performed non-progressive passive stretches. Outcome measures included: weight, body fat, isokinetic dynamometry muscle strength (shoulders and quadriceps), shoulder flexibility, tender point count, total myalgic score, fibromyalgia impact questionnaire (FIQ), and scales for anxiety, depression, self-efficacy and quality of life. The evaluating investigator (KJ) was blinded to group assignment and collected all outcome measures except for body fat and muscle strength (which were collected by a blinded exercise science technician). *Results:* Ninety three percent (n=63) of women returned for post-testing. Final statistical comparisons were made on 56 subjects who attended a majority of classes. Within group testing of pre and post intervention outcome measures showed a significant improvement in both treatment group (14 measures) and control group (7 measures). No statistically significant differences were found on independent t-tests between the treatment and control group. Change scores indicated that all measures, except flexibility, improved more in the treatment group than the control group. Improvements in strength were not associated with worsening in any measured outcome including pain scores.

Conclusion: It is feasible for fibromyalgia patients to take part in a specially tailored muscle-strengthening program and experience an improvement in overall disease activity, without a significant exercise induced flare in pain. Flexibility training alone also results in overall improvements, albeit of a lesser degree.

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CHAPTER I

INTRODUCTION

FM Symptoms and Impact

FM is a common, chronic condition that results in a clinical triad of wide-spread pain, non-restorative sleep and fatigue. The widespread pain of FM is present in at least three of four body quadrants and is commonly described by patients as aching, tender, stiff, throbbing and burning (Burckhardt, Clark & Bennett, 1992). Localized pain in FM patients is present when pressure is applied to selected muscle-tendon junctions; these junctions are termed tender points. The American College of Rheumatology (ACR) provides criteria for classification and diagnosis of FM. The criteria have a sensitivity of 88.4% and a specificity of 81.1% (Wolfe et al., 1990). Table 1 lists the ACR criteria for diagnosing FM. Figure one is a graphic representation of tender point locations described in Table 1.

Table 1

American College of Rheumatology Diagnostic Criteria for Fibromyalgia Syndrome

History of widespread pain of at least 3 months duration
Pain is considered widespread when all of the following are present:

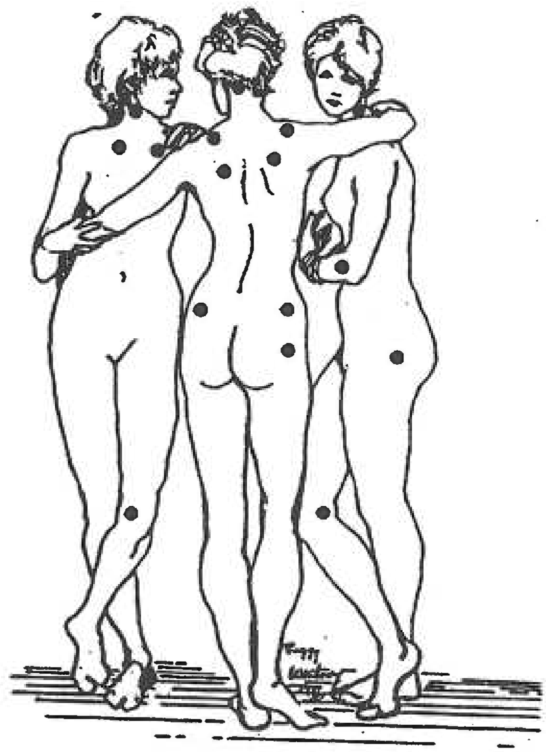
Pain in the left side of the body
Pain in the right side of the body
Pain above the waist
Pain below the waist

In addition, axial skeleton pain (cervical spine or anterior chest or thoracic spine or low back) must be present. Shoulder and buttock pain is considered as pain for each involved side. "Low back" pain is considered lower segment pain.
Pain on digital palpation in 11 of the 18 following sites of tender points:

1. Occiput: bilateral, at the suboccipital muscle insertions.
2. Low cervical: bilateral, at the anterior aspects of the intertransverse spaces at C5-C7.
3. Trapezius: bilateral, at the midpoint of the upper border.
4. Supraspinatus: bilateral, at origins, above the scapular spine near the medial border.
5. Second rib: bilateral, at the second costochondral junctions, just lateral to the junctions on upper surfaces.
6. Lateral epicondyle: bilateral, 2 cm distal to the epicondyles.
7. Gluteal: bilateral, in upper outer quadrants of buttocks in anterior fold of muscle.
8. Greater trochanter: bilateral, posterior to the trochanteric prominence.
9. Knee: bilateral, at the medial fat pad proximal to the joint line.

Reprinted with permission from: Wolfe, F, et al. (1990). The American College of Rheumatology 1990 criteria for the classification of fibromyalgia: Report of the Multicenter Criteria Committee. Arthritis & Rheumatism, 33, 160-172.

Figure 1: Tender Points in Patients with Fibromyalgia Syndrome



Pain elicited in at least 11 of these 18 specific points when digitally palpated is part of the diagnostic criteria for fibromyalgia syndrome. Point tenderness is assessed by the provider applying approximately the amount of pressure required to blanche one's fingernail (4 kgs).

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People with FM also report non-restorative sleep and fatigue. Fatigue may also enhance pain. Researchers are investigating the relationship between fatigue and disrupted sleep. Moldofsky (1993& 1997) demonstrated through sleep studies that patients with FM have frequent alpha wave intrusion resulting in a marked decrease in time spent in deep sleep (Moldofsky & Scarisbrick, 1976; Moldofsky, 1993). He also demonstrated that patients with FM usually get deep sleep in the hour or two immediately before morning awakening unlike most adults whose deepest sleep comes at the beginning of the sleep cycle. Lack of deep sleep and awakening too early could account for patients' complaints of feeling exhausted or unrefreshed even after a full night's sleep.

In addition to the classic FM symptoms of pain, fatigue and disrupted sleep, a constellation of other nonspecific symptoms adds to the FM experience. These commonly include irritable bowel and bladder syndrome, headaches, numbness/parathesias, restless leg syndrome, cold sensitivity, dry eyes and mouth, anxiety, depression and concentration and memory deficits (Copenhagen Consensus Declaration, 1992; Goldenberg, 1989a; Goldenberg, 1989b; Grace, Nielson, Hopkins & Michelle, 1999; McCain, 1993). This constellation of other symptoms plus the chronic incurable nature of FM, is associated with significant physical, psychosocial and economic impact. Work difficulties add to the economic impact of FM as many people with FM are unable to remain competitively employed throughout the disease trajectory. Symptom chronicity in FM often interferes with quality of life and function.

FM affects nearly six million Americans; approximately 80-90% of persons with FM are women between the ages of 30 to 50 years (Wolfe, Ross, Anderson, Russell, & Herbert, 1995). Rheumatologists report that FM visits are second in number only to visits by patients with rheumatoid arthritis (Marder et al., 1991). FM recognition is on the rise in both primary care practice and speciality clinics since uniform diagnostic criteria are now available to clinicians (Wolfe et al., 1990). The annual financial toll of FM is estimated to be $15.9 billion in direct and indirect health care costs thus constituting a significant public health problem (Thorson, 1996).

FM Fitness Findings and Muscle Physiology

Objective as well as functional muscle strength and endurance have been shown to be lower in patients with FM than healthy age-matched controls (Valim et al., 1999) . A negative cycle of cardiovascular and muscular deconditioning is common in FM patients in which pain and fatigue beget inactivity, leading to deconditioning, which then leads to more pain and fatigue (Bennett et al., 1989). It is hypothesized that pain in FM is due to both peripheral and central mechanisms. The peripheral component involves nociceptive input from muscles; the central component is thought to involve abnormal sensory processing at the level of the spinal cord and brain (Mountz et al., 1995; Russell, 1996; Paiva, Deodar, Jones & Bennett, 1999; Crofford, 1996). These systems work together to perpetuate pain and deconditioning. Deconditioned muscles are more likely to experience muscle microtrauma which will cause more pain (often 2-5 days) after activity (Backman, Bengtsson, Bengtsson, Lennmarken, & Henriksson, 1988; Bengtsson, Henriksson & Larsson, 1986; Elert, Rantapaa Dahlqvist, Henriksson-Larsen, & Gerdle, 1989; Henriksson, Bengtsson, Larson, Lindstrom, & Thornello, 1982). Thus a cycle is established which produces microtrauma, increased local pain and increased generalized pain.

Clinical trials of aerobic exercise, flexibility and muscle strengthening have offered evidence that FM patients who can tolerate the intervention can improve their aerobic capacity, muscle strength and decrease their FM symptoms (King, Wesel, Sholter & Maksymowych, 1999; Clark, /burckhardt & Bennett, 1995b; Hoydalsmo, Johannson, Harstad, & Jacobsen Kryger 1992; Isomeri, Mikkelsson, & Latikka, 1992; Martin et al., 1996; McCain, Bell, Mai & Halliday, 1988; Mengshoel, Komnaes & Forre, 1992; Nichols & Glenn, 1994; Norregaard, Lykkegaard, Mehlsen & Danneskoid Samsoe, 1997; Wigers, Stiles & Vogel, 1996). However, these studies often employed interventions geared to the general public, perhaps without recognizing the possible central and peripheral mechanisms in play in FM. These studies suffered from drop out rates as high as 40-87% (Martin et al., 1996; Mengshoel et al., 1992; Norregaard et al., 1997), with some patients reporting that the intervention actually increased their FM symptoms. Thus, many believe that although exercise is essential in the treatment of FM, much work remains in designing and successfully implementing a program tailored to accommodate the special needs of patients with FM (Bennett & McCain, 1995; Sherman, 1992; Rossy et al., 1999). Some researchers further believe that if the cycle of deconditioning is to be broken in FM patients, an exercise program that focuses on muscle strengthening might be a first logical step in preparing the person with FM to engage successfully in future more comprehensive exercise programs designed to improve muscle strength, flexibility and aerobic capacity (Hannonen, Rahkila, Kallinen & Alen, 1995; American College of Sports Medicine Position Stand, 1998).

Muscle strengthening has been shown to have multiple benefits, including increases in muscle strength, positive changes in body composition as well as improvements in functional abilities, self-efficacy, and psychological status, in young healthy, elderly healthy and cardiac populations (Fiatarone et al., 1990; Frontera et al., 1988; Verrill & Ribisl, 1996a). Only one study that solely addressed muscle strengthening with FM patients has been reported. The study was small (18 completed the treatment) and has not been replicated. Also, it did not measure changes in body composition or any of the other variables which are known to change as a result of muscle strengthening. However, the authors did conclude that symptoms could be decreased and aerobic fitness and muscle strength improved with strength training (Hannonen et al., 1995).

Conceptual Framework

In order to design an exercise intervention sensitive to the needs of FM patients, both physiological processes and attention to adherence were considered. Principles of self-efficacy have been applied to increase adherence in multiple interventions in apparently healthy, chronically ill and rheumatic populations (Fitzgerald, 1991; Lev, 1997; Thoresen & Kirmil-Gray, 1983; Lorig, 1993). Self-efficacy has been identified as the most powerful explanatory construct in predicting exercise initiation and maintenance (Dzewaltowski, 1989). Through self-efficacy, actions are causally linked to expectations. Self-efficacy scores have been shown to increase as a result of an exercise program (Ewardt, Gillian, Kalemen, Manley & Kalemen, 1986). Self-efficacy can also activate biological processes that decrease the stress response and improve psychological status (Bandura, Taylor, Williams, Mefford & Barchas, 1985). In addition to self efficacy exercise, adherence is influenced by demographic factors such as age, gender, economic status and patient preference. Previous exercise studies have also noted that smaller class size, social support, opportunities for personalized instruction and building games or fun into the classes may have contributed to enhanced class attendance (Nichols & Glenn, 1994; Rossy et al., 1999).

Specific Aims and Hypothesis

The specific aims of this study were to:

1) initiate a 12-week controlled clinical trial of women with FM randomized to either a muscle strengthening intervention (treatment group) or a stretching intervention (control group);

2) compare the differences in the two groups for producing changes in: a) muscle strength, b) FM symptoms, c) body composition, d) self-efficacy, and e) psychological status. The general hypothesis tested was that a muscle strengthening intervention tailored to the special physiologic needs of patients with FM and adherence principles in exercise studies would improve muscle strength as well as other selected physiological and psychological outcomes more so than a stretching intervention.

Significance to Nursing

Nurses have demonstrated a long standing commitment to health promotion related interventions to maximize the health status of their patients. In diseases such as FM in which a cause or cure remains elusive, interventions to improve functioning and quality of life are key. Advanced practice nurses are commonly faced with diagnosing and treating FM, a condition associated with significant dysfunction and co-morbidity. Knowledge from the study is expected to assist clinicians in prescribing exercise for women with FM thus decreasing the significant impact of FM.

CHAPTER II

REVIEW OF THE LITERATURE AND THEORETICAL FRAMEWORK

Introduction

An in-depth review of the proposed study variables, their relationship to previous research and how this study fills a gap in the FM literature will be presented. The review of literature will be divided into discussions of 1) muscle changes in FM, 2) central nervous system changes in FM, 3) fitness characteristics in people with FM, 4) exercise physiology in a variety of populations including FM and 5) a review of exercise interventions in FM. A summary will review how attention to these physiologic changes in FM may be applied to exercise interventions. Throughout the discussion, attention will be directed to the outcomes measured in this study: muscle strength, body composition, flexibility, pain, FM impact, anxiety, depression and quality of life.

The conceptual framework will include a description of the attention to 1) physiology of FM and strength training, and 2) principles of adherence and self-efficacy. Combining these concepts were key to conceptualizing the intervention.

Muscle Changes in FM

As the pain of FM is perceived by patients to originate in peripheral muscle, the early years of FM research focused on striated muscle. The following discussion will review the literature in assessing baseline and contractile properties of peripheral muscle in FM, and assessment of muscle strength and flexibility in FM.

Muscle Biopsy Findings

Peripheral muscle biopsy can yield data on the morphology, histochemistry, ultrastructure and biochemistry of muscle in FM. However, many factors may potentially confound the results and implications in FM populations. For example, parameters such as muscle size and metabolism are highly dependent on the training status of the biopsied muscle (Saltin & Gollnick, 1983). As many patients with FM find that physical exertion/overexertion aggravates their symptoms of pain and fatigue, they demonstrate considerable muscle deconditioning.

Researchers have as yet failed to detect any signs of inflammation or capillary density changes between FM patients and healthy controls on routine light microscopic evaluation of biopsied muscle (Bengtsson et al., 1986; Kalyan Raman, Kalyan Raman, Yunus, & Masi, 1984; Schroder, Drewes, & Andreasen, 1993; Lindman et al., 1991). Two research teams detected a phenomenon termed "rubber band" morphology in FM patients although the etiology remains unclear (Bartels & Danneskiold-Samsoe,1986; Norregaard, Bulow, Prescott, Jacobsen, & Danneskoild-Samsoe, 1993). Detraining is also thought to contribute to the "rubber band" phenomenon through a reduction in muscle ATP. Detraining refers to a cascade of physiological changes that occur when one's level of physical activity decreases. Most of these changes occur rapidly and include a decline in cardiorespiratory fitness, and a reduction in muscle ATP which contributes to lowered cardiorespiratory fitness. Earlier evidence of detraining was demonstrated in histochemical staining by Henriksson and colleagues (1982) who reported that muscle fibers in FM patients had a "moth eaten" appearance similar to that of muscle disuse or immobilization (Henriksson et al., 1982; Sargeant, Davies, Edwards, Maunder, & Young, 1977). In a larger study, Bengston (1986) confirmed Henriksson's findings including their closer correlation of "moth eaten appearance" with detraining than as a primary pathology in FM (Bengtsson et al., 1986). Elert et al. (1989) found that patients with FM were less able to relax their muscles back to baseline between isokinetic muscle contractions (Elert et al., 1989). Vitali and colleagues (1989) demonstrated hyper excitability of the neuromuscular system in FM due to increases in intracellular calcium (Vitali et al., 1989). Backman et al (1991) postulated that detraining may influence contractile properties of muscle resulting in a reduced rate of relaxation (Backman et al., 1988).

Muscle Strength Findings

FM studies examining both isometric and isokinetic muscle strength have demonstrated a 50% reduction in strength when compared to matched healthy controls (Elert, Rantapaa Dahlqvist, Henriksson-Larsen & Gerdle,1992; Jacobsen & Danneskiold-Samsoe, 1987; Mengshoel, Forre & Komnaes, 1990; Nordenskiold & Grimby, 1993). Muscle endurance is also markedly lower in FM patients compared to controls (Jacobsen & Danneskiold-Samsoe, 1992). Twitch interpolation studies of the hand and quadriceps have revealed a further reduction of maximum voluntary contraction strength in FM patients (Backman et al., 1988). There are currently no published prospective studies of muscle strength in FM, yet the primary FM symptom of perceived muscle fatigue and loss of function necessitates that muscle strength continue to be investigated.

Muscle Flexibility Findings

Muscle flexibility measures are markedly reduced in women with FM. One study of 70 women with rheumatic disease including FM found that approximately 80% of the subjects' flexibility scores were below average or poor as measured by a sit and reach box when compared to healthy age matched controls (Burckhardt, Clark & Nelson, 1988). A number of studies have demonstrated that patients with rheumatic disease are able to improve flexibility scores with appropriate instruction (Byers, 1985; Ekdahl, Anderson, Moritz, & Svensson, 1990; Fisher, Pendergast, Gersham, & Calkins, 1991; Minor, Hewett, Webel, Anderson, & Kay, 1989). Flexibility also directly impacts joint range of motion which influences a number of functional movements for patients with rheumatic disease. Shoulder girdle inflexibility is implicated in patients' complaints of decreased ability to perform activities of daily living such as washing/drying their hair or reaching high shelves.

Summary of Muscle Changes in FM

Although muscle pain is a prominent symptom in FM, no specific histological, histochemical, or functional muscle and/or tissue abnormalities have been identified (Bennett & Jacobsen, 1994). Skeletal muscle biopsy in people with FM reveal only nonspecific changes such as a "moth-eaten" and atrophied appearance of muscle fiber (Yunus & Kalyan-Raman, 1989). These findings may in part explain the muscle fatigue and pain reported by many people with FM during and after excessive exercise. However, these muscle changes are nonpathologic and are also associated with disuse (Bortz, 1982). Disuse and deconditioning predispose FM patients to muscle pain originating from muscle microtrauma, a normal occurrence where exertion induced damage to the muscle cell causes an influx of calcium and contraction of the injured area. This contracted area becomes tender to pressure and may not heal normally in persons with FM (Bennett & Jacobsen, 1994). On a large muscle level one study has shown that patients with FM are less able to relax their muscles between isokinetic contractions. This problem could also lead to increased risk of microtrauma and muscle fatigue (Elert et al., 1989). Knowledge of detraining, delayed return to baseline and hyper excitability of muscle, although not specific to FM or its etiology, is essential in planning muscle strengthening interventions for this population.

Central Nervous System Changes and Pain Pathways in FM

Pain is a universal experience that serves the vital function of triggering avoidance and as such is a necessary sensation for normal human life. Although acute pain pathways are well documented, the mechanisms of chronic pain appear more complex. One of the critical documented differences in the two forms of pain is that chronic pain may lack an obvious injury or pathologic process that can be linked to the continued experience of pain. Brain imaging studies have yielded a greater appreciation for the chronic pain of FM. Blood flow abnormalities of the thalamus and the caudate nucleus have been documented in FM patients as compared to healthy controls (Mountz et al., 1995).

Neurochemical Findings

Recent research has lead to several neurochemical findings that can be helpful in explaining the chronic wide-spread pain of FM. First, peripheral pain nerves (nociceptors), such as those found in skeletal muscles when repeatedly stimulated by stretching or pressure can become sensitized sufficiently to cause the release of neurotransmitters in the spinal cord. The resulting impulses are carried to the central nervous system where "central sensitization" occurs. Central sensitization includes a reduction in pain threshold, increased response to painful and non painful stimuli, an increase in the duration of pain after the stimulation and increase in receptive field. Another recent finding is that diffusion of substance P, one of the neurotransmitters within the spinal cord, is capable of sensitizing neighboring dorsal horn neurons that serve anatomical locations that may be unrelated to the region of a previous injury (Mense, 1996; Hoheisel, Mense & Ratkai, 1995). Thus, pain in FM may become wide-spread as a result of spillover of substance P to previously unaffected tissues.

Other neurochemical abnormalities in FM include changes in serotonin and growth hormone. Depletion of serotonin results in decreased inhibition of pain impulses by the brain stem and sleep disturbances. Approximately one-third of patients with FM have documented growth hormone deficiency (Bennett et al., 1997). Growth hormone, which is necessary for normal tissue repair, is produced primarily in adults during deep sleep, a part of normal sleep in which FM patients are deficient (Bennett, Clark, & Walcyzk, 1998). More recent growth hormone studies have revealed that patients with FM fail to exhibit an exercise-induced increase in their serum growth hormone levels as compared to healthy controls. Paiva and colleagues (1999) studied 20 female FM patients and 10 age matched controls by asking that they exercise to volitional exhaustion on a treadmill (modified Bruce protocol). Serum growth hormone was measured at times: minus one hour, zero hour, immediately post exercise and one hour post exercise. The test was repeated one month later with the addition of an oral administration of 30 mg pyridostigmine given one hour prior to exercise. Pyridostigmine inhibits hypothalamic somatostatin tone (Valcavi et al., 1993). Healthy controls mounted a predictable exercise induced increase in growth hormone. FM patients failed to exhibit exercise induced increase in their growth hormone levels at time one. At time two, with pyridostigmine added, FM patients exhibited a 13-fold increase in growth hormone which is similar to the increases seen in healthy controls. The study authors postulated that the findings may be related to the up-regulation of hypothalamic somatostatin tone by the stress-induced secretion of corticotrophin releasing hormone (Paiva et al., 1999). Larger trials are needed to confirm these findings.

Limbic System Findings

A final central nervous system factor to be examined is the limbic system. The sensory pain experience is especially prominent in patients with FM. Because of the connections between the cortical areas and subcortical areas, emotion and mood contribute to the total chronic and persistent pain experience (Crofford, 1996). Over the past few years, a number of reports have shown the benefits of cognitive-behavioral therapy in the treatment of the sensory experience of pain in patients with FM. Significant improvements in pain coping and self-efficacy along with decreases in catastrophizing and global severity of symptoms have been reported (Goldenberg et al., 1994; Nielson, Wlaker & McCain, 1991; White & Nielson, 1995). Among the most useful strategies reported in these studies included assisting patients to prioritize their time and activities so that they are able to include meaningful work, pleasurable leisure activities, as well as the activities of daily living. Patients also benefit from relaxation strategies, meditation-based stress reduction programs, and cognitive techniques that assist them to reconceptualize pain as sensation over which they can exert control and to restructure negative cognitions that have left them feeling helpless and hopeless.

Summary of Central Nervous System Changes in FM

Recently a number of neurophysiologic changes have been linked to FM. These include neurochemical alterations such as higher levels of substance P and nerve growth factor (X/GF) in cerebral spinal fluid, decreased serum serotonin, decreased serum growth hormone at baseline and with exercise, a normalization of growth hormone with the administration of pyridostigmine and abnormalities of regional cerebral blood flow in the thalamus and the caudate nucleus (Mountz et al., 1995; Russell, 1996; Paiva et al., 1999) and FM interventions to reduce the impact of sensory pain experiences. These studies are important milestones in research and aid in understanding the symptoms and possible etiologies of FM. The vast majority of FM etiology studies point to the central nervous system rather than peripheral muscle as the key issue for future investigation in FM.

Descriptive Fitness Data from Rheumatic and FM Populations

Historically, the concept of total bed rest was the standard of care for patients with painful "muscular" or "rheumatic" complaints until a landmark study in the mid 20th century revealed the undesirable effects of prolonged bed rest such as sarcopenia (Deitrick, Whedon, & Shorr, 1948; Jivoff, 1975-1976). Clark (1993) and other research teams conclude that patients with FM are generally at a lower fitness level than the average population (Bennett et al., 1989; Clark, Burckhardt, Campbell, O'Reilly, & Bennett, 1993). A negative cycle of deconditioning is common in patients with FM in which pain and fatigue encourage inactivity, leading to deconditioning, which then leads to more pain and fatigue (Sherman, 1992).

Generally, patients with FM are at a lower aerobic fitness level than the average population and at a lower fitness level when matched with healthy patients reporting similar exercise histories. Burckhardt et al. (1988) assessed aerobic fitness estimated by a 12-minute walk test in 40 women with rheumatic disease including FM. Over half the women with rheumatic disease were found to have very poor fitness compared with less than 25% of age and exercise history matched controls (Burckhardt et al., 1988). Bennett et al. (1989) studied baseline aerobic fitness 25 women with FM by having them cycle to volitional exhaustion. They found that greater than 80% of the sample were aerobically unfit by VO_2 max measurement based on widely accepted, published standards (Bennett et al., 1989; Pollock, Wilmore, & Fox, 1984). Clark et al. (1993) studied 95 women with FM using a Balke treadmill protocol and found that 64% of patients with FM exhibited poor or fair aerobic fitness when compared with norms for healthy women of comparable age (Bennett et al., 1989; Clark et al., 1993). In a field measure of aerobic endurance in women with FM (6-minute walk test), the average 46 year old patient exhibited the fitness level predicted for a 60 year old woman in poor physical condition (Mannerkorpi, Burckhardt, & Bjelle, 1994).

Field measures have also been employed to study muscle strength and flexibility in FM. Strength and flexibility are important in activities of daily living. FM patients are particularly concerned with their ability to function in their vocations, avocations (Henriksson, 1992; Mason, Simons, Goldenburg, & Meenan, 1989) and their daily lives (Mannerkorpi et al., 1994). Impaired muscle strength and range of motion of the shoulders limits activities such as reaching high shelves or washing one's hair. Adequate internal/external rotation of the shoulder is necessary in accessing functional movements of the arm as patients need range of motion of at least 120 degrees to perform such daily activities (Bradley, Wagstaff, & Wood, 1984). A test of shoulder rotation successfully used in FM populations asked patients to perform hand-to-neck and hand-to-scapula movements. Mannerkorpi and colleagues (1994) compared 97 subjects with FM to 30 age-matched controls and less than 1/3 of patients with FM in one study possessed this ability (Mannerkorpi et al., 1994).

Mannerkorpi also tested strength in the same study using the chair test. The chair test is a field measure of muscle strength, endurance and power in the lower body and asks FM patients to rise from a seated position in a chair (44 cm) as many times as possible in one minute while keeping their arms on their chest (Mannerkorpi et al., 1994). When administering the chair test, they found that people with FM had very poor performance scores compared with controls. Forty percent of the FM patients were unable to rise from the chair more than 16 times during the one minute test. By comparison, the control group only had one person with a score of 16 as everyone else's score was higher (Mannerkorpi et al., 1994).

Dynamic endurance of the lower extremities has been measured in a FM population using a 20 cm step test (Mengshoel et al., 1992). Patients are asked to climb up and down a single 20 cm high step at a predetermined climbing speed; Menghsoel and colleagues (1992) studying patients with FM, selected 100 steps per minute, controlled by a calibrated metronome. The test is performed such that the right lower extremity does concentric muscle work (muscle contraction while the muscle is shortening), while the opposite leg performs eccentric muscle work (contraction while the muscle is elongated). The climbing period can be measured in seconds until exhaustion and recorded as dynamic endurance time. Since this study, other FM researchers have advised against eccentric muscle work as it has been found to increase post exercise muscle soreness and fatigue (Clark, 1994). Clinical experience and anecdotal data support Clark's recommendation as patients with FM report that the eccentric muscle contraction required for descending stairs is a particularly difficult undertaking. Knowledge of this baseline information regarding muscle strength, endurance and flexibility in FM is essential when planning and implementing exercise interventions for women with FM (Clark et al., 1993).

In the next section a review of exercise benefits and muscle strengthening will be examined. The relationship between FM physiology and exercise benefits in FM and related populations will also be explored.

Physical Fitness Benefits Across Populations

Exercise has been demonstrated to have wide-ranging beneficial effects in a host of conditions including coronary artery disease, obesity, cancers and all-cause mortality (Blair et al., 1989). Since the Committee on Exercise and Cardiac Rehabilitation of the American Heart Association's Counsel on Clinical Cardiology recognized physical inactivity as an independent risk factor for heart disease, research into physical fitness has increased dramatically. Populations most closely related to the current study include fitness status and exercise participation in apparently healthy, chronically ill, elderly, rheumatic/arthritic and FM populations. Data from each of these groups are vital for designing an exercise intervention for women with FM.

Physical Inactivity Rates in Apparently Healthy Populations

Despite the overwhelming scientific evidence regarding the benefits of physical activity, nearly 80% of the United States' population fails to participate in adequate physical activity (Pate et al., 1995) and 60% are completely sedentary (Siegel, Brackbill & Frazier, 1991). Approximately one-third of adults engage in no leisure-time physical activity (Crespo, Keteyian, Health & Sempos, 1996). Physical inactivity rates are highest among persons over 45 years of age, non-college graduates, and minorities (Clark, 1995a; Galuska, Serdula, Pamuk, Siegel & Byers, 1996; Pate et al., 1995). Furthermore, research shows that approximately 50% of participants drop out of exercise programs during the first three months (Dishman, 1982). Physical activity and exercise attrition rates are even more dismal for persons experiencing a chronic or painful disease. Merely disseminating the facts regarding the links between physical activity and health will not be sufficient to influence the physical activity levels of most Americans. These data suggest that information matching exercise prescription to patient demographics should be considered in designing effective exercise interventions.

Chronically Ill Populations

Perhaps the largest body of literature generated about fitness status and exercise focuses on the chronically ill. Lack of physical activity was first linked to coronary artery disease in 1953 when authors found that sudden death and three-year mortality were twice as high for sedentary bus drivers as for active conductors (Morris et al., 1953). Since that time, coronary artery disease began to be understood as a chronic rather than acute condition; lifestyle interventions then began to surface in the heart disease literature. Initially these interventions focused on aerobic activity, diet and relaxation. For many years muscle strengthening was thought to be potentially hazardous for the cardiac patient due to the risk of cardiovascular complications form adverse hemodynamic responses. More recently, however, muscle strengthening interventions have facilitated earlier return to vocational and avocational activities and improvements in morbidity after cardiac arrest (Verrill & Ribisl, 1996a). Since strength training was found to be safe and effective in properly screened patients with heart disease, researchers in a variety of other chronic illnesses began applying muscle strengthening interventions to their study populations. Unfortunately, until recently the vast majority of exercise studies in apparently healthy or chronic disease populations have exclusively studied men. Therefore, in order to more fully understand exercise in women with FM, other related populations were examined.

Elderly Populations

Aging is associated with declines in both upper and lower extremity muscle strength in a number of cross-sectional studies (Borges, 1989; Clement, 1974; Frontera, Hughes, Lutz & Evans, 1991; Phillips, Burce, Newton & Woledge, 1992). More recently, longitudinal studies have also documented strength losses with age (Kallman, Plato & Tobin, 1990; Metter, Conwit, Tobin & Fozard, 1997). However many of these debilitating changes have been demonstrated to be reversible. Exercise studies in the elderly are of particular interest in the current study because 1) more women are including in the study sample, and 2) their are physiologic similarities in deconditioning seen in the elderly and in women at midlife with FM. As stated earlier, Mannerkorpi, Burckhardt, and Bjelle (1994) found that the average 46 year old female FM patient in their study exhibited the fitness level predicted for a 60 year old woman in poor physical condition (Mannerkorpi et al., 1994). Health behaviors such as exercise are recognized for not only their potential to impact elderly individuals physiologically, but also for improvements in quality of life and health care cost containment (Omenn, 1990). Randomized controlled trials have shown that previously sedentary older adults can benefit from moderate intensity home or group-based exercise (King, Haskell, Taylor, Kraemer & Dubusk, 1991). Muscle strengthening interventions in the elderly have demonstrated improvements in strength, gait and balance and are associated with a decrease in falls (Topp, Mikesky, Wigglesworth, Holt & Edwards, 1993). An appreciation of the attention to the deconditioned status of many elderly people provides exercise prescription information potentially useful in FM populations.

Rheumatic and Arthritic Populations

Arthritis and other rheumatic conditions (e.g. osteoarthritis, rheumatoid arthritis, gout, FM and other disease in the joints) are a leading cause of disability and are among the most prevalent chronic conditions in the United States, affecting approximately 40 million persons in 1995 and a projected 60 million persons in 2020 (Centers for Disease Control, 1994; LaPlante & Carlson, 1996). Leisure time physical activity rates in the National Health Interview Survey, United States (n=14,071) revealed that 34.8% of the sample with arthritis (as defined above) engaged in no leisure time physical activity. In those with "disabling" arthritis, leisure time inactivity rates rose to 47.7% (Centers for Disease Control, 1997). For nearly three decades, physical activity has been known to help persons with arthritis control pain and delay disability (Ekblom, Lovgen, Alderin, Fridstrom & Satterstrom, 1975a & b; Mason et al., 1989; Henriksson, 1992; Bradley et al., 1984; Centers for Disease Control, 1994). More recently exercise interventions in this population have been found to be successful in home based interventions with community samples (Stenstrom, Arge & Sunbom, 1997). Multiple studies employing strength training in persons with osteoarthritis have reported positive findings (Fisher et al., 1991; Bradley et al., 1984; Topp, Mikesky, Wigglesworth, Holdt & Edwards, 1993; King, Haskell, Taylor, Kraemer & Dubusk, 1991). Physical activity data and exercise interventions in these populations are of interest in this study not only for the specificity of the disease but also because women are more likely to experience chronic rheumatic conditions than men. Therefore data from this body of literature are more likely to involve women.

Summary of Exercise Benefits Across Populations

Exercise has been demonstrated to have wide-ranging beneficial effects in a host of conditions including coronary artery disease, obesity, cancers and all-cause mortality (Blair et al., 1989). Some of these benefits include improvements in strength, endurance, aerobic capacity, and a variety of quality of life measures. Most research on exercise interventions has emphasized aerobic conditioning which is known to enhance psychological well being along with exercise performance. More recently muscle strengthening has been recognized for its capacity to improve functional ability as well as self-efficacy and psychological status (Fletcher et al., 1996). Reports from high risk cardiac rehabilitation groups, indicate that muscle strengthening interventions can replace aerobic training interventions as initial therapy because of their wide ranging beneficial effects and safety (Verrill & Ribisl, 1996a). Many researchers suggest that regular activity may play a preventive/protective role in the development of chronic pain syndromes like FM and should definitely be a part of the treatment (Bennett, 1989). The next section will discuss health benefits of isolated resistance training as compared to aerobic training and provide strength training recommendations from various leading health organizations.

Health Benefits of Resistance Training

Although resistance training has long been accepted as a means for developing and maintaining muscular strength and mass (Atha, 1981; Komi, 1991), it has only recently been recognized as a factor to promote health especially in chronic disease states

(Pollock & Vincent, 1996; Pollock & Evans, 1999; US Department of Health and Human Services, 1996). Prior to 1990, neither the American Heart Association or the American College of Sports Medicine (ACSM) recommended guidelines for exercise training or cardiac rehabilitation focusing on strength training. It was the ACSM who first recognized resistance training as a significant component of a comprehensive fitness program for healthy adults of all ages (American College of Sports Medicine Position Stand, 1990). Although the mechanisms for fitness improvement may be different for aerobic endurance exercise versus resistance training, both appear to have similar effects on overall fitness. Table two outlines evidence based differences in aerobic and strength training. Because many of the improvements due to strength training are known to decrease risk factors for heart disease, the American Heart Association now recommends strength training in primary, secondary and tertiary prevention of heart disease.

Table 2

Comparison of the Effects of Aerobic Endurance Training with Strength Training on Selected Fitness Variables (Adapted from Pollock & Vincent , 1996)

VARIABLE	AEROBIC EXERCISE	RESISTANCE EXERCISE
Bone mineral density	↑↑	↑↑
Body composition		
% Fat	↓↓	↓
Lean Body Mass	↔	↑↑
Strength	↔	↑↑
Glucose metabolism		
Insulin response to glucose	↓↓	↓↓
Basal insulin levels	↓	↓
Insulin sensitivity	↑↑	↑↑
Serum lipids		
HDL	↑↔	↑↔
LDL	↓↔	↓↔
Resting heart rate	↓↓	↔
Stroke volume, resting and maximal	↑↑	↔
Blood pressure at rest		
Systolic	↓↔	↔
Diastolic	↓↔	↓↔
VO_2 max	↑↑↑	↑↔
Basal metabolism	↑	↑↑
Submaximal and maximal endurance	↑↑↑	↑↑

LBM-Lean Body Mass
HDL-high-density lipoprotein cholesterol
LDL-low-density lipoprotein cholesterol
Arrow key: ↑ indicates values increase; ↓ indicates values decrease; ↔ indicates values remain unchanged; ↑ or ↓ indicates small effect; ↑↑ or ↓↓ indicates medium effect; ↑↑↑ or ↓↓↓ indicates large effect.

Strength Training Recommendations

Although the mechanisms underlying the positive fitness benefits of strength training remain incompletely understood, there is now a preponderance of research findings correlating strength training with a variety of fitness markers. Several major health organizations have published consensus statements regarding the timing, intensity and duration of strength training known to produce positive health effects (U.S. Department of Health and Human Services, 1996; American College of Sports Medicine Position Stand, 1990; American Heart Association; 1995; Centers for Disease Control and Prevention, 1996; American Association of Cardiovascular and Pulmonary Rehabilitation, 1999). Because many Americans state that "lack of time" is a major deterant to exercise, researchers have investigated the frequency, intensity and duration of exercise, including strength training, necessary to bring about positive changes. It has been learned that 75% of the positive changes associated with strength training three times per week occurs in training sessions twice a week (U.S. Surgeon General's Report, 1996; American College of Sports Medicine Position Stand, 1990 & 2000). Strength training findings are listed in Table three.

Table 3

Standards, Guidelines and Positions Statements Regarding Prescribing Strength Training

RECOMMENDING ORGANIZATION	SETS; REPS	STATIONS/ DEVICES	FREQUENCY
Healthy/sedentary adults 2000 ACSM Guidelines (Medicine, 2000)	1 set; 8-15 reps	8-10 exercises	2 days per week, minimum
1998 ACSM Position Stand	1 set; 8-12 reps for persons under 50-60 years, 10-15 reps for persons over 50-60 years	8-10 exercises	2-3 days per week
1995 CDC/ACSM Statement (Pate, 1995)	Addressed, but not specified		
1996 Surgeon General's Report (Services, 1996)	1-2 sets; 8-12 reps	8-10 exercises	2 days per week, minimum
Elderly persons Pollock et al (Pollock, 1994)	1 set; 10-15 reps	8-10 exercises	2 days per week, minimum
Cardiac patients 1995 AHA exercise standards (Fletcher, 1996)	1 set; 10-15 reps	8-10 exercises	2-3 days per week
1999 AACVPR guidelines	1 set; 12-15 reps	8-10 exercises	2-3 days per week

ACSM-American College of Sports Medicine
AHA-American Heart Association
CDC-Centers for Disease Control and Prevention
AACVPR- American Association of Cardiovascular and Pulmonary Rehabilitation
reps- repititions
"exercises" defined as minimum 1 exercise per major muscle group: eg, chest press, shoulder press, triceps extension, biceps curl, pull-down (upper back), lower-back extension, abdominal crunch/curl-up, quadriceps extension or leg press, leg curls (hamstrings), calf raise.

Conceptual Definitions of Strength Related Measures

In order to critique strength related changes and measures in exercise studies, definitions of strength, power and endurance were explored.

Strength

Strength is a force generated during or while attempting a given movement. Strength is measured during isometric or isokinetic activity. Isometric activity involves activating muscle fiber without changing a joint angle. Pushing against a wall without bending the elbow would be an example of an isometric muscle activity. Isokinetic muscle activity involves activation of the muscle groups with an accompanying change in joint angle. Performing a biceps curl while bending at the elbow is an example of an isokinetic muscle activity. Isokinetic muscle activity can be measured during the concentric or eccentric phase of muscle contraction. The concentric phase occurs when there is a decrease in the joint angle. The eccentric phase occurs when there is a lengthening of muscle associated with an increase in the joint angle.

In FM studies, the commonly assessed strength measures are of knee and trunk extensions and shoulder rotation (Jacobsen & Danneskiold-Samsoe, 1987; Jacobsen & Danneskiold-Samsoe, 1992). Strength in large, lower body muscle groups are necessary for locomotion and most aerobic interventions. Strength in the upper body is necessary for performing many activities of daily life such as grooming. Improving strength in both of these major muscle areas may reduce injury which may result from a reliance on smaller, less appropriate, ancillary muscle groups to perform activities of daily living (e.g. back).

Isokinetic dynamometry assesses maximum isokinetic strength of a number of major muscle groups. During isokinetic muscle contraction, the muscle shortens at a constant rate. Isokinetic muscle strength testing requires a mechanism which controls movement by keeping the joint angle velocity at a constant preset speed (Gransberg & Knutsson, 1983). An isokinetic dynamometer is currently considered the gold standard measure in assessing muscle strength in FM and has been found more reliable than isometric measures (Jacobsen, Wildschiodtz, & Danneskiold-Samsoe, 1991). Power output can be measured at a number of angular velocities. Theoretically the nondominant side in deconditioned person may be weaker than the dominant side. Testing the nondominant side may result in greater improvements over the course of the intervention and increase the likelihood of detecting a difference from muscle strengthening.

Power

Power, another concept of interest in strength measurement, is a measure of work (force x distance) performed over a unit in time. Power depends on the ability to generate force as well as extremity velocity and to coordinate movement. Measuring power in aging or disuse syndromes is of particular importance because it may be more directly related to losses in physical function than strength measures. While strength is definitely a factor influencing power, central and peripheral nervous system functioning such as agility and reaction time also influence power. Power is usually measured in one of two ways. First, short term power is maximal work performed over a short period of time. The goal is to reach maximum work early and to maintain that level of exertion for the duration of the measure. Stationary cycling against a given load for 10-15 seconds would be one method of measuring short term power. Another measurement of power is immediate or explosive power which is measured in the first few seconds of an activity. Immediate or explosive power measures are more likely to be reported in the exercise physiology literature with elite athletes and young healthy subjects. Because of potential injury during testing, they are less likely to be utilized in aging or deconditioned populations. However, Rooks and colleagues (1999) reported safety and reliability (r=0.99) of the one-repetition maximum test for assessing muscle strength in women with FM. Twenty-five with FM women ages 30-55 were asked to complete a single chest press and a single leg press with 3 minute rest periods between attempts until volitional exhaustion. Twenty four participants completed testing and only one of those reported an increase in pain at the time of the test or after 48 hours (Rooks et al., 1999b).

Endurance

Muscle endurance is commonly reported in the strength literature. It is postulated to be lowered in fatigue states, disuse syndromes and may predict ability to perform activities of daily living. Muscle endurance is often measured by plotting a fatigue curve of strength measures over the time to volitional exhaustion during a given activity. There are a number of laboratory and field measures of muscle endurance. However, of all the commonly reported strength measures, muscle endurance is often noted to have reliability and validity problems. Research participants who are aging or suffer from conditions involving muscle or joint pain may find measurements of muscle fatigue excessively uncomfortable and discontinue testing prior to exhaustion.

Relationship Between Body Composition and Muscle Strength

Anthropomorphic measures including height, weight and percentage body fat are increasingly commonplace in health sciences research and are powerful predictors of morbidity and mortality (Watkins, Roubenoff & Rosenberg, 1992). Body fat, a common measure of body composition is often measured in fat free versus fat mass. Measuring body fat may be a proxy measure for estimating muscle mass. Fat free mass is generally muscle and bone tissue whereas fat mass is adipose. Subcutaneous fat mass is often estimated by skin caliperimetry at three to seven body sites. Fat or fat free mass can also be estimated by body imaging such as bone densitometry, CT and MRI scanning. Total body fat (subcutaneous and visceral fat) can be estimated by underwater body immersion weighing. Although underwater weighing is considered a gold standard laboratory measure of fat mass, there are limitations to its application. People who have a higher percentage of body fat may find immersion difficult. Also, the technique of exhaling as much air as possible for immersion is a learned skill. Finally, the mathematical formulas used to interpret immersion data are based on age and gender population norms and may be less applicable in certain lung disease states such as asthma and chronic obstructive pulmonary disease.

Excess body weight (increased BMI) is associated with increased risks of total mortality, as well as increased incidence of a variety of diseases including hypertension, cardiovascular diseases, osteoarthritis, diabetes mellitus, and certain cancers (Pi-Sunyer, 1993). Clinical observations of women with FM reveal a tendency toward obesity with aging. Excess body weight is also associated with functional limitations in middle-aged and older women (Coakley et al., 1998). Persons who are overweight often have lower fitness levels than normal weight persons.

Muscle mass is commonly reported in the strength literature and strength is proportional to muscle mass providing information regarding changes in total body composition. Muscle mass is generally higher in men than women, younger adults compared to older adults and in heavier persons (Baumgartner, Waters, Gallagher, Morley & Garry, 1999). People who are morbidly obese are reported to have disproportionate increases in lower body muscle mass compared to upper body muscle mass because of the load they carry. Physical inactivity and disuse has been proposed as an important mechanism underlying muscle loss in elderly and chronically ill persons (Bortz, 1982). Accelerated loss of muscle mass leads to a condition termed sarcopenia, or a deficiency of relative skeletal muscle mass. Sarcopenia is associated with impaired functional performance, increased physical disability and increased risk for falls. Potential causal factors include declines in anabolic steroid hormones associated with aging, declines in growth hormone factors and a variety of disease specific changes in chronic illnesses (Bortz, 1982; Rudman, 1985). One potential neurochemical link to sarcopenia in the FM population was noted by Bennett and colleagues in demonstrating low growth hormone factor values in a subset of FM patients (Bennett et al., 1997) and subsequent improvements in growth hormone factor values with the addition of a somatostatin blocking agent (Paiva et al., 1999).

Body Composition Effects of Weight Training in Women

Evidence suggests that weight training may rely on intramuscular triglyceride stores for fuel sources, and may also be capable of modifying lipoprotein concentrations and increasing lipolysis similar to aerobic training programs (Wallace, Moffatt, Haymes & Green, 1991). Resting metabolic rates are also influenced by weight training, particularly in females. Women usually have a 5-10% lower resting metabolic rate than men. The differences may not be gender related but due to the metabolic activity of specific tissues. Women usually possess a greater percentage of body fat than men of similar weight and fat is less metabolically active than muscle. Weight gain is also a risk factor when persons possess low resting metabolic rates. In prescribing exercise for women, resistance training should be a high priority because of the potential benefits in maintaining or increasing strength levels, preventing losses in fat free mass and unfavorable changes in resting metabolic rate. (Williford, Scharff-Olson & Blessing, 1993).

Evaluation of Existing Exercise Interventions in FM

The vast majority of people with FM are inactive and have low levels of aerobic fitness, and aerobic exercise has been shown to improve their aerobic fitness and symptomatic complaints (Bennett et al., 1989; Clark et al., 1995b). Sixteen exercise intervention studies with FM patients have been reported to date and are detailed in Table four (McCain et al., 1988; Mengshoel et al., 1992; Hoydalsmo et al., 1992; Isomeri et al., 1992; Nichols & Glenn, 1994; Clark et al., 1995; Hannonen et al., 1995; Wigers et al., 1996; Martin et al., 1996; Norregaard et al., 1997; Gowans et al., 1999; King et al., 1999; Busch et al., 1999; Rooks et al., 1999; Martin et al., 1999; White et al., 1999). Aerobic training interventions included low impact aerobic dancing, walking and cycling. Compared with community-based exercise programs for essentially healthy individuals, exercise interventions for FM patients generally employed lower intensity activities with a variety of frequencies and durations of exercise. The intensity of exercise, when reported, measured from 40-70% of predicted heart rate maximum or 120-150 heart beats per minute. Exercise frequency ranged from two to five times per week for 20 minutes to three and one half hours' (non-consecutive) duration per session. Many of the aerobic dance studies included a brief period of non-progressive muscle toning and stretching after the aerobic portion of the class. Outcomes for most the studies included measures of aerobic fitness and pain. Only two of these studies measured extensive psychological outcomes (Hannonen et al., 1995; Wigers et al., 1996). Most interventions were found to reduce pain and improve aerobic capacity in participants who completed the studies, however drop-out rates are high.

No FM exercise intervention studies have described pauses between strengthening exercises to allow muscle to return to baseline tone, described movements kept near the body's midline or a stated appreciation for muscle detraining and risk for microtrauma common in FM. No FM intervention study to date has offered graduated strength training at a number of levels and in a variety of positions to decrease stress on known FM tender points. No FM intervention study to date includes detailed demonstration of safe and effective position changes from standing to sitting to lying to avoid the perception of lightheadedness and balance problems that plague women with FM. Stretching only interventions have not produced changes in any outcomes commonly measured in FM (sleep, fatigue, quality of life, anxiety, depression and fitness) except flexibility and possibly pain (improvement) (McCain et al., 1988).

Table 4

Summary of 16 Exercise Interventions in Fibromyalgia (1988-1999) (Results Bolded)

AUTHOR/ YEAR	"N" & ATTRITION & SELECTION CRITERIA	INTERVENTION	DURATION	AEROBIC MEASURES RESULTS: TX/CNTR	STRENGTH & FLEXIBILITY MEASURES RESULTS: TX/CNTR	PAIN/SYMPTOM MEASURES RESULTS: TX/CNTR	PSYCHOLOGICAL MEASURES RESULTS: TX/CNTR
McCain 1988	42 with FM (gender not disclosed) randomized Attrition: 14%CV 5%Flex (Smythe criteria)	CV: bicycle ergometry & flexibility	60 min/ 3x/wk/ 20 weeks	2-stage heart rate analysis, PWC 170 ***Tx: +168.7*** **(sig) Cnt:-7.3**	None	1)VAS pain **Tx:-23.2 Cntr: -8.5 (NS)** 2)Likert sleep **Tx:-23 Cntr:-8.5 (NS)** 3)pain diagram **Tx-1.7 Cntr:-.01 (NS)** 4) total myalgic score **Tx:+40 Cntr:-8.5(sig)** based on # tender points score range 1-5	Psychological Distress Scale **both groups improved equally (NS)**

Conclusion: It is possible to improve fitness scores in patients with FM who undergo aerobic training, but symptoms (pain, sleep, psychological distress) may not improve.

Author/ Year	"N" & Attrition & Selection Criteria	Intervention	Duration	Aerobic Measures Results: Tx/Cntr	Strength & Flexibility Measures Results: Tx/Cntr	Pain/Symptom Measures Results: Tx/Cntr	Psychological Measures Results: Tx/Cntr
Mengshoel 1992	25 females with FM randomized Attrition: 39% treatment 18% control (ACR criteria)	low impact aerobics(n=11) & tx as usual (n=14)	60mins/ 2x/wk 20weeks	Aastrand's method/ cycle ergometry **Tx: 165 to 142 (sig within group)** **Cnt: 155 to 147 (NS between groups)**	1)grip strength/ hand held manometer **Tx: 60 to 66 (sig within group)** **Cnt: 58-60** **(Sig between groups)** & 2)20 cm step/ metronome @100 steps/min **Tx: 450 to 144 (Sig within group** **Cnt: 157 to 134 (sig within group)** **(NS between groups)** 3)static endurance/ shoulder **Tx: 115 to 104 (NS)** **Cnt: 123 to 124 (NS)**	1)Pain: VAS **Tx: 51 to 60** **Cnt: 59 to 66** **(NS within or between)** 2)Fatigue/Sleep: VAS **Tx: 60 to 46** **Cnt: 52 to 37** **(NS within or between)** 3)Pain coping: Vanderbilt Pain Management Inventory **Active: Tx: 21 to 23** **Cnt: 20 to 21** **Passive: Tx: 29 to 27** **Cnt: 28 to 25** **(NS within or between)**	None
Conclusion: Aerobic dance improved hand grip scores in the treatment group, but symptoms (pain, fatigue, coping) may not improve.							

Author/ Year	"N" & Attrition & Selection Criteria	Intervention	Duration	Aerobic Measures Results: *Tx/Cntr*	Strength & Flexibility Measures Results: *Tx/Cntr*	Pain/Symptom Measures Results: *Tx/Cntr*	Psychological Measures Results: *Tx/Cntr*
Hoydalsmo 1992	30 with FM (gender not disclosed) Attrition: Not disclosed Criteria not disclosed	one group only "aerobic fitness and flexibility"	45 mins/ 5x/day 4weeks (3 ½ hrs/day)	Aastrand's method/ cycle ergometry **"average" patient improved aerobic capacity by 24% (p<0.00005)**	None	# tender points **increased in 1 patient** **unchanged in 15 patients** **decreased in 9 patients**	None
Conclusion: In a non-controlled study it was demonstrated that 30 FM patients could improve their aerobic capacity 24% and decrease # of tender points in 9 patients.							
Isomeri 1992	45 with FM (39 female, 6 male) mean age 43.7 yrs Attrition: Not reported Criteria not disclosed	3 groups: 1)amitript. and light physical training, 2)aerobic training and amitript, 3)aerobic training only	hospital x 3 weeks then home x 3 months	Not disclosed	None	1) pain VAS **Improved in all 3 groups (NS)** 2)# tender points **improved only in aerobics + amyitript group**	None
Conclusion: VAS measures of pain improved in all groups at 3 weeks. Only the combination of amitripytiline and aerobic training yielded improvements in at 3 months. Thus combination treatment of FM than either of these modalities alone.							

Author/ Year	"N" & Attrition & Selection Criteria	Intervention	Duration	Aerobic Measures Results: Tx/Cntr	Strength & Flexibility Measures Results: Tx/Cntr	Pain/Symptom Measures Results: Tx/Cntr	Psychological Measures Results: Tx/Cntr
Nichols 1994	24 recruited 19 with FM (17 females, 2 males) completed Attrition: 17% Tx 25% control (ACR criteria)	aerobic walking (n=10) & sedentary controls (n=9) (did not meet)	20 mins 3x/wk 8 weeks	Not measured	Not measured	Pretest scores not disclosed 1)McGill Pain Questionnaire **Tx: 8.9 items chosen rating index of those items 19.1** **Cnt: 10.4 items chosen rating index of those items 23.0** **Results: Tx group showed non sig trends toward pain improvement compared to controls.** 2)Sickness Impact Profile (physical dimension) **Tx: 9.2** **Cnt: 5.7** **Results: sig between group difference at post test**	Pretest scores not disclosed 1) Sickness Impact Profile (psychological dimension) **Tx: 16.2** **Cnt: 21.1** **NS between group difference**
Conclusion: Non significant trends toward improvements in pain and psychological ratings and worsening physical disability scores in the treatment group.							

Author/ Year	**"N" & Attrition & Selection Criteria**	**Intervention**	**Duration**	**Aerobic Measures Results: Tx/Cntr**	**Strength & Flexibility Measures Results: Tx/Cntr**	**Pain/Symptom Measures Results: Tx/Cntr**	**Psychological Measures Results: Tx/Cntr**
Clark 1995	30 females with FM (23 completed) Attrition: 20% Tx 27% Control Criteria not disclosed	aerobic cycling n=12 & sedentary control n=11	3x/wk	Gould metabolic cart (cycle) % change per graph **Tx -18 to 52** **Cnt:--14 to 25** **(sig within tx group difference)**	None	1)total myalgic score **improved in Tx group (#s not reported)** 2)global assessment **improved in Tx group (#s not reported)**	Quality of Life **no differences**
Conclusion: FM patients are able to exercise at a training index sufficient to produce changes in aerobic capacity while improving pain and global assessment scores. No changes in quality of life were noted.							
Hannonen* 1995	40 females Attrition: 0% aerobic group 18% muscle strengthening (ACR criteria)	aerobic training (AT) n=22 v. muscle strengthening (MS) n=14 (home-based, monitored through training diaries)	not disclosed but outcomes measured at 6 months and 1 year	VO2 max measured but not protocol discussed **sig within group improvements AT only** **NS between group difference**	trunk flexors and extensor strength measured but not discussed how **sig within group improvements MS only** **NS between group difference**	1)VAS pain **sig within group decrease AT & MS** **NS between groups** 2)Nottingham Health Profile **improved but NS within or between** 3)HAQ **improved but NS within or between**	Quality of Life **"modest non significant changes within both groups"**
Conclusion: AT produced statistically significant within group changes in VO2 max at 6 months and one year. MS produced statistically significant within group changes in strength at 6 months and one year. Both groups experienced statistically significant within group improvements in pain. There were modest nonsignificant improvements in quality of life and functional capacity in both groups.							

AUTHOR/ YEAR	"N" & ATTRITION & SELECTION CRITERIA	INTERVENTION	DURATION	AEROBIC MEASURES RESULTS: *TX*/CNTR	STRENGTH & FLEXIBILITY MEASURES RESULTS: *TX*/CNTR	PAIN/SYMPTOM MEASURES RESULTS: *TX*/CNTR	PSYCHOLOGICAL MEASURES RESULTS: *TX*/CNTR
Wigers 1996	60 (55 females, 5 males) Attrition: aerobic exercise: 20% stress management: 25% Tx as usual: 20% (Yunus & Smith criteria)	3 groups: n=20/group 1) aerobic exercise, 2) stress management, 3) treatment as usual	45 mins 3x/wk 14 wks and 4.5 year f/u	work capacity by cycle ergometry **1) 0.7 to 0.8 (sig) to 0.8** **2) 0.7 to 0.7 to 0.6** **3) 0.6 to 0.6 to 0.7** **NS between group**	none	**NS between group on all** dolorimetry pressure kg scores **1) 2.2 to 2.9 to 2.4** **2) 2.0 to 2.5 to 2.4** **3) 1.8 to 1.6 to 1.1** **NS within group** pain distribution % drawings **1) 69 to 30 (sig) to 64 (NS)** **2) 76 to 57 (sig) to 38 (NS)** **3) 68 to 66 to 39 (NS)** VAS for pain, **1) 70 to 59 (sig) to 64 (NS)** **2) 75 to 57 (sig) to 67 (NS)** **3) 67 to 75 to 69 (NS)** VAS for fatigue **1) 81 to 54 (sig) to 63 (NS)** **2) 82 to 68 to 67 (NS)** **3) 68 to 71 to 63 (NS)** VAS for disturbed sleep **1) 65 to 55 to 53 (NS)** **2) 60 to 49 to 64 (NS)** **3) 45 to 43 to 46 (NS)** global subjective improvement **1) sig within group improvement (75%)** **2) 47% (NS)** **3) 12% (NS)**	VAS depression **1) 30 to 26 to 25 (NS)** **2) 45 to 20 (sig) to 43 (NS)** **3) 37 to 37 to 27 (NS)** **NS between groups**
Conclusion: Both stress management and aerobic exercise showed similar short term improvements. There were no obvious between group differences in symptom severity at long term following up possibly due to considerable compliance problems.							

Author/ Year	"N" & Attrition & Selection Criteria	Intervention	Duration	Aerobic Measures Results: Tx/Cntr	Strength & Flexibility Measures Results: Tx/Cntr	Pain/Symptom Measures Results: Tx/Cntr	Psychological Measures Results: Tx/Cntr
Martin 1996	60 (58 females, 2 males) Attrition: 40% exercise 33% relaxation (ACR criteria)	2 groups: 1)exercise (aerobic walking, strength training and flexibility) n=18 & 2)relaxation n=20	60 mins 3x/wk 6 wks	modified Balke treadmill to volitional exhaustion **Tx: 808.05 to 952.5** **Cnt: 767.5 to 686.9** **Between group sig dif** $p<0.05$	Cybex isokinetic dynamometer (flexion & extension knee) internal and external rotation of the shoulders **NS between or within group change for strength or endurance (#s not reported)** Sit and reach box **sig within Tx group difference, NS between group difference (#s not reported)**	Total myalgic score **Tx: 28.33 to 19.22** **Cnt: 30.89 to 27.17** **(sig between and within groups)** # tender points **Tx: 12.79 to 10.22 (within only sig)** **Cnt: 12.94 to 12.89 (NS)** VAS pain **results not reported** FIQ **Tx: 418.63 to 388.06 (NS within group)** **Cnt:407.44 to 433.11 (NS within group)** **FIQ difference sig between groups** ASES (which subscale not identified) **Tx: 435.83 to 530.56** **Cnt: 484.44 to 486.61 (NS within or between)**	Illness Intrusiveness Questionnaire **Tx 65.44 to 59.89** **Cnt: 66.67 to 66.83** **(NS between or within group)**
Conclusion: Exercise training produced statistically significant improvements over relaxation for myalgic score, tender points and VO_2 max at 6 weeks. Attrition was high for such a short study.							

Author/ Year	"N" & Attrition & Selection Criteria	Intervention	Duration	Aerobic Measures Results: Tx/Cntr	Strength & Flexibility Measures Results: Tx/Cntr	Pain/Symptom Measures Results: Tx/Cntr	Psychological Measures Results: Tx/Cntr
Noregaard 1997	38 females Attrition: 87% total from recruitment (176/23) 60% attrition from time of consent (23/38) 33% aerobic 27% exercise 12% hot pack ACR criteria	3 groups: 1) aerobic dance, n=5 2) steady exercise, n=11 3) hot packs, n=7	50 mins 3x/wk 12 wks	Bicycle ergometry via Astrand (NS)	isokinetic dynamometer for quads and biceps (NS)	1)VAS pain (NS) 2)VAS fatigue (NS) 3)FIQ (NS) 4)# tender points (NS)	Beck depression (NS)
Conclusion: No significant between or within group changes on any measured outcome. Highest attrition rate in any FM exercise study.							
Gowans 1999	41 females Attrition: 9% @6wks, n=30 at 3 months ACR criteria	2 groups: 1) water aerobic, strength and flexibility exercise plus education(20) & 2) wait listed control group who eventually received tx.(21)	Exercise: 30 minutes 2x/wk/6wk plus Education: 1 hr/ 2x/ wk x 6/wks	6-minute walk **Tx@6wks** **330.7 to 402.7** **Cntl@6wks** **350 to 372.6** **Between group** **p<0.05**	none	1) FIQ **feel bad Tx 7.6-6.2** **Cnt 8.3-8.3** **p<0.05** **morning fatigue** **Tx 8.1-7.4** **Cnt 8.5-8.7** **p<0.05** 2) ASES **NS between groups** 3) knowledge test **NS between groups**	None
Conclusion: Water aerobics plus education produced significant improvements in aerobic fitness, well-being, fatigue, knowledge and self-efficacy at 3 months Gains in fatigue and knowledge were lost at 6 month follow-up.							

AUTHOR/ YEAR	"N" & ATTRITION & SELECTION CRITERIA	INTERVENTION	DURATION	AEROBIC MEASURES RESULTS: TX/CNTR	STRENGTH & FLEXIBILITY MEASURES RESULTS: TX/CNTR	PAIN/SYMPTOM MEASURES RESULTS: TX/CNTR	PSYCHOLOGICAL MEASURES RESULTS: TX/CNTR
King 1999	114 females Attrition not reported ACR criteria	4 groups: 1) aerobics only 2) education only 3) aerobics & education 4) control	12 weeks duration, frequency not disclosed	6 minute walk **1) within group, p=.001** **3) within group, p=sig** **1), 2), 4) between group, p=0.018**	none	FIQ **3) within group, p=0.004)**	QOL (NS) Chronic Self Efficacy Scale **3) only within group sig**
Conclusion: The combination of exercise and education is more effective than either treatment alone.							
Busch 1999	104 females Attrition: 1) 38.6% 2) 36.4% 3) 10.5% ACR criteria	3 progressive homebased groups: 1) short bout aerobics 2) long bout aerobics 3) control	sb: two 5 min bouts 3x/wk to two 15 min bouts 5x/wk lb: one 10 min bout 3x/wk to one 30 min bout 5x/wk	VO_2 max with modified Balke **(LB compared to C, sig difference)**	no strength measures	1)FIQ **(SB within group sig difference)** **(LB compared to C, sig difference)** 2) AIMS **(NS)** 3) tender points **(NS)**	1) chronic pain self efficacy **(SES function LB compared to C, sig difference)**
Conclusion: Short bout exercise positively impact disease severity while long bout exercise improves VO_2 max scores.							

Author/ Year	"N" & Attrition & Selection Criteria	Intervention	Duration	Aerobic Measures Results: Tx/Cntr	Strength & Flexibility Measures Results: Tx/Cntr	Pain/Symptom Measures Results: Tx/Cntr	Psychological Measures Results: Tx/Cntr
Rooks 1999	13 females Attrition: 19% Criteria not disclosed	combined progressive muscle strength, aerobics and flexibility No control group	1 hour/ 3x/week 20 weeks	6 minute walk **(539.2 +/- 79.7m to 639.0 +/-72.3m, p=0.002)**	one repetition maximum muscle strength **measures in upper (56.8+/- 16.9 to 73.3 +/-17.4, p=0.004) and lower extremities (178+/-52.6 to 256.2+/-64.4, p=0.0002)**	FIQ subscores **tired (p<0.002)** **#days felt good (2.6 =/-2 to 3.5 +/- 2.1, p=0.03)** **level of pain (6.4 +/-1.6mm to 4.9+/-2.4mm, p=0.03)** **level of stiffness (7.2+/- 1.6mm to 4.9+/-2.1mm, p=0.02)**	
Conclusion: A non controlled study indicating that exercise significantly improves upper and lower body strength, aerobic fitness and FIQ measures of tiredness, number of days felt good, level of pain and stiffness.							
Martin 1999	111 females Attrition 3% ACR criteria	1) aerobic, flexibility & muscle strengthening 2) same exercise + self-management education	one hr/class 3x/week/x 6 weeks Outcomes measured at baseline, 6 weeks, 4 months, 8 months and 10 months	6 minute walk **(sig within group change)**	KinCom dynamometer **(no change)** sit and reach flexibility box **(sig within group change)**	1)FIQ **(sig within group change)** 2)tender points **(sig within group change)** 3) total myalgic score **(sig within group change)** 4) illness intrusiveness (IIRS) **(sig within group change)**	1)self efficacy scale **(sig within group change)**
Conclusion: There were no significant between group differences. There were significant within group differences at 6 weeks, 4 and 8 months on FIQ, IIRS, self-efficacy, flexibility, aerobic fitness and total myalgic score. Perhaps adding self management to exercise is no more adventagous than exercise alone.							

AUTHOR/ YEAR	"N" & ATTRITION & SELECTION CRITERIA	INTERVENTION	DURATION	AEROBIC MEASURES RESULTS: TX/CNTR	STRENGTH & FLEXIBILITY MEASURES RESULTS: TX/CNTR	PAIN/SYMPTOM MEASURES RESULTS: TX/CNTR	PSYCHOLOGICAL MEASURES RESULTS: TX/CNTR
White 1999	6 females 25% Attrition ACR criteria	warm water aerobics, flexibility and strength no control group	one hour/week 3x/week 6 weeks	VO2 max-unchanged **(25.5+/- 4.1 v. 20.7 +/-12.6 mg/kg/min)** 6 minute walk **(15+/11 v 11 +/- 3, p=0.01)** **VO2 to 6MW correlation (r=.77, p=.07)**		FIQ-**unchanged** # tenderpoints **(15+/-1 v. 11+/- 3, p=0.01)**	
Conclusion: A non controlled study indicating that warm water exercise improves exercise tolerance and pain scores but does not impact FIQ scores.							

*the single FM study to date employing a muscle strengthening only group

Tx- Treatment
Cntr- Control
FM- Fibromyalgia

CV- Cardiovascular Training
Flex- Flexibility Training
NS- Not Significant

VAS- Visual Analogue Scale
HAQ- Health Assessment Questionnaire
FIQ- Fibromyalgia Impact Questionnaire

AIMS- Arthritis Impact Questionnaire
ASES- Arthritis Self- Efficacy Questionnaire

Critique of 16 Exercise Studies in FM

The following discussion is a narrative description of Table four. In the first exercise intervention study in FM, McCain and colleagues (1988) randomized 42 patients with FM into either a cardiovascular fitness program or a flexibility program. Both groups met for 60 minutes three times per week for 20 weeks. The cardiovascular group trained at expected heart rate levels to produce changes in aerobic fitness (greater than 150 beats per minute) on bicycle erogmeters. The flexibility group received stretching interventions; the heart rate did not exceed 115 beats per minute. Results included significant improvements in estimated aerobic fitness scores as measured by a simple 2-stage heart rate analysis, PWC 170, that predicted, by nomogram, the peak work capacity at 170 beats per minute for each individual. No significant changes were noted in pain, tender point, sleep and psychological distress scores. The attrition rate was 14% in the cardiovascular group and 5% in the flexibility group. The authors conclude that it is possible to improve aerobic fitness in patients with FM, but this improvement does not necessarily include improvements in symptoms (McCain et al., 1988).

Mengshoel et al. (1992), postulated that they could improve aerobic capacity and FM symptoms with an aerobic dance program rather than bicycle erogmetry with which many patients are unfamiliar/uncomfortable. They studied 26 women with FM in an experimental, parallel, matched group test design with age as a randomization block factor in a 20 week fitness training program. A control group (n=14) was instructed not to change their physical activity level. The treatment group received a low-impact aerobic dance program 60 minutes twice a week. Heart rate intensity was kept at 120-150 beats per minute. In an attempt to tailor the program for FM patient needs, exercises involving jumping and extensive motion of the shoulders and hips were omitted in an effort to reduce pain in FM tender points. No description of static or dynamic muscle strengthening exercises or pauses between movements to allow the muscle to return to baseline were mentioned. The study suffered a 39% attrition rate in the treatment group and an 18% in the control group with patients who dropped out reporting an increase in pain, fatigue or "other unrelated" illness. The outcome variable, dynamic muscle endurance of the lower extremity was measured with a step test. This type of eccentric activity is now known to worsen post-exercise pain in FM patients. Patients who were able to complete the program had a significant increase in dynamic endurance muscle strength (Mengshoel et al., 1992).

Hoydalsmo and colleagues (1992) were the first to report the effects of a multidisciplinary training program in FM, but it is of limited value as it was published only in abstract form. Thirty patients exercised 45 minutes 5 times daily for 4 weeks (3 ½ hours/day). The intervention was described only as "aerobic fitness and flexibility" (p.64). This study, without a control group, reported a significant improvement in aerobic capacity (via Astrand-Rhyming cycle ergometry) and a decrease in number of tender points in 36% of the sample. The authors did not report attrition rates (Hoydalsmo et al., 1992).

Isomeri and colleagues (1992) studied 45 FM patients (39 female, 6 male, ages 24-55 years, mean 43.7 years) by randomizing them into three groups: 1) amitriptyline and undefined light physical training, 2) aerobic training and amitriptyline and 3) aerobic training only. The participants received the intervention (described only as above and published in abstract form only) in the hospital for 3 weeks and continued at the patients homes for an additional 3 months. After 3 months, pain, as measured by VAS, improved only in the amitriptyline and aerobic training group. This study filled an important gap in the exercise and FM literature by attempting to control a pharmacologic variable (amitriptyline use) which was by this point becoming a standard of care in FM. A major fallacy in the reporting of this study was the omission of attrition rates, which was becoming evident as a problem in FM exercise research (Isomeri et al., 1992).

Nichols and Glenn (1994) continued the study of aerobic activity in the treatment of FM due to the premise that activation of central or peripheral beta-endorphin systems through aerobic activity may release adrenocorticotropic hormone or cortisol. In healthy controls and other rheumatologic conditions, this hypothesized release may have been responsible for improved psychological status and reduced pain in earlier studies. They postulated that aerobic walking would positively impact FM symptoms. They enrolled 19 people with FM (17 female, 2 male) and nine subjects with FM as sedentary controls. Participants were matched for age and gender and randomized into one of the two groups. Participants in the treatment group met 20 minutes three times per week for eight weeks; they walked on an indoor track at a pace producing 60-70% of their age-predicted maximum heart rate. The control group, who were not exercising regularly, met once at the beginning of the study and once at the end to complete questionnaires. Results included nonsignificant trends toward improvement in pain (McGill Pain Questionnaire, Sickness Impact Profile: Physical Dimension) and psychological status (Sickness Impact Profile: Psychological Dimension) in the treatment group. The attrition rate for this shortest intervention study to date was 17% for the treatment group and 25% for the control group, lower than some preceeding FM studies (Nichols & Glenn, 1994). The statistically inconclusive results necessitated further study of the intervention but the lower drop out rate was touted, by the authors, as due to efforts toward socialization and group coherence during the study. Efforts toward socialization and group coherence could potentially serve to decrease drop-out rates in both treatment and control groups in future studies.

Clark and colleagues (1995) conducted a three month program of aerobic exercise demonstrating that FM patients are able to exercise at a training index to improve aerobic capacity by an average of 20%. Thirty women with FM were randomized into either a treatment group (aerobic cycling) or a control group. In addition to improvements in oxygen consumption as measured by a Gould metabolic cart (cycle), the experimental group also had lower myalgic scores, and improved global assessment compared to the control group. Neither group demonstrated significant differences in quality of life score. Attrition rates were 27% for the control group and 20% for the treatment group (Clark et al., 1995b).

Wigers and colleagues (1996) randomized 60 FM patients equally into one of three groups: aerobic exercise, stress management treatment and treatment as usual. The three group experimental design necessitated the largest sample size in an FM exercise intervention study at the time. The aerobic exercise group met 45 minutes, three times per week for 14 weeks. Training was interval and described as warm-up, followed by high intensity training for 3-4 minutes four times during the session. The high intensity period (as verified by heart rate at 60-70% of age predicted maximum heart rate) was followed by 15 minutes of aerobic games such as tag and ball. Each game also included a four minute rest time. The classes concluded with warming down and stretching. The stress management treatment group met 90 minutes for 20 sessions over 14 weeks. The treatment as usual group were characterized as continuing their baseline treatments mostly consisting of pharmacologic therapy (tricyclics: n=8, analgesics: n=6, muscle relaxants: n=3, and hypnotics: n=3). All patients were followed by phone, mailed questionnaire, and tender point assessment periodically for an additional 4.5 years. Results demonstrated that immediately after the 14 week intervention, both the aerobic exercise group and the stress management group showed positive changes in pain, sleep, energy and depression; but the aerobic exercise group demonstrated the greatest improvements. The attrition rate for the aerobic exercise group at the end of 14 weeks was 20%. The attrition rate for the aerobic exercise group at the end of 4.5 years was 80%. The authors concluded that short term aerobic exercise when tailored for FM patients is effective and suffers minimal attrition problems; but FM symptoms return over time as there are obvious compliance issues when patients attempt to maintain aerobic exercise for a number of years (Wigers et al., 1996).

Martin and colleagues (1996) randomized 60 FM patients into either an exercise or a relaxation group. The exercise group met three times per week for six weeks for sixty minutes of supervised exercise which included 20 minutes of aerobic walking, 20 minutes of strength training on a universal gym machine (bench press, hamstring curls, leg press, latisimus dorsi pull downs, and abdominal curls). Patients who “had difficulty” (number not disclosed) with the universal gym machine substituted strength exercise using surgical tubing. The classes concluded with 20 minutes of flexibility training. The relaxation group met three times per week for six weeks for supervised visualization, yoga and autogenic relaxation. The exercise group experienced significant improvements in tender point scores, total myalgic index and aerobic fitness (as measured by motorized treadmill using a modified Blake protocol). No significant changes in muscle strength were noted with Cybex isokinetic dynamometer. The exercise group experienced a 40% attrition rate and the relaxation group a 33% attrition rate, which is particularly concerning since the intervention only lasted six weeks (Martin et al., 1996).

Next Norregaard and colleagues (1997) conducted an exercise study in women with FM employing three groups: traditional aerobic dance, a steady exercise group and a control group. The aerobic dance group (40% of the sample) met 50 minutes, three times each week for 12 weeks. The intervention is described as "running and other fast movements of the legs and arms" (p.73). The steady exercise group (40% of the sample) met 50 minutes, twice a week for 12 weeks. Their intervention focused on "increasing body awareness" (p.74) and gentle stretching. The control group (20% of the sample) received whole body hot packs applied for 30 minutes twice weekly for 12 weeks. The study suffered an 87% attrition rate (176 recruited, 23 completed) and those that did complete the study showed no significant improvement in pain, fatigue, general condition, sleep, depression, functional status, muscle strength or aerobic capacity. Norregaard's high attrition rate is partly a product of his definition of attrition as his "drop outs" are calculated from those recruited rather than from those who actually entered the study and completed informed consent. The authors concluded that their study "illustrates the difficulty in treating FM with physical modalities " (Norregaard et al., 1997, p. 72).

Five exercise interventions in FM were reported in the 1999 literature. Gowans and colleagues (1999) studied 45 women with FM by randomly assigning them to one of two groups: 1) a six week water exercise plus education program for FM patients or 2) a wait listed control group (Gowans et al., 1999b). Both groups eventually received the same intervention. The education classes were one hour long twice a week and met immediately before the exercise classes. Education class content included information on exercise, postural correction, activities of daily living, sleep, relaxation, medication, nutrition, psychosocial coping strategies and relaxation techniques. The exercise classes consisted of 20 minutes of walking/jogging/side-stepping/arm exercise against water resistance and 5 minutes of stretching at the beginning and end of each class. The exercises were preformed at 60-75% age adjusted maximum heart rate. Outcome measures were collected at program completion, three months and six months post program. Measures included 6-minute walk, FIQ scale, ASES scale and a knowledge questionnaire based on information presented in the classes. Results demonstrated significant post-intervention improvements in 6-minute walk distance, well-being (FIQ), fatigue (FIQ), self-efficacy (for controlling pain and symptoms), and knowledge. At follow-up immediate gains in walk distance, well-being, and self-efficacy were maintained, but gains in fatigue and knowledge were lost. The authors concluded that short-term exercise and educational programs can produce immediate and sustained benefits for patients with FM. Only four participants failed to complete the study (n=41) limitation of the study was the inability to separate the effects of exercise and education since both interventions occurred in all subjects (Gowans et al., 1999b).

King and colleagues (1999) studied 111 women with FM by randomly assigning them to one of four groups: 1) aerobic exercise, 2) FM education, 3) aerobic exercise plus FM education and a 4) control group. The groups meet over 12 weeks, but the frequency and duration of each class session was not noted. Outcome measures included the 6 minute walk, the fibromyalgia impact questionnaire (FIQ), the quality of life scale and the chronic disease self-efficacy scale. Through two-way analysis of variance with repeated measures and Tukey pot-hoc comparison, King et al. concluded that the group receiving FM education plus aerobic exercise improved most (FIQ F=4.70, p=.004; 6 min walk F=3.53, p=0.18). Attrition was not disclosed (King et al., 1999).

Rooks and colleagues (1999) enrolled 13 women into a combined progressive strength, aerobic and flexibility intervention. Classes met one hour per week, three times per week for 20 weeks. Statistically significant improvements were seen in upper and lower body muscle strength, 6 minute walk times and FIQ scores. They concluded that their intervention was safe and effective for women with FM. Attrition rates were 19%. This study is significant in the FM exercise intervention literature because it provided a progressively increasing exercise program. This study was limited by 1) small number of participants, and 2) lack of experimental design (no control group). It is difficult to ascertain which portion of the intervention was responsible for muscle strength gains in an exercise intervention that provides aerobics, muscle strength and flexibility to all participants (Rooks et al., 1999a).

White and colleagues (1999) enrolled 8 women with FM into a warm water aerobics class consisting of aerobics, flexibility and strength training. Classes met one hour per week, three times per week over six weeks. Outcome measures included VO_2 max, 6 minute walk and FIQ scores and tender points. They concluded that the VO_2 max scores and 6 minute walk scores were highly correlated (r=.77, p=.07). Tender points improved but FIQ scores and aerobic measures were unchanged. The authors concluded that at baseline the aerobic scores normal thereby limiting the possibility of measurable improvement. This study is important in the FM exercise literature because it is the first to attempt a warm water aquatic intervention. It is limited by its small size (n=6 after 25% attrition) and its lack of a control group. It also provided a combination of aerobics, muscle strength and flexibility to all participants thereby reducing the ability to correlate changes with a particular exercise type (White et al., 1999).

Busch and colleagues (1999) studied a 16 week home-based videotaped progressive aerobic exercise program in 150 women with FM. The treatments included 1) a *short bout* exercise group that exercised twice a day for five minutes three to five times per week (n=57), 2) a *long bout* exercise group that exercised one 10 minute session per day three times a week to one 30 minute session per day three times a week (n=55) and 3) a control group who maintained their usual activity (n=38). Outcomes were measured at baseline, eight weeks and 16 weeks. 104 participants completed the study with attrition of 10.5% in the control group, 38.6% in the short bout group and 36.4% in the long bout group. Measures included VO_2 max by modified Balke protocol, tender points, FIQ, self-efficacy, and AIMS. The authors concluded that their program produced beneficial effects on disease severity but only the long bout group improved VO_2 max scores. This study is important in the FM exercise literature as it offered an 1) experimental design, 2) a progressive intervention, and 3) was the first to attempt to meet the latest NIH guidelines that recommend physical activity be increased by exercising in several short bouts throughout the day (Busch et al., 1999).

<u>Critique of the Single Muscle Strengthening Only Study in FM</u>

Only one study, published in abstract form, compared a muscle strengthening

(MSG) only group to an aerobic training (AT) only group (Hannonen et al., 1995). Hannonen et al. (1995) enrolled 40 female patients fulfilling the ACR 1990 criteria for FM into the year long exercise intervention trial. The patients were randomized into two groups: MSG or AT. Baseline testing revealed no significant differences with regard to age, body mass index, or disease duration. The actual intervention was not described but training diaries were evaluated to determine participation. Results of this study revealed that the MSG experienced knee and trunk flexor and extensor increases (measurement technique not disclosed); the AT group experienced an increase in maximal oxygen uptake (measurement technique not disclosed), and both groups experienced decreased pain and increased functional ability and modest improvements in quality of life as measured by the Nottinhgam Health Profile. The authors concluded that FM patients were motivated to follow individually tailored and effective training programs for six months.

FM Exercise Intervention Summary

Sixteen exercise interventions in FM have been reported to date. The first in 1988 increasing in frequency to five studies in 1999. This trend confirms the notion that exercise is a major component in the treatment of FM and that much remains to be learned about the most effective exercise treatments. The interventions to date have been largely aerobic or combined aerobic, flexibility and strength (15 of 16). Some of these studies have been limited by attrition rates of 38-87% (4 of 16). Some did not report attrition (4 of 16). Some did not employ a control group or meet criteria for an experimental design (4 of 16).

Only one study to date isolated muscle strengthening as the treatment intervention and aerobic exercise as the alternative treatment. This study provided data that muscle strengthening can be tolerated by patients and improve outcomes. It is limited by its publication as an abstract, its relatively small sample size and its lack of reporting attrition.

No study to date has compared a muscle strengthening to a flexibility training program for women with FM Flexibility was the first control group treatment in the original 1988 FM exercise intervention. Flexibility is considered a safe, yet minimal, standard of care in conservative exercise treatment in FM. Muscle strengthening has been used successfully across a variety of populations including apparently healthy, elderly, chronically ill, rheumatic disease, and FM (1 study). The American College of Sports Medicine suggests that improving the strength of the large muscle needed for aerobic exercise (hips and thighs) may be a safe and effective first step in reversing the effects of detraining seen in various populations (American College of Sports Medicine Position Stand, 1998). A randomized, controlled exercise study comparing the standard of care, flexibility, to progressive muscle strengthening is a logical next step in the FM exercise literature.

Theoretical Framework

The theoretical framework that guided this exercise intervention was a combination of 1) the physiology of FM, 2) exercise physiology, and 3) factors that increase adherence in exercise, especially the concept of self-efficacy. Clear knowledge of the central and peripheral physiology of FM and exercise, can provide a framework for an intervention that is both sensitive and specific to FM. However, as many published exercise studies have demonstrated, even the most carefully designed exercises can fall victim to class attrition if factors of adherence are not attended to.

The first portion of chapter two provided state of the art knowledge regarding baseline physical functioning status of FM and central and peripheral physiology of FM. Next exercise physiology and muscle strengthening in FM and a variety of closely related populations were described and critiqued.

A discussion of factors that increase adherence in exercise, especially the concept of self-efficacy will be presented here. A brief summary of physical inactivity and exercise attrition rates will conclude this section.

Self-Efficacy

Self-efficacy grew from the mid twentieth century social learning theories. Major social learning theories of this time can be collapsed into three types of learning theories: operant, classical and more recently, vicarious. Operant learning theorists were generally concerned with operant conditioning, a psychological learning theory founded by Thorndike and developed and popularized by Skinner (Skinner, 1971). This theory focused on reward and reinforcement as a necessary component of learning.

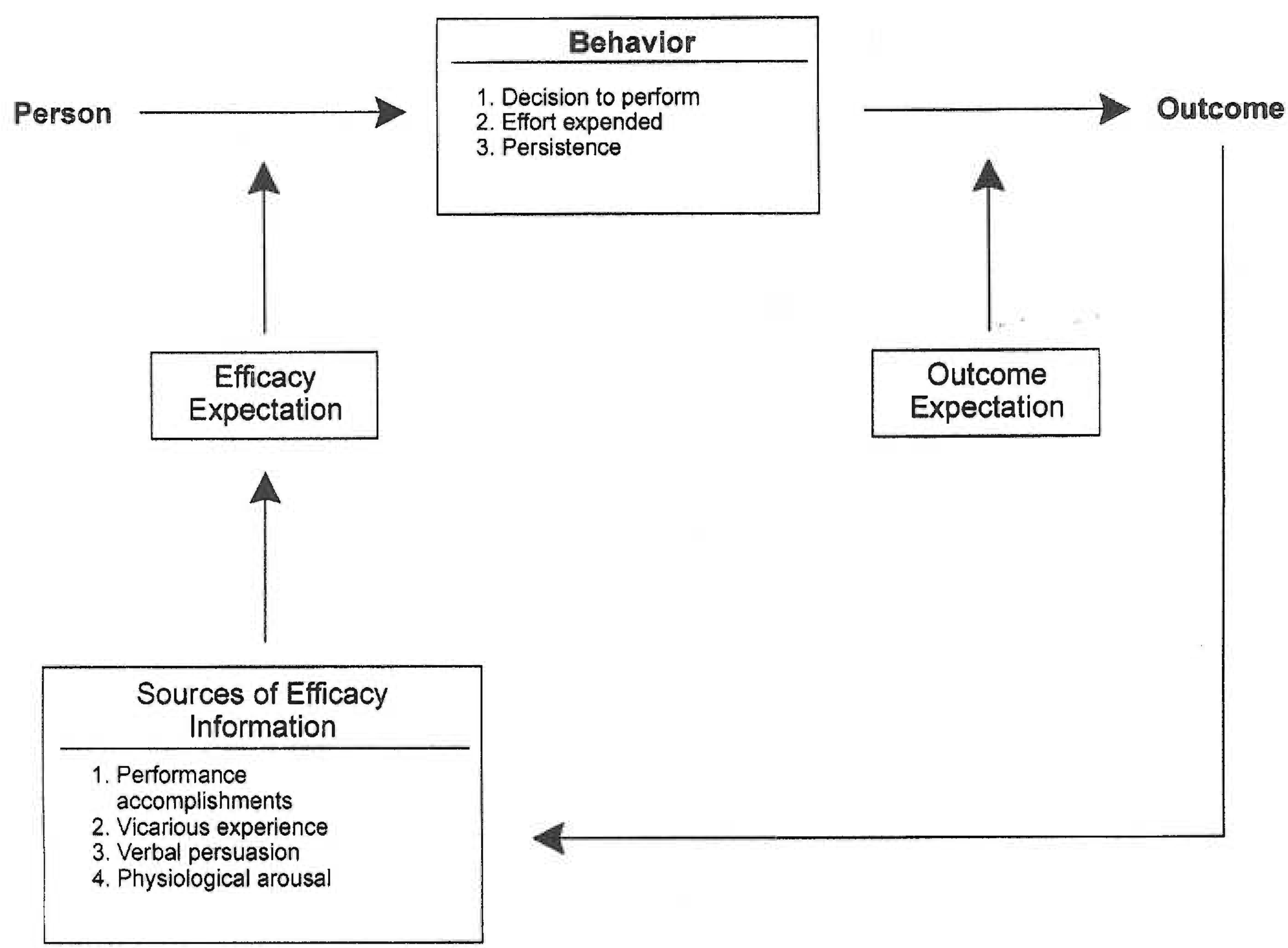
Classical learning theorists approached behavior in a Pavlovian or classical conditioning manner. They were primarily concerned with responses that are not voluntary. Over time, both operant and classical learning theories fell short in explaining learning as an internal process. These learning theories relied heavily upon relatively inflexible conceptualizations of personality in terms of types and traits. Dissatisfaction with these views grew as a result of poor measurement abilities and a general disbelief in the finality of human personality as static or unmalleable (Froman, 1997) .

What was needed was a theory that recognized cognitive processes of both performance and learning. In the 1960s vicarious learning theories were introduced and were concerned with learning the performance of a specific response after the learner observes someone else performing the response (Bandura & Walters, 1963). Concepts such as expectancies, values, choice and locus of control were introduced in the literature on personality at this time. It was in this setting that Bandura began to make his contributions. Self-efficacy is an example of vicarious learning.

Bandura has variously described self-efficacy as a mechanism, a construct, a facet, a generative capability, an outcome and a mediator. Eventually Bandura labeled his body of work social cognitive theory to recognize self-regulatory process beyond those related to learning (Bandura, Taylor, Williiams, Mefford & Barchas, 1985). In Bandura's view, social cognitive theory is larger than social learning theory because it includes more than an explanations of learning. It encompasses the social origins of thought and action, motivation and affect, both conscious and unconscious. Bandura defines self regulation as a self-set standard for behavior which allows cognitive structures in the person to perceive, evaluate and regulate behavior. Self-regulation helps the individual select and attend to realistic models, engage in setting achievable goals and derive satisfaction from meeting those goals (Bandura, 1986). Although self-regulation is a basic component in Bandura's original theory it has thus far been largely omitted in attempts to operationalize and measure self-efficacy (Gredler, 1992).

Self-efficacy consists of two primary components: efficacy expectations and outcome expectations (Bandura, 1986). Efficacy expectations are defined as judgments of one's capability to accomplish a certain level of performance. Outcome expectations form an integral part of self-efficacy theory and represent consequences a behavior will produce. Thus efficacy expectations represent judgements of personal competence, while outcome expectations represent judgements of the likely impact of a given behavior. The vast majority of self-efficacy research to date has focused on efficacy expectations over outcome expectations (Fitzgerald, 1988). Figure two represents an author adaptation of the classic linear relationship between persons and outcomes via self-efficacy theory (Bandura, 1977).

Figure 2. Self-Efficacy Components



Self-efficacy refers to the belief that an individual can competently cope with a challenging situation; it is concerned more with personal judgements than personal skills. Bandura postulates that once efficacy information is received, it must be cognitively processed and is used by individual to judge their capabilities (Bandura, 1977; Bandura, 1986). If a person judges herself capable of performing a behavior, like exercise, she will be more likely to act. Self-efficacy judgements do not necessarily need to be accurate to influence behaviors and outcomes. In a seminal study establishing the causality of self-efficacy and exercise performance, female participants were told erroneously that their physical stamina and muscle strength outpaced their competitors whose gender was unknown to them. A group of male participants, who were equally blinded to the gender of the female group, were told, also erroneously, that their performance was less than the competing group. The female group experiencing the higher illusory beliefs of physical strength and stamina went on perform at an enhanced level while the male group the performed more poorly. Self-beliefs of physical efficacy, heightened in the females and deflated in the males, obliterated the large preexisting gender difference in physical strength between the groups (Weinberg, Gould & Jackson, 1979). This study demonstrated that variations in self-efficacy beliefs made a substantial contribution to variations in motivation and performance accomplishments.

Bandura identified four major sources of information that influence self-efficacy. Listed in their hypothesized power to influence efficacy expectations the sources of information include: performance accomplishment, vicarious experiences, verbal persuasion and physiological arousal. Performance accomplishment refers to learning through personal experience where one achieves mastery over difficult or previously feared tasks; for example, a wheelchair bound athlete successfully completing a marathon. Vicarious experiences are a second and powerful source of self-efficacy information. They involve observing others similar to oneself successfully performing the behavior in question; an example might be an exercise class consisting entirely of persons with a given disease. For modeling to be most effective, the participants should match on several levels: age, gender, disability/ability for example. Verbal persuasion is a third source of efficacy information. An example includes a respected authority (e.g. nurse or doctor) verbalizing their confidence in an individuals' ability to successfully perform a task. Finally, physiological arousal or physical feedback informs efficacy. For example decreases in pain, fatigue, anxiety or depression as a result of an exercise program positively influences self-efficacy. Assisting an individual to use relaxation training to reduce anxiety can improve efficacy expectations related to negative physiological arousal.

Each of the four efficacy expectations may vary on several dimensions which have an important effect on performance. The three principal dimensions are magnitude, generality, and strength. Magnitude refers to the level of difficulty of a task. For example, people how exhibit low magnitude may only be successful in simple tasks whereas people who exhibit higher magnitude may successfully negotiate more complex tasks. Generality refers to the extent that an expectation can be generalized to other situations. In the area of exercise training, an example of generality would be the likelihood that someone who is successful exercising in a supervised group may be successful in exercising unsupervised at home. Finally, the dimension of strength may be thought of as a continuum from stronger or weaker. Weaker expectations are easily eliminated, while strong expectations are more likely to persevere.

Self-efficacy is not thought to be widely generalizable. Therefore people do not have self-efficacious personalities. Instead the efficacy is specific for a given activity under a given set of circumstances. For example someone who is highly self efficacious for swimming may not be so for strength training. Therefore it is important to compare self-efficacy studies or questionnaire responses on specific populations and specific circumstances. For example weight training has been demonstrated to improve self-efficacy and facilitate return to daily vocational and avocational activities in a variety of populations (Verrill & Ribisl, 1996a). This study gives researchers information specifically about strength training and self-efficacy.

A circular pattern among self-efficacy has been noted. In other words, higher beliefs in the ability to perform an activity results in higher adoption of the activity; this continued successful mastery results in higher self-efficacy scores and activity maintenance. Higher self-efficacy scores predict higher adherence to exercise prescription (McAuley, Lox & Duncan, 1993).

Two meta-analyses comparing a variety of health-promoting lifestyle theories found self-efficacy theory to be the most powerful predictor of health promotion related behavior change including exercise (Gillis, 1993; Salazar, 1991). Self-efficacy theory has shown the greatest promise for explaining physical activity adoption among adult populations (Marcus & Owen, 1992; McAuley et al., 1993; Sallis, Hovell & Hofstetter, 1992) and is the strongest predictor of exercise initiation and maintenance in a myriad of chronic conditions including FM (Buckelew et al., 1996; Clark, 1996). A recent study of predictors of exercise behavior among 600 FM patients revealed that the most important predictor of regular exercise was exercise efficacy. People with high levels of confidence in their ability to exercise under adverse conditions were four times more likely than non-exercisers to participate in a regular exercise program (Gallagher, Cronan, Walen & Cronan, 1999).

A discussion of demographic variables that influence exercise adherence follows.

Demographic Variables that Influence Adherence to Exercise

Knowledge of the patient's age, gender, socioeconomic status, and ethnicity has been demonstrated to be useful in predicting activity adoption and maintenance; all have been found to be factors in physical activity patterns and preferences (DiPietro, 1995). For example, children are more active than adults, and as they grow older, girls become less active than boys. At 12 years of age, 70% of children participate in vigorous physical activity, but by age 21 this declines to 42% of men and 30% of women (U.S. Department of Health and Human Services, 1996) Recent evidence suggests that physically inactive Americans are disproportionately less educated, female, elderly, economically disadvantaged, and live under unfavorable social circumstances (Crespo et al., 1996). By contrast, most studies of physical activity have involved middle-aged, white males of middle socioeconomic status.

A recent poll of 1,599 urban residents found that low-income people are just as likely as those with higher incomes to realize the importance of exercise (Shape up America, 1995). Persons of lower socioeconomic status report many logistical obstacles to exercise, such as feeling unsafe exercising outdoors in their own neighborhoods, a lack of access to public exercise facilities, and an inability to afford private facilities or equipment. This may account in part for the two groups that have the highest rates of physical inactivity: African American and Mexican-American women (Crespo et al., 1996).

In addition to socioeconomic status, gender is a major predictor for exercise motivation. Several studies have found that women exercise to control weight, improve appearance, and improve stress-mood (Cash, Novey & Grant, 1994; Gill & Overdorf, 1994). More specifically, older women report exercise for social interaction and mastery of new skills (Gill & Overdorf, 1994). Men on the other hand are motivated when the activity is competitive, exciting and challenges their abilities. Increased muscle strength/mass is also a motivator for men (Stephens, Craig & Farris, 1996; Tappe, Duda & Menges-Ehrnwald, 1990). Men and women differ in the amount and type of exercise they undertake. Women tend to exercise less frequently than men and often chose activities such as walking, swimming or aerobic dance. Men tend to participate in sport related activities and weight training (National Center for Health Statistics, 1988). Previous exercise studies with women have noted that smaller class size, social support, opportunities for personalized instruction and building games or fun into the classes may have contributed to enhanced class attendance (Nichols & Glenn, 1994). Considerations of demographic data and patient preferences may increase adherence in an exercise program.

Summary of Theoretical Framework

Despite a wealth of sound scientific data now available regarding the positive effects of physical activity, 60-80% of Americans remain inadequately physically active. Much work remains to be done to improve adoption and maintenance of physical activity.

Self-efficacy is believed by many to be a key component of a successful exercise intervention. The ultimate purpose of any health promotion theory is to enable researchers to develop interventions and strategies that will be maximally effective. Furthermore, knowledge of exercise characteristics based on demographic factors may increase adherence to an exercise program.

Chapter Two Summary

FM is an increasingly common, costly and debilitating problem, the complexity of which necessitates a bio/psycho/social lens be used to view the disorder and its treatments. While specially tailored aerobic exercise is currently recognized as a safe and effective treatment modality, many clinicians report FM patients' inability to comply and thus, encourage only gentle stretching exercises (Reiffenberger & Amundson, 1996; Sherman, 1992). There is a need to know the effects of an isolated muscle strength training program for women with FM. A significant gap in the FM and exercise literature exists in the failure of exercise studies to 1) isolate muscle strengthening, 2) provide an intervention that is sensitive to the musculoskeletal and fitness needs of patients with FM, and 3) to holistically evaluate patient motivation for participation in exercise interventions by measuring both self-report symptom severity and psychological variables along with the more commonly gathered physiologic measures.

CHAPTER III

RESEARCH DESIGN AND METHODS

Introduction

This chapter will detail the study's research design and methods. Particular attention will be devoted to the design, population, sample, inclusion/exclusion criteria, power analysis, subject recruitment, setting, intervention, selection of measures for study variables, sequence and procedures, protection of human subjects and statistical procedures.

Design

An experimental design was chosen for this study. Female FM patients were randomized to receive either a program of muscle strengthening (treatment group) for 12 weeks or stretching (flexibility training) for 12 weeks (control group). Randomization was accomplished with a coin flip. Data were collected within two weeks before and after the intervention. All measures were taken at baseline and at the conclusion of the study. The principal investigator (PI), who was blinded to group assignment, collected flexibility, tender point measures and self-report symptom scales. An exercise physiologist, also blinded to group assignment, collected muscle strength and body mass measures. Additionally, weight was measured monthly by the participants and recorded by the exercise instructor. This experimental design allowed for giving the control group flexibility training, the normal standard of care for FM, and providing an equal amount of attention to both groups.

Population and Sample

Population

The target population was adult females ages 20-60 years who had been diagnosed with FM by ACR criteria and who were medically able to engage in an exercise program. Diagnosis was confirmed by the PI at the initial lab visit (see appendix one). Only women were included in this study for four reasons: 1) FM is primarily a syndrome of women, 2) the accessible population was 95% women, 3) some of the outcome criteria are sex specific, and 4) the exercise needs may be different for men and women and would have necessitated developing two different protocols based on gender. Even with only women, the results of this study have potential to generalize to the large majority of persons with FM.

The accessible population was comprised of three sources. First, a registry of 5,000 FM patients who had been seen on referral to the Rheumatology practice at a teaching university in the northwestern United States (US) was made available to the PI. Second, 800 participants at a FM conference held six month prior to the intervention had the opportunity to complete a form indicating an interest in research participation (see appendix two). Third, additional women with FM were recruited by an advertisement in a university generated monthly campus newsletter and e-mail service.

Inclusion and Exclusion Criteria

Patients were eligible for the study if they met the following inclusion and exclusion criteria. Inclusion criteria included: 1) female, 2) between 20-60 years of age, 3) a definitive diagnosis of FM based on the American College of Rheumatology (ACR) criteria (Wolfe et al., 1990). Exclusion criteria included 1) current or past history of cardiovascular, pulmonary, neurological, endocrine or renal disease that would preclude involvement in an exercise program, 2) current use of medications, such as moderate or high dose beta blockers, that would significantly affect normal physiological response to exercise, 3) current cigarette smoking, 4) score of 29 or greater on the Beck depression scale modified for FM (higher scores indicate more depression with a range of 0-63), and 5) current participation in a regular exercise program. Inclusion criteria were selected to target the population most likely to seek care for FM. The exclusion criteria were selected to reduce the risk of enrolling a patient in the study with undiagnosed acute or chronic disease that would require in-depth medical clearance prior to participation in the study.

Power Analysis

The sample size, set originally at 60, was based on the desire to detect a 30% change in the main outcomes, muscle strength and endurance, using a one-tailed t-test with alpha set at .05. Available data on improvements in muscle strength in healthy populations ranged from 20-50% (Verrill & Ribisl, 1996a). There were no muscle strengthening data in FM to use for this calculation; therefore, a moderate estimate of effect was chosen. Thirty subjects in each group could provide power in excess of 80% to detect this difference. There could be up to a 20% drop out from each group and still maintain adequate (80%) power.

Subject Recruitment

Subject recruitment was a multi-step process occurring over a three month period. The following steps were employed: 1) screening from data bases, 2) invitation by letter, 3) return card indicating interest in study participation, 4) follow-up phone interview and invitation to orientation session from returned interest cards, 5) attendance at a single orientation session in which participation expectation was described at length, and 6) individual screening by PI in laboratory, including review of Beck depression, exercise history questionnaires and FM diagnosis status.

Screening from Potential Subject Sources

A computerized spreadsheet of 5,000 FM patients who had been seen on referral to the rheumatology practice at a teaching university in the northwestern U.S. was shared with the PI. The data base was screened for age and zip code (11 mile radius of campus). This screening resulted in an invitation letter to 1,480 potential subjects.

Invitation by Letter

A letter (see appendix three) was sent to 1,480 potential participants inviting them to return a postage paid envelope if they met inclusion/exclusion criteria and were interested in learning more about participating in an exercise intervention in FM. Two hundred and sixty seven potential participants returned a letter of interest.

Follow-up Phone Call

The PI called all persons who returned the letter of interest and screened again for inclusion/exclusion criteria and gave a brief over view the study. Phone calls were also placed to interested persons who had responded to a call for participants at the FM conference (n=84) and campus newsletter (n=48) (described above). Potential participants were invited to attend a single two-hour Saturday morning orientation session at the university where the intervention took place.

Orientation Session

Seventy five potential participants attended the Saturday orientation session by the

PI. The first hour included an update about FM treatments and research by two FM experts and a question and answer session with participants. During the second hour, the study was presented in detail including timing of classes, laboratory visits and potential risks and benefits of the participation. At the conclusion of the session, persons who remained interested in participating in the study made appointments for a meeting in the laboratory with the PI sometime during the following two weeks. Sixty one persons who attended the orientation session elected to participate in the study.

Additional Subject Recruitment

Seven additional subjects were enrolled in the study during the two week period between the orientation session and beginning of the classes. Five of these seven were persons who responded to the campus newsletter advertisement. Two additional people were referred by study participants (a daughter and a friend).

Setting

The setting for the intervention was a large, northwestern US urban, academic medical center accessible by public and private transportation. The intervention occurred at the university's fitness center in a large multipurpose exercise room. Monthly weights were measured in the multipurpose exercise room. All other outcome measures were obtained in university's exercise physiology laboratory located on the second floor of the fitness center.

Intervention

Treatment

The treatment group received a progressive muscle strengthening program which began with five minutes of warm up and gentle stretching followed by muscle strengthening exercises consisting of up to nine standing, six sitting and seven lying exercises (40 minutes total). Class sessions were 55 minutes 2 times per week for 12 weeks. The exercises minimized eccentric work and provided four count pause between each repetition to demonstrate an appreciation for the delayed return to baseline muscle tone in FM found by Elert (Elert et al., 1989). As an alternative to the pause, sometimes the opposing limb was worked during the pause phase. Each class strengthened the same 12 major muscle groups with single sets, initially with four to five repetitions and progressing to 12 repetitions by the end of the study. Furthermore, the specific selection of exercises was sensitive to the deconditioned state that predispose FM patients to microtrauma, delayed muscle pain, and aggrevation of FM tender point areas. The intervention provided balance, body posture, and alternative exercises for transient low back, knee and shoulder pain common in FM (Bou-Holaigah & Flynn, 1997; Hudson, Starr, Esdaile & Fitzcharles, 1995). Because FM patient's complain of perceived instability and lightheadedness with rapid position change, gradual means of position change from standing to lying, and vice-versa, were incorporated between exercises. Participants were encouraged to increase resistance (muscle load) over the 12-week program with hand weights (1-3 pound), surgical tubing (Therabands: "light" resistance-pink; "moderate" resistance-green) and a greater percentage of floor versus standing or chair exercise. Shortening the Theraband length was also an alternative mode taught to increase muscle load. Particpants were instructed to have no tension in the bands at the end of the down phase in an effort to promote complete muscle relaxation. Progressive resistance has been demonstrated to significantly improve muscle strength and endurance in similar studies (Topp et al., 1993; Topp, Mikesky & Bawel, 1994). The program progressed from week to week with earlier sessions focusing on education, body mechanics and some muscle strengthening exercises. Later classes offered more variety in meeting individual fitness needs (e.g., less fit people could choose more chair exercises; moderately fit persons could chose more standing exercises; fitter persons could chose more lying exercises). Participants were encouraged to "listen to their bodies" and reduce training load (intensity of load or number of repetitions) on days they were experiencing a symptomatic flare. A 5-minute cool down and stretching segment concluded each class.

Control

The control group received a stretching program designed by FM experts to minimize injury from deconditioned muscle and FM tender point location. Supervised classes meet 55 minutes 2 times per week for 12 weeks. Class began with a low intensity warm up of marching in place for 3-5 minutes and proceeded to stretch the same 12 major muscle groups at each session. Stretches were done standing, sitting or lying depending on the body area of focus. Participants could elect to use a towel to maximize stretch in some muscle groups (e.g. side lying thigh stretch, sitting hamstring stretch). Stretches were static rather than ballistic. Each stretching class concluded with eight to ten minutes of guided imagery and relaxation. Stretching programs are considered the standard of care, should not increase pain and are a typical exercise prescribed for patients with FM (Sherman, 1992). The control group received equal group and leader support as the treatment group so that attention was controlled.

Individual Attention to Participants for Exercise Modification

Cues for patient readiness to progress were monitored by the fitness instructor and an exercise physiologist with FM expertise. The exercise physiologist attended half of the muscle strengthening exercise classes and half of the stretching classes. She provided individual assistance with exercise modification, posture, and balance and responded to participants who had a specific complaint (e.g. tender point or injury).

A regional non-profit FM foundation provided each class member with her own professionally produced muscle strengthening or stretching videotape free of charge. The videotape provides the same exercises as described above. All classes (treatment and control) were taught by a fitness instructor with experience teaching groups and personal training of FM clients. If subjects were unable to attend the class, they were encouraged to use the videotape to replace one class per week; subjects kept a log detailing how often they used the tape, which exercises they did and length of time for exercise session. The combination of supervised and home exercise sessions has been found to improve compliance and decrease attrition in exercise trials (Topp et al., 1993).

In an effort to increase compliance and encourage group coherence, class size was limited to 17 participants. This meant that the classes, both experimental and control, were offered 4 times/week. Initiation of class start dates were staggered by 2 weeks in an effort to maximize participant choice for participation and allow the principal investigator 4 rather than 2 weeks to collect baseline and post intervention measures. Personalized attention was available for any participant's specific concerns by the university's FM treatment and research team. All exercise tests of subjects in this study were conducted according to the American College of Sports Medicine guidelines for safety (American College of Sports Medicine, 1995). First aid and emergency resuscitation equipment were available in both the laboratory and exercise facility.

Attempts to increase self-efficacy included activities to enhance performance accomplishment, vicarious experiences, verbal persuasion and physiological arousal. The progressive nature of the intervention was designed to provide participants with a sense of personal mastery. Individual attention by the exercise physiologist also enhanced performance accomplishment. Vicarious experience enhancement was accomplished by keeping the class sizes small and consisting of women with FM. This provided an opportunity to observe others similar to oneself successfully perform exercises. Verbal persuasion was provided by at least three persons: the exercise instructor and the exercise physiologist during the classes and the PI during the first laboratory visit. Finally physiologic arousal was addressed by the specific selection and sequence of exercises. The exercises were designed to be sensitive to pain and deconditioning in FM and therefore would not worsen symptoms in FM.

Measurements

All pre and post intervention outcomes, excluding monthly weights, were measured by the either the PI or an exercise physiologist who was blinded to group assignment. The PI measured tender points, flexibility and distributed paper and pencil scales which were completed during the lab visit. The exercise physiologist measured muscle strength in the shoulder and thigh and body fat. Monthly weights were measured by the participants and recorded by the fitness instructor.

Measuring Muscle Strength and Flexibility

The methodological criteria for selecting outcome measures for assessing muscle strength and flexibility are complex. The tests should be affordable, reliable, valid, accessible and known to produce measurable change in the population being studied.

Finally, the tests should produce clinically significant in addition to statistically significant (p value) changes. The trade-offs for commonly employed direct laboratory measures versus indirect field or functional measures were debated in chapter two (Burckhardt, Moncur & Minor, 1994b). The conceptual and operational definitions for measures used in the present study are below.

Strength

Strength is a force generated during or while attempting a given movement. Muscle strength, the main outcome variable, was measured by testing maximum isokinetic strength of nondominant knee extension and flexion and nondominant shoulder internal and external rotation with a Cybex II isokinetic dynamometer (Cybex Inc.) (Jacobsen & Danneskiold-Samsoe, 1987; Jacobsen & Danneskiold-Samsoe, 1992). The dominant side was used if the participant had history of an injury or a concern about testing the nondominant side. Power output was measured at an angular velocity of 60 degrees per second, the standard degrees per seconds index of maximum muscular strength (Fleck & Kraemer, 1987). The Cybex II isokinetic dynamometer was then reconfigured with manufacturer's adapters to shoulder test shoulder internal and external rotation strength. During shoulder internal and external rotation testing, power output was measured at an angular velocity of 60 degrees per second.

During the strength testing, the exercise physiologist instructed the participant to attempt five shoulder rotations and five thigh extensions prior to recording their scores. For quadriceps strength testing the participant sat with hips and knees at 90 degrees on a padded chair. The dominant leg was strapped to the chair per manufacturer's instructions. The actual test consisted of five complete knee extensions, starting at 90 degrees knee flexion and performing each repetition to full 180 degree knee extension. For shoulder strength testing the isokinetic dynamometer was altered so that the participant was supine with her non dominant arm extended forming right angles at the axilla and elbow. Knees were flexed and supported by a wedge pillow. Hips were strapped to the stretcher per manufacturer's instructions. The actual test consisted of five complete shoulder internal and external rotation repetitions. The exercise physiologist provided the same amount of moderate verbal encouragement to each participant for both tests.

Flexibility

Flexibility was conceptualized as the ability of a muscle group and its articulating joint(s) to comply with demands for compliance via stretching. Flexibility measures were directed at assessing movements for activities often limited in FM. Patients frequently complain of insufficient range of motion, strength and endurance to perform daily activities such as grooming or reaching high shelves. There are fewer laboratory measures that assess flexibility and range of motion thus necessitating the selection of a functional or field test for flexibility. The flexibility measure for this study was chosen because of its previous successful use in FM populations and its specificity for the muscle group of interest. Flexibility measures to assess these movements included: external and internal rotation of the shoulders by a hand to neck and hand to scapula movement. Subjects were asked to reach behind their head with one arm and as far beyond their neck as possible. Next subjects were asked to reach behind their backs with one arm and up toward their scapula as far as possible. Each of these two movements were scored on a 0- to 4-point scale, where 0 is normal range of motion and 4 is worst range of motion

(Mannerkorpi et al., 1994). The flexibility scoring scale is located in appendix four.

Measuring Body Composition

Body composition may include multiple components such as height, weight and percent body fat. Percent body fat is commonly conceptualized as fat free versus fat mass. Measures for body composition in the current study included body weight in pounds, height in inches and % body fat by seven point skin fold caliperimetry. Body fat was measured in seven sites (chest, axilla, triceps, subscapula, abdomen, suprailiac, thigh) by the exercise physiologist using a two prong spring loaded caliper (Harpenden) per anthropomorphic standardized guidelines (Wilmore & Behnke, 1988). Body weight was measured in pounds using the same calibrated standing model scale (Detecto). Body height was elicited by self report and recorded in inches. Although all body composition analysis tests proposed in this study are sensitive to change from exercise in healthy and cardiac populations (American College of Sports Medicine, 1995), they are not commonly reported in patients with FM. Such measures are able to detect small changes in body composition, taking place over a relatively short period of time in related non-FM populations (Poskitt, 1995). Body composition scoring scale in located in appendix five.

Measuring Physical Activity Levels

Baseline amount of physical activity in the current study was measured by evaluating selected items in The Physical Activity Scale for the Elderly (PACE). The PACE is a self-report measure of physical activity over the previous two weeks and inquires about work, home and leisure time activity (Washburn, Smith, Jette & Janney, 1993). Leisure time activity is divided into light sport, moderate sport and strenuous sport. Light sports include activities such as badminton, billiards, bowling, fishing off a pier, golf with a cart, shuffleboard and table tennis. Moderate sports include activities such as dancing, golf without a cart, skating, softball, doubles tennis, and non competitive volleyball. Strenuous sports include activities as aerobic dancing, backpacking, basketball, racquetball, mountain hiking, rowing, skiing, soccer, stair climbing, swimming laps and singles tennis. The PACE also inquires about regular muscle strengthening activities such as push-ups, sit-ups, calisthenics, weight-lifting or physical therapy with weights. To date, there are no tools for assessing baseline amounts of physical activity exclusively for FM populations. This scale was chosen because the FM population at midlife has been found to be similar to elderly populations in terms of physical fitness (Clark et al., 1995b; Mannerkorpi et al., 1994). This scale also asked specifically about participation in muscle strengthening exercises.

Measuring FM Symptoms: Pain, Disrupted Sleep, Fatigue and FM Impact

Pain has long been described as a subjective multidimensional phenomenon with sensory, affective and cognitive dimensions (Melzack & Wall, 1965). For the purposes of this study, pain was conceptualized by the classic definition from the International Association for the Study of Pain (IASP) (1979) - "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage"(p.247) (International Association for the Study of Pain; 1979). A combination of three subjective pain measures specific to FM were operationalized for this study.

Symptom measures for pain included number of tender points measured in 18 sites as described in the ACR 1990 FM Criteria (Wolfe et al., 1990) and a cumulative myalgic score. The degree of tenderness at each site was elicited by patient report when the PI applied pressure at 18 specific muscle tendon junctions. Pain was rated as 0 = no pain to 3 = withdrawal of the patient from the examiner. The tender point score is both sensitive and specific for FM and reflects localized pain. A cumulative myalgic score was then calculated for each patient by totaling tender point scores. Higher scores indicate more pain. The cumulative myalgic score reflects generalized pain and therefore complements the localized pain measures of the tender point score.

The Fibromyalgia Impact Questionnaire (FIQ), the second measure of pain in the study, also measures other FM symptoms . The FIQ is a 10-item instrument that measures physical functioning and symptoms of pain, fatigue, morning tiredness, stiffness, depression and anxiety along with job difficulty and overall well-being in the past week. The instrument has been validated and has shown sensitivity to change as a result of treatment (Bennett et al., 1996). Individual scales items and a total score can be calculated to determine FM impact on functioning (Burckhardt, Clark & Bennett, 1991). The FIQ was chosen for this study (over other rheumatologic and chronic disease scales) as it was developed and tested specifically for FM populations and is reported in virtually all FM studies. The sensitivity and specificity of the FIQ for FM and its ability to change as a result of an intervention have widely replaced previously employed pain scales (e.g. McGill Pain Questionnaire, Arthritis Impact Questionnaire, Health Assessment Questionnaire). Burckhardt and colleagues (1991) completed the first formal psychometric evaluation on two of the most commonly applied tools (the Health Assessment Questionnaire [HAQ] and the Arthritis Impact Questionnaire [AIMS]) and the newer Fibromyalgia Impact Questionnaire (FIQ) (Burckhardt et al., 1991). They studied 89 women, mean age 45 years, with FM and no other rheumatic diseases and found the FIQ more sensitive and specific for an FM population. The FIQ, and all other paper and pencil scales can be found in appendix six..

Measuring Psychological Status in FM:, Depression, Anxiety, and Quality of Life

Because the FIQ provides limited information on anxiety, depression and quality of life in FM, additional scales were employed to measure these constructs. Anxiety, depression and quality of life were measured in the current study with three commonly employed scales: The Beck Depression, Beck Anxiety and Quality of Life Scales. The Beck Depression Inventory is a well-known, 21-item scale that measures mood and behaviors characteristic of depression (Beck, Rush, Shaw & Emery, 1979). The Beck Depression Inventory has a well-documented 25 year history of reliability and validity in a variety of conditions (Beck, Steer, & Gerbin, 1988). This scale is selected because it has been adapted for use with FM patients by removing from the total score three items that are characteristic of all FM patients (fatigue, sleep difficulties and effort required to get things done), and which, therefore, do not correlate well with major depressive disorder. This adaptation has better accuracy (74-85%), sensitivity (45-65%) and specificity (78-96%) in an FM population than the original. A score of 13 or higher indicates a moderate level of depression while scores above 21 are very specific for major depression in FM patients (Burckhardt et al., 1994a). Gowans and colleagues (1999) completed a study measuring exercise-induced mood changes in fibromyalgia. They compared five common paper and pencil measures of assessing psychological status in women with FM over a 23 week home based exercise intervention. They concluded, that the Beck Depression Inventory is recommended over the other tested scales for exercise studies in FM populations because Beck's cognitive subscore is unaffected by changes in somatic complains that can accompany both FM and depression (Gowans, deHueck & Abbey, 1999a).

The Beck Anxiety Inventory is a 21 item instrument used to measure the severity of anxiety while discriminating anxiety from depression. Scores range from zero to 63 with a higher score indicating more anxiety. Psychiatric group means average about 25 with a standard deviation of 11 (Beck et al., 1988). A mean of 16 with a standard deviation of 10 has been found in patients with FM. In a six month multidisciplinary intervention of 104 women with FM, the Beck Anxiety Inventory was demonstrated to be sensitive to change as a result of treatment in FM populations (from 15.72 +/-10.2 to 11.01+/- 8.8 at p less than 0.0001) (Bennett et al., 1996).

The Quality of Life Scale (QOLS) is a 16-item Likert-type scale that measures well-being and satisfaction with multiple domains of life (comforts, health, relatives, children, significant others, friends, altruism, community, learning, self understanding, work, creativity, socializing, passive recreation and active recreation). Scores for each item range from 1 (terrible) to 7 (delighted). Possible scores range from 6 to 112 with higher scores indicating better well-being and quality of life. It has been validated in a FM sample (internal consistency reliability alpha = .82 to .88 and test-re-test reliability r = .84) and is sensitive to change (Burckhardt, Woods, Schultz & Ziebarth, 1989; Burckhardt, Clark & Bennett, 1993). The QOLS was originally developed in the 1970s on 3,000 randomly selected American adults (Flanagan, 1978). It has since been validated in a FM sample (internal consistency reliability alpha = .82 to .88 and test-re-test reliability r = .84) and has been proven sensitive to change in a study of 272 women with chronic disease including FM (Burckhardt et al., 1989; Burckhardt, Clark & Bennett, 1993).

Measuring Self Efficacy in FM

As detailed in chapter two, self-efficacy refers to the belief that an individual can competently cope with a challenging situation and is the strongest predictor of exercise initiation and maintenance in a myriad of chronic conditions including FM (Buckelew et al., 1996; Clark, 1996). Higher self-efficacy scores predict higher adherence to exercise prescription (McAuley et al., 1993). Weight training has been demonstrated to improve self-efficacy and facilitate return to daily vocational and avocational activities in a variety of populations (Verrill & Ribisl, 1996a).

Self-efficacy was measured with the Arthritis Self Efficacy Scale (ASES). The ASES is a 20 item scale rating an individual's certainty for performing a given task such as walking 100 feet on level ground in 20 seconds. Certainty is measured on a scale of 10 (very uncertain) to 100 (very certain) in 10 point increments. The scale contains three subscales - pain, function and other symptoms. The score for each subscale is computed by taking the average of the items that make up the subscale. Higher scores indicate higher self-efficacy. The ASES is the most common scale used to measure self-efficacy in rheumatic, arthritic and FM populations. To date, there is no measure of self efficacy exclusively for FM populations. The ASES has been shown to be reliable, valid and sensitive to change and was selected over other self efficacy scales because of its extensive successful use in rheumatic populations (Lorig et al., 1989).

Sequence and Procedures

The laboratory visit sequence was as follows: patients scheduled a one hour visit at the university's exercise physiology lab and were met there by the PI and an exercise physiologist. First the PI obtained informed consent and the participant was asked to summarize their understanding of the purpose of the study, their exercise expectations and potential risks and benefits of participation. Next, the PI reviewed the depression scale (Beck) and exercise frequency history results and confirmed the remaining inclusion/exclusion criteria. Then, participants completed all self report scales, underwent tender point examination and flexibility testing as described in the measures section above. Next, participants had their body fat estimated by skin fold caliperimetry and muscle strength testing by isokinetic dynamometry by the exercise physiologist. The rationale for the sequence selected was that measuring strength through isokinetic dynamometry might result in muscle fatigue and mild pain which might influence how participants responded to pain measures and self-report symptom questionnaires.

The post-intervention laboratory visit mirrored the pre intervention visit with the exception of consent and review of inclusion/exclusion criteria. Sequence and procedure of testing were the same. At the conclusion of data collection, a research assistant asked participants to disclose group assignment and number of times they had used the video tape at home. After data entry was concluded, group assignment and frequency of home video use were checked against attendance records submitted to the PI from the exercise instructor. Body fat, strength testing, tender point and flexibility measures were shared with each participant at the post intervention lab. Participants were also asked to complete a self-addressed envelope if they would like group study results mailed to them.

Protection of Human Subjects

The proposed study was reviewed and approved by the university's Institutional Review Board and reviewed by the university's exercise physiology laboratory. Code numbers were assigned to data collection tools and signed consent forms were stored in a separate location from the data. All raw data was housed in a locked file with access restricted to the investigator. All computer data was protected with a password. Only group data were reported. Subjects were assured that their desire to withdraw from the study would be respected and complied with at any time during the course of the study and that withdrawal would not affect their healthcare. The Consent Form is located in appendix seven.

Subjects were advised that they may or may not personally benefit from the exercise intervention. Subjects were supplied with phone numbers of the principal investigator, the exercise instructor and the exercise physiologist who attended the classes. The PI checked voice mail twice daily, seven days a week to screen messages for participant inquiries. The chief of rheumatology at the university assumed medical responsibility in the event of adverse reaction such as injury or worsening of FM symptoms. Participants were directed to call 911 or go immediately to the nearest emergency room in the event of an emergency.

Statistical Procedures

Data analysis for the two specific aims included descriptive statistics (frequencies and chi-squares) to profile the sample and verify that the two groups are similar at baseline. Changes in scores pre and post intervention were analyzed by independent group t-tests to compare the means for the treatment versus the control group at time two.

Within group changes were compared by paired t-tests. The alpha level was be set at $p<0.05$ for all tests. All data was stored and analyzed by SPSS version 10.

CHAPTER IV

RESULTS

This chapter will describe the characteristics of the sample including demographics, exercise and medication history, and pre and post intervention physiologic and symptom self report measures.

Sample Size

The sample at baseline consisted of 68 women with FM. Demographic and baseline data are reported on all subjects. Five subjects did not return for post testing; thus, post intervention data were collected on 63 subjects. Four of the five subjects who did not return for post intervention testing did not attend enough classes to be included in the final statistical analysis. Class attendance records by the exercise instructor indicated that a natural break in the attendance data occurred at 13 or greater classes (n=58). There were incomplete data on two cases yielding the final number for statistical comparison at n=56 with 28 subjects in each group.

Baseline Data

Variables at Baseline (summary found in table five):

Demographics

Age of participants ranged from 28-59 years with a mean of 47.8. *Education level* revealed that the 86% of the sample (59) had either some college/trade school, a college degree or a graduate degree. *Employment Status* data indicated that 70% (48) were employed full time or part time outside the home. *Occupations* included 29% (20) in executive/professional positions, 27% (19) in semi professional positions, 11 in clerical/sales positions, and the remaining 11 were retired, homemakers or "other".

Number of years with FM ranged from 2-14 years with a mean of 7.4 years. *Marital Status* included married or living together 63% (43), divorced or single or "other" 37% (25). *Ethnic Background* included white 63 (92%), black 2, Latina 2, Native American 1.

Medication History

The majority of the sample took on average one over the counter medication (most commonly Acetaminophen [Tylenol]) and one prescription antidepressant (most commonly Elavil [Amitriptyline] or a selective serotonin inhibitor) medication per day. Slightly less than half of the sample took a narcotic pain medication or narcotic precursor medication (e.g. Ultram [Tramadol]) every week. Approximately 30% of the sample took a daily prescription nonsteriodial anti-inflammatory (e.g. Naprosyn [Naproxsyn]) or muscle relaxant medication (most commonly Flexeril [Cyclobenzaprine]). Less than 15% of the sample reported regular use of vitamin or herbal medications. Over 50% of the sample took a daily prescription medication not related to FM treatment (most commonly estrogen replacement or an antihypertensive).

Exercise History

The majority of the sample were either completely sedentary or reported walking two or less times per week at an intensity not thought to improve aerobic fitness. No subjects reported regular participation in muscle strengthening activities such as calisthenics, push ups, weight lifting or physical therapy.

Physiologic Variables

Subjects demonstrated a high amount of pain according the *number of tender points* (scale range 0-18; mean score 16.2) involved and moderate amounts of generalized pain according the *total myalgic scores* (scale range 0-54; mean score 33.8). The majority of the sample was overweight or obese according to *weight* (mean 194.7 lbs.) and *percent body fat* (mean 35.2%). Subjects demonstrated very low mean *strength scores* measured in foot pounds of torque (knee extension 73.9, knee flexion 34.3, shoulder internal rotation 7.3 and shoulder external rotation 7.1), markedly so in the upper body. *Hand to neck flexibility* and *hand to scapula flexibility* scores indicated no significant limitations in range of motion/flexibility as most all participants could reach to the midline of their neck posteriorly and behind their back to their scapula. Scale range 0-4, higher numbers indicating more impairment, with neck mean of 0.88 and scapula mean of 1.64.

Scale Item Scores

The mean total *Fibromyalgia Impact Questionnaire* indicated a moderate amount of disease impact at baseline; scale range was 0-80 with a mean score of 49.32; higher numbers indicate greater negative impact of FM. The mean revised *Beck Depression Inventory* and *Beck Anxiety Inventory* scores indicated moderate amounts of depression and/or anxiety at baseline; scale range for each inventory was 0-63 with a mean depression score of 11.6 and a mean anxiety score of 15.4; higher numbers indicate greater depression or anxiety. No subjects scored high enough on the Beck depression inventory to necessitate exclusion from the study. *Quality of Life* scores were low at baseline indicating a poor perceived global quality of life; scale range was 16-106 with a mean of 80; higher numbers indicate greater perceived quality of life. The mean scores for the *Arthritis Self Efficacy subscales for pain, function and other symptoms* were at or near the midpoint of the scale ranges at baseline indicating some basic self efficacy with ample room for improvement during the intervention.

Other Data Analysis for Baseline Assessment

Scatterplots and minimum and maximum scores were examined on each subject for each variable. No outliers were noted that could have skewed the data means.

Baseline Data Comparing Treatment and Control

Analysis by independent group t-tests indicated that there were no significant differences between treatment and control group composition on any variables including demographics, medication or exercise history, physiological or symptom self report measures.

Between Group Changes on Independent Group t-Tests

Independent group t-tests indicated that there were no significant differences between the treatment and control group at time two.

Between Group Change Scores

Independent t-tests on between group change scores yielded no statistically significant differences on any measures variable. These findings were confirmed by running ANOVA tests for interaction effects, which yielded identical p values.

Table 5

Baseline Data Summary Table

Demographic and Baseline Variables			
Variable	Combined Groups Mean (Standard Deviation)	Mean (Standard Deviation) (greater than 12 classses attended)	
	(N=68)	Treatment (N=28)	Control (N=28)
Age in years	47.8 (7.27)	49.22 (6.36)	46.39 (8.59)
Years with FM	7.4 (6.33)	6.9 (6.6)	7.7 (5.5)
Marital Status			
Married	41	18	17
Divorced	11	4	5
Single	11	6	5
Living Together	2	0	1
Other	3	0	0
Ethnic Background			
White	63	25	26
Non-White	5	3	2

Demographic and Baseline Variables			
Variable	Combined Groups Mean (Standard Deviation)	Mean (Standard Deviation) (Greater than 12 classses attended)	
	(N=68)	Treatment (n=28)	Control (n=28)
Education			
10-12 Grade	1	1	0
High School Graduate	7	4	3
Some College/Trade School	24	7	13
College Degree	24	10	10
Graduate Degree	11	6	2
Other	1	0	0
Employed Outside Home			
Full Time	38	18	16
Part Time	10	2	4
Not Employed	20	8	8

Demographic and Baseline Variables			
Variable	Combined Groups Mean (Standard Deviation)	Mean (Standard Deviation) (Greater than 12 classses attended)	
	(N=68)	Treatment (N=28)	Control (N=28)
Occupation			
Executive/Professional	20	10	7
Technical/Semiprofessional	19	6	10
Clerical/Sales	11	6	5
Retired/Homemaker	11	5	4
Other	6	2	3
Myalgic Score	33.79 (7.74)	34.18 (7.49)	27.82 (10.11)
Number of Tender Points	16.2 (1.92)	16.5 (1.7)	15.7 (2)
Weight in Pounds	194.7 (47.7)	196.1 (42.8)	201.7 (50.5)
Percent Body Fat	35.2 (4.82)	35.81 (3.75)	35.9 (4.69)
Knee Strength in Foot Pounds			
Extension	73.9 (22.06)	71.71 (21.53)	77.11 (21.33)
Flexion	34.29 (11.62)	34.21 (10.29)	36.26 (10.52)

Demographic and Baseline Variables			
Variable	Combined Groups Mean (Standard Deviation)	Mean (Standard Deviation) (Greater than 12 classses attended)	
	(N=68)	Treatment (N=28)	Control (N=28)
Shoulder Strength			
Internal Rotation	7.28 (5.62)	6.54 (5.80)	6.82 (5.54)
External Rotation	7.12 (5.59)	6.21 (5.69)	7.14 (5.85)
Flexibility			
Hand to Neck	0.88 (.86)	0.68 (0.72)	1.0 (0.83)
Hand To Scapula	1.64 (.93)	1.64 (0.87)	1.67 (1.00)

Demographic and baseline variables			
Variable	Combined groups Mean (Standard Deviation)	Mean (Standard Deviation) (greater than 12 classses attended)	
	(N=68)	Treatment (N=28)	Control (N=28)
Fibromyalgia Impact Questionnaire			
Total	49.32 (12.86)	37.8 (13)	43.36 (14.6)
Physical Subscale	15.52 (8.46)	14.63 (8.43)	16.48 (9.09)
Shopping	1.06 (0.91)	1.11 (0.92)	1.00 (0.94)
Laundry	1.09 (1.03)	1.00 (1.05)	1.21 (1.11)
Meal Prep	1.25 (0.93)	1.18 (0.90)	1.31 (0.97)
Wash Dishes	1.35 (0.99)	1.38 (1.01)	1.38 (1.01)
Vacuum	2.00 (1.11)	1.90 (1.08)	2.32 (1.11)
Make Beds	1.49 (1.17)	1.36 (1.10)	1.66 (1.29)
Walk Several Block	1.53 (1.17)	1.46 (1.17)	1.54 (1.17)
Visit Friends	1.26 (1.06)	1.17 (1.14)	1.34 (1.04)
Yard Work	2.15 (1.03)	2.19 (0.92)	2.08 (1.15)
Drive Car	0.63 (0.90)	0.62 (0.82)	0.69 (1.04)
Climb Stairs	1.26 (0.97)	1.28 (0.84)	1.31 (1.14)
Days Felt Good	2.50 (1.94)	2.28 (1.71)	2.55 (2.10)

Demographic and Baseline Variables			
Variable	Combined Groups Mean (Standard Deviation)	Mean (Standard Deviation) (Greater than 12 classses attended)	
	(N=68)	Treatment (N=28)	Control (N=28)
Fibromyalgia Impact Questionnaire (cont.)			
Days Missed Work	2.10 (2.21)	2.28 (2.22)	1.82 (2. 02)
Work Difficulty	6.30 (2.06)	6.21 (2.10)	6.39 (1.89)
Severe Pain	6.39 (1.98)	6.59 (2.10)	6.11 (1.83)
Tired	7.70 (1.78)	7.69 (1.47)	7.72 (2.15)
Awoke Very Tired	7.74 (2.27)	7.71 (2.12)	7.62 (2.61)
Stiffness	6.99 (2.09)	6.86 (2.29)	6.83 (2.02)
Anxious	4.57 (4.16)	4.10 (3.10)	4.79 (3.12)
Depressed	4.16 (2.86)	3.76 (2.97)	3.93 (2.53)
Beck Depression Inventory	11.60 (7.03)	10.78 (6.90)	10.64 (6.35)
Beck Anxiety Inventory	15.47 (9.79)	14.39 (9.19)	13.78 (7.85)
Quality of Life	70.94 (17.36)	70.82 (20.4)	72.14 (15.9)

Demographic and baseline variables			
Variable	Combined groups Mean (Standard Deviation)	Mean (Standard Deviation) (Greater than 12 classses attended)	
	(N=68)	Treatment (N=28)	Control (N=28)
Arthritis Self-Efficacy Scale			
Total	1219.10 (314.3)	1243.7 (266.6)	1256.4 (340.9)
Physical	263.43 (82.44)	258.52 (83.51)	273.21 (93.85)
Symptom	314.33 (11.3)	302.59 (113.56)	326.79 (112.61)
Function	651.06 (171.1)	682.59 (147.74)	656.43 (177.16)

Within Group Changes on Paired t-Tests

There were a number of significant within group changes found on paired t-tests. The treatment group demonstrated statistically significant changes in 14 measures (total myalgic score, number of tender points, VAS for pain, knee strength at extension and flexion, shoulder strength at internal and external rotation, hand to neck and hand to scapula flexibility, fibromyalgia impact questionnaire score, Beck depression inventory questionnaire score, Beck anxiety inventory questionnaire score, quality of life questionnaire score and self efficacy scale score). The control group demonstrated statistically significant changes in 7 measures (knee strength at extension and flexion, shoulder strength at internal and external rotation, hand to neck and hand to scapula flexibility, and self efficacy scale score). Change scores indicated that on all measures expect flexibility, the treatment group improved more than the control group. Table six lists paired t-tests scores, significance and change scores.

Table 6

Paired t-test Results Table

	Paired T-tests							
Variable	T_x Mean Time 1 Time 2	Change	% Change	Significance (2 tail)	Control Mean Time 1 Time 2	Change	% Change	Significance (2 tail)
Total Myalgic Score	34.18 28.46	5.82	20.0	0.005	32.14 27.82	4.32	16.0	0.15
# Tender Points	16.46 15.00	1.46	10.0	0.016	15.68 14.68	1.00	7.0	0.121
Weight in Pounds	196.11 196.43	0.33	2.0	0.745	201.71 204.57	2.86	2.0	0.125
Percent Body Fat	35.81 36.66	0.85	2.0	0.046	35.90 35.36	0.54	2.0	0.97
Knee Strength in Foot Pounds								
Extension	71.71 86.18	14.46	20.2	0.000	77.11 86.81	9.7	11.0	0.001
Flexion	34.21 40.36	6.15	18.0	0.001	36.26 40.04	3.78	9.4	0.039

Paired T-tests								
Variable	Tx Mean Time 1 Time 2	Change	% Change	Significance (2 tail)	Control Mean Time 1 Time 2	Change	% Change	Significance (2 tail)
Shoulder Strength								
Internal Rotation	6.54 14.61	8.07	123.0	0.000	6.82 14.71	7.89	115.7	0.000
External Rotation	6.21 11.71	5.5	89	0.000	7.14 12.93	5.79	81.1	0.000
Flexibility								
Hand to Neck	0.68 0.18	0.5	277.7	0.003	1.0 0.07	0.93	1328.0	0.000
Hand To Scapula	1.64 0.49	1.15	234.6	0.000	1.67 .22	1.45	659.0	0.000
FM Impact (FIQ)								
Total Scale Score	48.08 37.81	10.27	27.0	0.002	47.14 43.36	3.78	8.8	0.171
Physical Subscale	4.29 3.76	0.52	14.0	0.058	4.77 4.02	0.76	19.0	0.018

Paired T-Tests								
Variable	T_x Mean Time 1 Time 2	Change	% Change	Significance (2 tail)	Control Mean Time 1 Time 2	Change	% Change	Significance (2 tail)
FIQ items:								
Shopping	.96 .76	.20	26.0	0.134	1.04 .93	.11	12.0	.265
Laundry	.96 .74	.22	30.0	0.110	1.15 1.04	.11	11.0	0.416
Meal Prep	1.15 1.07	.08	6.9	0.626	1.33 1.15	.18	16.0	0.170
Wash Dishes	1.32 .96	.36	38.0	0.026	1.41 1.26	.15	12.0	0.404
Vacuum	1.81 1.65	.16	10.0	0.404	2.29 1.95	.34	17.0	0.130
Make Beds	1.23 1.31	.08	7.0	0.574	1.70 1.44	.26	18.0	0.129
Walk Several Blocks	1.41 1.30	.11	8.0	0.542	1.56 1.33	.17	13.0	0.185
Visit Friends	1.14 1.07	.07	7.0	0.646	1.39 .93	.46	49.0	0.030

Paired T-tests								
Variable	T_x Mean Time 1 Time 2	Change	% Change	Significance (2 tail)	Control Mean Time 1 Time 2	Change	% Change	Significance (2 tail)
FIQ continued								
Yard Work	2.08 2.04	.04	2.0	0.770	2.18 1.91	.27	14.0	0.248
Drive Car	.57 .43	.14	33.0	0.212	.71 .61	.10	16.0	0.449
Climb Stairs	1.25 1.11	.14	13.0	0.355	1.36 1.04	.32	31.0	0.071
Days Felt Good	2.29 4	1.71	75.0	0.000	2.50 3.18	.68	27.2	0.30
Days Missed Work	2.12 1.27	.85	67.0	0.014	1.65 1.31	.34	26.0	0.223
Work Difficulty	6.14 4.43	1.71	39.0	0.001	6.35 5.23	1.12	21.0	0.031
Severe Pain	6.50 4.61	1.89	41.0	0.000	6.15 5.14	.69	13.0	0.059
Tired	7.64 5.21	2.43	47.0	0.000	7.68 7.00	.68	10.0	0.178

PAIRED T-TESTS								
VARIABLE	T_x MEAN TIME 1 TIME 2	CHANGE	% CHANGE	SIGNIFICANCE (2 TAIL)	CONTROL MEAN TIME 1 TIME 2	CHANGE	% CHANGE	SIGNIFICANCE (2 TAIL)
FIQ continued								
Awoke Very Tired	7.74 5.44	2.3	42.0	0.040	7.57 7.04	.53	8	0.166
Stiffness	6.82 4.86	1.96	40.0	0.001	6.93 6.14	.79	13.0	0.094
Anxious	4.00 3.21	.79	25.0	0.090	4.79 3.75	1.04	28.0	0.061
Depressed	3.64 2.57	1.07	42.0	0.005	3.86 3.71	.15	4.0	0.783
Beck Depression Inventory	10.78 7.11	3.67	52.0	0.001	10.64 8.8	1.82	21.0	0.156
Beck Anxiety Inventory	14.39 11.89	2.5	21.0	0.029	13.7 14.4	.6	4.1	0.687
Quality of Life	70.82 78.5	7.68	11.0	0.000	72.14 76.43	4.3	5.9	0.088

Paired T-tests								
Variable	T_x Mean Time 1 Time 2	Change	% Change	Significance (2 tail)	Control Mean Time 1 Time 2	Change	% Change	Significance (2 tail)
Arthritis Self-Efficacy Scale								
Pain	258.52 323.7	65.18	25.2	0.004	273.21 308.21	35	13.0	0.093
Symptom	298.57 383.93	85.36	29.0	0.001	656.4 722.5	66.1	10	0.016
Function	682.59 717.04	34.45	5	0.135	323.79 366.55	42.2	13.0	0.023
Function items:								
Walk 100 feet	67.78 77.50	9.75	14.4	0.040	67.86 73.57	5.7	8.4	0.178
Descend 10 steps	65.71 77.14	11.46	17.4	0.060	68.57 68.21	0.36	0.5	0.936
Rise quickly from armless chair	48.93 66.07	17.14	35	0.005	56.07 66.07	10	17.9	0.044
Scratch back	64.64 63.57	1.07	1.6	0.141	71.79 79.29	7.5	10.4	0.000

Data Analysis on Subjects Whose Pain Scores Worsened (n=6)

Six participants (three per group) experienced a worsening of one or more of the following pain measures: FIQ VAS for pain, total myalgic score, and number of tenderpoints. Scatterplots were made for difference scores for these variables from time one to time two and compared with all demographic, physiologic and self-report measures. Scatterplots were also made for time one scores only on the same variables. No discernable patterns were uncovered including likelihood to drop out.

Data Analysis on Subjects Who Did Not Return for Post Intervention Testing or Who Did Not Attend Enough Classes to be Included in Statistical Analysis (n=10)

There were no statistically significant differences in any demographic, physiologic variables or scale item scores between those who completed the study and those who dropped out. There were however some nonsignificant differences between those who completed the study and those who dropped out that may have clinical implications. The differences are outlined below.

Demographics

The mean age of drop out subjects was approximately 2.5 years older than those who completed the study (50.30 [+/-4.69] versus 47.59 [+/- 7.59]). Demographic variables which were the same as the group who completed the study included: years with FM, education, employment outside the home, occupation, and marital status. One minority subject (Latina) failed to complete the study.

Physiologic Variables

Total myalgic score and number or tender points were the same between drop outs and completers. Those who did not complete the study had lower mean body weight (164 lbs [+/-34.5] versus 198.9 lbs [+/-47.4]) and slightly lower percent body fat (32.9 [+/- 6.17] versus 35.6 [+/-4.49]). Strength scores at knee extension and flexion were slightly lower in participants who dropped out (69.60 [+/-22.87] extension; 74.67 [+/- 22.04] flexion versus 29.30 [+/-14.97] extension; 35.16 [+/- 10.87] flexion). Upper body strength scores were slightly higher in those who dropped out (10.10 [+/-5.45] internal rotation and 9.40 [+/- 4.90] external rotation versus 6.79 [+/- 5.55] internal rotation and 6.72 [+/-5.64] external rotation). Flexibility scores were no different between those who completed the study and those who dropped out.

Scale Item Scores

Beck depression scores were the same between those who completed the study and those who did not, but Beck anxiety scores were higher in those who dropped out (22 [+/-13.8] versus 14.3 [+/-8.6]). Total fibromyalgia impact questionnaire scores (including physical subscale) scores, quality of life scores and self-efficacy scores were the same between those who completed the study and those who dropped out.

CHAPTER V

DISCUSSION AND CONCLUSIONS

Introduction

This study was undertaken to pilot two exercise interventions in fibromyalgia: progressive muscle strengthening and flexibility training. The present study shows that female FM patients can effectively perform a twice weekly, 12 week program of either muscle strengthening or flexibility training with multiple improvements. Those who participated in muscle strengthening demonstrated statistically significant within group improvements in the 14 following outcomes: total myalgic score, number of tender points, VAS for pain, knee strength at extension and flexion, shoulder strength at internal and external rotation, hand to neck and hand to scapula flexibility, fibromyalgia impact questionnaire score, Beck depression inventory questionnaire score, Beck anxiety inventory questionnaire score, quality of life questionnaire score and self efficacy scale score. Those who participated in flexibility training demonstrated statistically significant within group improvements in the following 7 outcomes: knee strength at extension and flexion, shoulder strength at internal and external rotation, hand to neck and hand to scapula flexibility, and self efficacy scale score. The flexibility training group failed to demonstrate statistically significant within group improvements in pain (number of tender points, total myalgic score or FIQ VAS for pain), FM impact, anxiety, depression and quality of life. The current study failed to uncover significant between group differences on any measured variable. This may indicate that either activity is beneficial in the treatment of FM. However, magnitude of change scores indicated that the improvement of measured outcomes was greater for the muscle strengthening group on all measures except flexibility.

Advantages of Study

A strength of the current study is that it isolated muscle strengthening and compared it to the standard of care, flexibility training. The majority of exercise studies in FM employee aerobic or mixed (aerobic, strengthening and flexibility) interventions (Busch et al., 1999; Clark et al., 1995b; Gowans et al., 1999b; Hoydalsmo et al., 1992; Isomeri et al., 1992; King et al., 1999; Martin et al., 1996; Martin et al., 1999; McCain et al., 1988; Mengshoel et al., 1992; Nichols & Glenn, 1994; Norregaard et al., 1997; Rooks et al., 1999a; White et al., 1999; Wigers et al., 1996). Although skeletal muscle has been postulated to act as a target organ in FM, muscle strength training has only been tested as an isolated therapy in a single study (Hannonen et al., 1995). This study provided encouraging outcomes including increases in aerobic capacity in an aerobic trained group, increases in strength in a strength trained group and moderate quality of life and pain improvements in both groups. Further investigation is needed to follow up Hannonen's seminal work as the study employed only 20 subjects in each group, had an 18% attrition rate and was only published as an abstract, leaving future researchers limited information needed to replicate the study. Since Hannonen's study, several major health organizations have recognized the value of strength training in a variety of populations and published major consensus statements regarding strength training (U.S. Department of Health and Human Services, 1996; American College of Sports Medicine Position Stand, 1990 and 2000; American Heart Association; 1995; Fletcher et al., 1996; Centers for Disease Control and Prevention, 1996; American Association of Cardiovascular and

Pulmonary Rehabilitation, 1999). FM studies examining isolated strength training may provide information regarding how to best improve muscle related outcomes, such as strength, endurance and flexibility, and give future researchers clearer guidelines about designing a strength training component of more comprehensive FM exercise interventions (aerobic, strength and flexibility).

Another strength of the study was that it was a randomized, controlled trail with the two data collectors blinded to group assignment. Random assignment was employed to randomly allocate variance between the groups. Independent t-tests comparing treatment to control groups at baseline yielded no statistically significant differences indicating that two groups were similar at baseline and that random assignment was successful. The PI and the exercise science technician performed all pre and post measures utilizing the same standardized protocol, the same calibrated instruments and the same amount of verbal encouragement.

Another strength of the current study is the low attrition rate. This may be due in part to the multiple step recruitment process employed prior to consent. The current study is the only one of the 16 FM exercise interventions to date that describes a multiple step process to enroll subjects. Six separate steps were utilized each requiring potential participants response or attendance. This is seen as advantageous not only from a cost and utility standpoint but from the potential negative psychological effects drop out may have on other group members. Perhaps research participants who were motivated to complete all the screening steps were less likely to drop out after the intervention began. The current study had an attrition rate of 17% from the treatment group and 11% from the control group. This is a lower attrition rate than all but four of the 16 FM exercise interventions reported to date (Gowans et al., 1999b; Hannonen et al., 1995; Martin et al., 1999; McCain et al., 1988). Of the four FM exercise studies with a lower attrition than the current study, only McCain (1988) was longer in duration (20 versus 12 weeks) (McCain et al., 1988). High attrition from short exercise studies severely limits the utility of their findings. Insufficient power to find significant differences and minimal generalizability may occur with small sample sizes.

Other possible reasons for the low drop out rate in the current study could include 1) the sensitivity and specificity of the exercises improved physiologic measures as well as symptomatic measures. For example the FIQ VAS pain scores in the treatment group improved from 6.5 to 4.6. While the FIQ does not have published norm referenced data, pain control from VAS measures in the cancer pain control literature indicates that scores of 4 or less indicate good pain control (Ramer et al., 1999), 2) personalization of exercise instruction given to members of both groups by a doctorally prepared exercise physiologist with clinical and research experience in FM, 3) no adverse events or injuries during the intervention, 4) promotion to continue by the exercise instructor who employed a number of games, rewards and encouragement systems to encourage attendance 5) small class sizes (4 classes of 17 each), 6) equal attention to both groups and 7) employment of self-efficacy as a guiding theoretical framework. A final factor that may have positively impacted attrition was that all but two of the participants invited to enter in the study lived within an eleven mile radius of the exercise facility. There are data regarding how far rural versus urban residents are willing to travel for non urgent medical care suggesting that urban dwellers are less likely to travel great distances to seek care (Hong & Kindig, 1992; Kleinman & Makuc, 1983). Both of the two participants who lived greater than eleven miles from the fitness center dropped out of the study (one due to pneumonia; the other found that making the commute alone was not enjoyable). An exception was made for these two participants to enter the study as they were FM support group leaders, well known to the research team. In retrospect, perhaps adherence to the proximity requirement should have been required.

A final strength of the current study is that the sample size was larger than 13 of the 16 reported FM exercise interventions. Only three studies reported in the 1999 literature (after the current study was completed) had a larger sample size (Busch et al., 1999; King et al., 1999; Martin et al., 1999). Two of these studies necessitated a larger sample because they employed a three or four group design (Busch et al., 1999; King et al., 1999).

Limitations of the Study

The limitations of the study can be categorized as possible limitations related to the study design and to the selection and measurement of outcomes.

Possible Limitations Related to Study Design

There were no statistically significant differences in strength measures between the strengthening and stretching groups although the magnitude of change was greater in the strength trained group (20.2% versus 11%). There are several possible reasons for this lack of difference.

The stretching intervention was more likely a "light exercise" group rather than a sedentary control group. The stretching exercises may have loaded the opposing muscle group while stretching the targeted muscle group. For example, the biceps may have been held in contraction while stretching the triceps. The use of towels to augment stretches could have strengthened the upper body as well. This could partly account for improvements in strength scores in the stretching group.

Another possible reason that there were no statistically significant differences between groups on strength could have been that the strengthening intervention was not monitored to assure that subjects increased the load throughout the 12 weeks. Instead participants were encouraged to "listen to their bodies" and increase the intensity as they thought they could tolerate. Strength training programs in healthy, cardiac and elderly populations generally increase the strength training load every two weeks (Fleck & Kraemer, 1987). Load is generally increased based on the amount of weight a participant can lift using correct form, breathing and full range of motion during a single repetition (1 repetition maximum, 1 RM). Low intensity strength training (40% RM) and moderate intensity strength training (60% RM) have been recommended for patients participating in supervised cardiac rehabilitation programs to restore strength necessary for daily living activities. Some advise that strength training in women may be further graduated so that the lower body trains at a higher resistance than the upper body (Verrill & Ribisl, 1996b). In two muscle strengthening versus flexibility training interventions in cardiac rehabilitation patients, muscle strengthening was found to have statistically significant between and within group differences without subjects suffering any adverse cardiac events (Beniamini, Rubenstein, Faigenbaum, Lichtenstein & Crim, 1999; Trash & Kelly, 1997). One of these studies trained at a high intensity (80% RM) without adverse side effects (Beniamini et al., 1999). Neither of these studies enrolled enough women to analyze their data independent of the males in the sample. The safety and reliability of 1 RM (chest press and leg press) testing for women with FM has recently been reported (r=0.99) (Rooks et al., 1999b) making strength training intensity alterations based on 1RM scores easier to implement.

Within the FM literature, Norregaard (1997) attempted to progressively increase the training load during the muscle strengthening component of his aerobic exercise group but found that "despite much effort by the physiotherapist [this was] very difficult to implement" (p.76). Norregaard reports that his study suffered from low rate of volunteers (only 13% invited to participate agreed) and poor compliance (60% attrition after consent). It is not surprising, therefore, that he was unable to demonstrate statistically significant within or between group changes on isokinetic dynamometry for quadriceps or biceps strength (Norregaard et al., 1997). Martin (1996) substituted surgical tubing for a universal gym machine for patients who "had difficulty" (number not disclosed) with strength training exercises (Martin et al., 1996). Like Norregaard, Martin was unable to demonstrate statistically significant strength differences on isokinetic dynamometry between his exercise group and his relaxation group. This could perhaps be due to the short duration of the intervention (six week) or the high attrition (40% from exercise and 33% from relaxation) (Martin et al., 1996).

Another possible limitation of the current study was that there was a lack of data to do power analysis from an FM population on change in the main outcome variable (muscle strength) using a similar intervention. One could argue that the current study should have only piloted the muscle strengthening intervention and subsequent studies could have then compared strengthening to other exercises or interventions. However, the number of participants completing study was sufficient to produce significant within group difference. The problem was that the stretching group also improved their strength scores which necessitated a larger n to achieve between group statistically significant differences. Retrospective power analysis for between group changes based on knee extension strength scores from the current study revealed that 137 subjects divided between the 2 groups would have been necessary. Alternatively, 68 subjects (the number recruited for the current study) would have been sufficient to produce significant change if, perhaps, a non physical treatment such as education would have been employed instead of stretching. McCain (1988) employed cycle ergometry versus flexibility training in the first FM exercise intervention and found a statistically significant between group difference in aerobic fitness and total myalgic scores. He also demonstrated non significant improvements in the cycle trained group on VAS pain, Likert sleep and pain diagram measures. McCain only described his flexibility intervention as "flexibility maneuvers, such that sustained heart rate responses greater than 115 beats per minute were not attained" (p.1136). Therefore, it is not known if towels, bands or oppositional loading were utilized in his stretching group (McCain et al., 1988).

Possible Limitations Related to Outcome Measures

A possible limitation of the study related to outcome measures was that the upper body strength measures were collected at a Cybex setting of 60 degrees per second. This setting could have resulted in a floor effect in measurement. Since no shoulder rotation strength measures from isokinetic dynamometry had been reported in the FM literature at the time this intervention took place, the standard strength measures were used for the Cybex.

Another potential limitation of the study related to measures was the use of two field rather than laboratory measures. Percent body fat and flexibility could have been measured in a manner yielding potentially less error variance and perhaps a wider spread of scores. CT imaging or underwater weighting could have been employed in place of skin fold caliperimetry for percent body fat testing. Goniometetry or computer modeling could have been used for the four point field measure for flexibility. The trade-offs, however, are the at these laboratory measure involve a much greater expenditure of resources and would have necessitated a separate laboratory visit for each participant. This most likely would have lengthened the time between time one data collection and the intervention and time two data collection after the intervention. A two week window for pre and post testing around the intervention was deemed necessary to minimize changes likely to occur the primary outcome variable, muscle strength. At the time of the current study, no percent body fat measures had been reported in an FM exercise intervention. The field measure of flexibility that was selected had been used in descriptive FM studies in the past. Using the same field measure makes comparison between FM studies more meaningful. Since neither flexibility or percent boy fat were the primary variables of interest in the current study, choices regarding their measurement were appropriate.

A final theoretical limitation of the current study is that the PI collected all pain and flexibility measures. Using one investigator only to perform the tender point examinations may be disadvantageous, as the exactness of the recordings was not verified against the results from another investigator. On the other hand, using one person to make all measurements has the benefit of eliminating the inter-rater reliability problem.

Directions for Future Research

Directions for future research can be categorized into suggestions for alterations in study design and alterations in selection and measurement of outcomes.

Suggested Alterations in Future Study Design

Future studies could either substitute a non physical modality such as education or employ a true control group as a third group when comparing flexibility to muscle strengthening. The author does not suggest replicating the current study with a larger sample size but instead encourages a less active control intervention or a more progressive strength training intervention. Examples of less active control groups in the FM exercise literature include: McCain (1988)-(McCain et al., 1988) flexibility, Mengshoel (1992) (Mengshoel et al., 1992), Wiggers (1996) (Wigers et al., 1996), King (1999) (King et al., 1999) and Busch (1999) (Busch et al., 1999)- treatment as usual control, Isomeri (1992) (Isomeri et al., 1992) -amitriptyline only, Nichols (1994) (Nichols & Glenn, 1994) and Clark (1995) (Clark et al., 1995b) sedentary controls, Martin (1996) (Martin et al., 1996)-relaxation, Norregaard (1997) (Norregaard et al., 1997)- hot packs, and King (1999) (King et al., 1999) education only and true control. Among these studies, the four that measured muscle strength or flexibility failed to produce statistically significant between group changes on muscle strength or flexibility failed to produce statistically significant between group changes on those measures (Martin et al., 1996; Martin et al., 1999; Mengshoel et al., 1992; Norregaard et al., 1997). The lack of detectable change could have been due to attrition or lack of documentation regarding systematically increasing the intensity of the exercise group. A number of symptomatic variables (pain, fatigue, sleep) and aerobic markers (VO_2 max, 6 minute-walk) were demonstrated to have significant between group differences in these studies.

One novel control group idea utilized in a muscle strengthening intervention similar to the current study was employed by Topp (Topp et al., 1993). Studying older persons with osteoarthritis of the knee, Topps' control group attended American Association of Retired Person's drivers education classes during the same time frame as the muscle strengthening treatment group giving them equal group support and attention but not muscle strengthening. Topp was able to demonstrate significant between and within group differences in his study. In another study, cardiac patients were able to demonstrate between and within group differences in a strength trained versus a flexibility trained group. Although the flexibility intervention in the cardiac study did employ towels to maximize the stretch, the strength group trained on weight machines at 80% RM, very high intensity (Beniamini et al., 1999). Perhaps a difference in these studies compared to FM exercise studies, is that FM appears to have some centrally mediated pain dysfunction. It is not yet clearly understood how exercise in FM may mediate central processes and thereby regulate pain.

Future studies could consider means to quantify the progressive nature of a muscle strengthening intervention. There are several commonly employed methods to quantify progressions in a muscle strengthening intervention. Three possible protocols are shared: increases based on 1RM scores, Therabands and body position. All three have been implemented in strength training interventions in the elderly (Pollock, Graves, Swart & Lowenthal, 1994). This population is appropriate as female FM patients may resemble the elderly in terms of muscle strength and endurance. A muscle strengthening intervention in frail elderly populations based on 1RM scores typically progresses as follows (Pollock et al., 1994). Weeks one and two may consist of one set of 5 pound biceps curls at 10 repetitions. Weeks three and four may increase the load by 20% to 6 pound biceps curls although the participant may only complete 8 repetitions. Within the next two weeks, strength gains would be expected and when participants could perform 10 repetitions at 6 pounds the load could be increased another 20% to 7.2 lbs. and so forth through the end of the study. As an alternate to free weights or calibrated weight machines, researchers may chose to progressively increase the exercise load with alterations in Therabands. The exercise instructor would need to instruct participants to increase load by shortening the distance gripped on the bands or moving to a higher strength band (signified by color change in Therabands e.g. pink to green). Another alternative for increasing strength load could be to change body positions for exercise such as progressing from chair or wall exercises to standing or even lying exercises.

Another possible change in future strength training interventions could be to meet more frequently for shorter periods of time, for example 30 minutes three times a week rather than 60 minutes twice a week. The rationale for training more frequently is that certain muscle groups (e.g. abdominals and low back) have been demonstrated to hypertrophy with daily training whereas limb muscles require remodeling time between training session (Hunter, 1985).

In the current study, the decision was made to meet twice weekly. Because many Americans state that "lack of time" is a major deterrent to exercise, researchers have investigated the frequency, intensity and duration of exercise, including strength training, necessary to bring about positive changes. It has been learned that 75% of the positive changes associated with strength training three times per week occurs in training sessions twice a week (Feigenbaum & Pollock, 1997). Furthermore, attrition has been a major problem in FM exercise interventions making twice weekly exercise a sensible starting place given the paucity of FM strengthening only interventions. Mengshoel et al. (1992) had to reduce the aerobic exercise frequency from thrice to twice weekly because of compliance problems in a pilot FM exercise intervention (Mengshoel et al., 1992).

Since data were only collected at baseline and 12 weeks (completion of the study), it is not known precisely when improvements in outcomes occurred. The trade-offs for increasing load (intensity) and timing (frequency) of the muscle strengthening intervention would need to be weighed against the risks for worsening symptoms in FM (delayed-onset pain, fatigue, QOL, FM impact). Further study is needed to determine where that line may lie. An intermediate step to implementing progressive muscle strengthening based on 1 RM scores in an FM intervention may be to learn more about how muscle strengthening and flexibility mediate pain in FM.

The current exercise protocol was found to be sensitive to the negative process of central sensitization common in FM patients, as patients improved strength while reporting less pain and other FM symptoms. Furthermore, medication use did not increase during the study indicating that decreases in pain may have been the result of a sensitive exercise protocol rather than increases in medication.

Now that the safety and efficacy of progressive strength training has been demonstrated in the current study, it would be interesting to examine the effectiveness of strength training prior to aerobic training. Perhaps the strength gains in the major muscle groups demonstrated in the current study would prepare women with FM to successfully participate in aerobic interventions which have been demonstrated to produce positive changes in aerobic fitness and may activate neurochemical processes thought to mediate pain in FM. The author suggests further study regarding how exercise, specially strength training, mediates muscle pain be undertaken before more strenuous strength training interventions are attempted.

Perhaps the growing body of literature in two areas will best help guide future strength training interventions in FM populations: 1) strength training in deconditioned elderly (Pollock et al., 1994) will enhance future FM exercise interventions as muscle in FM patients has been demonstrated to be similar to muscle found in deconditioned persons such as the sedentary elderly (Bortz, 1982; Yunus & Kalyan-Raman, 1989), and 2) central sensitization and pain modulation in FM will inform future FM exercise studies by providing information that will assure that exercises are sensitive to underlying mechanisms that perpetuate FM symptoms.

Finally further study is needed to determine the long term effects of strength training or flexibility training in FM. Additional studies are also needed regarding the generalizability of the current study's findings to a community based sample of women with FM.

Suggested Alterations in Outcome Measures in Future Studies

The author suggests measuring muscle endurance in future muscle strengthening interventions in FM. Muscle endurance changes can be measured with an isokinetic dynamometer and may give researchers information that may assist with other FM exercise interventions such as circuit weight training.

Future researchers should consider setting the shoulder speed for isokinetic dynamometry to 180 degrees per second as a possible floor effect may have occurred in this study. At higher speeds, the isokinetic dynamometer would be easier to push possibly yielding a greater spread of scores pre and post intervention. This would be appropriate given the fact that 1) the shoulder muscles are a smaller muscle group than the knee extensors and flexors, 2) most people with FM exhibit muscular deconditioning, and 3) those people who are overweight or obese will have a disproportionate amount of strength in their lower bodies compared to their upper bodies simply from carrying their body weight. Observations in the laboratory by the PI revealed that many subjects had difficulty forming a 90 degree angle at the shoulder and elbow while lying supine and then generating enough strength to press the Cybex forward. An alternate suggestion for measuring upper body strength in people with FM would be to test biceps/triceps strength instead of shoulder rotation. Biceps/triceps strength testing would avoid the known tender point at the second rib anterior insertion near the sternum. The trade-off for selecting biceps/triceps over the shoulder girdle is that the shoulder girdle is implicated in a number of activities directly related to quality of life and activities of daily living in FM.

Conclusions

General trends in exercise FM studies over 12 years are that the interventions have become less intense producing less dramatic physiologic changes in variables such as VO_2 max, but demonstrating greater improvements in symptomatic and quality of life outcomes related to FM. This is perhaps due to an increased appreciation for the role of central sensitization and baseline aerobic and muscle status in FM patients. The current study adds to that literature by demonstrating that statistically significant strength gains can occur with 12 weeks of progressive strength training. Concurrently positive changes in FM symptoms, impact, anxiety, depression and quality of life were demonstrated.

Since diagnostic guidelines for FM were published in the rheumatology literature one decade ago, a Medline search reveals a five fold increase in the number of citations regarding FM. The frequency of patient visits will continue to increase both in speciality and primary care settings as providers continue to gain awareness of the diagnostic guidelines and effective treatments. Interventions to maximize the health and quality of life of people with FM will therefore be increasingly sought after by an ever-widening audience of FM patients and providers.

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APPENDIX A

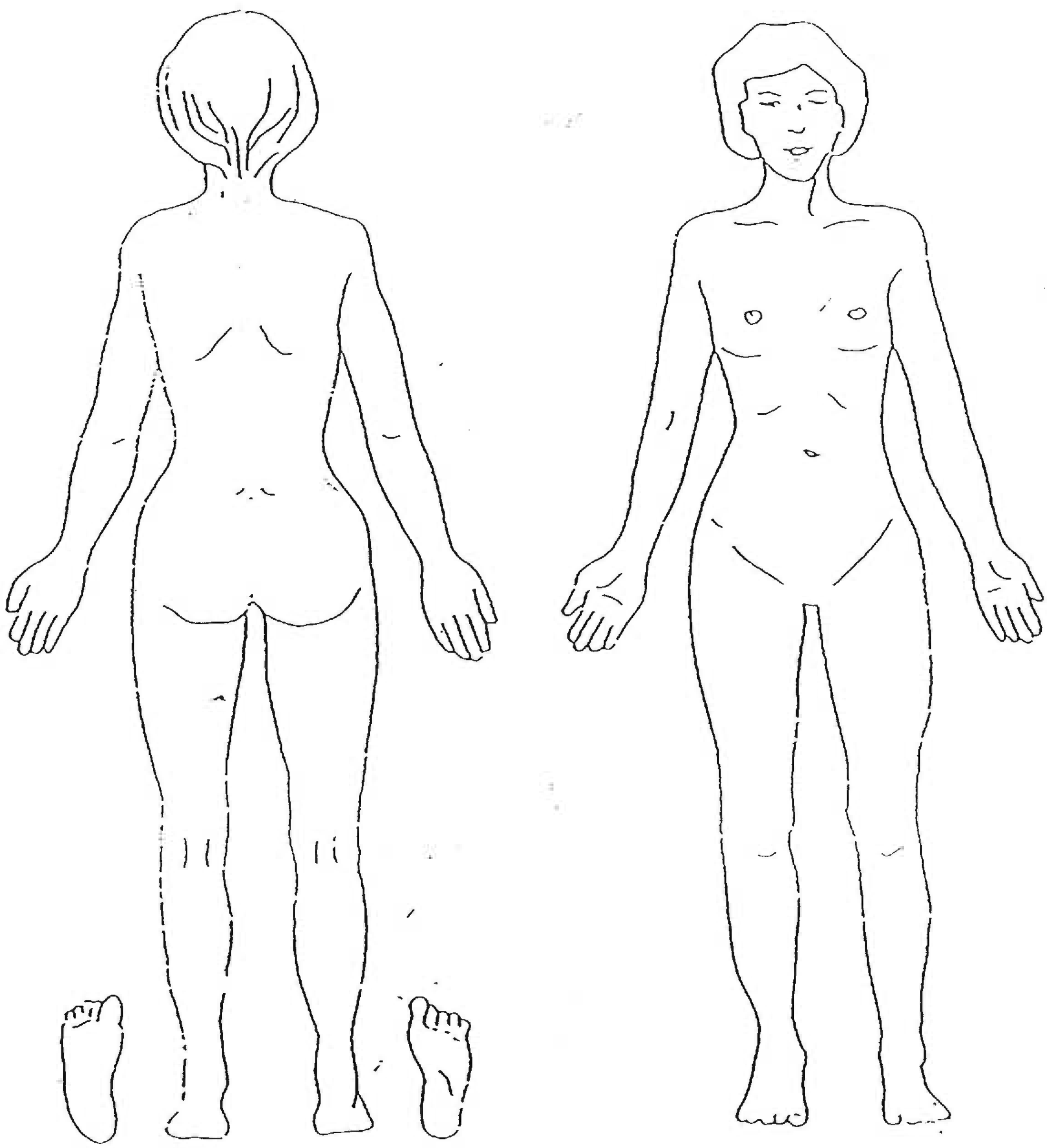
Diagnostic Confirmation Form List of Appendices

SYMPTOM SURVEY

1. HAVE YOU HAD WIDE-SPREAD BODY PAIN FOR AT LEAST THE PAST THREE MONTHS?

   1 YES
   2 NO

2. ON THE DIAGRAM BELOW, PLEASE MARK WITH AN (X) OR SHADE THE AREAS OF YOUR BODY THAT ARE PAINFUL **TODAY**.



APPENDIX B

Research Interest Query Form

We Need Your Help

Advances in science come from carefully conducted research studies. The Division of Arthritis and Rheumatic Disease at OHSU, headed by Dr. Robert Bennett, has been involved in fibromyalgia research for the past 18 years. If you would like to learn more about participating in a research study focusing on fibromyalgia and exercise please complete this form.

1. I have fibromyalgia and am willing to attend an orientation session to learn more about participating in an exercise study at OHSU ☐ yes ☐ no

2. I am willing to travel to OHSU for exercise classes two times a week for 12 consecutive weeks ☐ yes ☐ no

3. I prefer one hour classes that are offered (mark all that apply)

   between 9 am and 11 am Monday through Friday ☐

   between 1:30 pm and 4:30 pm Monday through Friday ☐

   between 6 pm and 9 pm Monday through Friday (free parking) ☐

   between 9 am and 5 pm Saturday (free parking) ☐

   between 11 am and 5 pm Sunday (free parking) ☐

Name: ____________________________ Age: ______

Address: ____________________________

____

____

Phone numbers: ____________________________

e-mail address: ____________________________

Thank You!

If you received this form via mail, please return in the postage paid envelope. If you received this form the Division of Arthritis and Rheumatic Diseases at OHSU, please leave with the receptionist.

CAMPUS GRAM ADVERTISEMENT

VOLUNTEERS NEEDED FOR AN EXERCISE STUDY IN FIBROMYALGIA

The OHSU School of Nursing seeks volunteers for an exercise study in fibromyalgia. In addition to having fibromyalgia, eligible participants must be female, 20-60 years of age, not currently participating in an exercise program, non-smoking and free from any health conditions that would preclude participation in an exercise program. Participants would attend exercise classes twice a week for 12 weeks at the OHSU Health and Fitness Center. Participants will also receive body fat analysis and strength testing. Classes and testing will be provided free of charge. No monetary compensation will be provided. For more information, please call Kim Jones RN @ 494-3837

APPENDIX C

Invitation Letter

OHSU
SCHOOL OF NURSING

OREGON HEALTH SCIENCES UNIVERSITY
PORTLAND CAMPUS
3181 S.W. SAM JACKSON PARK RD.
PORTLAND, OR 97201-3098
503-494-7100

ASHLAND • KLAMATH FALLS • LA GRANDE • PORTLAND

February 1, 1999

Hello,

You are receiving this letter because Dr. Robert Bennett has treated you for fibromyalgia. He and his colleagues would like to ask you to participate in an upcoming exercise study at Oregon Health Science University (OHSU). As you may already know, people with fibromyalgia who can tolerate exercising feel much better than those who do not exercise at all. The problem is that exercising too much or too strenuously can temporarily worsen some fibromylagia symptoms. The study hopes to determine what type of exercise is best for people with fibromyalgia.

If you choose to participate, you will attend exercise classes at OHSU twice a week for 12 weeks beginning in April 1999. The classes will focus on strengthening and stretching muscles rather than traditional aerobic activities. The classes and a professionally made video tape of the exercises will be provided to you free of charge.

To qualify for participation you must be:

*female
*20-60 years old
*have fibromyalgia
*not exercise regularly
*not smoke
*not have any health condition that would prevent you from participating in an exercise program consisting of muscle strengthening and stretching exercises.

If you would like to learn more about participating in this study, please complete the attached page and return it to us in the postage paid envelope enclosed. Thank you for sharing your valuable time with us so that we can learn more about the causes and treatments for fibromyalgia.

Sincerely,

Kim Jones RN, FNP

The OHSU Fibromyalgia Research and Treatment Team
Robert Bennett, MD — Sharon Clark, RN, PhD
Carol Burckhardt, RN, PhD — Kim Jones, RN, FNP

APPENDIX D

Flexibility Scale

Appendix D
Scale for Scoring Functional Movements of the Arm

Hand-to-neck

0 The fingers reach the median line of the neck without delay and with full abduction and external rotation.

1 The fingers reach the median line of the neck but not with full abduction and/or external rotation.

2 The fingers reach the median line of the neck, but with compensation by adduction of the arm or by shoulder elevation.

3 The fingers touch the neck.

4 The fingers are unable to reach the neck.

Hand-to-scapula

0 The hand reaches the opposite scapula or 5 cm beneath it.

1 The hand reaches the opposite scapula 6-15 cm beneath it.

2 The hand reaches to opposite crista iliaca.

3 The hand reaches the same side buttock.

4 The hand cannot move behind the trunk.

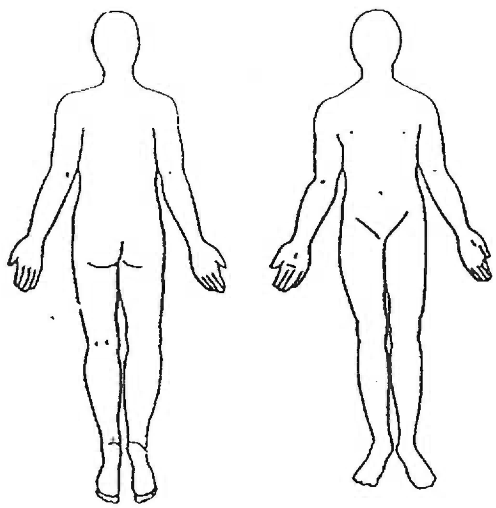
APPENDIX E

Body Composition and Muscle Strength Recording Form

Form 12-2: Skinfold Measurements Form

SKINFOLD MEASUREMENTS

PATIENT: ____________ ______________ AGE: ______ WEIGHT: __________ DATE: ______________



CHEST ______________

AXILLA ______________

TRICEPS ______________

SUBSCAPULA ______________

ABDOMEN ______________

SUPRAILIAC ______________

THIGH ______________

TOTAL$_1$ (SUM 7) ______________

FEMALE

1.097

− ______________ (.00046971) × (SUM 7)

+ ______________ (.00000056) × (SUM 7)^2

− ______________ (.00012828) × (AGE)

= ______________ TOTAL$_2$

$\left(\frac{4.95}{\text{TOTAL}_2}\right) - 4.5 =$ __________ % BODY FAT

NOTES:

MALE

1.112

− ______________ (.00043499) × (SUM 7)

+ ______________ (.00000055) × (SUM 7)^2

− ______________ (.00028826) × (AGE)

= ______________ TOTAL$_2$

$\left(\frac{4.95}{\text{TOTAL}_2}\right) - 4.5 =$ __________ % BODY FAT

Name ______________________________ **Subject #** ______

Height__ Weight ____

Body Composition ______ Lean Mass ______ Fat Mass__ __

CYBEX DATA side (L/R)____

Knee	60 deg/sec	Extension	Max power=_ ___ft-lbs @ __deg Peak % BW Ratio___
		Flexion	Max power=_ ____ft-lbs @ ___deg Peak % BW Ratio ____
Shoulder	60deg/sec	Internal Rotation	Max power–_______ft-lbs @ ____ deg Peak % BW Ratio ______
		External Rotation	Max power · _______ft-lbs @ _____ deg Peak % BW Ratio______

APPENDIX F

Self-Report Scales

Name________________
Date________________

FIBROMYALGIA IMPACT QUESTIONNAIRE (FIQ)

Directions: For questions 1 through 11, please circle the number that best describes how you did overall for the past week. If you don't normally do something that is asked, cross the question out.

Were you able to:	Always	Most	Occasionally	Never
1. Do shopping?	0	1	2	3
2. Do laundry with a washer and dryer?	0	1	2	3
3. Prepare meals?	0	1	2	3
4. Wash dishes/cooking utensils by hand?	0	1	2	3
5. Vacuum a rug?	0	1	2	3
6. Make beds?	0	1	2	3
7. Walk several blocks?	0	1	2	3
8. Visit friends or relatives?	0	1	2	3
9. Do yard work?	0	1	2	3
10. Drive a car?	0	1	2	3
11. Climb stairs?	0	1	2	3

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

0 1 2 3 4 5 6 7

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

0 1 2 3 4 5 6 7

continued on back of page

Date ____________

FIBROMYALGIA IMPACT QUESTIONNAIRE (FIQ)

Directions: For the remaining items, mark the point on the line that best indicates how you felt overall for the past week.

14. When you worked, how much did pain or other symptoms of your fibromyalgia interfere with your ability to do your work, including housework?

No problem with work — Great difficulty with work

15. How bad has your pain been?

No pain — Very severe pain

16. How tired have you been?

No tiredness — Very tired

17. How have you felt when you get up in the morning?

Awoke well rested — Awoke very tired

18. How bad has your stiffness been?

No stiffness — Very stiff

19. How nervous or anxious have you felt?

Not anxious — Very anxious

20. How depressed or blue have you felt?

Not depressed — Very depressed

LEISURE TIME ACTIVITIES

1. Over the past 7 days, how often did you participate in sitting activities such as reading, watching TV or doing handcrafts?

[0] NEVER	[1] SELDOM	[2] SOMETIMES	[3] OFTEN
↓	(1-2 DAYS)	(3-4 DAYS)	(5-7 DAYS)
GO TO Q.#2	↓	↓	↓

1a. What were these activities?

1b. On average, how many hours per day did you engage in these sitting activities?

[1] LESS THAN 1 HOUR [2] 1 BUT LESS THAN 2 HOURS

[3] 2-4 HOURS [4] MORE THAN 4 HOURS

2. Over the past 7 days, how often did you take a walk outside your home or yard for any reason? For example, for fun or exercise, walking to work, walking the dog, etc.?

[0] NEVER	[1] SELDOM	[2] SOMETIMES	[3] OFTEN
↓	(1-2 DAYS)	(3-4 DAYS)	(5-7 DAYS)
GO TO Q.#3	↓	↓	↓

2a. On average, how many hours per day did you spend walking?

[1] LESS THAN 1 HOUR [2] 1 BUT LESS THAN 2 HOURS

[3] 2-4 HOURS [4] MORE THAN 4 HOURS

3. Over the past 7 days, how often did you engage in light sport or recreational activities such as bowling, golf with a cart, shuffleboard, fishing from a boat or pier or other similar activities?

[0] NEVER	[1] SELDOM	[2] SOMETIMES	[3] OFTEN
↓	(1-2 DAYS)	(3-4 DAYS)	(5-7 DAYS)
GO TO Q.#4	↓	↓	↓

3a. What were these activities?

3b. On average, how many hours per day did you engage in these light sport or recreational activities?

[1] LESS THAN 1 HOUR [2] 1 BUT LESS THAN 2 HOURS

[3] 2-4 HOURS [4] MORE THAN 4 HOURS

4. Over the past 7 days, how often did you engage in moderate sport or recreational activities such as doubles tennis, ballroom dancing, hunting, ice skating, golf without a cart, softball or other similar activities?

[0] NEVER	[1] SELDOM	[2] SOMETIMES	[3] OFTEN
↓	(1-2 DAYS)	(3-4 DAYS)	(5-7 DAYS)
GO TO Q.#5	↓	↓	↓

4a. What were these activities?

4b. On average, how many hours per day did you engage in these moderate sport and recreational activities?

[1] LESS THAN 1 HOUR
[2] 1 BUT LESS THAN 2 HOURS
[3] 2-4 HOURS
[4] MORE THAN 4 HOURS

5. Over the past 7 days, how often did you engage in strenuous sport and recreational activities such as jogging, swimming, cycling, singles tennis, aerobic dance, skiing (downhill, cross country) or other similar activities?

[0] NEVER	[1] SELDOM	[2] SOMETIMES	[3] OFTEN
↓	(1-2 DAYS)	(3-4 DAYS)	(5-7 DAYS)
GO TO Q.#6	↓	↓	↓

5a. What were these activities?

5b. On average, how many hours per day did you engage in these strenuous sport and recreational activities?

[1] LESS THAN 1 HOUR
[2] 1 BUT LESS THAN 2 HOURS
[3] 2-4 HOURS
[4] MORE THAN 4 HOURS

6. Over the past 7 days, how often did you do any exercises specifically to increase muscle strength and endurance, such as lifting weights or pushups, etc.?

[0] NEVER	[1] SELDOM	[2] SOMETIMES	[3] OFTEN
↓	(1-2 DAYS)	(3-4 DAYS)	(5-7 DAYS)
GO TO Q.#7	↓	↓	↓

6a. What were these activities?

6b. On average, how many hours per day did you engage in exercises to increase muscle strength and endurance?

[1] LESS THAN 1 HOUR
[2] 1 BUT LESS THAN 2 HOURS
[3] 2-4 HOURS
[4] MORE THAN 4 HOURS

HOUSEHOLD ACTIVITY

7. During the past 7 days, have you done any light housework, such as dusting or washing dishes?

   [1] NO [2] YES

8. During the past 7 days, have you done any heavy housework or chores, such as vacuuming scrubbing floors, washing windows, or carrying wood?

   [1] NO [2] YES

9. During the past 7 days, did you engage in any of the following activities? Please answer YES or NO for each item.

		NO	YES
a.	Home repairs like painting, wallpapering, electrical work, etc.	1	2
b.	Lawn work or yard care, including snow or leaf removal, wood chopping, etc.	1	2
c.	Outdoor gardening	1	2
d.	Caring for another person, such as children, dependent spouse, or an other adult	1	2

WORK-RELATED ACTIVITY

10. During the past 7 days, did you work for pay or as a volunteer?

    [1] NO [2] YES

10a. How many hours per week did you work for pay and/or as a volunteer?

_______________ HOURS

10b. Which of the following categories best describes the amount of physical activity required on your job and/or volunteer work?

[1] Mainly sitting with slight arm movements. [Examples: office worker, watchmaker, seated assembly line worker, bus driver, etc.]

[2] Sitting or standing with some walking. [Examples: cashier, general office worker, light tool and machinery worker.]

[3] Walking and heavy manual work often requiring handling materials weighing less 50 pounds. [Examples: mailman, waiter/waitress, construction worker, heavy tool and machinery worker.]

[4] Walking and heavy manual work often requiring handling of materials weighting over 50 pounds. [Examples: lumberjack, stone mason, farm or general laborer.]

Beck Anxiety Inventory

.ne________________________ Date______________

Below is a list of common symptoms of anxiety. Please read each item in the list carefully. Indicate how much you have been bothered by each symptom during the PAST WEEK, INCLUDING TODAY by placing an X in the corresponding space in the column next to each symptom.

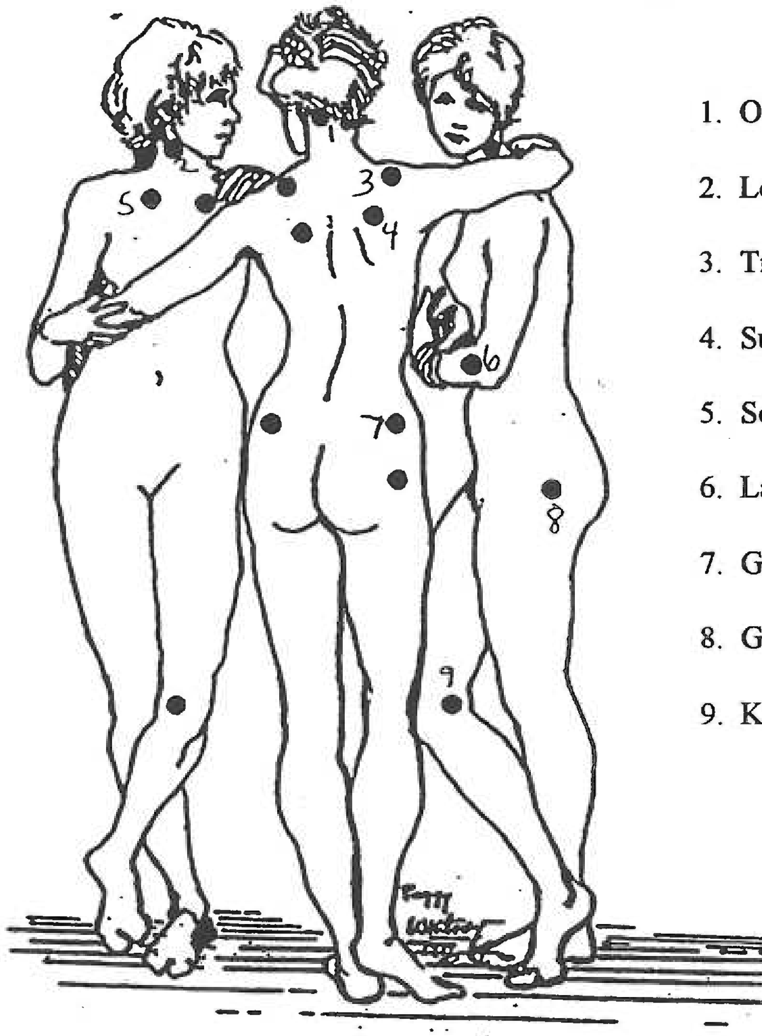
		Not at all	Mildly It did not bother me much	Moderately It was very unpleasant but I could stand it	Severely I could barely stand it
1	Numbness or tingling.				
2	Feeling hot.				
3	Wobbliness in legs.				
4	Unable to relax.				
5	Fear of the worst happening				
6	Dizzy or lightheaded.				
7	Heart pounding or racing.				
8	Unsteady.				
9	Terrified.				
10	Nervous.				
11	Feelings of choking.				
12	Hands trembling.				
13	Shaky.				
14	Fear of losing control.				
15	Difficulty breathing.				
16	Fear of dying.				
17	Scared.				
18	Indigestion or discomfort in abdomen.				
19	Faint.				
20	Face flushed.				
21	Sweating (not due to heat).				

Name ____________________
Date ____________________

QUALITY OF LIFE SCALE (QOL)

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

		Delighted	Pleased	Mostly Satisfied	Mixed	Mostly Dissatisfied	Unhappy	Terrible
1.	Material comforts—home, food, conveniences, financial security.	7	6	5	4	3	2	1
2.	Health – being physically fit and vigorous.	7	6	5	4	3	2	1
3.	Relationships with parents, siblings & other relatives – communicating, visiting, helping.	7	6	5	4	3	2	1
4.	Having and rearing children.	7	6	5	4	3	2	1
5.	Close relationships with spouse or significant other.	7	6	5	4	3	2	1
	Close friends.	7	6	5	4	3	2	1
7.	Helping and encouraging others, volunteering, giving advice.	7	6	5	4	3	2	1
8.	Participating in organizations and public affairs.	7	6	5	4	3	2	1
9.	Learning – attending school, improving understanding, getting additional knowledge.	7	6	5	4	3	2	1
10.	Understanding yourself – knowing your assests and limitations – knowing what life is about.	7	6	5	4	3	2	1
11.	Work – job or in home.	7	6	5	4	3	2	1
12.	Expressing yourself creatively.	7	6	5	4	3	2	1
13.	Socializing – meeting other people, doing things, parties, etc..	7	6	5	4	3	2	1
14.	Reading, listening to music, or observing entertainment.	7	6	5	4	3	2	1
15.	Participating in active recreation.	7	6	5	4	3	2	1
16.	Independence, doing for yourself.	7	6	5	4	3	2	1



	L	R
1. Occiput	_____	_____
2. Low Cervical	_____	_____
3. Trapozius	_____	_____
4. Supra spinatus	_____	_____
5. Second rib	_____	_____
6. Lateral epicondyle	_____	_____
7. Gluteal	_____	_____
8. Greater Trochanter	_____	_____
9. Knee	_____	_____

0 = no pain
1 = some pain
2 = ouch
3 = moves away

Total Myalgic Score _____
# of Tender Points _____

APPENDIX G

Consent Form

Consent Form
IRB # 5348

Approval Date:

OREGON HEALTH SCIENCES UNIVERSITY

CONSENT FORM

TITLE: A Muscle Conditioning Intervention in Fibromyalgia

PRINCIPAL INVESTIGATOR: Kim Dupree Jones RNC, MN, FNP
Doctoral Candidate, 503-494-3837

CO-INVESTIGATORS: Carol S. Burckhardt, PhD, RN, PMHNP, Assistant Professor Medicine (Research), Division of Arthritis and Rheumatic Diseases, Professor, School of Nursing, Dissertation Chair
Sharon R. Clark, PhD, RN, FNP, Assistant Professor of Medicine (Research), Division of Arthritis and Rheumatic Diseases
Robert M. Bennett, MD, FRCP, Professor of Medicine, Division of Arthritis and Rheumatic Diseases, Department of Medicine
Kathleen Potempa, DNSc, RN, Dean and Professor, School of Nursing

PURPOSE: You are being asked to take part in this research study because you have fibromyalgia. Previous research at Oregon Health Sciences University (OHSU) has revealed that patients with fibromyalgia have low levels of muscle strength, exercise endurance and fitness. The purpose of this study is to determine whether muscle conditioning exercises tailored to the special needs of patients with fibromyalgia will improve muscle strength in the large muscle groups as well as other selected physical and psychological outcomes.

PROCEDURES: You must be between 21-60 years old to participate in this study. If you choose to participate in this study, you will spend about 1 hour in the Human Performance Lab at OHSU on 2 occasions approximately 3 months apart. The same tests and procedures will be performed on both occasions. Between these two visits to the lab you will be asked to participate in an exercise class two times per week for 45 minutes each session for 12 weeks. These classes will be offered to you free of charge at OHSU. The focus of your group will either be muscle flexibility or muscle strength.

FIRST TESTING PERIOD:

1. You will be randomly assigned (like flipping a coin) to one of two exercise groups. The principal investigator (Kim Jones) will not know to which of the two groups you were assigned.

2. When you visit the lab, you will be asked to complete questionnaires about how you are feeling.

3. You will be asked to complete two tests that provide information about your ability to do everyday tasks. These will include asking you to place your hand to your neck and your hand to your shoulder blade.

4. Skin fold measurements will be taken with skin fold calipers at seven sites (arm, back, chest, abdomen (2 sites), hip and leg) to access body fat.

5. You will be asked to complete a test of muscle strength and endurance in your thighs and muscle strength in your shoulders. The following procedure will be used:

5a. Sit comfortably on the Cybex isokinetic dynamometer (weight lifting machine).

5b. You will have a brief muscle warm up guided by an exercise physiologist.

5c. While you are seated you will be asked to extend and flex one knee at three different positions. Then you will be asked to perform as many knee extensions as you can comfortably do.

5d. Lastly you will be asked to perform a single internal and external rotation of one shoulder (like turning a doorknob with your elbow straight).

5e. The entire Cybex test will take about 7 minutes and will be stopped at any time if you indicate a desire to stop.

6. The entire time of the visit is expected to be approximately 60 minutes.

SECOND TEST PERIOD:

Within two weeks of completing the exercise classes, you will asked to return to the Human Performance Lab at OHSU. You will be asked to complete the same tests, in the same order as you did prior to beginning the exercise classes.

RISKS AND DISCOMFORTS:

The following risks and discomforts may result from participation:

1. Using the Cybex machine to test thigh and shoulder strength may cause some temporary muscle discomfort at the time of the test and delayed onset muscle soreness over a few days following the test.

2. The exercise interventions were designed by fibromyalgia and exercise experts. If however, you experience soreness or discomfort from the exercises, you can receive individualized

counseling and exercise modification from the exercise instructor or Dr. Sharon Clark, exercise physiologist, 503-228-3217.

3. If a serious medical problem should occur as a result of participation in the study, or if you should seek medical attention for any purpose during the course of the study, you should contact Dr. Clark or your fitness instructor. The course of action will be determined in consultation with Dr. Robert Bennett.

4. It is not known how this exercise intervention could affect an unborn child. If you are capable of becoming pregnant, you must use an effective method of birth control while participating in this research. If you become pregnant during the research study, you must notify your doctor immediately.

BENEFITS:

You may or may not personally benefit from participating in this study. However, by serving as a participant, you may contribute new information which may benefit fibromyalgia patients in the future. The results of the Cybex test will be discussed with you so that you will know more about your muscular strength and endurance. Your individual fitness may also be improved.

CONFIDENTIALITY:

Your name, address, and telephone number will be kept strictly confidential. All records related to the study will be kept securely in the offices of Kim Jones. Neither your name nor your identity will be used for publication or publicity purposes.

COSTS:

You will not be charged or have to pay anything for having the laboratory tests or attending the exercise classes. You will be responsible for transportation and parking costs.

LIABILITY:

The Oregon Health Science University, as a public institution, is subject to the Oregon Tort Claims Act, and is self-insured for liability claims. If you suffer any injury from this research project, compensation would be available to you only if you establish that the injury occurred through the fault of the University, its officers, or employees. You have not waived your legal rights by signing this form. If you have further questions, please call the Medical Services Director at 503-494-6020.

PARTICIPATION:

Your participation in this research study is voluntary. Kim Jones and her colleagues have agreed to answer any questions you have regarding this study. Ms. Jones' telephone number is 503-494-3837. If you have questions about your rights as a research subject, you may contact the Oregon Health Sciences University Institutional Review Board at 503-494-7887.

The study doctor, Dr. Bennett, may withdraw you from the study, if among other reasons, you do not comply with investigation instructions, if you experience any adverse reactions, or for any other reasons your doctor feels appropriate.

You may refuse to participate, or you may withdraw from this study at any time without affecting your relationship with, or treatment, at the Oregon Health Sciences University.

You will receive a copy of this consent form.

Your signature below indicates that you have read the foregoing and agree to participate in this study.

________________________________ ____________________

Signature of Patient Date

________________________________ ____________________

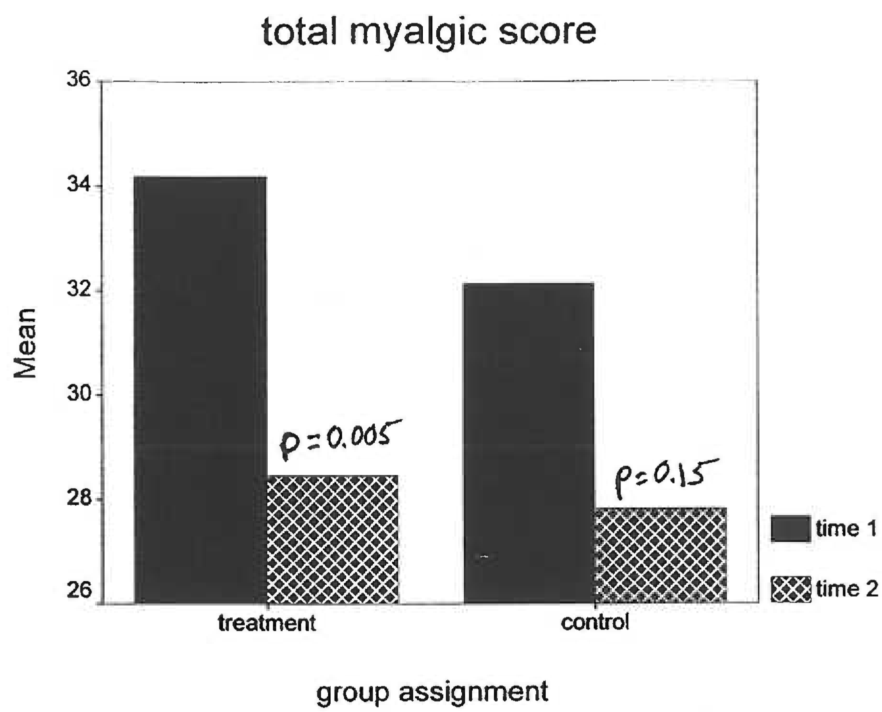
Signature of Witness Date

________________________________ ____________________

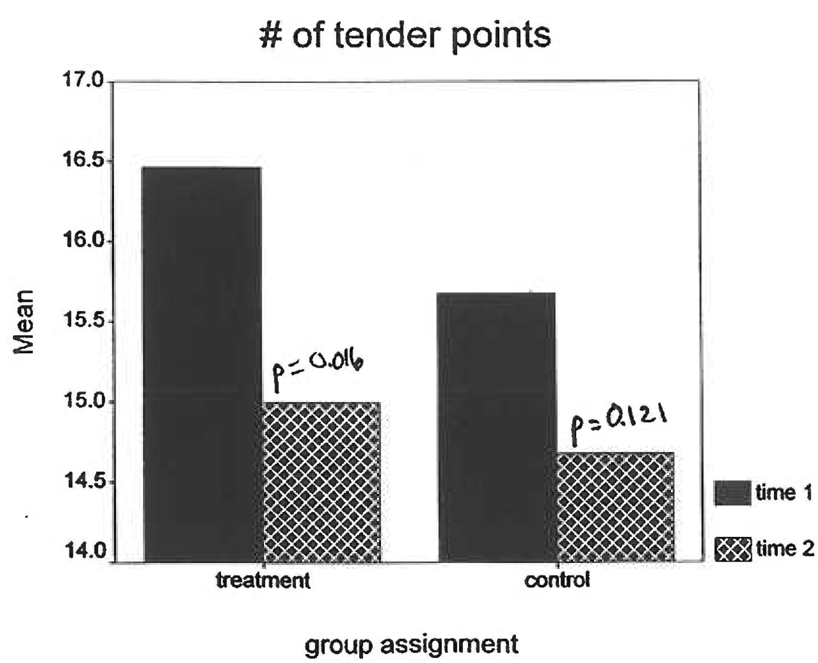
Signature of Principal Investigator Date

APPENDIX H

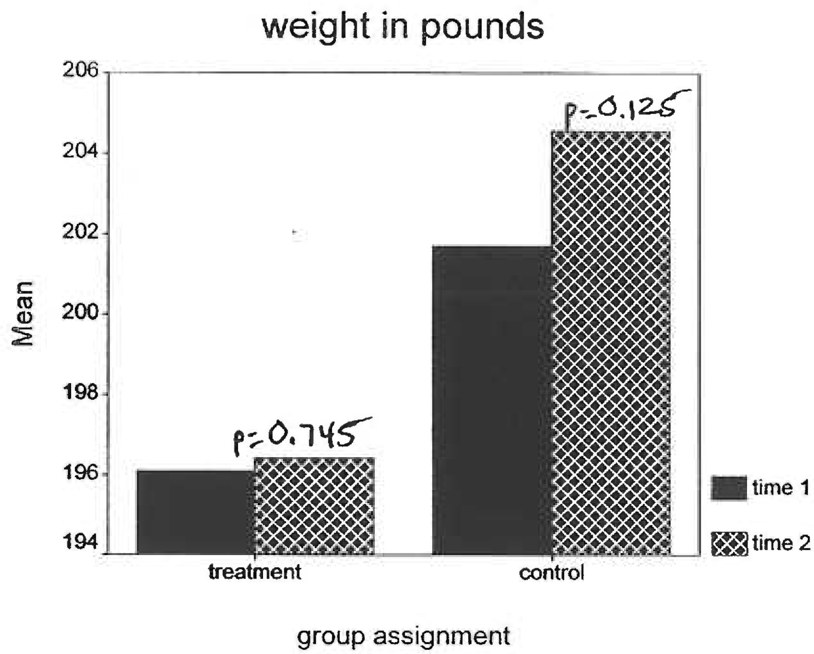
Bar Graphs of Paired t-tests

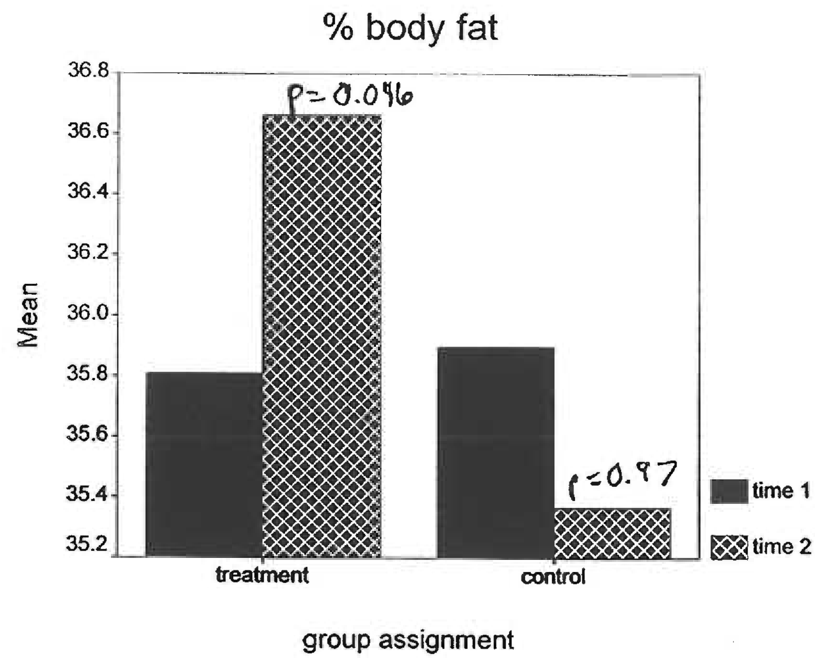

total myalgic score
36
34
32
30
28
26
Mean
p=0.005
p=0.15
time 1
time 2
treatment
control
group assignment

Graph

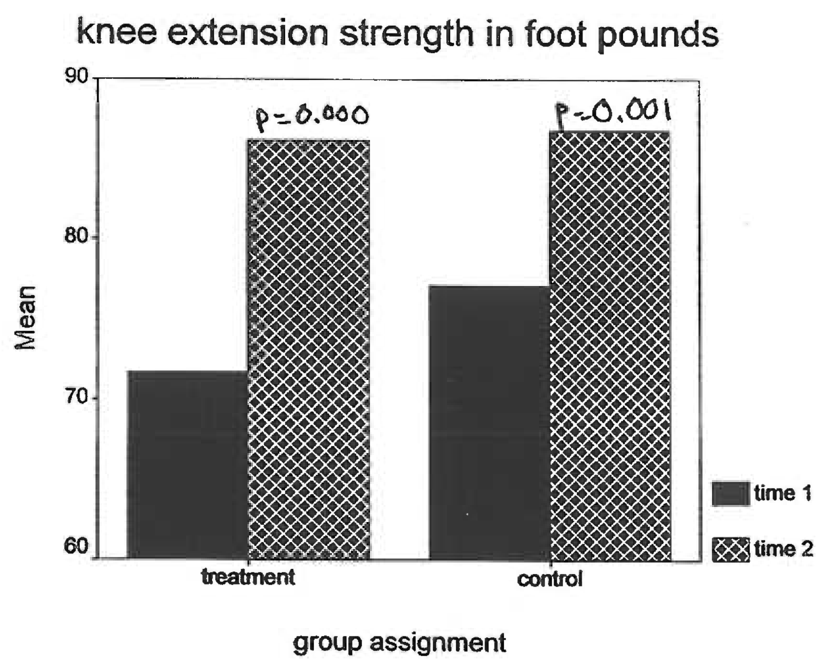

# of tender points
17.0
16.5
16.0
15.5
15.0
14.5
14.0
Mean
p=0.016
p=0.121
time 1
time 2
treatment
control
group assignment

Graph

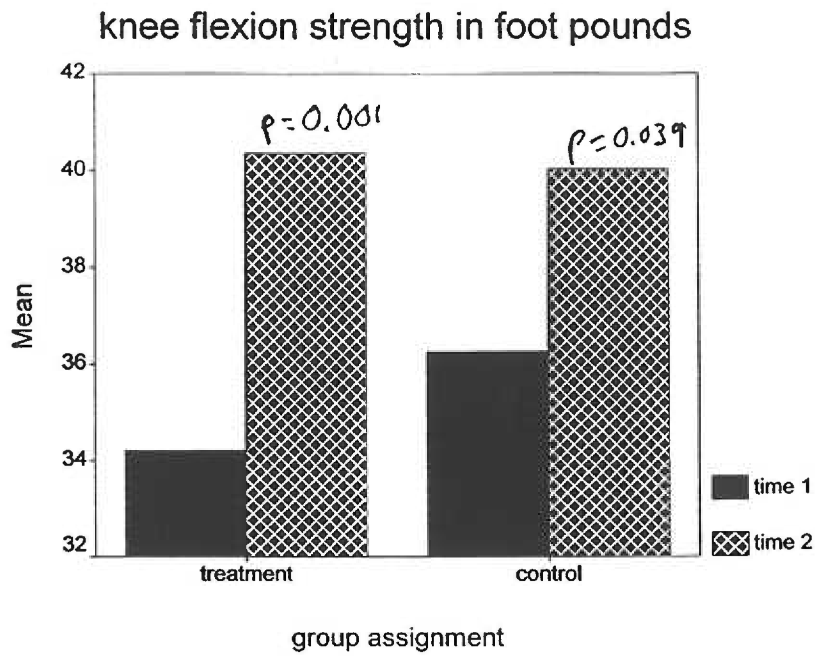

weight in pounds
206
204
202
200
198
196
194
Mean
p=0.125
p=0.745
treatment
control
group assignment
time 1
time 2


% body fat
p=0.046
p=0.97
36.8
36.6
36.4
36.2
36.0
35.8
35.6
35.4
35.2
Mean
treatment
control
group assignment
time 1
time 2

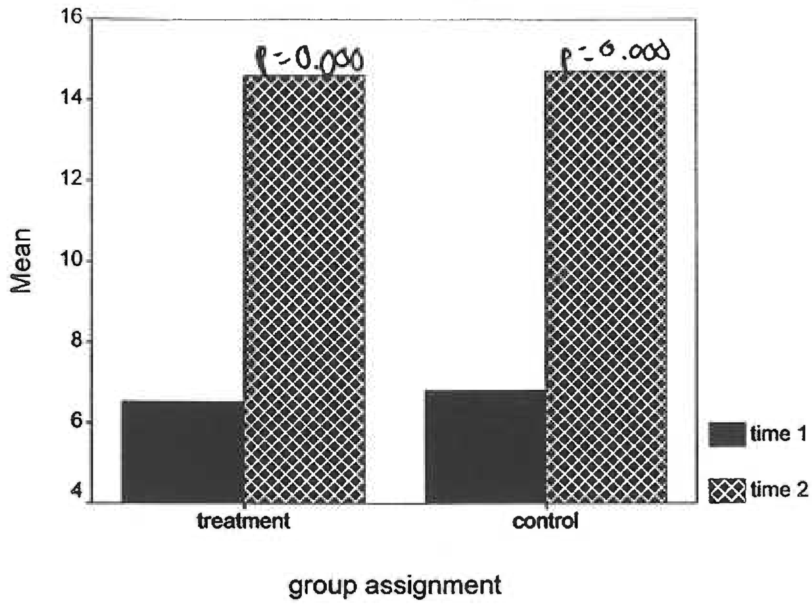
Graph


knee extension strength in foot pounds
p=0.000
p=0.001
90
80
70
60
Mean
treatment
control
group assignment
time 1
time 2

Graph

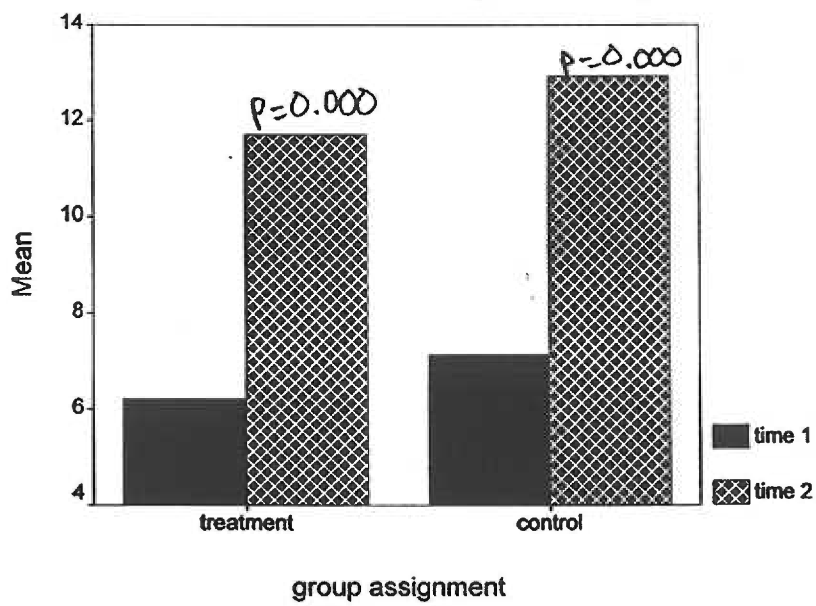

knee flexion strength in foot pounds
p=0.001
p=0.039
42
40
38
36
34
32
Mean
time 1
time 2
treatment
control
group assignment

int. rotation shoulder strength in foot pounds

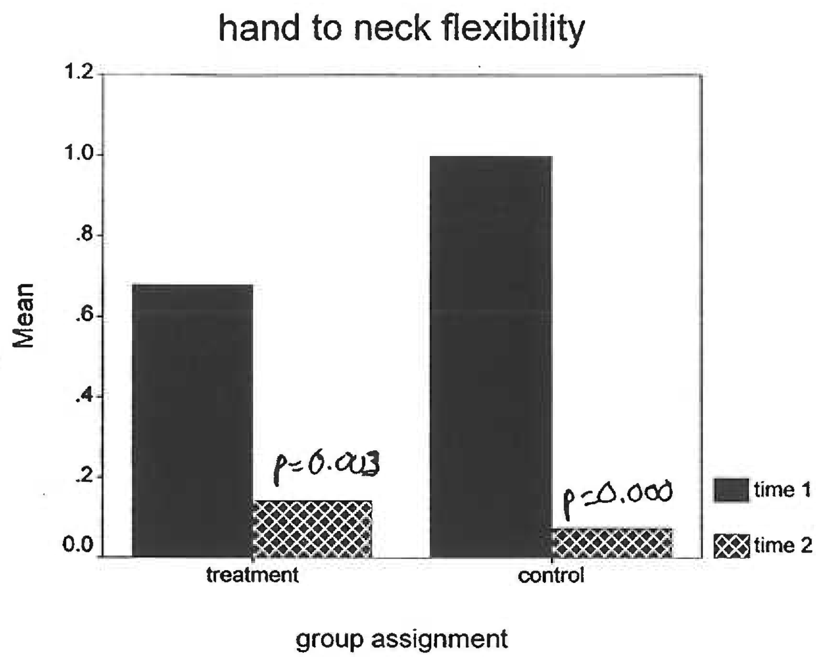


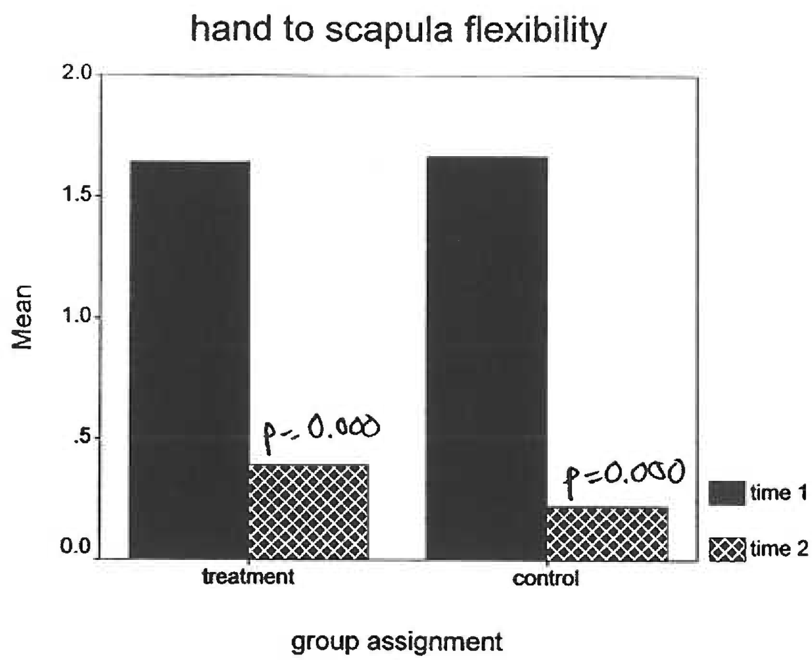
Graph

ext. rotation shoulder strength in foot pounds

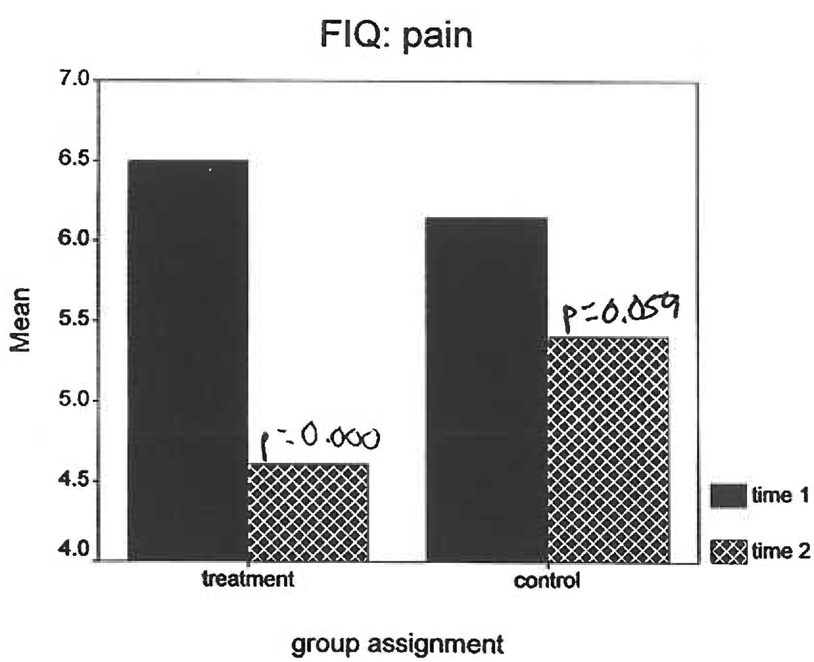


Graph

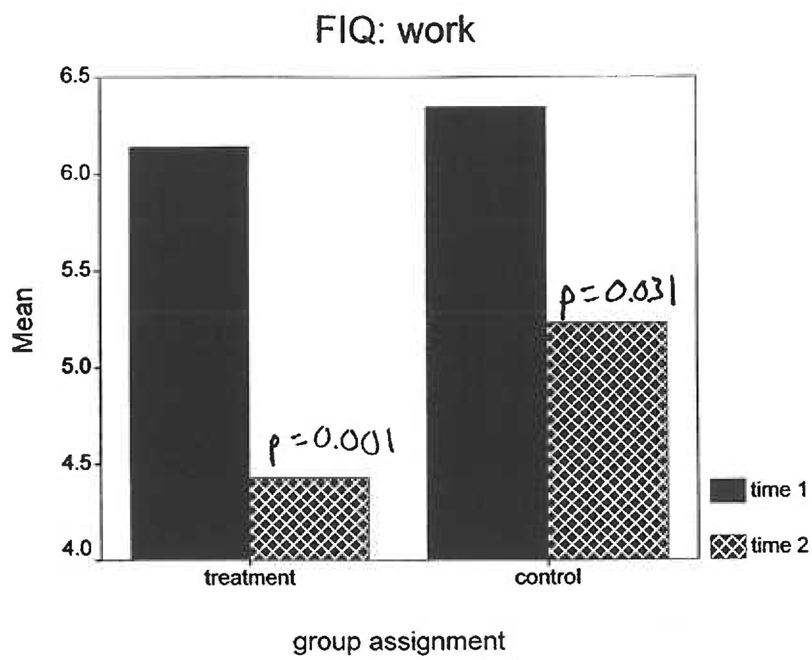

hand to neck flexibility
1.2
1.0
.8
.6
.4
.2
0.0
Mean
p=0.003
p=0.000
time 1
time 2
treatment
control
group assignment

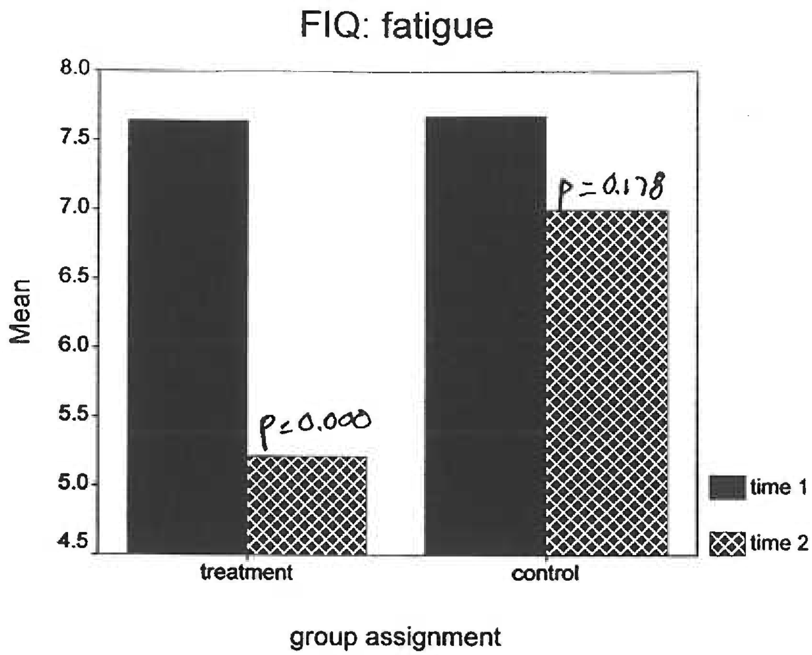

hand to scapula flexibility
2.0
1.5
1.0
.5
0.0
Mean
p=0.000
p=0.000
time 1
time 2
treatment
control
group assignment

Graph

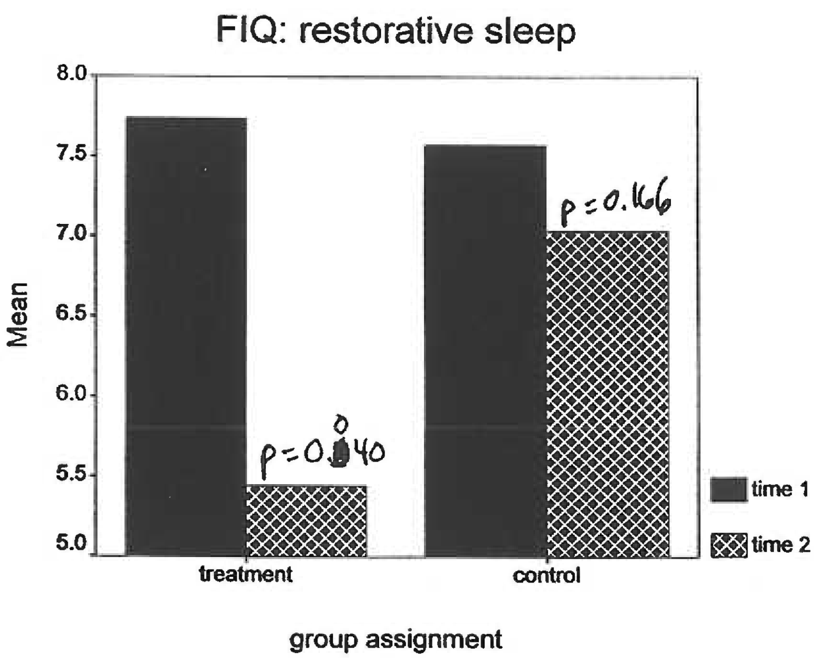

FIQ: pain
7.0
6.5
6.0
5.5
5.0
4.5
4.0
Mean
p=0.059
p=0.000
time 1
time 2
treatment
control
group assignment

Graph

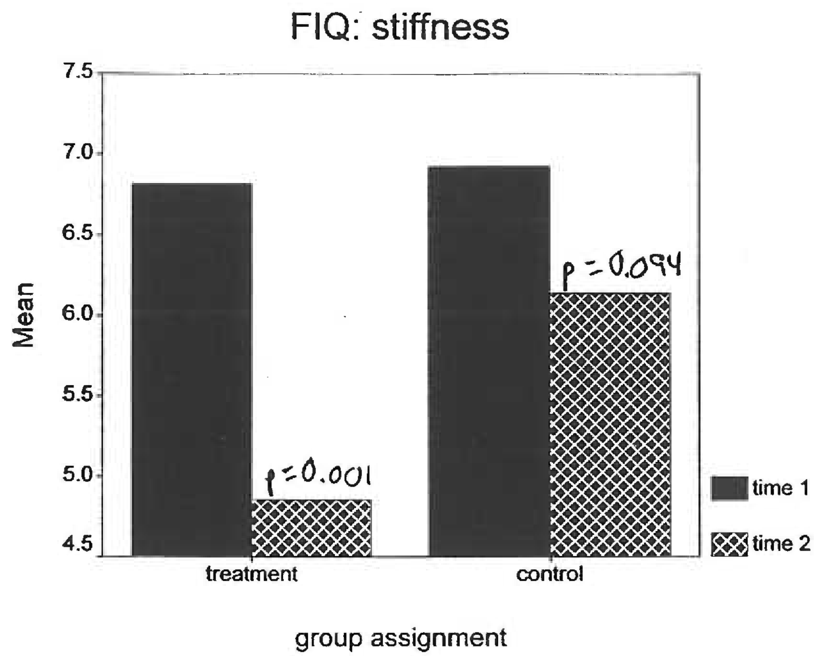

FIQ: work
6.5
6.0
5.5
5.0
4.5
4.0
Mean
p=0.031
p=0.001
time 1
time 2
treatment
control
group assignment

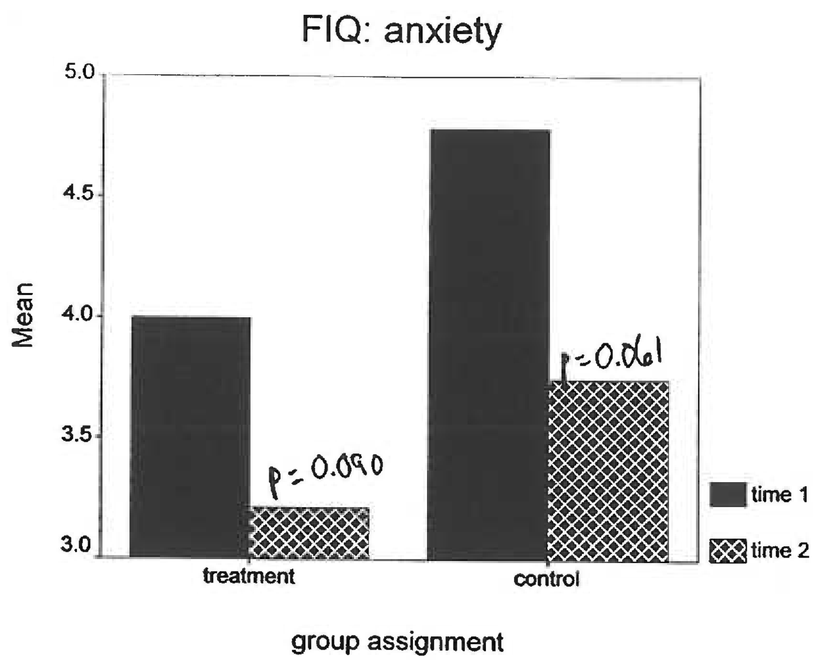

FIQ: fatigue
Mean
8.0
7.5
7.0
6.5
6.0
5.5
5.0
4.5
p=0.000
p=0.178
treatment
control
time 1
time 2
group assignment

Graph

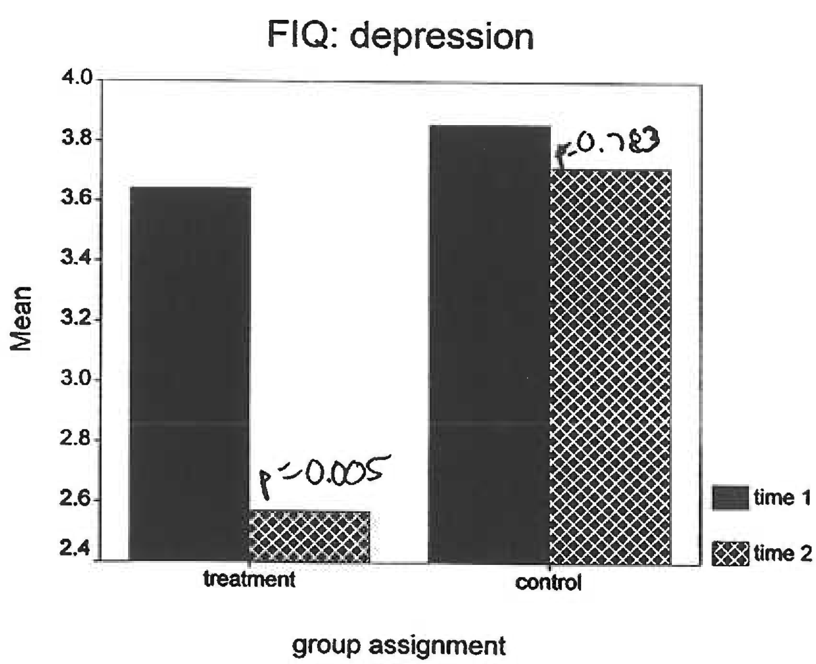

FIQ: restorative sleep
Mean
8.0
7.5
7.0
6.5
6.0
5.5
5.0
p=0.040
p=0.166
treatment
control
time 1
time 2
group assignment

Graph

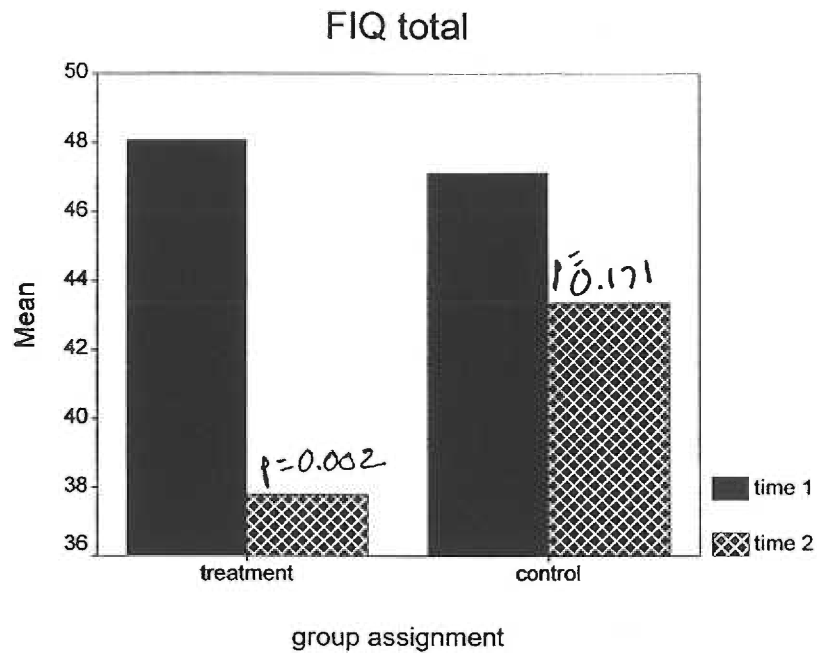

FIQ: stiffness
7.5
7.0
6.5
6.0
5.5
5.0
4.5
Mean
p=0.001
p=0.094
time 1
time 2
treatment
control
group assignment

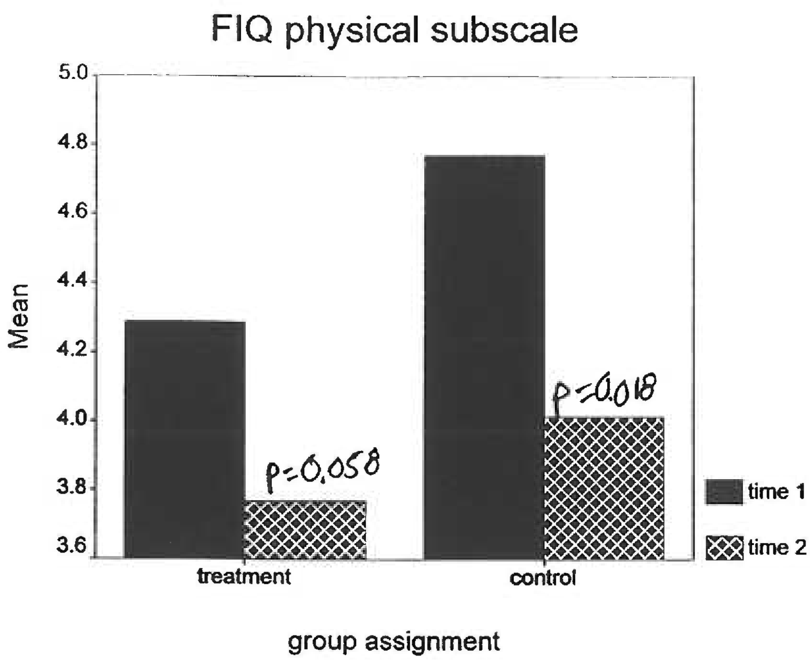

FIQ: anxiety
5.0
4.5
4.0
3.5
3.0
Mean
p = 0.090
p = 0.061
time 1
time 2
treatment
control
group assignment

Graph

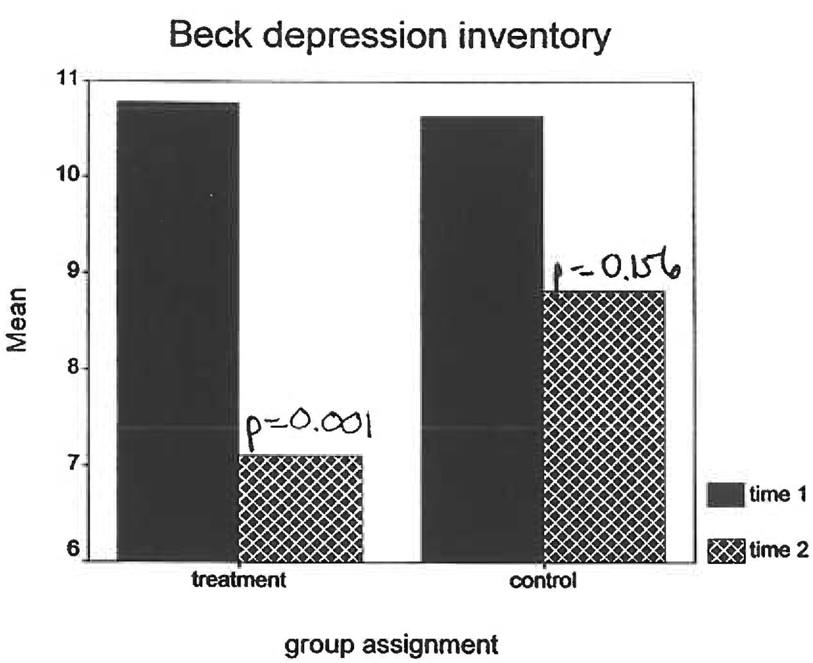

FIQ: depression
4.0
3.8
3.6
3.4
3.2
3.0
2.8
2.6
2.4
Mean
p = 0.005
p = 0.783
time 1
time 2
treatment
control
group assignment

Graph

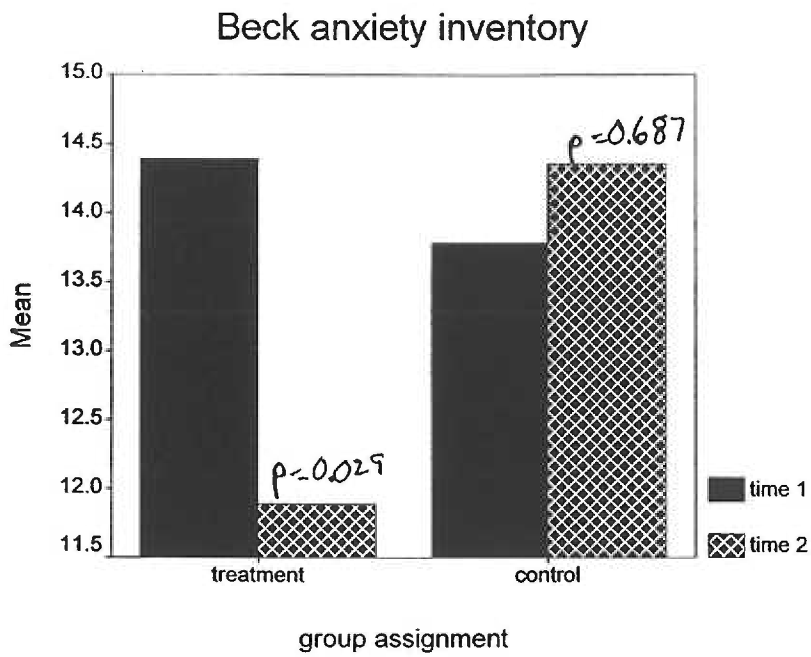

FIQ total
Mean
50
48
46
44
42
40
38
36
p=0.002
p=0.171
time 1
time 2
treatment
control
group assignment


FIQ physical subscale
5.0
4.8
4.6
4.4
4.2
4.0
3.8
3.6
Mean
p=0.058
p=0.018
time 1
time 2
treatment
control
group assignment

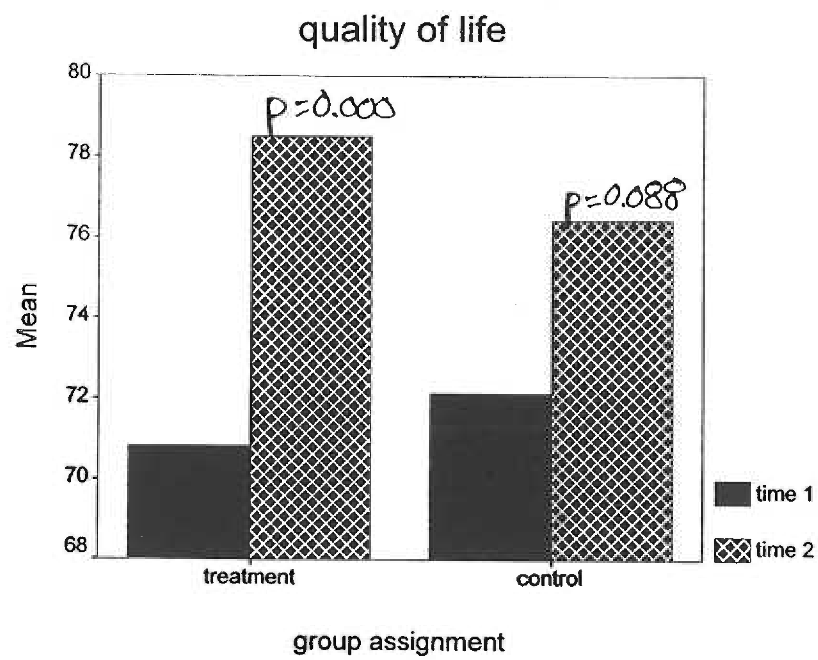
Graph


Beck depression inventory
11
10
9
8
7
6
Mean
p=0.001
p=0.156
time 1
time 2
treatment
control
group assignment

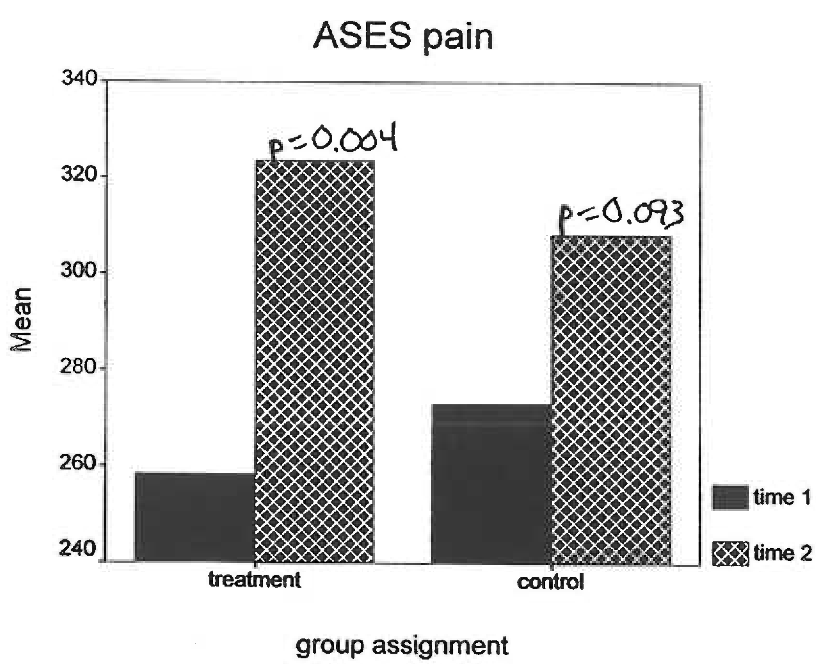
Graph


Beck anxiety inventory
15.0
14.5
14.0
13.5
13.0
12.5
12.0
11.5
Mean
p=0.687
p=0.029
time 1
time 2
treatment
control
group assignment

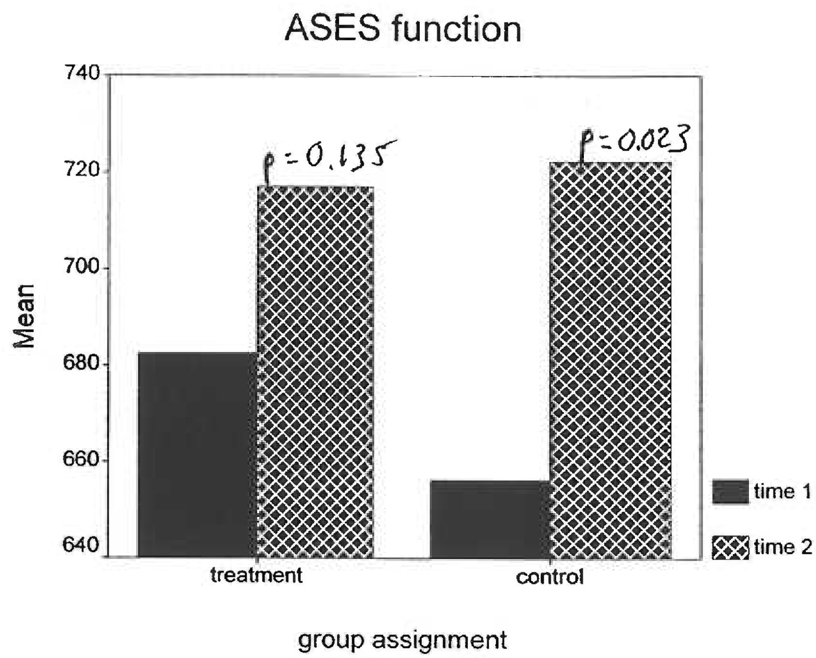
Graph

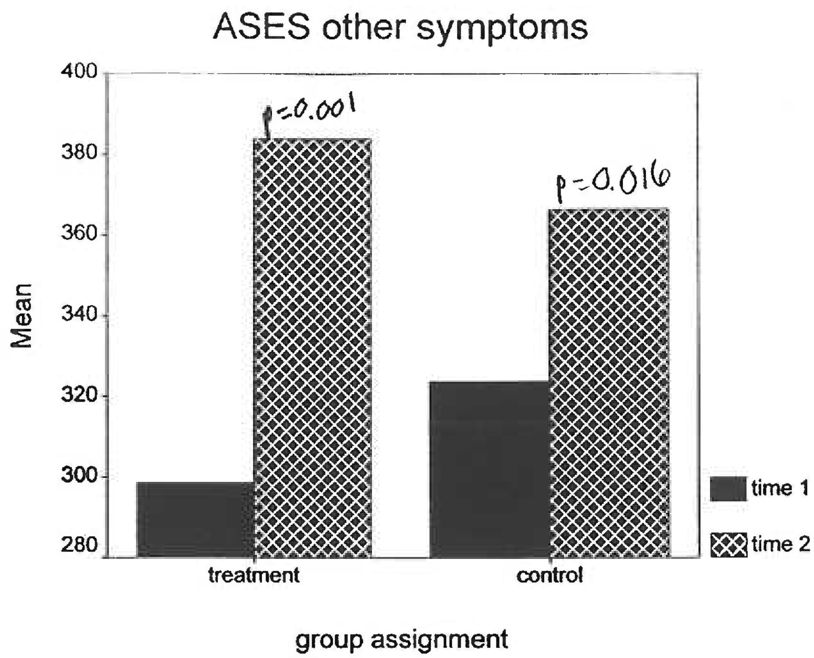

quality of life
80
78
76
74
72
70
68
Mean
p=0.000
p=0.088
time 1
time 2
treatment
control
group assignment

Graph

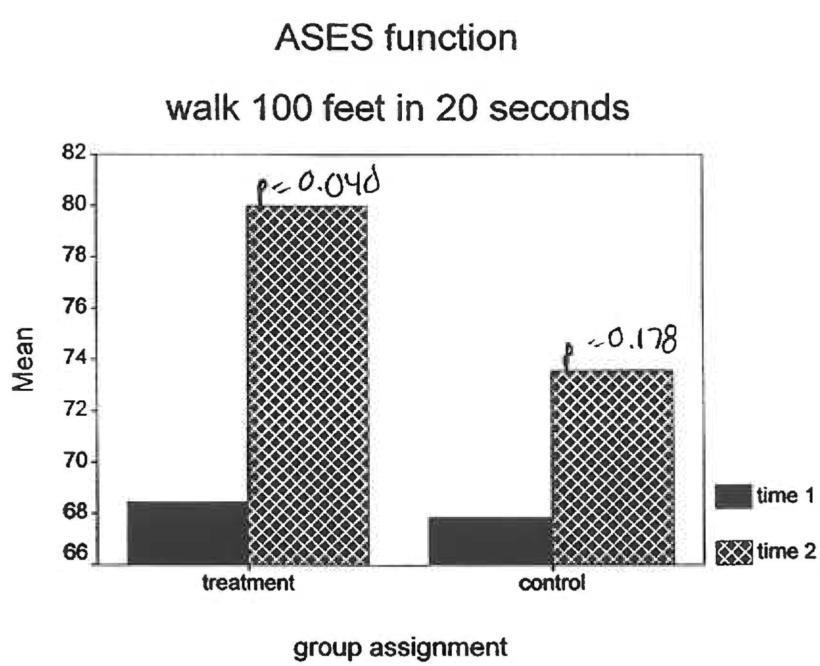

ASES pain
340
320
300
280
260
240
Mean
p=0.004
p=0.093
time 1
time 2
treatment
control
group assignment

Graph

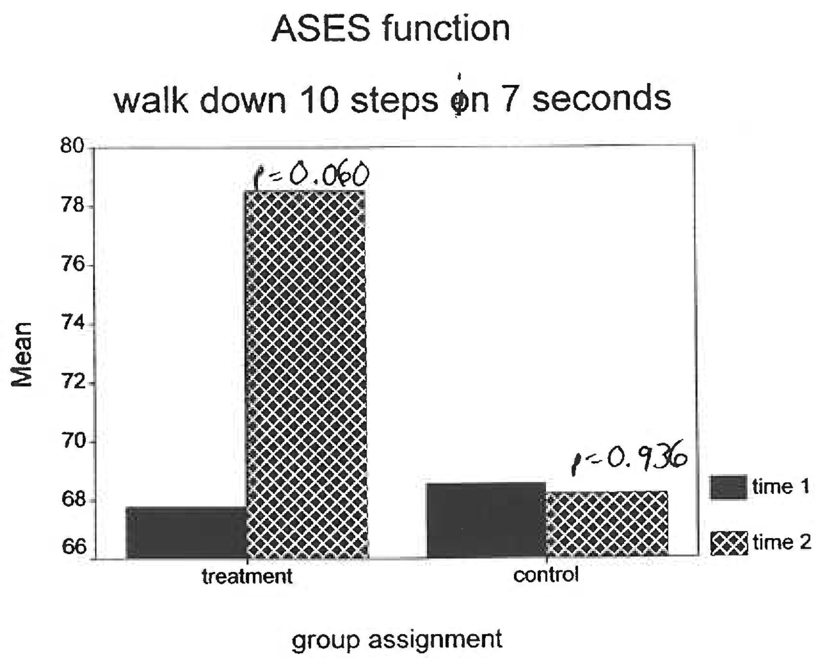

ASES function
740
720
700
680
660
640
Mean
p=0.135
p=0.023
treatment
control
group assignment
time 1
time 2


ASES other symptoms
400
380
360
340
320
300
280
Mean
p=0.001
p=0.016
time 1
time 2
treatment
control
group assignment

Graph

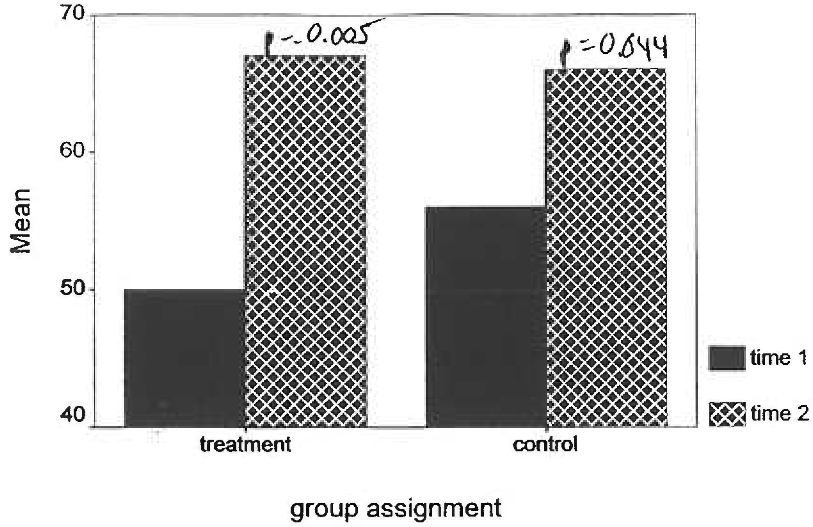

ASES function
walk 100 feet in 20 seconds
82
80
78
76
74
72
70
68
66
Mean
p=0.040
p=0.178
time 1
time 2
treatment
control
group assignment

Graph


ASES function
walk down 10 steps on 7 seconds
Mean
80
78
76
74
72
70
68
66
p=0.060
p=0.936
treatment
control
group assignment
time 1
time 2

ASES function

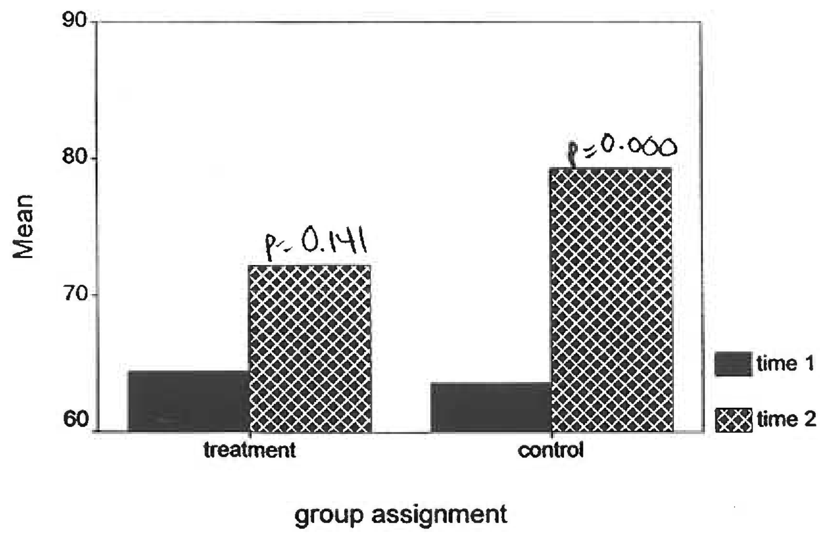
get out of armless chair quickly

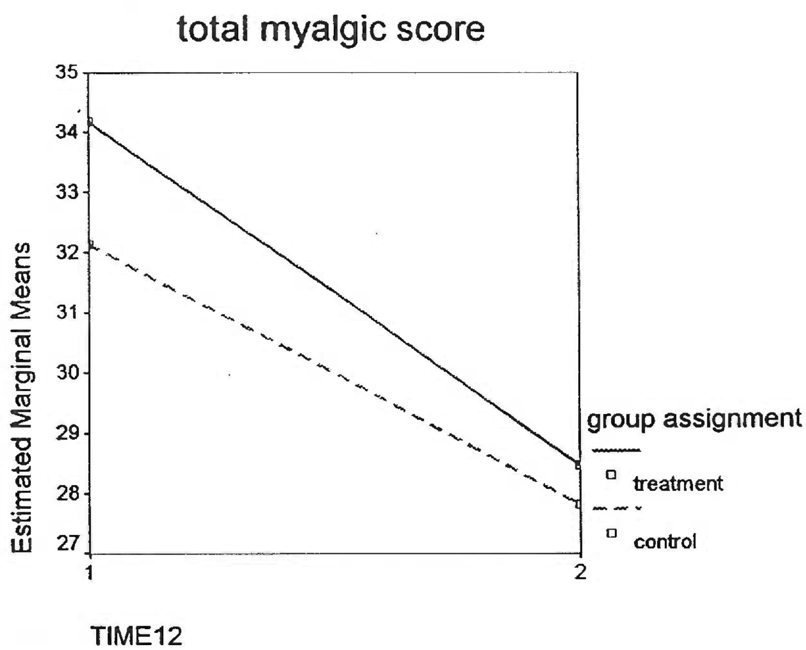


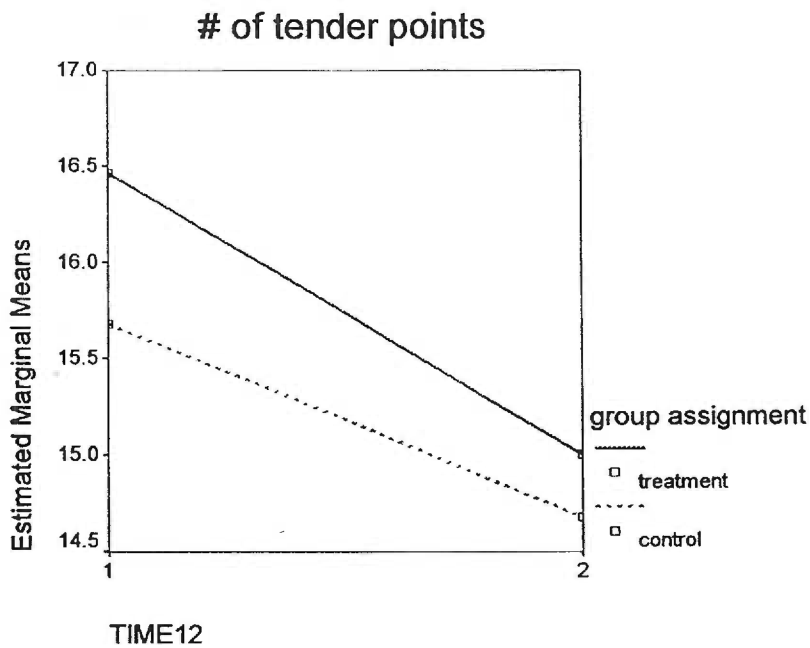
Graph

ASES function

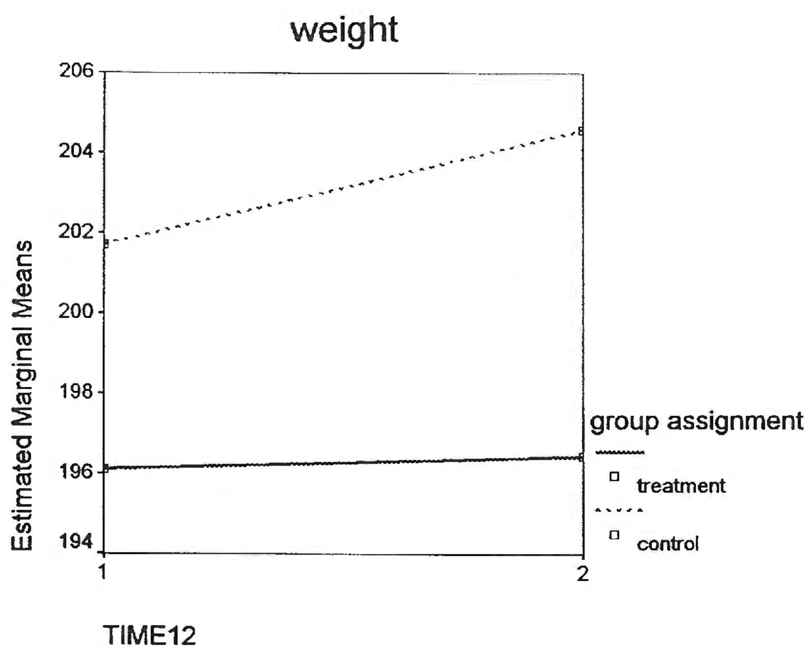
scratch back

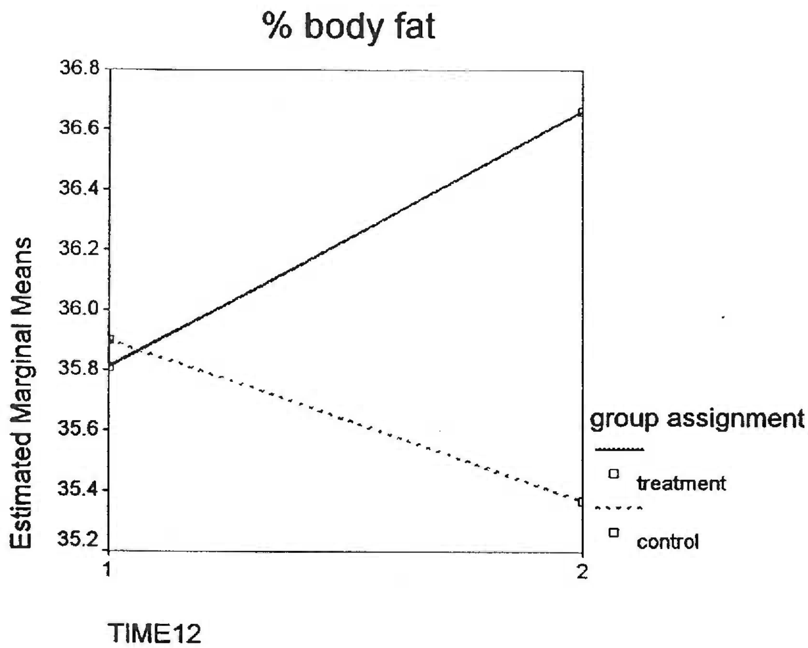


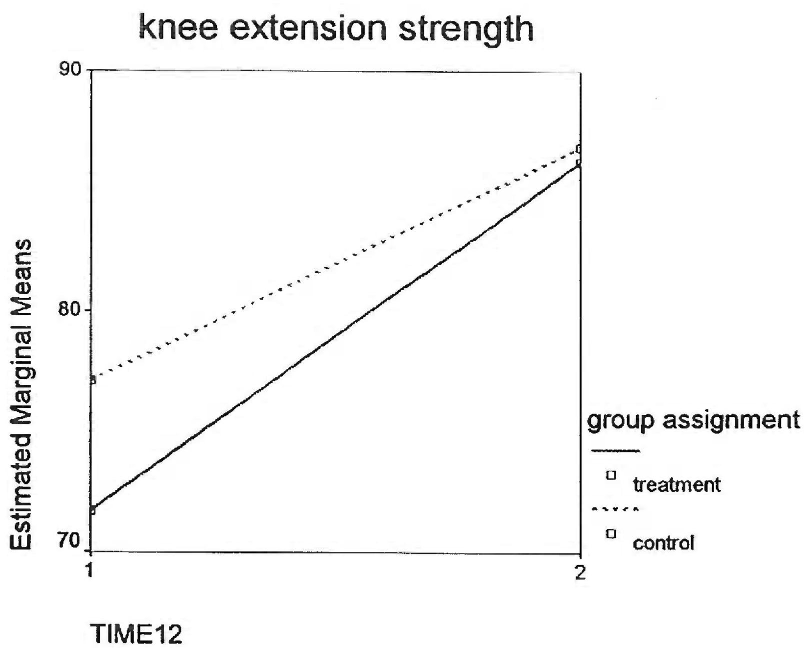

total myalgic score
Estimated Marginal Means
35
34
33
32
31
30
29
28
27
1
2
TIME12
group assignment
treatment
control

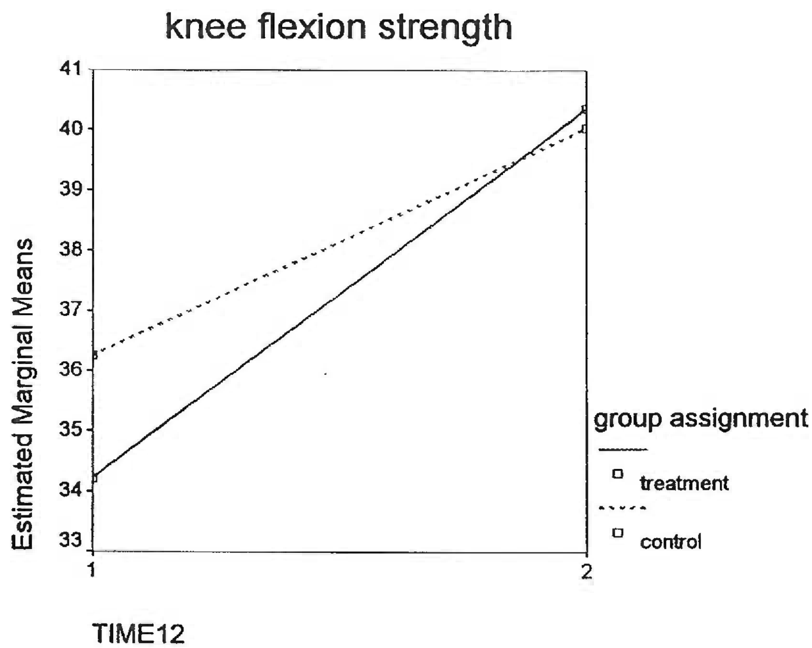


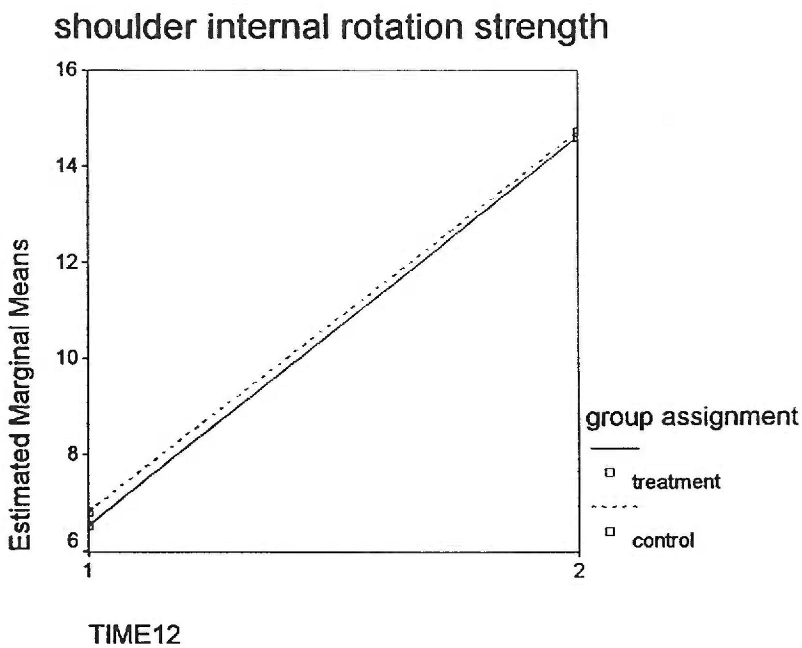
# of tender points
17.0
16.5
16.0
15.5
15.0
14.5
Estimated Marginal Means
1
2
TIME12
group assignment
treatment
control

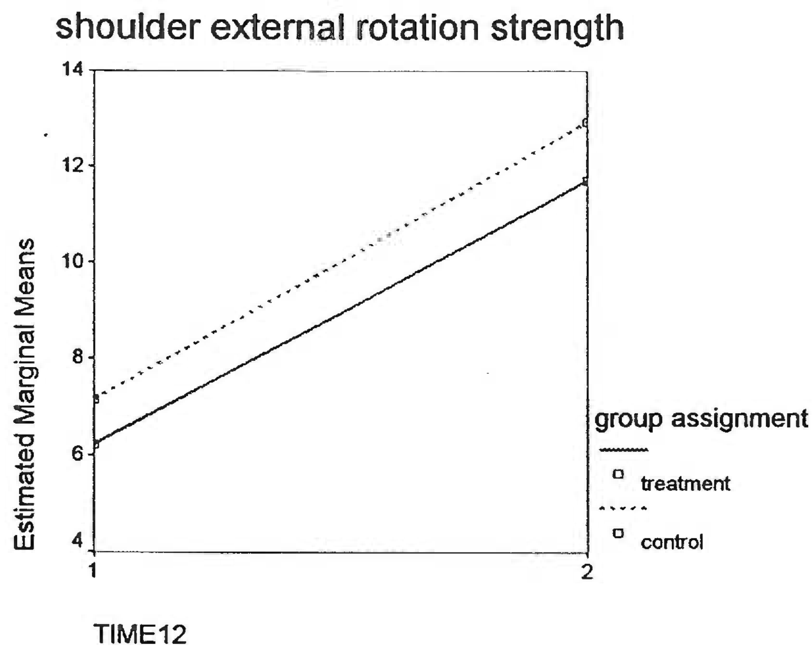

weight
Estimated Marginal Means
206
204
202
200
198
196
194
1
2
TIME12
group assignment
treatment
control

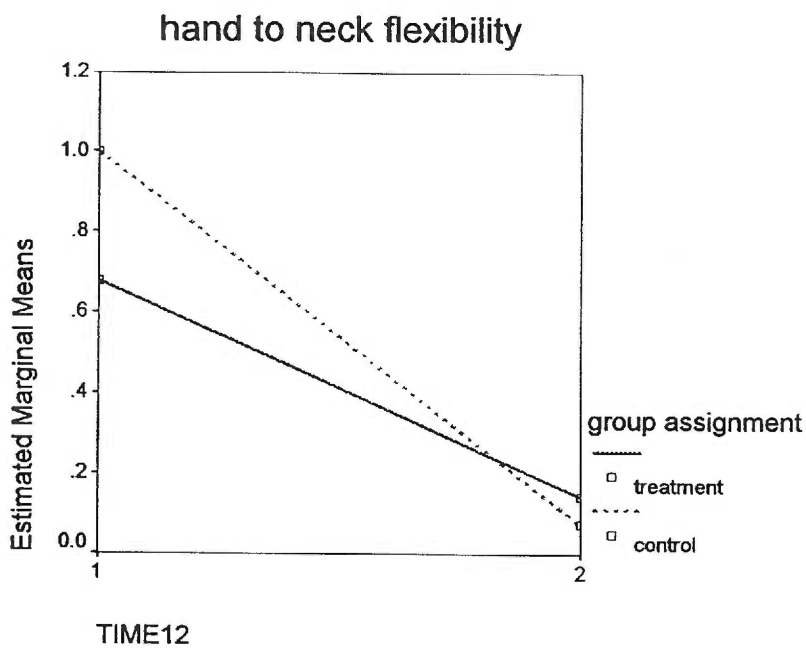

% body fat
Estimated Marginal Means
36.8
36.6
36.4
36.2
36.0
35.8
35.6
35.4
35.2
1
2
TIME12
group assignment
treatment
control

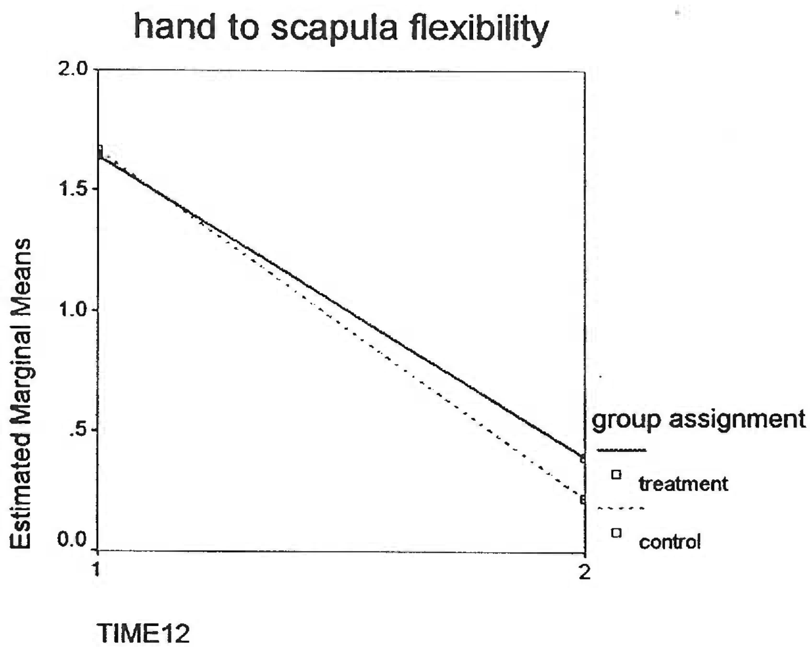

knee extension strength
90
80
70
Estimated Marginal Means
1
2
TIME12
group assignment
treatment
control

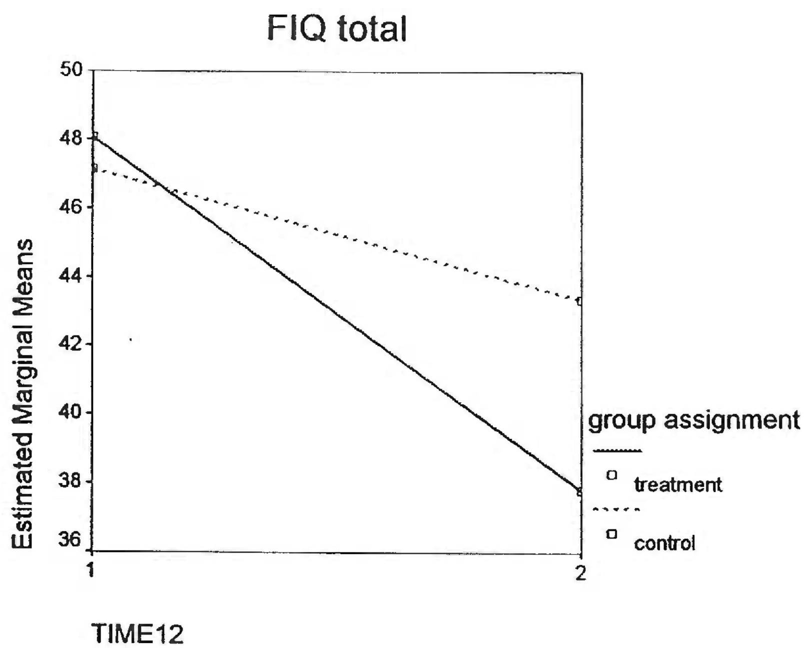

knee flexion strength
41
40
39
38
37
36
35
34
33
Estimated Marginal Means
1
2
TIME12
group assignment
treatment
control


shoulder internal rotation strength
Estimated Marginal Means
16
14
12
10
8
6
1
2
TIME12
group assignment
treatment
control

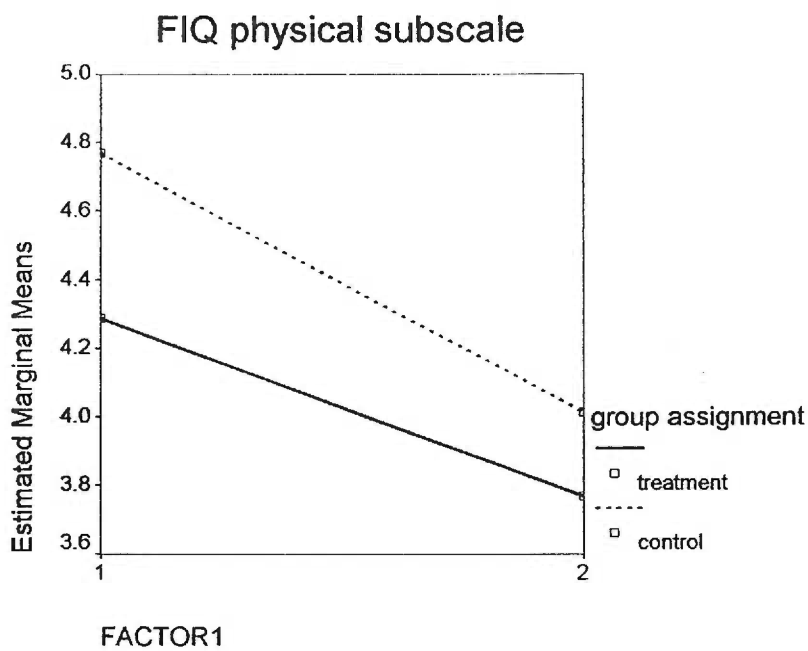

shoulder external rotation strength
Estimated Marginal Means
14
12
10
8
6
4
1
2
TIME12
group assignment
treatment
control

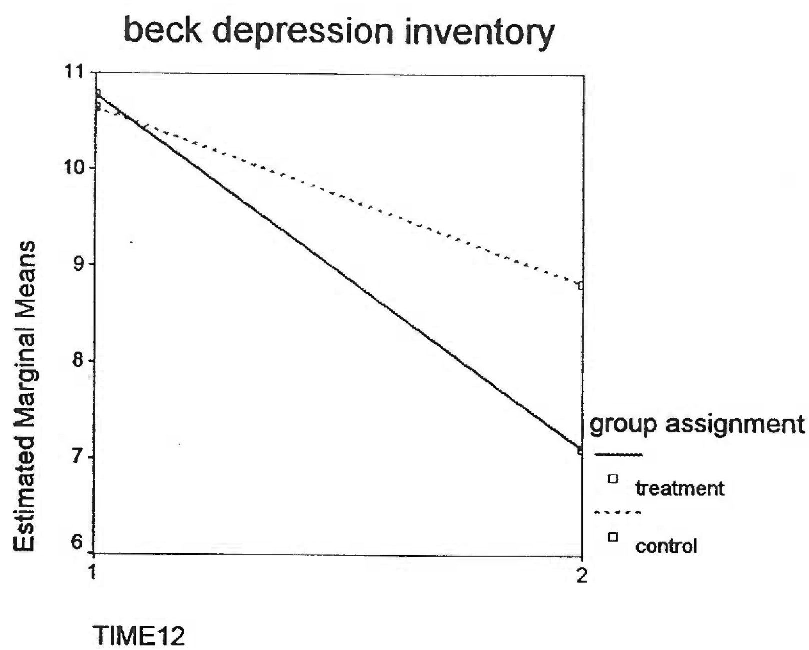

hand to neck flexibility
Estimated Marginal Means
1.2
1.0
.8
.6
.4
.2
0.0
1
2
TIME12
group assignment
treatment
control


hand to scapula flexibility
2.0
1.5
1.0
.5
0.0
Estimated Marginal Means
1
2
TIME12
group assignment
treatment
control

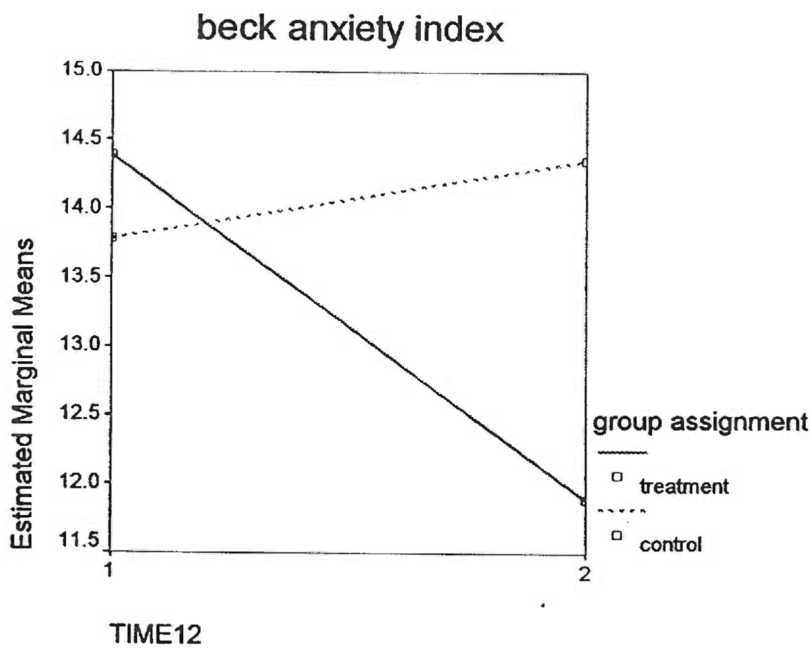


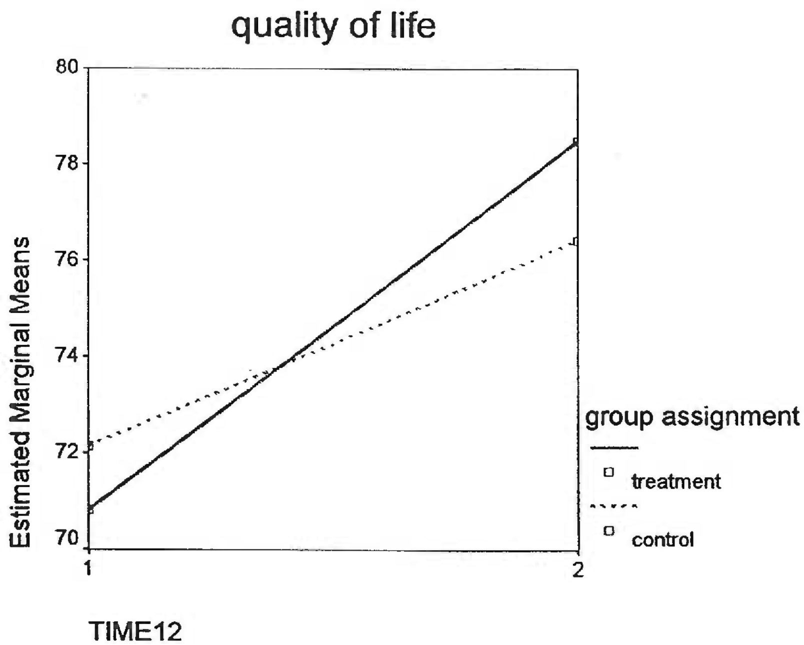
FIQ total
Estimated Marginal Means
50
48
46
44
42
40
38
36
1
2
TIME12
group assignment
treatment
control

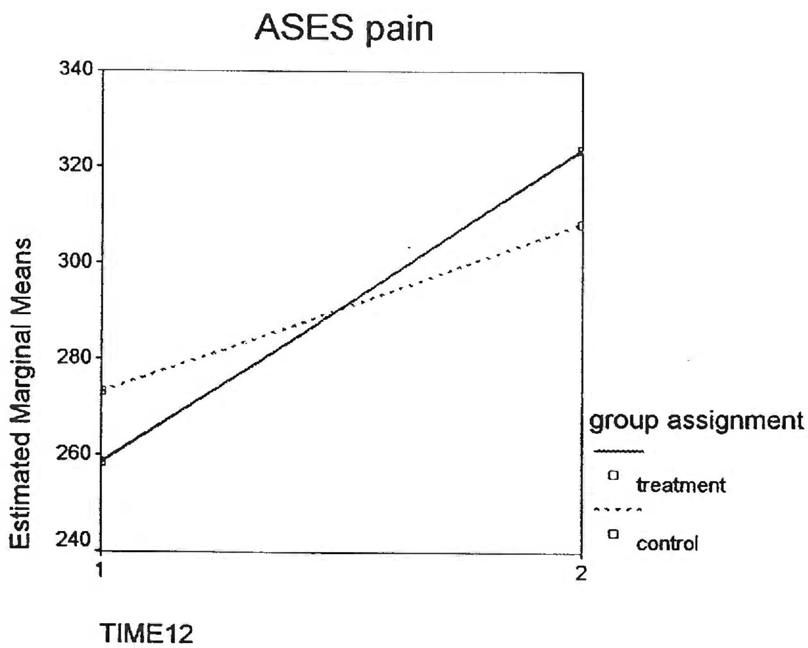

FIQ physical subscale
Estimated Marginal Means
5.0
4.8
4.6
4.4
4.2
4.0
3.8
3.6
1
2
FACTOR1
group assignment
treatment
control

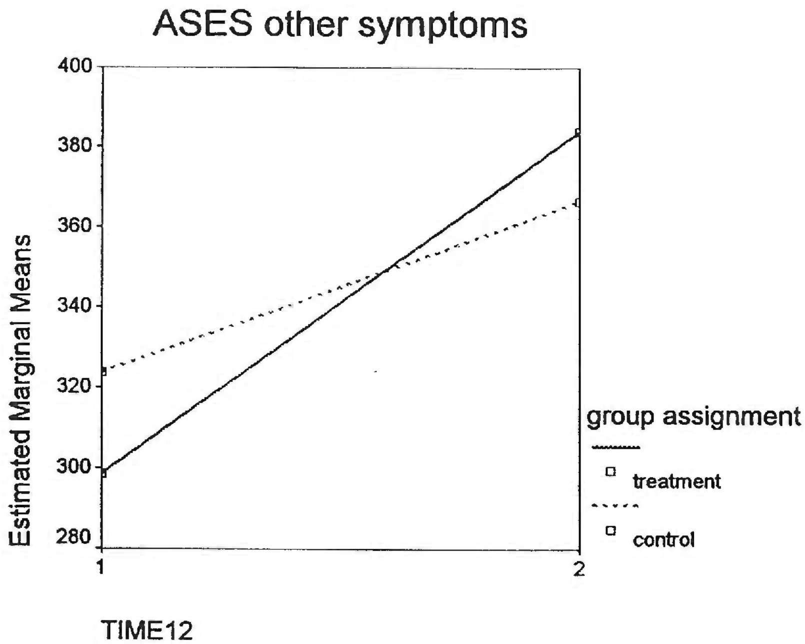


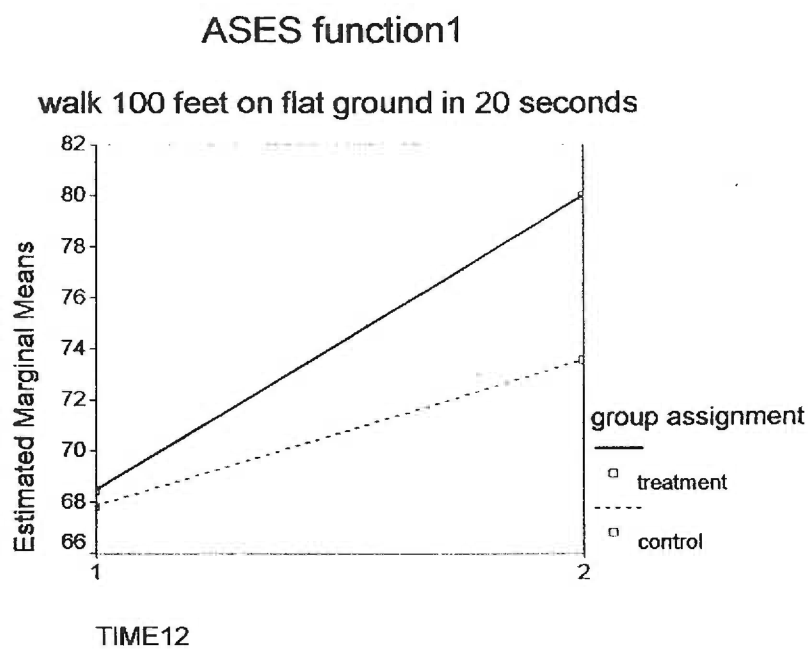
beck depression inventory
Estimated Marginal Means
11
10
9
8
7
6
1
2
TIME12
group assignment
treatment
control


beck anxiety index
Estimated Marginal Means
15.0
14.5
14.0
13.5
13.0
12.5
12.0
11.5
1
2
TIME12
group assignment
treatment
control

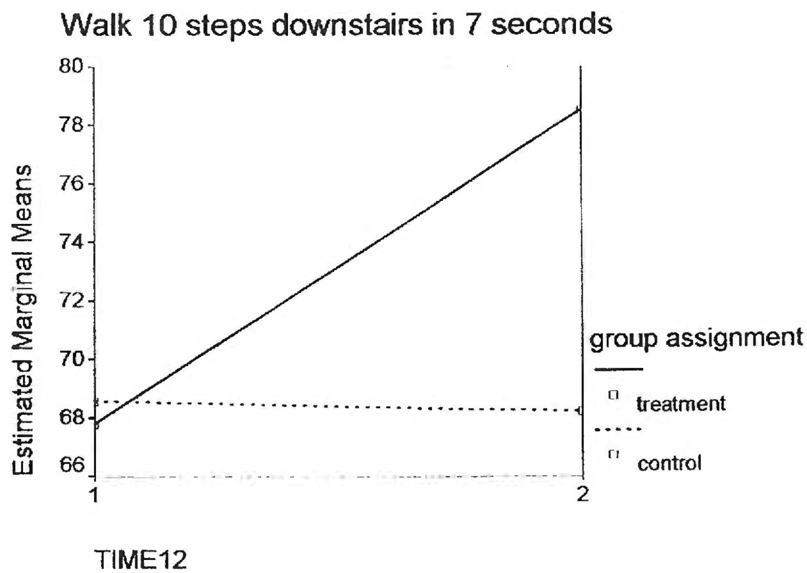

quality of life
80
78
76
74
72
70
Estimated Marginal Means
1
2
TIME12
group assignment
treatment
control

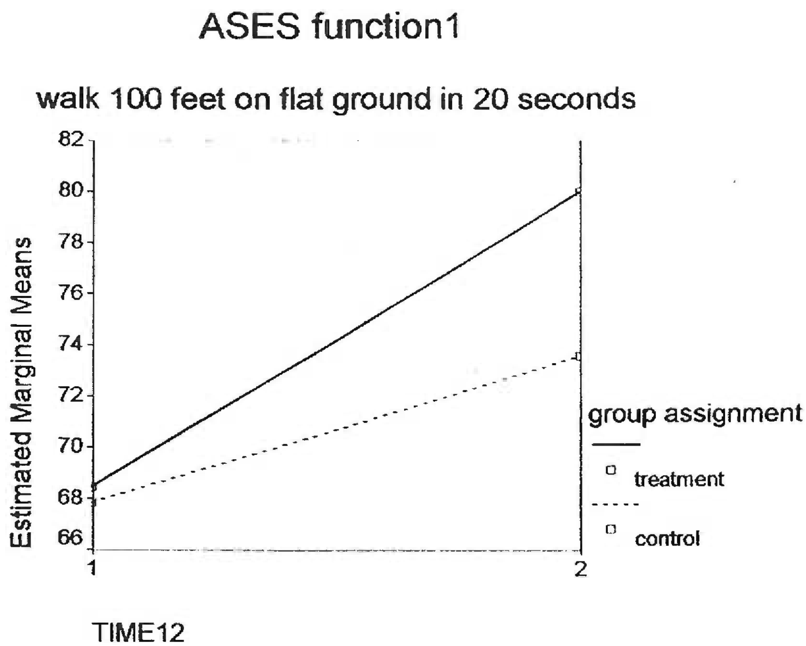

ASES pain
Estimated Marginal Means
340
320
300
280
260
240
1
2
TIME12
group assignment
treatment
control


ASES other symptoms
Estimated Marginal Means
400
380
360
340
320
300
280
1
2
TIME12
group assignment
treatment
control

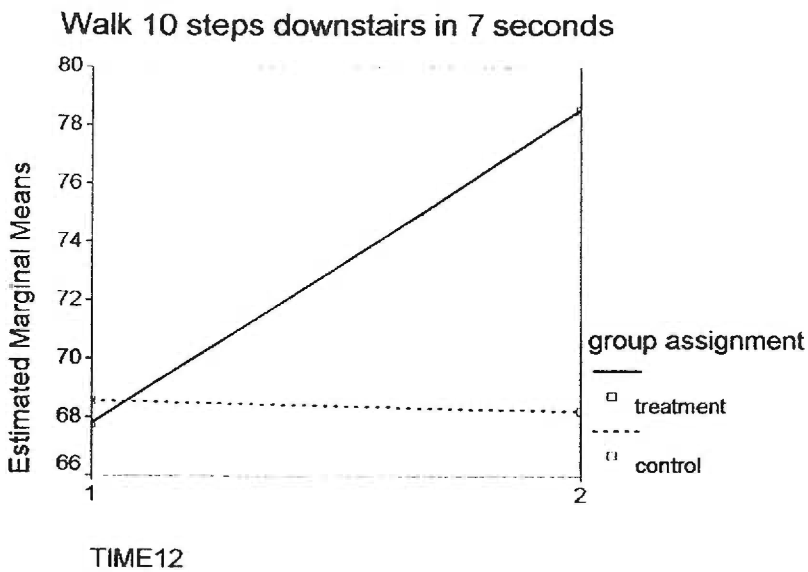

ASES function1
walk 100 feet on flat ground in 20 seconds
Estimated Marginal Means
82
80
78
76
74
72
70
68
66
1
2
TIME12
group assignment
treatment
control

ASES function 2

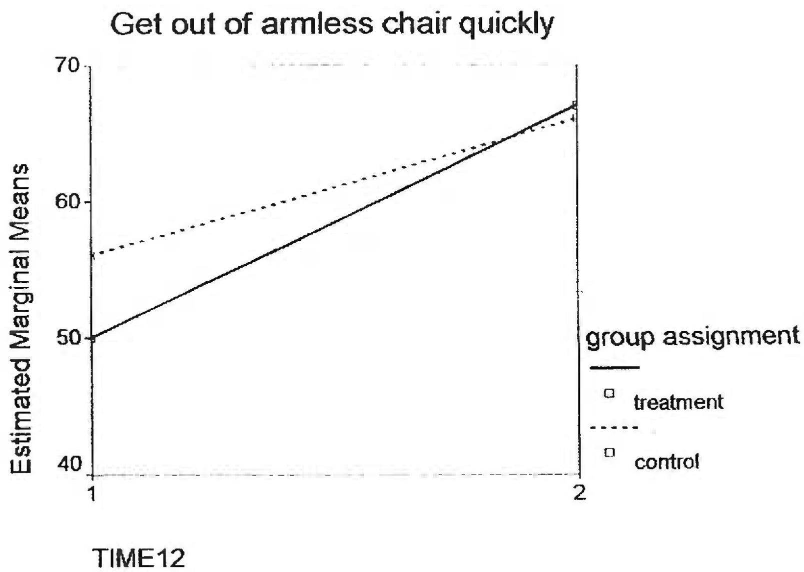



ASES function1
walk 100 feet on flat ground in 20 seconds
Estimated Marginal Means
82
80
78
76
74
72
70
68
66
1
2
TIME12
group assignment
treatment
control

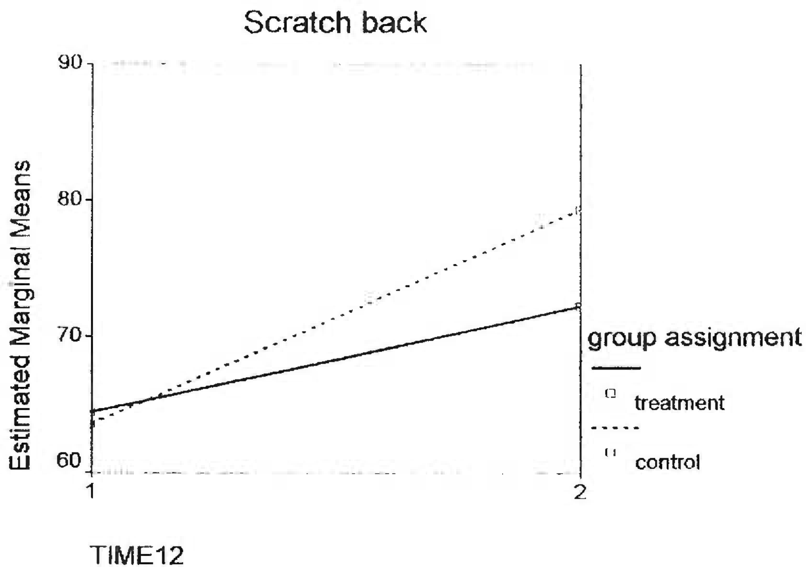
ASES function 2



ASES function 3



ASES function 7



APPENDIX I

Fibromyalgia Study Results Information Form for Participants

Fibromyalgia Study Results

Pre-Test Body Composition

Body Weight_______
% Body fat_______± 3-4%
Lean mass (lbs.)_______
Fat mass (lbs.)_______

Post-Test Body Composition

Body Weight______
% Body fat_______± 3-4%
Lean mass (lbs.)_______
Fat mass (lbs.)_______

Pre-Test Strength

Knee Extension
Max power______ft-lbs
Peak % BW ratio_______

Knee Flexion
Max power______ft-lbs
Peak % BW ratio_______

Shoulder Internal Rotation
Max power______ft-lbs
Peak % BW ratio_______

Shoulder External Rotation
Max power______ft-lbs
Peak % BW ratio_______

Post-Test Strength

Knee Extension
Max power______ft-lbs
Peak % BW ratio_______

Knee Flexion
Max power______ft-lbs
Peak % BW ratio_______

Shoulder Internal Rotation
Max power______ft-lbs
Peak % BW ratio_______

Shoulder External Rotation
Max power______ft-lbs
Peak % BW ratio_______

Tenderpoints Pre-Test

Total number______
Cumulative score______

Tenderpoints Post-Test

Total number______
cumulative score______

APPENDIX J

Power Point Presentation of Study

A Randomized Controlled Study of Strength Training Versus Flexibility in Fibromyalgia

Acknowledgments

- The National Institutes of Nursing Research (T32 and F31 Awards)
- The Arthritis Foundation (Doctoral Dissertation Award)
- Oregon Fibromylagia Foundation

Purpose

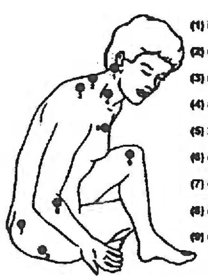
Pilot study comparing two types of exercise in FM:

progressive strength training

or

flexibility training

The Fibromyalgia [Syn]drome



(1) insertion of nuchal muscles into occiput;
(2) upper border of trapezius-mid-portion;
(3) muscle attachments to upper medial border of scapula;
(4) anterior aspects of the C5, C7 intertransverse spaces;
(5) 2nd rib space - about 3 cm lateral to the sternal border;
(6) muscle attachments to lateral epicondyle ;
(7) upper outer quadrant of gluteal muscles;
(8) muscle attachments just posterior to greater trochanter;
(9) medial fat pad of knee proximal to joint line.

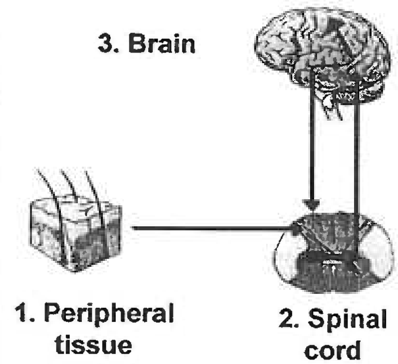
A total of eleven or more tender points in conjunction with a historv of widespread pain is characteristic of the fibromyalgia syndrome.

Research Findings: Muscle

- No specific muscle pathology, Changes also found in disuse ("moth-eaten" appearance)
- Delayed return to baseline resting status between isokinetic contraction

Research Findings: Central Nervous System

- ↓ Brain Blood Flow
- ↑ Substance P in CSP
- ↓ Serum Serotonin
- ↓ Serum Growth Hormone
- Limbic System Changes



Research Findings: Fitness & Exercise

- ↓ Aerobic fitness
- ↓ Muscle strength & endurance
- ↓ Muscle flexibility
- Lack of endurance may be due to inactivity rather than disease.
- Aerobic fitness can be improved.

Research Findings: Exercise Interventions

- 15 of 16 aerobic or combined
- 1 muscle strengthening versus aerobic training
- General trend: more gentle interventions with less physiologic improvements but more symptomatic improvements

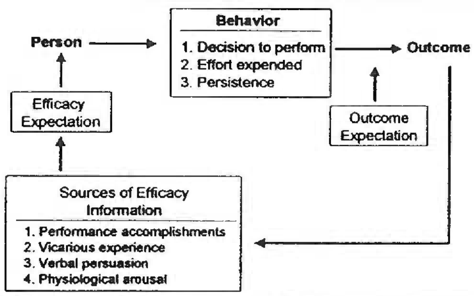
Physical Activity Motivators

Exercise Adherence

"We will not do anything for any length of time, simply because it is good for us. Conversely, we will do anything, for any length of time because it is play."

George Sheehan

Self Efficacy



Design

Randomized controlled study of 68 women with FM who received either 12 weeks of strength training or 12 weeks of flexibility training.

Data were collected within 2 weeks pre and post intervention.

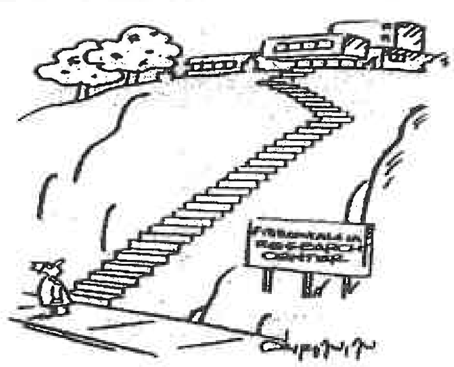
Subject Criteria

- Inclusion Criteria
- Exclusion Criteria

Recruitment
3 Month / 6 Step Process

Screening from Computerized Data Base from the Department of Rheumatology, OHSU and 1998 International Meeting of the Oregon Fibromyalgia Foundation

Campus Newsletter Solicitation



Intervention

- Certified exercise instructor
- Class size
- Personalization of exercises by exercise physiologist
- Exercise descriptions: Strengthening vs. stretching

Measures

- Outcome measures were collected pre and post intervention at the Human Performance Laboratories at OHSU
- Physiological Measures:
  - muscle strength of the shoulder and quadriceps via isokinetic dynamometry, seven point skin fold testing for body fat, height, weight, shoulder flexibility, tender point count, total myalgic score

Measures

- Self-Report Symptom Scales:
  - Fibromyalgia impact
  - Anxiety
  - Depression
  - Quality of Life
  - Self-Efficacy

Sample

- 68 women ages 38-55 years (mean 47) with FM per the American College of Rheumatology Guidelines: able to participate in a 12 week exercise intervention.
- No significant differences between treatment and control groups on variables.

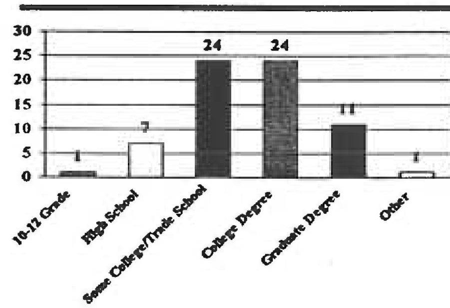
Demographic Characteristics of Sample

- **Age:** 47.8 yrs (7.27 yrs)
- **Years with FM:** 7.4 yrs (6.33 yrs)

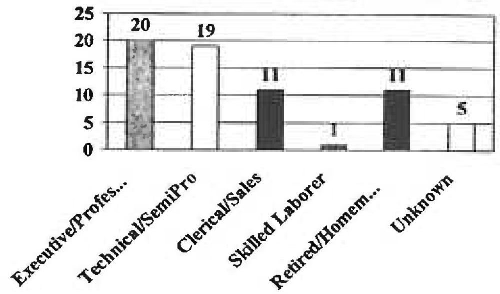
Ethnic Background

	N
• White	63
• Black	2
• Native American	1
• Latina	2

Education



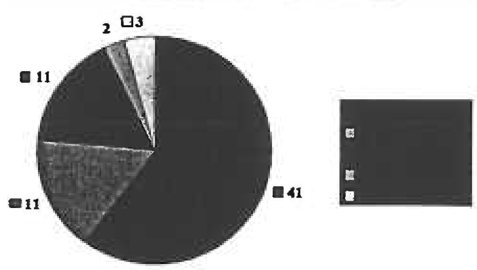
Occupation



Employment

	N
• Employed outside home full time	38
• Part time	10
• Not employed	20

Marital Status



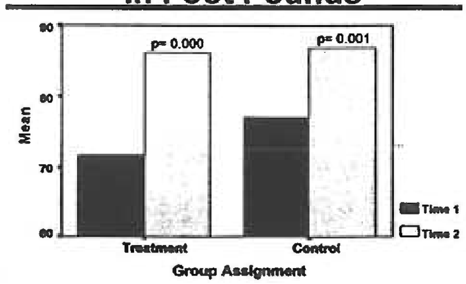
Sample Characteristics

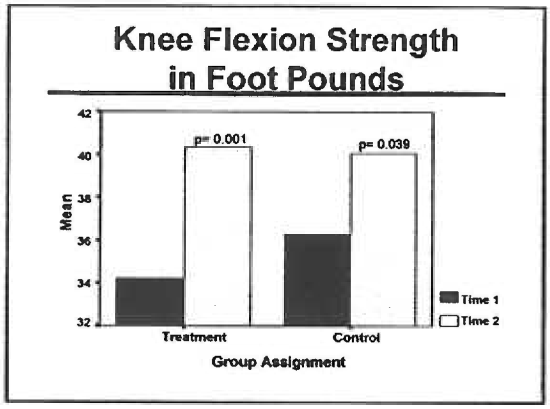
- Exercise History
- Medication History

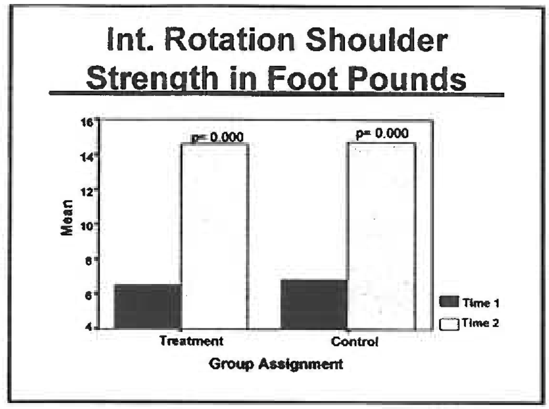
Attrition

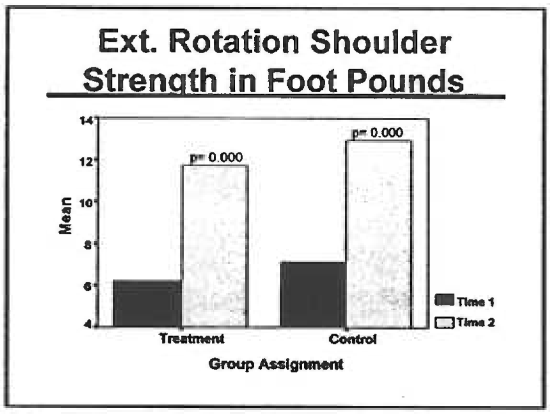
- Ninety three percent (63 of 68) of the women returned for post-testing.
- Eighty five percent (58 of 68) of the women participated in at least 13 of 24 class sessions.
- Attrition was 17% (n=6) in the treatment and 10% (n=4) control group.

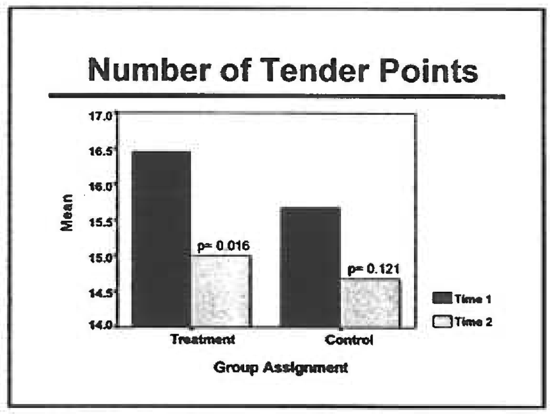
Knee Extension Strength in Foot Pounds

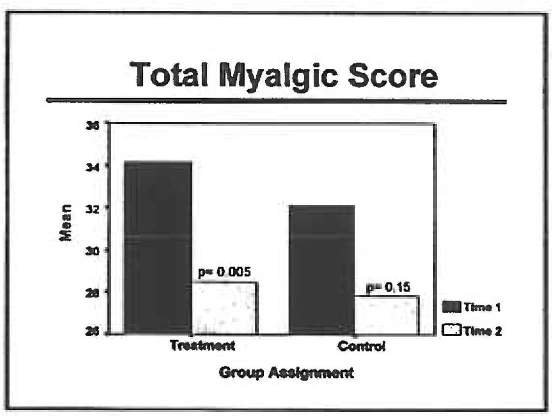


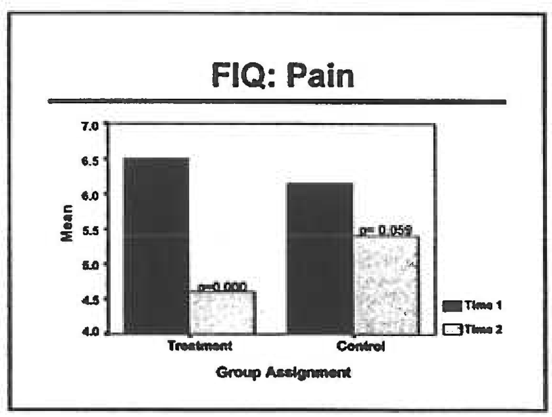

Knee Flexion Strength in Foot Pounds
p= 0.001
p= 0.039
Mean
Treatment
Control
Group Assignment
Time 1
Time 2

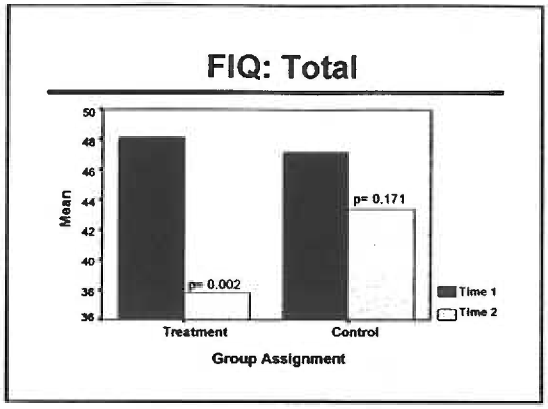

Int. Rotation Shoulder Strength in Foot Pounds
p= 0.000
p= 0.000
Mean
Treatment
Control
Group Assignment
Time 1
Time 2

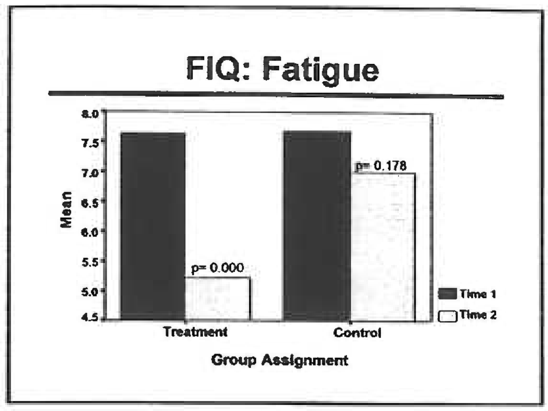

Ext. Rotation Shoulder Strength in Foot Pounds
p= 0.000
p= 0.000
Mean
Treatment
Control
Group Assignment
Time 1
Time 2

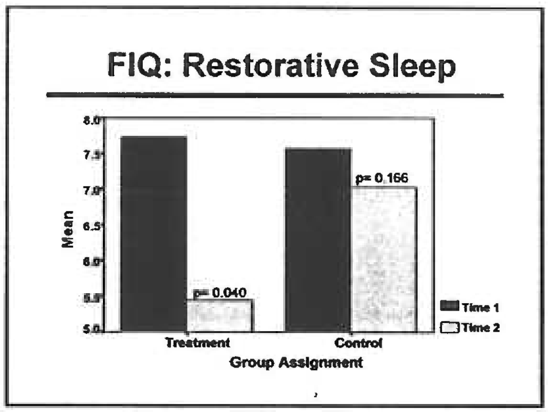

Number of Tender Points
p= 0.016
p= 0.121
Mean
Treatment
Control
Group Assignment
Time 1
Time 2

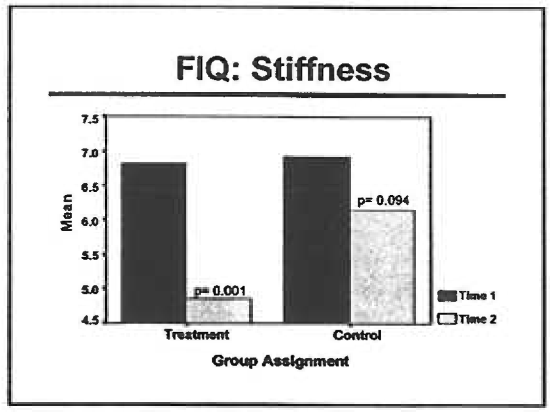

Total Myalgic Score
p= 0.005
p= 0.15
Mean
Treatment
Control
Group Assignment
Time 1
Time 2

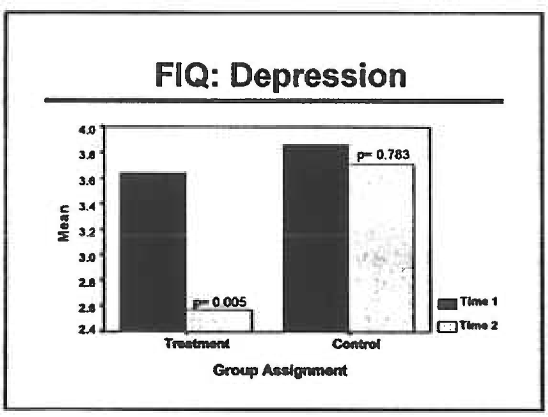

FIQ: Pain
p=0.000
p= 0.059
Mean
Treatment
Control
Group Assignment
Time 1
Time 2

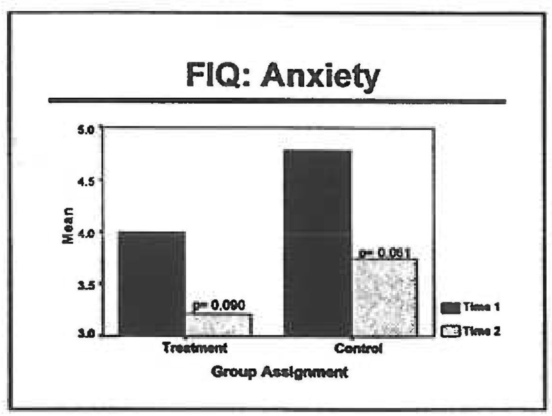

FIQ: Total
Mean
p= 0.002
p= 0.171
Time 1
Time 2
Treatment
Control
Group Assignment

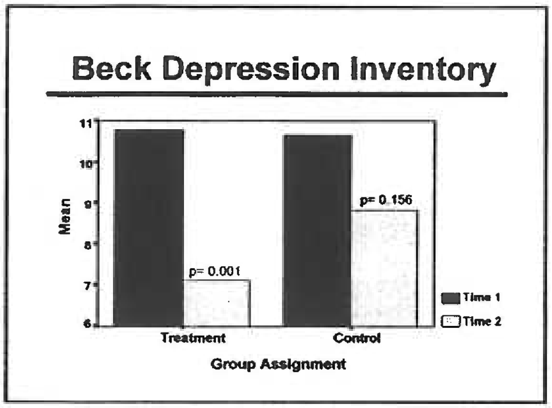

FIQ: Fatigue
Mean
p= 0.000
p= 0.178
Time 1
Time 2
Treatment
Control
Group Assignment

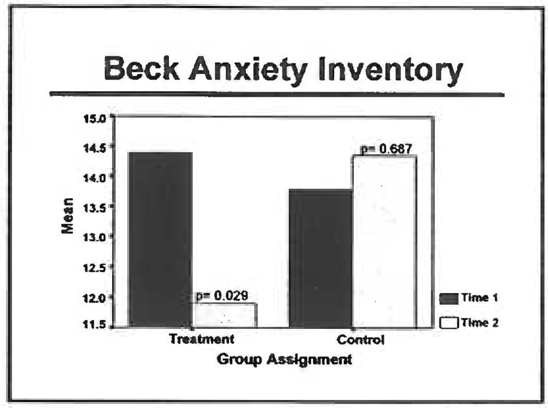

FIQ: Restorative Sleep
Mean
p= 0.040
p= 0.166
Time 1
Time 2
Treatment
Control
Group Assignment

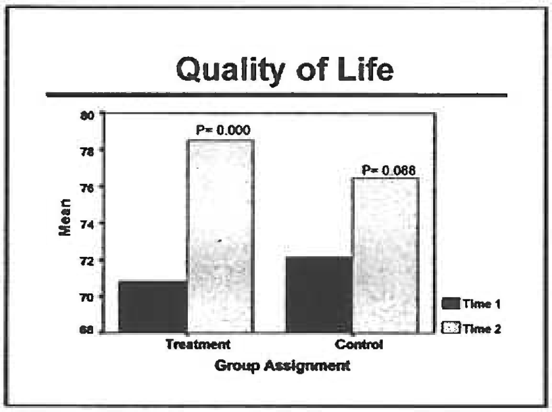

FIQ: Stiffness
Mean
p= 0.001
p= 0.094
Time 1
Time 2
Treatment
Control
Group Assignment

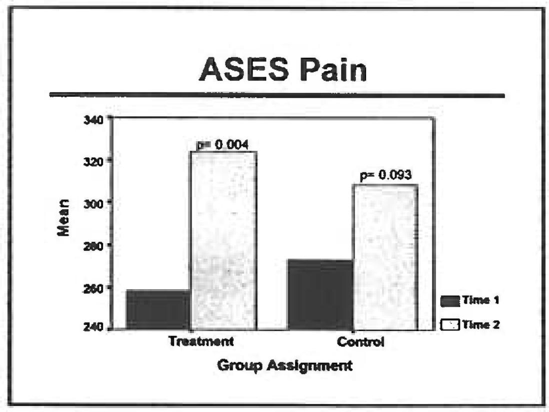

FIQ: Depression
Mean
p= 0.005
p= 0.783
Time 1
Time 2
Treatment
Control
Group Assignment

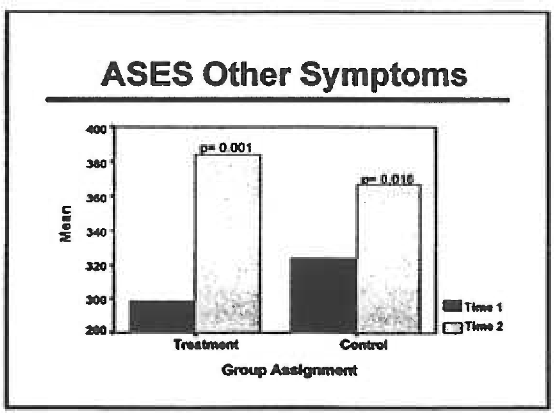

FIQ: Anxiety
Mean
p= 0.090
p= 0.061
Time 1
Time 2
Treatment
Control
Group Assignment

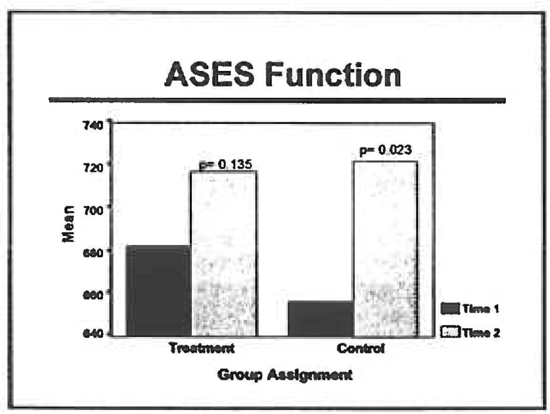

Beck Depression Inventory
Mean
11
10
9
8
7
6
p= 0.001
p= 0.156
Treatment
Control
Group Assignment
Time 1
Time 2


Beck Anxiety Inventory
Mean
15.0
14.5
14.0
13.5
13.0
12.5
12.0
11.5
p= 0.029
p= 0.687
Treatment
Control
Group Assignment
Time 1
Time 2

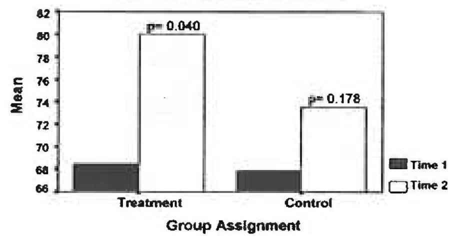

Quality of Life
Mean
80
78
76
74
72
70
68
P= 0.000
P= 0.088
Treatment
Control
Group Assignment
Time 1
Time 2


ASES Pain
Mean
340
320
300
280
260
240
p= 0.004
p= 0.093
Treatment
Control
Group Assignment
Time 1
Time 2

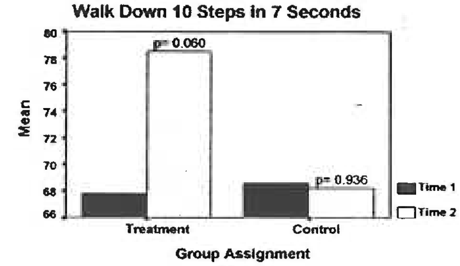

ASES Other Symptoms
Mean
400
380
360
340
320
300
280
p= 0.001
p= 0.016
Treatment
Control
Group Assignment
Time 1
Time 2


ASES Function
Mean
740
720
700
680
660
640
p= 0.135
p= 0.023
Treatment
Control
Group Assignment
Time 1
Time 2

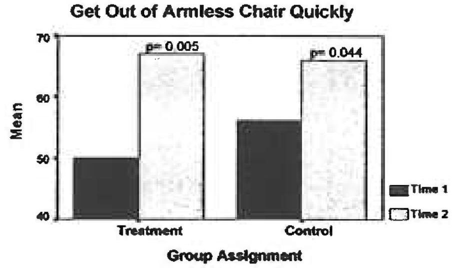
ASES Function



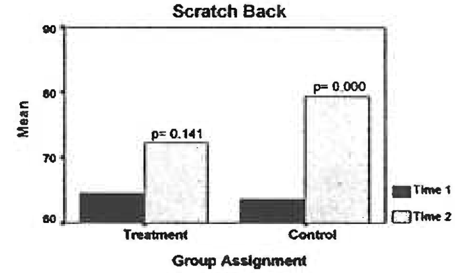
ASES Function



ASES Function



ASES Function



Results: Between Group Differences

There were no statistically significant differences found on independent t-tests between treatment and control group means at post test.

Results: Within Group Differences

Paired t-tests revealed statistically significant within group difference in 14 measures in the strength training group and 7 measures in the flexibility group

Results: Change Scores

Change scores indicated that on all measures except flexibility,
the treatment group improved more than the control group.

Conclusions

Both stretching and muscle strengthening improve outcomes in women with FM

Conclusions

- Improvements in strength were not associated with worsening in any measured outcome including pain scores.

Study Strengths

- Isolation of muscle strengthening versus flexibility
- Randomized, controlled, blinded
- Large sample size
- Low attrition

Study Limitations

- Lack of documentation of progressive nature of intervention
- Limited generalizability to community based sample

Guidelines for Future Studies

- Test shoulder strength at 180 degrees / second
- Conduct power analysis based on strength scores changes in FM population
- Investigate how strength training mediates symptoms in FM
- Consider designing future strength training interventions based on 1RM strength scores