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A pilot study to examine a therapeutic exercise intervention on fibromyalgia symptoms

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A PILOT STUDY TO EXAMINE A THERAPEUTIC EXERCISE INTERVENTION ON FIBROMYALGIA SYMPTOMS

by

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GRADUATE COMMITTEE APPROVAL

of a thesis submitted by

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This thesis has been read by each member of the following graduate committee and by majority vote has been found to be satisfactory.

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As chair of the candidate's graduate committee, I have read the thesis of Mara H. Nelson in its final form and have found that (1) its format, citations, and bibliographical style are consistent and acceptable and fulfill university and department style requirements; (2) its illustrative materials including figures, tables, and charts are in place; and (3) the final manuscript is satisfactory to the graduate committee and is ready for submission to the university library.

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ABSTRACT

A PILOT STUDY TO EXAMINE A THEREAPEUTIC EXERCISE INTERVENTION ON FIBROMYALGIA SYMPTOMS

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Objective. To examine the feasibility of a home-based, video therapeutic exercise program on pain, fatigue, self-efficacy, and health status in fibromyalgia patients. *Methods*. Nine individuals who were previously diagnosed with fibromyalgia completed the study (out of an initial pool of 31). Subjects were randomly assigned to one of two groups: a group who received a home-based therapeutic exercise video and a control group who continued to undergo their current standard of care or "treatment-as-usual." The video group was instructed to conduct the exercises as prescribed in the 42-minute video at least 3 times per week for 4 weeks. The treatment-as-usual control group was instructed to continue to undergo their current standard-of-care and to not begin any new treatments during that time. Instruments measuring self-efficacy, pain, fatigue, self-rated health status and health distress were administered at baseline and 4 weeks.

Results. None of the variables analyzed showed a significant change between the treatment and control groups over the course of the 4-week study.

Conclusion. This study was not sufficiently powered to detect differences between the two groups. However, several of the treatment group participants subjectively indicated that they found the exercises to be helpful in the management of their fibromyalgia symptoms and the program did not exacerbate any of their symptoms. With this information, it appears that patients are able to tolerate the treatment and are able to complete the outcome measures. Between-group clinical outcomes will now need to be assessed in a larger clinical trial.

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A Pilot Study to Examine a Therapeutic Exercise Intervention on Fibromyalgia Symptoms

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ABSTRACT

Objective. To examine the feasibility of a home-based, video therapeutic exercise program on pain, fatigue, self-efficacy, and health status in fibromyalgia patients.

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INTRODUCTION

Fibromyalgia Syndrome (FMS) is a perplexing condition that affects approximately 3.7 million people in the United States (1). Although it is a condition that most commonly affects women, men and children have also been diagnosed. Prevalence has been estimated at 3.4% for women and 0.5% for men (1, 2). The main criteria for diagnosis include widespread pain and tenderness that must be experienced for at least three months along with the presence of at least 11 of 18 pre-determined tender points (3). Figure 1 illustrates the tender point areas that are commonly used for diagnosis.

Due to the uncertain etiology and the comorbid conditions associated with fibromyalgia, one specific standardized protocol for treatment has not yet been determined (4, 5). Successful treatment for FMS usually includes combinations of various pharmacologic and non-pharmacologic interventions (5, 6).

The concept that physical exercise is beneficial is common knowledge regarding many chronic diseases and conditions (7) and exercise has also been found to have beneficial effects with regards to fibromyalgia (5, 8-12). However, proper exercise prescription (13-15),and maintenance (16) is complicated. Although many modes, durations and intensities of exercise have been examined with FMS, it has not been determined whether one mode of exercise is significantly more beneficial than others (8).

Many research studies have focused on examining aerobic exercise programs and fibromyalgia symptoms(8). However, when compared to sedentary counterparts, individuals with FMS have lower levels of physical functioning (17) and lower peak

activity levels (18) than their healthy counterparts and this can lead to exacerbation of FMS symptoms upon the initiation of a standard aerobic exercise program (13).

Therefore, it appears as though less intensive exercise programs may result in greater initial compliance and it is often recommended that FMS patients begin with a light stretching program (13, 14, 19). Originally, flexibility/stretching programs were primarily used as control groups in FMS research studies (20, 21). However, additional research has focused on the benefits of flexibility/stretching programs on their own to assist in improving FMS symptoms (22-25).

Additional research is needed on initial low-intensity exercise programs that lessen the chance of symptom exacerbation and increase long-term exercise adherence (11, 14). To date, a home-based, video, therapeutic exercise program developed for individuals with FMS has not been studied. In order to determine if this program has therapeutic value, a large randomized clinical trial is required. The first step to complete this study is to determine its feasibility. Therefore, this pilot study evaluated the feasibility of the exercise intervention. This intervention was comprised of a 42-minute video that demonstrated stretches, therapeutic exercises, and light self massage techniques that are designed to facilitate reduction in fibromyalgia symptoms, as well as improve flexibility, enhance self-efficacy, and promote relaxation. The feasibility of the outcome measures and the extent to which participants would comply with the protocol was also evaluated.

METHODS

Recruitment of Subjects

Only individuals who were diagnosed with FMS by a physician were qualified to participate in this study. Subjects were recruited between June and November of 2005 from flyers and newspaper advertisements posted at BYU-Idaho and BYU-Provo, through participant and physician referrals, as well as via an email sent to a community information mailing list for employees of Intel-Oregon. Exclusion criteria included pregnancy or the presence of any condition that would contraindicate being involved in an unsupervised therapeutic exercise program as indicated by the participants' physicians.

Subjects

Thirty-two individuals (30 females and 2 males) volunteered to participate and were randomized into the study. Of those volunteers, eight were dropped from the study due to non-response/withdrawal and three individuals did not meet the criteria for compliance according to their physician's diagnosis. One participant was noncompliant and one provided insufficient data for the final analysis. Another nine individuals did not complete the study in time to be included in this analysis. This resulted in nine participants (mean age 48.22 ± 15.97; 9 females and 0 males) who were included for the final statistical analysis. Figure 2 includes a flow diagram for the volunteers recruited for this study.

Average duration of symptoms for participants was 12.45 (± 12.8) years and the average time since diagnosis was 5.02 (± 4.7) years. Average number of medications taken daily was three (±3.7). Table 1 includes the demographic characteristics of the participants.

Procedures

This study was approved by the Brigham Young University Institutional Review Board prior to commencement. Participants were randomly assigned via pairwise block randomization to the treatment video-exercise group or a treatment-as-usual control group. Materials were sent to participants for data collection at baseline and after four weeks of participation. All study materials were sent to participants via USPS mail. The first packet contained (i) a written informed consent and a copy for them to keep, (ii) an authorization form for the participants to sign that gave approval for the individual's physician to provide information regarding their FMS diagnosis for the purposes of this study (this was included in order to comply with regulations regarding the protection of healthcare information), (iii) a verification form for physician diagnosis which included an area for them to provide us with the name and fax number for their diagnosing physician, and (iv) a pre-addressed, stamped envelope to return the study materials. Verification of physician diagnosis was determined by faxing the signed "Authorization to Receive Healthcare Information" form along with a form that asked the physician to indicate the criteria used for FMS diagnosis and also to approve the patient for

participation in an unsupervised therapeutic exercise program. This form was modified from one used by Rooks et al (26).

Upon receipt of confirmation of physician fibromyalgia diagnosis, the baseline questionnaire materials were mailed via USPS mail. Four-week questionnaires were mailed out prior to the time when the participant was scheduled to complete their participation. All materials were returned by the participants using pre-addressed stamped envelopes that we included in their packets.

Therapeutic Exercise Program

The treatment video-exercise group was mailed the exercise video along with written instructions on how to start the program. The video consisted of a combination of therapeutic exercises and activities, along with verbal and visual instruction as to how to perform each activity. A listing of the exercises is included in Table 2. Participants were instructed to conduct the exercises as directed in the 42-minute video or until they experienced pain, fatigue, or exacerbation of symptoms. Each treatment participant was also given a logbook in which they were to record the mode, frequency and duration of any daily exercise sessions including those from the video as well any other exercise treatments. The accounts in this logbook were used to determine compliance to the exercise protocol.

This group was instructed to watch the video and conduct the prescribed exercises at least 3 times per week. Each participant was instructed to continue with any

other medications or treatments that they were conducting at the beginning of the study. Questionnaires were completed at Baseline and after 4 weeks of continuous participation.

Control Group

The treatment-as-usual control group was instructed to follow their standard treatment for FMS symptoms. They were also provided with a daily exercise logbook to record any exercises that they conducted throughout the course of the study. This group was also instructed to continue with any other medications or treatments that they were conducting at the beginning of the study. Questionnaires were also completed at baseline and after 4 continuous weeks in the study.

Outcome Measures

There is currently no single measure used for evaluating change in fibromyalgia research related studies (27) and a wide variety of measures are commonly used. In a comprehensive review of 16 high quality FMS studies, over 60 different outcome measures were used (8). All of the instruments used in this study involve self-report measures. However, patient questionnaires can be considered "as valuable as laboratory or imaging data" in rheumatology care (28).

Health status. The Fibromyalgia Impact Questionnaire (FIQ) is a two-page self-administered instrument developed for evaluation of health status with regards to individuals who have FMS (29). This 20-item instrument has subscales designed to measure physical function, work status, depression, anxiety, sleep, pain, stiffness, fatigue,

and general well being. Items are measured on a Likert-type scale. Construct validity and test re-test reliability have been established (29).

Self-efficacy. In order to measure change in participants' perception of their ability to cope with the pain and symptoms of FMS, the 8-item Stanford Arthritis Self Efficacy Scale (ASES) was used. This one page instrument was developed to measure patients' self-efficacy with regards to management of their rheumatic condition (30). This measure, developed by Lorig et al(30) consists of 8 items and is self-administered. Reliability as well as construct and concurrent validity have been established (30, 31). The ASES scale is used regularly in fibromyalgia research and is modified slightly in which the term "fibromyalgia" was exchanged for the term "arthritis" throughout the scale (31).

Pain and fatigue. As pain and fatigue are cardinal symptoms of fibromyalgia, pain and fatigue were measured using visual and numeric analog scales. These scales have been used previously and been found to be valid and reliable in previous chronic pain research studies (32-34). Questions examined the pain and fatigue experienced over the prior two weeks as well as pain and fatigue over the last month. These questions are similar to the ones used in the Fibromyalgia Impact Questionnaire (29).

Global health. Self-reported global health is a common measure in fibromyalgia research. Test-retest reliability has been demonstrated for this measure and has been found to be an excellent predictor of future health (35, 36).

Health distress. This four-item measure has been modified from the Medical Outcomes Study Health Distress Scale. Internal consistency reliability and test-retest reliability has been examined. This scale has been used effectively in chronic disease studies (36).

Analysis

Compliance to the exercise program was determined by examining the exercise logs that the participants returned. Individuals who conducted the exercises at least three times per week and completed all of the questionnaires were included in the analysis. Nine individuals were included in the final analysis. This analysis did not use intent-to-treat. Results were analyzed by means of ANCOVA using the baseline and post-treatment scores for self-efficacy, pain, fatigue, self-rated global health and health distress. The Baseline pre-test scores were used as the covariates to control for initial group differences. Statistical significance was set at $p < .05$.

RESULTS

Table 3 illustrates the mean values for the baseline and post-treatment outcome measures. This analysis did not reveal a significant effect for global health $F(1, 6) = .14$; $p = .7256$; health distress $F(1, 6) = .55$; $p = .4879$; fatigue at 2 weeks $F(1, 6) = .33$ $p = .5846$; fatigue at 4 weeks $F(1, 6) = .21$; $p = .6627$; pain at 2 weeks $F(1, 6) = .01$; $p = .9090$; pain at 4 weeks $F(1, 6) = 1.18$; $p = .3197$; or self-efficacy $F(1, 6) = .74$; $p = .4229$.

DISCUSSION

Two key points of this therapeutic exercise program are first, that it is an unsupervised, video-based program that is designed to be done at home and second, that it is a light therapeutic exercise program that potentially can benefit individuals who are either beginning to exercise or those who are already involved in a regular aerobic exercise program. The primary purposes of this feasibility study were to determine if the program could be tolerated without a significant exacerbation of FMS symptoms and determine if the video exercise program could successfully be adhered to without supervision. We determined that this pilot study of a 4-week therapeutic exercise program had no statistically significant effects in improving self-efficacy, pain, fatigue, self-rated health status or health distress in women who were diagnosed with fibromyalgia. While the treatment group appeared to experience a greater improvement than the control group for pain experienced in the prior 4 weeks, the results are not statistically significant possibly due to the small sample size.

An essential aspect of any exercise treatment program is that the activity must be tolerated (8). In our pilot study, only one participant indicated that she conducted the "wrist roll" exercises too aggressively and also experienced lymphatic breast pain after conducting the self-massage. No additional adverse effects were reported from conducting the exercises as demonstrated. Participants did not report an exacerbation of any fibromyalgia symptoms and this suggests that this program may be safe for FMS patients. The exercises were safely conducted with no supervised training or

personalized instruction from study personnel. Another possible benefit of this program is that many of the treatment group participants subjectively indicated that they found the exercises to be helpful in the management of their fibromyalgia symptoms. This suggests that this program could be clinically beneficial in spite of the lack of statistical significance.

High dropout and poor compliance rates are common in research dealing with individuals who have fibromyalgia. Other home-based, unsupervised FMS exercise programs have experienced high-dropout or poor compliance, and minor improvements, if any were found (37-39). In a well-designed study of a video-based low impact exercise program, problems of exercise adherence were evident in spite of the fact that the researchers were diligent in explaining the exercises and protocol to participants (40). The compliance rate for our study was 86%, indicating that most treatment participants conducted the exercises at home at least 3 times per week as indicated in the written study protocol. However, it is important to note that our study had such a small sample size (N=9) that a true representation is necessary with a larger sample size.

One possible limitation in our study is that 78% of participants reported that they were currently involved in regular exercise at baseline in the study. One study of an individualized 12-week cardiovascular home-based exercise program noted greater improvements and adherence in the program for women who had greater impaired function at baseline (41). It may be that women who have lower levels of physical fitness and greater levels of impairment may experience greater benefits from an exercise

program. In addition, the advertisements for our study recruited individuals who were interested in participating in a therapeutic exercise program. It is possible that we recruited a sub-group of individuals with FMS who were already physically active and/or were ready to adopt a new program or add to their existing regimen. While very few FMS exercise studies actually use involvement in a concurrent exercise program as exclusion criteria (8), it could be that physically active individuals with FMS would not experience significant improvements by adhering to this therapeutic exercise program as they are already involved in a regular aerobic exercise program.

In spite of the increasing amount of research over the last decade and a half, there remains a lot of unknowns and controversy surrounding fibromyalgia (4). Additional high-quality research is needed to determine effective home-based, therapeutic treatment programs as they are low in cost and are well tolerated by fibromyalgia patients. This specialized exercise program has several potential benefits. This program is designed to be (i) used at home, (ii) unsupervised and requires little or no equipment (only requires a VCR/DVD and a TV for the initial stages of learning the exercises), and (iii) used as an adjunct therapy to complement a patient's pre-existing exercise routine. With this information from our pilot study, it appears that patients are able to tolerate this intervention without an exacerbation of symptoms. While the results of this feasibility study are statistically insignificant, a larger clinical trial assessing between-group clinical outcomes is needed to determine the efficacy of this intervention.

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Table 1. Characteristics of Participants who Completed the Study

Characteristics	N (SD)	%
Sex		
Female	9	100%
Male	0	--
Marital Status		
Married	7	78%
Single	2	22%
Years of Education		
Graduate School	2	22%
College	3	33%
Some College	3	33%
High School	1	11%
Duration of Symptoms (years)	12.45 (12.8)	--
Years since diagnosis	5.02 (4.7)	--
Medications (per day)	3 (3.71)	--

Table 2. Therapeutic Exercises and Activities

Floor Exercises		
	Relaxation	Ankle rolls
	Relaxed breathing	Overhead reach
	"Walking" in place	Hip and leg rolls
	Neck rolls	Wrist rolls
	Knee rolls	"Child's pose"
	Diagonal arm movements (I and II)	Kneeling
	Diagonal leg movements (I and II)	Cobra position and look back
	Trunk and hip stretch	
Massage/Lymphatic Drainage		
	Feet, legs, and thighs	Cheeks
	Abdominal circles and press releases	Neck and shoulder squeezes
	Lower rib clearing	Ears
	Sternal release	Scalp
	Pectoral clearing	Jaw line
	Neck clearing	Nose
	Hands, arms, shoulders	
Posture Alignment, and Standing Movement Series		
	Postural alignment	Standing arm swings
	Forward/backward bending	Push-pulls
	Standing arm raise I	Push pulls and squats
	Standing arm raise II	"Parting the Mane"
	Scoop and push down	Arm and leg shakes
	Cherry picking	

Table 3. Mean values (SD) for outcome measures

	Control Group (N=5)		Treatment Group (N=4)	
Scale	Baseline	Post-Treatment (4 weeks)	Baseline	Post-Treatment (4 weeks)
Global Health	3.2 (.4)	3.33 (.5)	4.0 (1.0)	4.0 (1.0)
Health Distress	2.4 (.4)	2.4 (1.2)	3.3 (1.6)	2.4 (1.3)
Pain (2weeks)	4.3 (2.1)	4.8 (1.8)	6.0 (3.5)	6.0 (2.0)
Pain (4 weeks)	48.7 (9.4)	51.7 (11.6)	55.7 (17.0)	52.7 (15.3)
Fatigue (2 weeks)	7.2 (1.2)	5.8 (1.7)	6.3 (2.1)	7.0 (1.7)
Fatigue (4 weeks)	1.2 (.7)	1.5 (1.0)	.9 (.4)	1.5 (.4)
ASES	4.9 (1.5)	5.9 (1.4)	3.3 (1.4)	5.5 (2.8)

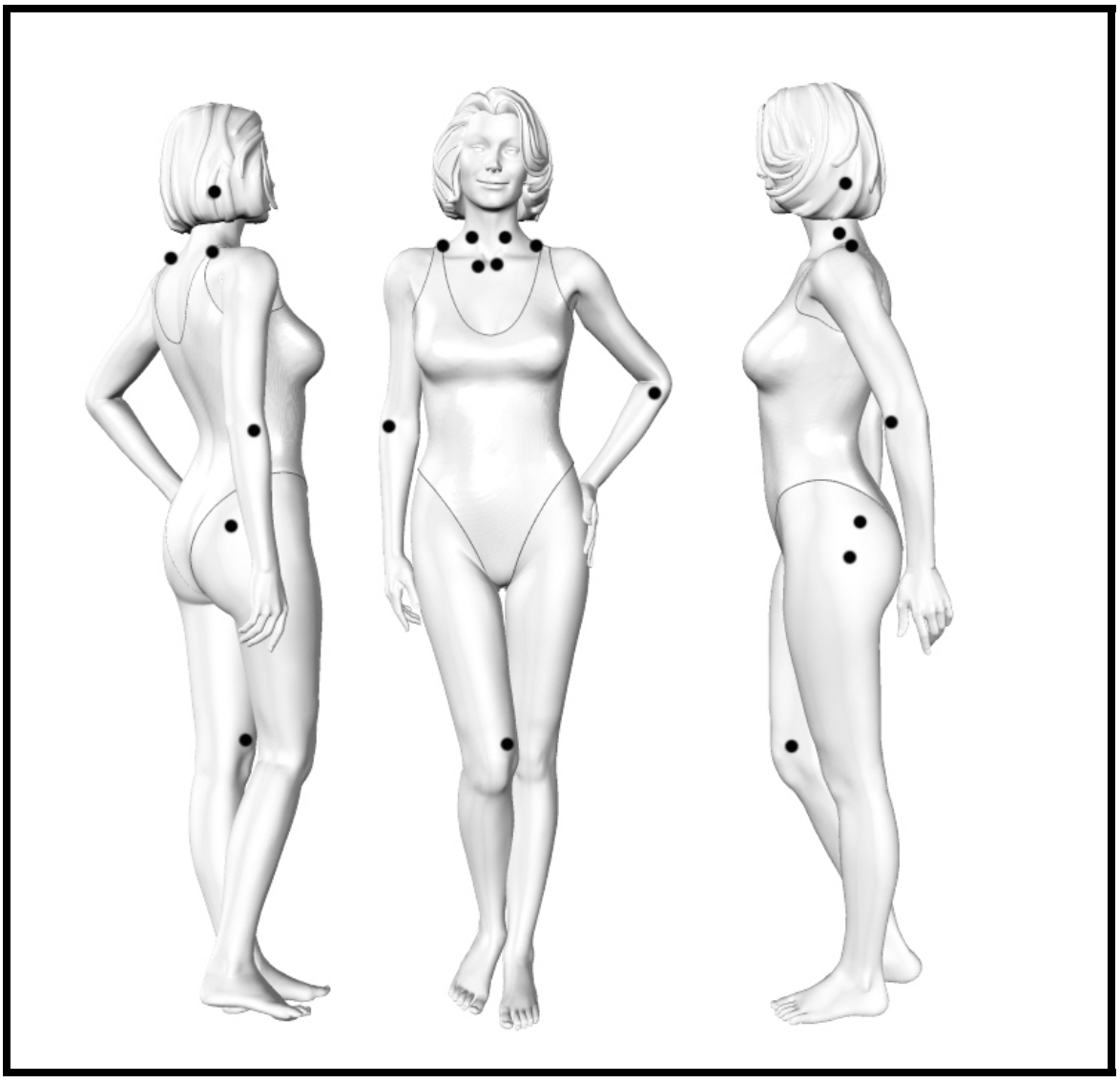

Figure 1. Location of Tender Points for Fibromyalgia Diagnosis (American College of Rheumatology Criteria)

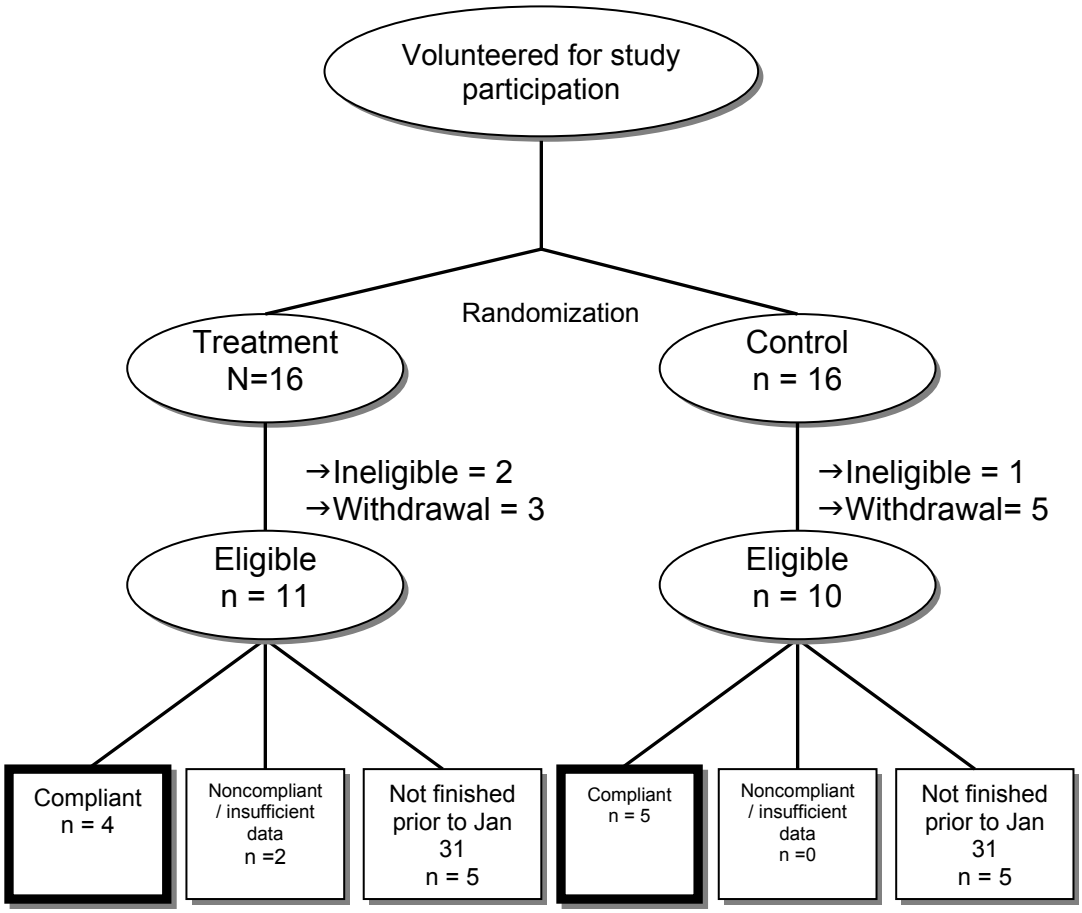

Figure 2. Flow Diagram for Study Participants

Appendix A

Prospectus

Chapter 1

Introduction

Fibromyalgia is a perplexing syndrome that currently affects 3.7 million people in the United States (1). Although it is a condition that most commonly affects women, men and children have also been diagnosed. Prevalence has been estimated at 3.4% for women and 0.5% for men (1, 2).

Fibromyalgia is a syndrome of unknown origin and multiple symptoms. The American College of Rheumatology (ACR) has determined official criteria for classification (3). The main criteria for diagnosis include widespread pain and tenderness that must be experienced for at least three months. This pain must be experienced above and below the waist, on the axial skeleton, as well as on both the right and left sides of the body (3). In addition to this widespread pain, a significant distinguishing criterion of the syndrome involves the palpation of tender points. Tender points are localized areas of tenderness that do not have any additional characteristics such as raised knotty tissue. For diagnosis according to the ACR criteria, mild or greater pain is experienced upon palpation of at least 11 of 18 predetermined tender points when applied with a force of 4kg/cm. These tender points include areas such as the upper midpoint of the trapezius, the upper outer quadrant of the gluteus maximus, and the knee at the medial fat pad proximal to the joint line (3). It is important to note, however, that the tender point criteria are often not strictly adhered to when a physician or rheumatologist diagnoses individuals in a clinical setting (4) and there is also a debate as to whether these criteria should be adhered to in clinical settings (5, 6).

Fibromyalgia Syndrome (FMS) is often found with various co-existing conditions such as depression, irritable bowel syndrome, and chronic fatigue syndrome (2, 4). Although the exact cause of fibromyalgia is unknown, suggestions vary and include theories such as low growth hormone secretion resulting from abnormal sleep patterns, (7) an "aberrant central pain mechanism," (8) and abnormal levels of Substance P (a neurotransmitter responsible for increased pain perception) (9).

Due to the uncertain etiology and the comorbid conditions associated with fibromyalgia, it has been difficult to determine effective treatment. One specific standardized protocol for treatment of fibromyalgia has not yet been determined (4). Treatment for FMS usually includes combinations of various pharmacologic and non-pharmacologic interventions (10, 11).

Although there are currently no medications that are specifically approved by the FDA for the treatment of FMS, various medications are often used to treat symptoms. Pharmacologic treatment may include various drugs such as nonsteroidal anti-inflammatory agents (NSAIDS), tricyclic anti-depressants, and serotonin reuptake inhibitors (4, 10). However, most of these drugs are ineffective in alleviating many of the symptoms and are often associated with negative side effects (10, 12). It is estimated that less than 50% of patients experience acceptable levels of relief due to these interventions (see (4, 10, 13) for review).

Non-pharmacologic treatments are varied and have even included non-traditional alternative medicine treatments such as hypnosis, (14) acupuncture, (15) chiropractors, and reflexologists (16). Successful treatment strategies include behavior therapies,

physical therapy, and exercise (10, 17, 18). Although the exact reason is not known, exercise interventions have proven to be most effective in the treatment of FMS (19, 11). Most successful treatment programs are multidisciplinary and should emphasize education, exercise, some medications, as well as cognitive behavioral therapy (11, 17).

A home-based therapeutic exercise program has been developed by a practicing physical therapist for individuals suffering from fibromyalgia and other forms of chronic pain and has shown promise when applied to FMS patients in a physical therapy practice. The proposed treatment intervention involves the use of an educational video that describes various stretches and therapeutic exercises that facilitate reduction in fibromyalgia symptoms such as pain and fatigue, as well as enhancing self-efficacy, flexibility, and relaxation. The home-based therapeutic exercise program titled, "Fibromyalgia: Keys to Recovery," involves 42 minutes of activities such as therapeutic exercises, stretching, breathing exercises, and light self massage.

Statement of the Problem

The purpose of this study is to evaluate the effects of a specialized therapeutic exercise program designed to improve self-efficacy and physical functioning and decrease pain and fatigue in fibromyalgia patients.

Hypothesis and Null Hypothesis

Hypothesis - The treatment group will experience a greater reduction in pain and fatigue as well as increased improvement in self-efficacy and physical functioning over the control group.

Null Hypothesis - The treatment group will not have improvement over the control group in the areas of pain, self-efficacy, and physical functioning.

Operational Definitions

Fibromyalgia or fibromyalgia syndrome (FMS) - A syndrome determined by the presence of predefined areas of tenderness and characterized by widespread pain and fatigue.

Tender point - A specific localized area of sensitivity or tenderness that is without distinguishing external characteristics. Pressure upon a tender point will elicit pain.

Treatment-as-usual (TAU) - Determined as the current treatment or standard of care that the individual is undergoing to treat the manifestations or symptoms of fibromyalgia. For example, treatment-as-usual can vary from use of various treatments including but not limited to pharmacologic drugs, acupuncture, massage, exercise, or no treatment at all. This group will serve as the control group for this study.

Self-efficacy – Confidence or certainty that an individual can perform certain tasks. Self-efficacy will be measured by the Stanford Arthritis Self-Efficacy Scale (ASES).

Functional ability- Individual's ability to accomplish daily, routine tasks. Functional ability will be measured by the Fibromyalgia Impact Questionnaire (FIQ).

Assumptions

1. Each treatment participant will follow the instructions in the "Quick Start Guide" that accompany the video and perform the exercises as recommended and detailed in the exercise video.

2. The treatment-as-usual or control group will not participate in any new exercise program that they were not involved in at the initiation of the study.
3. Subjects are not to be current participants in any other trials.
4. Each subject is expected to truthfully report and log all activities or interventions.

Delimitations

1. The participants will be allowed to remain on any current pharmacological treatments that they were on at the study initiation.
2. For this study, recruitment will involve volunteers that will be recruited in several communities in Utah, Oregon, and Montana.
3. Due to the relatively rare occurrence of fibromyalgia among men, it is expected that women will comprise the majority, if not all, of the subject sample.
4. As FMS has been rarely diagnosed in children and teens, we will only be recruiting participants aged 18 years of age and older.
5. As this treatment intervention is a pilot study and designed for individuals who have been examined by a physician and diagnosed with FMS, we will not exclude participants if their diagnosing physician did not strictly adhere to all of the diagnosis classification criteria established by the American College of Rheumatology.

Limitations

Fibromyalgia is a syndrome and there are currently no diagnostic laboratory tests to confirm diagnosis, therefore, fibromyalgia is largely a syndrome of pain and perception. As a result of this, all outcome measures involve self-reported data gathered from the

participants. However, all instruments to be used are used in FMS research studies. In addition, Wolfe states that patient questionnaires can be considered "as valuable as laboratory or imaging data" in rheumatology care (20).

Significance of the Study

Fibromyalgia is one of over 100 rheumatologic conditions contributing to pain and disability in the United States, and is the second most commonly seen diagnosis in rheumatologic practices (4). The prevalence of rheumatologic conditions is also expected to increase significantly effecting an estimated 18% of Americans by 2020 (1).

Exercise is a recommended treatment for fibromyalgia, however, "proper [exercise] prescription" still remains to be a crucial part in successful treatment (21). Jones and Clark suggest that "less intensive" exercise interventions result in greater compliance with participants and greater improvement regarding FMS symptoms (22). Moreover, they also recommend that successful exercise programs need to introduce activity gradually, lessen the chance of causing muscular microtrauma, and enhance self-efficacy which will increase the probability of exercise adherence (22). Most research studies have been conducted on supervised exercise programs. These programs are often costly, time consuming, and often experience low rates of compliance. Very little research has been conducted regarding the implementation of an effective home-based therapeutic exercise program designed specifically for individuals who suffer from fibromyalgia. The proposed research study will contribute to essential ongoing research to determine effective interventions in treating the symptoms and manifestations of this perplexing condition.

Chapter 2

Review of Literature

Fibromyalgia Syndrome (FMS) is a perplexing rheumatologic condition that currently affects approximately 3.7 million individuals in the United States. Prevalence estimates for this syndrome are 3.4% for women and .5% for men (1). Prevalence also increases significantly with age with the majority of cases involving women who are 50 years of age and older (1, 2).

Individuals who have this syndrome experience symptoms that are often considered disabling (23, 24). The most prominent characteristic involves chronic widespread pain lasting for at least 3 months. Other distinguishing characteristics include morning stiffness, fatigue, joint swelling, and sleep disturbances (2, 3, 24). Additional documented symptoms that are fairly common include paresthesias (abnormal sensations of the skin such as numbness), headaches, Raynauds phenomenon, Sicca symptoms (dry eyes/mouth), and psychological distress such as anxiety and depression (1). Symptoms of urinary urgency, excessively tender shin bones, and fascial pain have also been reported (4).

Along with chronic pain and other discomforting symptoms, individuals who suffer with FMS often suffer from various comorbid conditions. These separate conditions include Chronic Fatigue Syndrome, Irritable Bowel Syndrome, depression, Systematic Lupus Erythematosus, and Rheumatoid Arthritis (4). The simultaneous presence of these conditions often poses difficulty in distinguishing fibromyalgia from other concomitant diseases and/or conditions (4).

Diagnosis Classification

Although fibromyalgia syndrome (FMS) is the second most common diagnosis in rheumatology clinics (4) it is relatively new as a classified syndrome (3). Official classification criteria for diagnosis were not established until a comprehensive report was published by the American College of Rheumatology in 1990. The main criteria for diagnosis include widespread pain that must be experienced for at least three months. The pain is experienced above and below the waist, on both the right and left sides of the body, as well as on the axial skeleton (3).

In addition to this widespread pain, another distinguishing criteria for diagnosis of the syndrome involves the palpation of tender points (3). Tender points are localized areas of tenderness that do not have any additional distinguishing characteristics such as raised "knotty" tissue. For diagnosis, localized pain must be experienced upon palpation on at least 11 of 18 predetermined tender points when applied with a force of 4kg/cm (3). These tender points include areas such as the upper midpoint of the trapezious, the upper outer quadrant of the gluteus maximus, and the knee at the medial "fat pad" proximal to the joint line (3).

These criteria provide a specificity of 81% and sensitivity of 88% in distinguishing FMS from other types of chronic pain conditions such as Rheumatoid Arthritis (3, 4). While the criteria are not always used for diagnosis in medical practice, the criteria have proved beneficial in providing a reference for researchers investigating causes and effective treatment interventions

Etiology/Pathogenesis of fibromyalgia

Fibromyalgia has been described as an enigmatic condition as the exact pathogenesis and etiology of the condition have not been established. However, substantial research has been conducted to pinpoint possible underlying factors contributing to the cause and development of this syndrome. This section will address several theories regarding the pathogenesis and etiology in fibromyalgia.

Since "nonrestorative" sleep is a common complaint associated with fibromyalgia, (3, 25), sleep quality in FMS patients has been examined. The earliest of these findings was conducted by Modofsky and Scarisbrick (26). They found that fibromyalgia-like symptoms could be induced by interrupting slow wave or Stage 4 sleep in healthy, sedentary controls (26). Lentz et al (7) also found that disrupting slow wave sleep in individuals without decreasing total sleep in time resulted in discomfort, fatigue, decreased pain threshold and the increased "inflammatory response" as a result of pressure on the skin. In a review of several studies on sleep quality and FMS, Harding concludes that a "distinct relationship exists between poor sleep quality and pain intensity" (25). These studies all suggest that disturbed sleep may be one cause and/or may contribute to the pathogenesis of fibromyalgia.

As a significant symptom of fibromyalgia lies in the sensation of muscular pain, early research was also primarily focused on muscle and soft tissue irregularities. In a review of skeletal muscle abnormalities with FMS, Olsen and Park reviewed 8 studies that examined biopsies of trapezius or quadricep muscles of FMS patients. Findings were

noted such as “moth-eaten fibers, “rubber band morphology “abnormal mitochondria,” “compromised capillary circulation,” and “reduced number of capillaries” (27).

Due to the fact that FMS patients often exhibit reduced muscular strength and force, muscle metabolism has also been addressed in several studies. While reviewing studies of muscle metabolism and FMS, Olsen and Park (27) found that several studies demonstrate that PCr and ATP levels have been found to be lower in FMS in addition to reduced oxidative capacity and energy reserves. They conclude that these results could be due to damaged mitochondrial function and result in compromised muscle repair processes which in turn may bring about the pain and fatigue experienced in FMS (27).

However, the results of many of these studies have methodological flaws, and the presence or absence of muscle tissue abnormality has been debated. Simms authored several articles on the subject and concludes that most FMS biopsy studies demonstrate “nonspecific or normal findings” and suggests that the evidence indicates that fibromyalgia is due to a central mechanism as opposed to a peripheral or muscular mechanism (28, 29).

The concept of a central mechanism in fibromyalgia has been frequently studied. In an effort to understand pain perception in FMS, Bendtsen et al compared the stimulus response function in muscles of FMS patients vs. normal controls. They conclude that nociception is qualitatively altered in the muscles of FMS patients and suggest that fibromyalgic pain may be a result of an “aberrant central pain mechanism” (8).

This central pain mechanism in FMS may be the result of several factors. Substance P plays an important role in “the transmission of pain from the periphery to the

central nervous system" (9). Substance P is mediated by serotonin, which also contributes to sleep and pain mechanisms (9). Cerebrospinal fluid levels of Substance P in FMS patients were compared against levels taken from normal subjects. Results demonstrated that Substance P levels were found to be significantly higher by as much as 3 times in FMS patients compared to the healthy control group. Russell concludes that this increased level of Substance P may be a contributor to the decreased pain threshold in FMS patients (9). Cerebral blood flow has also been noted to have significantly decreased levels in FMS patients and may contribute to abnormal nocioceptive function (30, 31). While reviewing single photon emission photography (SPECT) procedures, Mountz et al concludes that abnormal pain perceptions may be sustained by modifications in proper function of the central nervous system function (31). Zimmerman also agrees that nociception plays an important role, and maintains that the exact mechanisms are still elusive and more research is needed (32).

Several researchers have examined the function of the various neuroendocrine axes and their possible contributions to the cause of fibromyalgia. Crofford et al (33) reviewed consistent neuroendocrine abnormalities found in the hypothalamic-pituitary-adrenal axis (HPA) and the hypothalamic-pituitary-gonadal axis (HPG). They hypothesize that the neuroendocrine abnormalities in FMS may be triggered by stress from a disease, injury, or from a psychological stressor. This "stressor" in turn leads to dysfunctional communication between the brain and the body and contributes to the development of fibromyalgia (33).

One review examined the musculoskeletal system, the neuroendocrine system and the central nervous system to determine possible links and contributing factors to FMS. Weigent concludes that a genetic susceptibility to physical/psychological stress leads to abnormalities within the neuroendocrine system. Muscular "microtrauma" or injury then leads to increased pain perception and pain threshold levels (34).

While the exact mechanisms still remain elusive, there is definitely a consensus that fibromyalgia pathogenesis and etiology is complex and multifaceted (32). Continued research will contribute to knowledge about fibromyalgia and ultimately result in more effective treatment strategies.

Treatment Interventions

Due to the uncertainty regarding exact mechanisms contributing to FMS, treatment interventions have been largely focused on theoretical observations (13). It has been widely stated that currently there is "no single highly effective treatment" for fibromyalgia (4). However, extensive research has been conducted to discover various ways of treating and managing this syndrome. Treatment usually involves the management of symptoms such as sleep irregularities, psychological factors, restoring functional physical fitness and activity levels, and addressing problems associated with concomitant illnesses (35).

Although most patients use a combination of therapies, this review divides FMS treatment strategies into two main categories of pharmacologic and non-pharmacologic treatments. A specific emphasis is placed on reviewing exercise-based treatment programs.

Pharmacological Interventions

Although there are currently no medications that are approved specifically to treat FMS, pharmacological treatments are commonly used among FMS patients (36) and are generally based on alleviating symptoms of pain and sleep disturbances (37). Two meta-analyses and several reviews were analyzed to briefly summarize the effects of the most commonly prescribed medications with FMS. These FMS pharmacological medications will be classified into three categories consisting of (1) anti-depressants, (2) analgesics and anti-inflammatory agents, and (3) other agents.

Antidepressants. Antidepressants have long been used to manage and treat pain in individuals and it is important to note that the analgesic effects "are independent of their effects on clinical depression" (38). Due to their analgesic properties and effects in improving sleep, antidepressants have been commonly used as a component in the management of fibromyalgia (39, 36, 40). Antidepressants most commonly used in the management of FMS include Tricyclic Antidepressants (TCAs) as well as Serotonin-Specific-Reuptake Inhibitors (SSRI's) (36).

According to a 7-year study investigating the use of various treatments with fibromyalgia patients, TCA's were used by 57% of the FMS population over a 7-year period (36). Amitryptaline is the most commonly prescribed (36) and studied TCA drug although other TCA's have also been studied (41). In a review of four controlled, and blinded studies investigating the efficacy of amitryptaline; Inanici notes improvements with various outcomes including morning pain/fatigue, sleep quality, subjective pain, as well as patient and physician global assessment (35).

Few contraindications are known for TCA's and they are non-addictive. However adverse effects may include sicca symptoms, postural hypotension, weight gain, constipation, and exacerbation of cardiac arrythmias (35, 42). Godfrey also emphasizes the fact that absorption and pharmacological effects may vary greatly among individuals (42). It is important to note that at best only half of patients actually show a significant improvement in their symptoms as a result of TCA treatment, (18, 42) and the beneficial effects diminish over time (43).

Due to the relative success with TCAs in treating symptoms of fibromyalgia, SSRIs or Selective Serotonin Reuptake Inhibitors have also been investigated (10). Wolfe approximates that 11% of FMS patients used an SSRI over a 7-year period (36). Several SSRI's have been examined in the treatment of fibromyalgia including citalopram, fluoxitine, and sertraline. However, fluoxitine has been most common SSRI studied in the treatment of FMS. While SSRI's may improve FMS symptoms with regards to a few outcome variables, their most beneficial effects involve alleviation of concomitant depression as well as improvement with sleep quality (10). Pain and tender point pain are usually not significantly affected. In a review on antidepressants in the management of pain, Cohen, indicates that most trials indicate TCA's to be "superior" to SSRI's and states, "in most circumstances, TCAs should remain the first-line antidepressants for chronic pain (38)."

In a meta-analysis of 13 randomized trials studying the effects of anti-depressant medications on FMS symptoms, O'Malley concludes that this class of drugs are effective at improving symptoms such as pain, poor sleep, and fatigue (40). However, it is

important to note that only 25-30% of individuals will obtain clinically significant improvements as a result of antidepressant therapy treatment (18).

Analgesic and Anti-inflammatory Agents. Despite a lack of convincing evidence (43), analgesic and anti-inflammatory agents have been used extensively by patients suffering with fibromyalgia (36). Non-steroidal anti-inflammatory drugs, or NSAIDs, are the most commonly used drugs among fibromyalgia patients (36), and have been described as the "mainstay of drug treatment" for musculoskeletal conditions(41). Approximately 81% of fibromyalgia participants at 6 centers had used NSAIDs over the course of 7 years, and 54% were currently using these drugs (36). It is also estimated that aspirin and acetaminophen are used by 50% and 60% of FMS patients respectively (36).

A meta-analysis conducted by Rossy et al (37) found that trials involving NSAIDs alone did not result in improvement on any outcome variables. Curatolo (41) also notes that NSAIDs have "limited effectiveness" with regards to musculoskeletal pain and notes that the "published evidence does not support the widespread use" (41). Similar conclusions have been made by Millea (44) and Alarcon (43). Negative side effects from the long-term use of NSAIDS include gastrointestinal and kidney problems (10).

Narcotic analgesics include drugs such as tramadol, codeine, and opioids (10) and are used by approximately 20% of FMS sufferers (36). However, prescription is not recommended as few trials have been conducted and results do not justify their use(10, 35).

Other Agents. Several other agents have been examined with regards to treatment of FMS. Three of these drugs will be briefly discussed. Anxiolytics are used by

approximately 43% of FMS patients (36). Alarcon (43) states that the only beneficial anxiolytic drug that has been studied in fibromyalgia is alprazolam, although other drugs are frequently prescribed. One double-blinded placebo controlled trial of ibuprofen with alprazolam found small improvements with regards to tender point and general pain (45). Alprazolam has demonstrated to have sedative effects and long-term use leads to dependency (10).

S-adensyl-L-methionine or SAMe has been studied due to its anti-depressive, analgesic, and anti-inflammatory characteristics (10). A few controlled trials have found SAMe to be more effective than a placebo in reducing symptoms of depression, pain, and tender point count (43). While no significant side effects have been documented, SAMe has not been approved as a prescription medicine in the United States (10).

Wolfe found that roughly one quarter of FMS patients have used Cyclobenzaprine at some point in time (36). Cyclobenzaprine is a skeletal muscle relaxant that is often used as an antidepressant and has been found in a few studies to improve sleep and pain severity (10). Inanici and Yunus summarized four studies ranging in length from 10 days to 6 months (35). Three of the four studies reported improvements in areas such as fatigue, stiffness, pain severity, and sleep. However, the longest study reported no benefits at 3 and 6 months into the study (35). Possible side effects of cyclobenzaprine include anticholinergenic and effects on the central nervous system (10).

In conclusion, Goldenberg notes that only 30%-50% of patients can expect to have improvements as a results of pharmacologic treatments (4), however, a 7 year outcome study showed that the average number of drugs taken by FMS patients was eight

(36). The results of a meta-analysis conducted on 49 fibromyalgia treatment interventions concluded that only antidepressants and muscle relaxants were associated with improvement based on physical status measures. The outcome measures of daily functioning were not improved via any pharmacological-based interventions (37).

While pharmacological treatment may play a role in alleviation of some symptoms of fibromyalgia, additional treatments need to be investigated. In a review of pharmacological treatment of various musculoskeletal disorders, including fibromyalgia, Curatolo (41) states, "It seems that prescribing drugs satisfies a humanitarian urge by offering some degree of pain relief. This may be a valuable achievement in the context of daily pain, but if complete resolution of pain and disability is the aim of the treatment, we must admit that there is no pharmacological therapy by which these goals can be reached."

Non-pharmacological Interventions

Due to poor pharmacological management of FMS, patients often seek other forms of treatments. Non-pharmacological interventions are usually based on addressing a wide a range of problems associated with fibromyalgia and its symptoms. Non-pharmacological treatments are varied and even include non-traditional practices such as herbal supplements or dietary modifications, reflexology, and chiropractors (16). However, three common non-pharmacological treatment interventions will be described for this review; Mind-Body Therapies, Acupuncture, and Exercise. A specific emphasis will be placed on the exercise-based interventions.

Mind-Body Therapies. Mind-Body Therapies are varied and can include therapies such as "autogenic training, relaxation exercises, meditation, cognitive behavioral training, hypnosis, guided imagery, biofeedback, and education" and have been investigated in the treatment of fibromyalgia (46). Several studies have combined various mind-body therapies with exercise-type programs and will be addressed in the "Exercise" portion of this review.

After noting successful treatment of some types of conditions with psychological factors, Haanen conducted a study comparing a hypnotherapy treatment group to a physical therapy control (14). Forty patients were randomly assigned to the 12-week programs. The hypnotherapy group reported significant improvements with regards to pain, fatigue, and sleep variables. However, the authors note that because subjects were "refractory" to physical therapy, the hypnotherapy group was being compared to a treatment that had previously not been successful for them (14).

In a literature review of mind-body therapies (MBT) conducted with FMS, Hadhazy found that exercise was found to be more beneficial than mind body therapies alone. While it is noted that MBT may assist with increasing self-efficacy, "there is no evidence to justify using mind-body therapies in place of other active therapies to either modulate pain or improve function (47)."

Acupuncture. Acupuncture is an ancient form of Chinese medical treatment that dates back thousands of years (48). It is a fairly common non-traditional therapy that is used for treatment of various illnesses and conditions including FMS (16, 49). Treatment involves the insertion of needles placed in specific areas of the body. The theory of

placement involves the correction of or releasing of energy flow or "qi" (15, 48). The mechanisms of action behind acupuncture are not clearly understood. Although most theories center on its analgesic effects some suggestions include the stimulation of the hypothalamus and pituitary glands and the releasing of endogenous opiods (49).

Few studies have examined the efficacy of acupuncture in the treatment of FMS. The most oft-cited study was conducted by Deluze and colleagues (50) and contained the "highest methodologic quality" (15). They conducted a double-blind randomized controlled trial comparing an electroacupuncture treatment group with an acupuncture sham treatment. After 3 weeks, the researchers found that the electroacupuncture group improved significantly over the sham treatment group in areas such as pain and sleep quality (50). Berman reports that these results are similar to six other lower quality studies that also examined fibromyalgia and acupuncture (15). However, additional high quality studies need to be conducted with long-term follow-ups to more effectively scrutinize the effects (15).

Adverse effects of treatment with acupuncture are rare, but include skin infections, fainting, bruising, and tissue or nerve damage (33). It is also important to note that some patients may be classified as "non-responders" and may have no positive effects from acupuncture treatments (15, 49). An NIH consensus panel of experts deemed acupuncture to be useful as an "adjunct treatment," an "acceptable alternative," or to be included in a "comprehensive management program" for fibromyalgia (49).

Exercise. Regular exercise has long been known for improving various aspects of health. In addition to reducing risk of chronic health diseases such as cancer and

cardiovascular diseases, exercise has proven to assist with weight loss or maintenance, promotion of healthy muscles, joints and bones, as well as improving psychological components of health such as reducing depression and anxiety.

Exercise has also proven to have beneficial effects in the treatment of fibromyalgia and is the most oft studied non-pharmacological treatment intervention. Interest in exercise as a significant component of FMS treatment programs initially began with the observations of Modofsky et al (26). In a study examining sleep physiology, they noted that fibromyalgia sufferers were more likely to experience non-refreshing sleep than healthy controls. While noting that exercise has positive influence on delta sleep, they also studied several healthy volunteers who exercised regularly and subjected them to Stage 4 sleep deprivation. These subjects did not experience increased pain or other symptoms that are noted with Stage 4 sleep deprivation (26).

In addition to these results Bennett et al found that 80% of fibromyalgia patients had lower levels of aerobic fitness compared to sedentary controls and pre-published standards (51). Borman investigated muscular strength as well as endurance in FMS patients (52). Results showed that FMS sufferers had decreased quadriceps strength and reduced aerobic performance capacities compared to healthy controls (52). However a study conducted that examined cardiorespiratory fitness and perceived in exertion in FMS patients versus healthy control subjects found that FMS patients had similar fitness levels as that of healthy control subjects, but a difference was seen with regards to a higher perception of exertion with the FMS patients (53).

A comprehensive literature search was conducted using software developed by the Dialog Corp (REF) and PubMed using the search terms *fibromyalgia* and *exercise* or *physical activity*. The bibliographies of articles found were also examined to include any articles that may not have come up during the computerized search. To be included in this review, articles must be written in English, published in a peer-reviewed journal prior to December 2004, and databased. Articles that were published in abstract form only were not included in this review.

Several studies are reviewed that included some form of exercise alone or in combination with other components such as education or cognitive behavioral therapy. The interventions ranged in length from approximately 4 weeks to 24 weeks. The studies involved various forms of exercise including aerobic activities, such as pool exercise or walking, to strength training and flexibility/stretching programs.

For the purposes of this review, the studies were divided into three categories as follows: (1) Studies that examined mainly an aerobic component of exercise, (2) studies that included significant strength/resistance training or passive exercise components into the programs, and (3) studies that involved a multidisciplinary approach which includes an specific educational component.

1. *Aerobic exercise interventions.* Several studies examined interventions that included mainly an aerobic exercise component for the intervention. The earliest of these studies, and most frequently cited, was conducted by McCain and colleagues (54). A 20-week supervised cardiovascular training program was conducted with 18 fibromyalgia patients using bicycle ergometers. Results of the training group (CVR) were compared

with a control group (n=20) that conducted simple flexibility exercises (FLEX). Significant improvements were noted in the CVR group in pain threshold levels, physician and patient global assessments, as well as in peak work capacity over the FLEX control group. The authors also noted a "trend towards significance" in the patient visual analog scales of reported pain and conclude that exercise may offer "some therapeutic benefit" for FMS sufferers although the exact mechanism is not known (54).

Meiworm et al (55) examined the effects of a 12-week program of walking, jogging, cycling, or swimming compared to a sedentary control group. The exercise group exercise for approximately 20 minutes 2-3 times per week at 50% VO2 Max. The exercise training improved aerobic fitness levels of the patients in the group with no significant negative side effects. The program also had a positive influence on patient wellness, tender point count, and painful body surface area (55). In a 20 minute modified low-impact aerobics program, Mengshoel et al (56) also found no exacerbation of FMS symptoms and improved dynamic upper body strength. However, no significant improvements were seen with measures of pain, pain coping, or fatigue (56).

In a similar study, Gowans et al (57) conducted a randomized 23-week exercise program to examine the effect of exercise on mood and physical functioning. Significant improvements were noted with aerobic measures as well as depression and other outcome measures (57).

Redondo and colleagues conducted a randomized parallel trial in which they compared 8 week of supervised physical exercise to 8 weeks of cognitive behavioral therapy(58). Significant improvements were seen in both groups at the end of the 8-week

interventions especially with regards to physical activity improvements in the exercising group. Follow-up at 6 months and one year, however, resulted in outcome measures returning to baseline values (58).

In an effort to compare the effects of land-based exercise vs. pool-based exercise, Jentoft et al (59) conducted a 20-week program to compare the two types of exercise. While both groups improved with regards to cardiovascular fitness measures and fatigue, the pool-based exercise group experienced greater improvements in a few other outcome measures such as anxiety and depression (59).

Not all fibromyalgia exercise programs have found significant improvements with regards to outcome measures. Since most exercise programs for patients who suffer from FMS are supervised, Ramsay et al conducted a study to compare the effects of a 12 week unsupervised home-based program (60). Patients were assigned to two groups. One group met one time with a physical therapist to receive instruction and information on how to perform the home-based program. The second group met one time per week with the physical therapist to get instructions for the program as well. Due to low compliance with the programs and lack of significance in improvements with regards to the outcome measures, the authors regrettably state," the results of this study are disappointing" (60). Norregaard et al also failed to find significance in pain, fatigue, depression, aerobic capacity, and muscle strength outcome measures when comparing a 12-week dance program to a steady exercise program and a control group (61).

In a 24-week unsupervised walking program at varying intensities, Meyer and Lemley (62) also found no significant changes due to low compliance and high dropout

among subjects. After noting similar inconclusive results, Nichols and Glenn recommended more studies to examine various types of exercise, studies that control for "social effects," studies that included larger numbers of subjects, as well as studies that measures actual aerobic improvements in cardiovascular programs (63).

Due to success of some stress management programs, Wigers and colleagues (64) conducted a study to compare the effects of a physical exercise program to a stress management program as well as a treatment as usual control group. The aerobic exercise group met 3x a week for 45 minutes for 14 weeks. The stress management group received instruction regarding stress management and met for 90-minute sessions 2x a week for 6 weeks, then only once per week for the remaining 8 weeks. Both of the treatment groups showed significant improvements with regards to tender point tenderness compared to the control group. The aerobic exercise group also experienced improvement regarding pain distribution and work capacity. While noting that both groups demonstrated positive short-term effects due to the interventions, at a 4-year follow-up no significant long-term effects were found (64).

Sackner and colleagues conducted a well-designed randomized control trial investigating the effects of a home-based videotape low impact aerobic exercise program on FMS symptoms (65). Volunteers were recruited into one of three groups: exercise training with one bout of exercise per day, training with two short bouts of exercise per day and a no exercise control group. After 16 weeks of progressive training, no significant differences were noted between the two exercise groups and only small differences were found with improvements of symptoms and physical functioning (65)

2. *Strength Training and Passive Exercise Interventions.* Due to the observations of a lower aerobic capacity in individuals with fibromyalgia (51), a majority of the studies have been conducted almost entirely on cardiovascular training programs. Rooks attributes the lack of strength training research to apprehension regarding "risk for subject injury and exacerbation of symptoms" (66). Several researchers have examined the safety and efficacy of exercise programs for FMS patients that involve specific strength training components. Several studies included interventions that had significant components involving weight training.

The earliest of these studies was conducted by Martin and colleagues (67). They examined a 6-week long exercise program that had a strength-training portion in addition to time devoted to aerobic exercise and flexibility. Thirty-eight subjects were randomly assigned to the training group or a flexibility control group. The training group participated in a 1 hour long training session 3x per week for the 6-week program (67). A significant decrease was noted in the training group in tender point counts as well as degree of tenderness. No difference were observed with reference to self-efficacy, or in the Fibromyalgia Impact Questionnaire (FIQ) designed to measure functional ability and several other psychological components. However, the researchers did note a trend towards significance with these variables. Recommendations were given to conduct studies that lasted longer than 6-weeks, as well as possibly initiating a more intensive program (67).

Rooks et al also conducted a similar study examining a multi-component exercise program that contained cardiovascular flexibility and strength training elements (66).

They found that the 20-week self-paced program (with exercise sessions 3x per week) did not aggravate the FM symptoms and no musculoskeletal injuries were reported. The authors cite a significant increase in muscle strength as a major study finding, and conclude the program to be "safe, feasible, and beneficial" (66).

Hakkinen et al decided to investigate the results of a weight-training program of healthy women compared to women who had fibromyalgia (68). After 21 weeks, they found that the fibromyalgia training group had increased their strength to the same extent as the healthy control-training group. Compared to a second control group of fibromyalgia women who did not train, the fibromyalgia training group decreased significantly in measures of neck pain, depression, and fatigue (68). Two other studies were conducted by Hakkinen et al and Valkeinen et al examining similar 21-week strength training programs to investigate neuromuscular function and the effects of strength training in elderly women with FMS . Similar improvements were noted (69, 70).

Karper et al (71) also examined a program of aerobic exercise and resistance training with machine weights. Participants exercised 3x a week for 6-12 months. A few participants (n=3) also chose to remain in the study and exercise 5x per week for an additional 6 months. The authors note that; " all of the groups in the program were helped to some extent on numerous fitness variables" (71). In 2003 they published an article on 4 participants that were still following this program after 3 years and 3 participants who had been following it for 2 years. All participants continued to maintain improvements over the additional follow-up period. Although this follow-up sample size

is small, this demonstrates that it is possible to maintain long term exercise programs and benefits in a supervised program (72).

Jones et al conducted a muscle-strengthening program and compared it to a simple supervised stretching program (73). After 12 weeks, improvements were seen with both training groups; however, the "magnitude of change" was greater in the strength-training group than in the flexibility control (73). Geel also conducted a fairly similar 8-week strength-training program and found comparable results (74). However, the study did not contain a non-exercise control group and only 9 of 12 subjects remained in the study through the conclusion (74).

Due to the potential anti-inflammatory effects of nitric oxide concentrations in the bloodstream, Sackner and colleagues examined passive whole body periodic acceleration on FMS symptoms. After 15 sessions on the motion platform device, improvements were noted in the areas of energy, pain, and sleep. However, the sample size was small (5) and no control group was used (75).

T'ai Chi exercise combines mind-body therapy with therapeutic exercise and was investigated by Taggart and colleagues in a 6 week study (76). After 12 training sessions, perception in health status and physical functioning improved significantly (76). Although no control group was used, these exercises are beneficial as they are slow, gentle movements and can be practiced at home after the movement sequences have been learned (76).

3. *Multidisciplinary Interventions.* Several studies examine multidisciplinary interventions that include exercise along with some sort of a cognitive/education

component. In a review regarding management of FMS Goldenberg states that there is strong evidence in support of patient education (11).

The earliest multidisciplinary program was conducted by Burkhardt and colleagues (77). Patients were randomized into 1 of three groups receiving education, education and exercise training, or a control group. The 12 week combination program included six 1 ½ hour long education classes and 1 hour of physical training a week. Participants were encouraged to also exercise on their own. Although there were no significant differences between the two intervention groups, both programs reported significant increases with self-efficacy and general quality of life measures. Although 71% of the experimental group subjects reported the program as "positive", the authors note that they did not collect information regarding the actual exercise actions of the patients (77).

In the longest of the multidisciplinary interventions, Mannerkorpi et al examined a 6 month long pool exercise program combined with a six session education program. The pool exercise was conducted just one time per week for 35 minutes (78). Compared to a control group, the combination group experienced significant improvements in 6 minute walk distance and the FIQ. While the exercise was not designed to specifically improve aerobic capacity, the researchers report that the program was designed to *encourage* physical activity as well as coping strategies. However, ½ of the participants reported positive changes in their lives such as increased levels of physical activity (78). Mannerkorpi and colleagues conducted a follow-up of this program 6 and 24 months after completion on this treatment program. Although few participants reported

continued pool exercise, most were still regularly conducting some form of physical activity and participants continued to report improvements compared to their pre-treatment values (79).

Gowans et al (80) also examined a pool exercise program combined with a 1 time per week education class. Compared to the waiting list control group, the intervention resulted in a significant increase in the 6-minute walk test, well being, and fatigue experienced in the morning. These benefits were maintained through a 6-month follow-up (80). Cedraschi and colleagues conducted a similar randomized program involving a 6-week pool exercise and education classes. They also noted sustained improvements not only after the 6 week program, but at 6 months follow-up as well (81).

Buckelew et al randomized participants into 4 groups receiving biofeedback/relaxation training only, exercise only, combination, or an educational/attention control group (82). No significant differences were found between the three treatment groups. However, all three of the treatment groups experience increases in self-efficacy as well as a lack of deterioration in tender point scores compared to the control. At a 2 year follow-up the combination group had reported results that were considered to be the best maintained (82). Van Santen and colleagues also conducted a 24-week program comparing an aerobic fitness program, biofeedback training, and a control group. Compared to the control group, neither treatment group experienced any significant improvements with regards to any outcome measure.

In a similar study, Mengshoel et al (83) examined a multidisciplinary program that included a cognitive portion with goal setting, addressing dietary factors, and other

topics along with relaxation techniques, body awareness exercise and strengthening and stretching exercises. The 10-week program resulted in an improvement regarding general pain intensity, but no significant changes regarding measures such as sleep or fatigue. Significant reductions in pain intensity were maintained through a 6-month follow-up (83).

A 12-week program was conducted by King et al in which they randomized participants into aerobic exercise and education, aerobic exercise only, education only, and control groups(84). The exercise programs consisted of various activities conducted 3 times per week including walking and pool exercises. The education groups met once per week for approximately 1-2 hours. After 12 weeks, the combination group reported increased coping ability with regards to FMS symptoms. Of note, however, at 6-month follow-up fitness improvements were maintained only with the exercise only group and not with the combination group. As with many FMS studies, however, full compliance with the actual programs was difficult (84).

Four studies examined pre-existing exercise-based programs with fibromyalgia patients. In a unique month long outpatient program, Mason et al (85) examined the efficacy of the Presbyterian Pain Treatment Program with FMS patients. The patients attended the full-day program 6 days per week for 1 month. The treatment plan included 4 hours of exercise including walking and work on exercise equipment along with a cognitive/educational component, and physical therapy with posture and flexibility exercises. Beneficial effects with psychological outcomes, and subjective pain were seen

after 1 month and at 6-month follow-up. The most significant measure was a marked decrease in depression (85).

Bailey et al also examined a pre-existing program with FMS patients (86). Fibro-Fit is a FMS exercise program designed by the Arthritis Foundation. This program included 3 sessions per week of a graded stretching, strengthening and aerobic exercise along with education and counseling session 1 time per week. At 12 weeks, significant improvements were found among various measures including aerobic fitness, upper body strength, flexibility, pain, and disability (86).

Kendall et al compared two exercise/therapy regimens in a 20-week study (87). The Mesendiak System (MS) consisted of 18 individual and 2 group sessions 1 time per week. The sessions consisted of one-on-one education with a physical therapist along with information regarding things like relaxation, breathing, balance, and posture. This program was compared with Body Awareness Therapy (BAT) conducted with a group 1 time per week for 90 minutes. The BAT consisted of 3 components including discussion on topics such as stress, instruction regarding body awareness movements, gait, balance, posture, and breathing, as well as awareness of relaxation and tension techniques. The BAT program participants experienced a decrease in global health after the study, but regained it after an 18-month follow-up. The MS group experienced increases in pain, overall impact, and self-efficacy and maintained these benefits through the 18-month follow-up (87).

In an effort to examine a Qi Gong exercise program with an educational component, Creamer et al conducted an 8-week study (88). The 2.5 hour sessions were

conducted 1 time per week and consisted of 30 minutes of cognitive/behavioral education training, 1 hour of meditation/relaxation, and 1 hour of Qi Gong exercise and movement therapy. Improvements were noted in pain outcome measures, 6 minute walk test as well as in the FIQ. These results were maintained up through the 4-month follow-up period. It is important to note, however, that with all of the four previously mentioned studies no control group was used (88).

Conclusion

In the United States, rheumatic conditions such as fibromyalgia, arthritis and other musculoskeletal disorders are the leading cause of disability in individuals over the age 65 years(1). The prevalence of rheumatologic conditions is also expected to increase significantly effecting an estimated 18% of Americans by 2020 (1). As fibromyalgia is the second most common diagnosis in rheumatology practices, significant research needs to be conducted in management of this syndrome (4).

Since the ACR criteria were established in 1990, there has been a significant increase in the number of published scientific articles that have examined various aspects of fibromyalgia (89). While some research has been conducted to pinpoint possible causes, additional research needs to determine the most effective treatments. In a three year study on pain and pain relief in fibromyalgia patients, most patients reported that exercise had the most beneficial effects compared to other treatments such as pharmacologic therapy and alternative medicine (90). It is recommended that the optimal treatment for FMS would include nonpharmacologic interventions, specifically exercise,

education, and cognitive behavioral therapy, in addition to appropriate medication management as needed for pain and sleep problems (4, 11, 37).

In 2002 a comprehensive report by the Cochrane Collaboration examined published research involving exercise and fibromyalgia syndrome (19). They found that supervised aerobic exercise programs proved advantageous with regards to physical functioning and some FMS symptoms. They report a need for additional studies to be conducted on programs that address strength training, flexibility, as well as long term benefits of exercise programs (19). A majority of the previously reviewed exercise intervention studies have documented the beneficial effects of various combinations of exercise programs on its effects on fibromyalgia and its symptoms. However, limitations are seen in many of the studies such as high participant dropout, poor compliance to the exercise regimen, small sample sizes, and lack of appropriate control groups. Most of the studies required supervision and lengthy amounts of time committed by the participants as well. This adds up to an increased cost for the patient and for health insurance companies.

Although exercise programs can be beneficial, "Proper prescription is the key element," as FMS symptoms are often exacerbated upon the initiation of an intense exercise program (21). Therefore, it is recommended that individuals with FMS begin with a gentle exercise program and then add on aerobic activities (21, 22, 91, 92). Therefore, additional research is needed on low-intensity exercise programs that lessen the chance of symptom exacerbation and increase long-term exercise adherence (22, 91)

as well as “home program(s) of muscle stretching, gentle strengthening, and aerobic conditioning” (48).

The proposed specialized exercise program has been designed to have several potential benefits in addition to its therapeutic effects. This program is designed to be (1) used at home, (no travel time is required and it can be done at any time during the day) (2) requires no supervision and very little equipment (only requires a VCR/DVD and a TV), and (3) it can be used as an adjunct therapy to complement a patient’s pre-existing exercise regimen.

Chapter 3

Methods

Subjects

Thirty subjects will be recruited, with a significant portion of the participants expected to be female (1). Prior to any recruitment, IRB approval will be obtained regarding the recruitment and participation of the subjects in the study. Since this version of the video is in English, participants must be able to understand English to understand the verbal instructions provided in the video. The subjects will be recruited from flyers posted on bulletins boards on BYU's campus, medical offices in Utah, Oregon, and Montana, through participant or physician referrals, as well as via an email sent to a community information mailing list for employees of Intel-Oregon.

Upon pre-entrance into the study, participants will be mailed a written letter of informed consent detailing the possible benefits or negative consequences of the study. The potential participants will also be contacted via phone and given the opportunity to have any questions that they have relating to the study answered.

Participants must be older than 18, previously evaluated by a physician, and diagnosed with fibromyalgia. Participants must not be pregnant or have cardiovascular disease and must not be currently participating in any additional clinical trials. In order to expedite verification of physician FMS diagnosis and approval for therapeutic exercise, we will modify a piloted procedure initiated by Rooks et al (66) in which a form will be mailed or faxed to each potential participant's physician. Rooks et al received 92% of the forms within a two-week time frame (66).

Instruments

There is currently no single measure used for evaluating change in fibromyalgia research related studies. All of the instruments to be used in this study involve self-report measures. However, patient questionnaires can be considered "as valuable as laboratory or imaging data" in rheumatology care (20). All of these instruments have previously been used in research studies involving FMS participants.

The Fibromyalgia Impact Questionnaire (FIQ) is a 2-page self-administered instrument developed for evaluation of health status with regards to individuals who have FMS (93). This is a 20-item instrument and is designed to measure physical function, work status, depression, anxiety, sleep, pain, stiffness, fatigue, and general well being. Items are measured on a Likert-type scale. Construct validity and test re-test reliability have been established (93).

In order to measure change in participants' perception of their ability to cope with the pain and symptoms of FMS, the 8-item Stanford Arthritis Self Efficacy Scale (ASES) will be used. This 1 page instrument has been developed to measure patients' self-efficacy with regards to management of their rheumatic condition (94). This measure, developed by Lorig et al, consists of 8 items and is self-administered. Reliability as well as construct and concurrent validity have been established (94). The ASES has been used previously to examine self-efficacy in FMS patients and the scale is modified slightly in which the term "fibromyalgia" is exchanged for the term "arthritis" throughout the scale.

Pain and fatigue will be measured using visual analog scales (95, 96). We will also use one item on the Stanford Chronic Disease Self-Efficacy scale to measure self-efficacy regarding ability to exercise (96).

Procedures

Upon signing the informed consent, demographic information will be collected along with a brief medical history. Baseline measurements will also be collected and recorded from results of the administration of the Fibromyalgia Impact Questionnaire (FIQ), the Arthritis Self-Efficacy Scale (ASES) and pain and fatigue visual analog scales. Each participant will also provide information as to his or her current regimen of treatment. These data will include information regarding any drugs currently being taken, therapeutic treatments, or exercise programs. Each participant will be asked to continue his or her current treatment(s) as needed throughout the length of the study.

Participants will be randomly assigned to a "treatment" group or a treatment-as-usual (TAU) control group. The treatment group will be provided with the exercise video and accompanying exercise booklet. This group will be instructed to watch the video and conduct the prescribed exercises at least 3 times per week and as much as twice a day. Instructions for beginning the exercise program will be provided in the "Quick Start Guide" that will be included with the video. The video consists of a combination of therapeutic exercises and stretches along with verbal and visual instruction as to how to perform each activity. Written instructions for the activities included in the video are also provided in an accompanying booklet. Participants will be instructed to conduct the exercises as directed in the "Quick Start Guide" or until they experience pain, fatigue, or

have completed the 42-minute video. Each treatment participant will also be given a logbook in which they will be instructed to record the frequency and duration of their daily exercise sessions as well as any other treatments such as medication or other therapies.

The treatment-as-usual (TAU) control group will be instructed to follow their standard treatment for FMS symptoms. Both groups will record their treatments, such as medications, therapy, and exercise. The control group will not receive the exercise video or descriptions until after the completion of the study. To encourage documentation of their treatments, all participants will be contacted halfway through the study via email, phone, or United States Postal Service mail to remind them to record their weekly treatment routines.

The items in the Fibromyalgia Impact Questionnaire (FIQ), the Arthritis Self-Efficacy Scale (ASES) and the VAS pain and fatigue scales will be measured at baseline and at the conclusion of the four-week study. Results will be recorded and statistically analyzed. After the completion of the study, the control group will have the opportunity to receive a free copy of the video and book that the treatment group received.

Design and Statistical Analyses

This study will use a randomized groups pre-test post-test design in which the exercise treatment group will be compared to the 'treatment-as-usual' control group. The outcome measures of the Fibromyalgia Impact Questionnaire, the Arthritis Self-Efficacy Scale, and pain and fatigue will be measured at baseline and at the end of week 4 in the study. The data will be analyzed using a random coefficient growth curve model by

means of SAS. The independent variables are the treatment groups and time. The primary dependent variables are the FIQ score for overall disease impact, self-efficacy as measured by the modified ASES, as well as pain and fatigue measured by the Visual Analog Scales. Compliance will be determined as having conducted the exercises at least three times per week for 4-week time frame.

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