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Role of Exercise and Education in the Management of Fibromyalgia

by

Sharla Joan King

A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfillment of the requirements for the degree of Doctor of Philosophy

Faculty of Rehabilitation Medicine

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Dedication

This document would not be possible without the incredible support and encouragement of my husband, Vang. He kept me focused on the end and helped me to believe in myself. Also to my parents who instilled in me the love of learning and the desire to do the best I possibly could.

Abstract

The purpose of this research project was to determine the effect of aerobic exercise and education in the management of fibromyalgia (FM). One hundred seventy-four women diagnosed with FM were randomly assigned to an exercise, education, combined exercise and education or a control group. The interventions were 12 weeks long. Testing was done immediately before the program, immediately upon completion and then 3 months later.

The exercise, education and the combination of exercise and education did not demonstrate significant differences on measures of disability, perceived ability to cope with pain and other symptoms, and function, life satisfaction, fitness, number of TPs and pain severity. Differences between groups only arose when compliance was analyzed. The subjects in the combined group significantly improved their perceived ability to cope with other symptoms, which was maintained at follow-up. In addition, the groups involving exercise significantly increased their walking distance. The improvement in walking distance was maintained at follow-up in the exercise only group, but not the combined group.

Peak metabolic, but not cardiovascular measures were improved after the training program. However, at submaximal exercise no improvements were demonstrated in metabolic or cardiovascular measures. Psychosocial and functional measures improved after an aerobic training program. No relationship was demonstrated between the improvements in peak oxygen consumption and the psychosocial and functional measures. Therefore, physiological

improvements did not appear necessary in order to significantly improve measures of disability, coping and function.

Select sociodemographic and psychosocial measures were significant, but not strong predictors of change in various dependent variables. Lower self-efficacy explained the greatest percentage of change in perceived ability to cope with pain and other symptoms. A higher education also predicted greater response in life satisfaction, perceived ability to function and number of TPs. Only 12-37% of all subjects responded to the interventions. Since no strong predictors were identified, other constructs or combination of constructs must explain the response to treatment in persons with FM. Overall, the studies indicate that current treatments involving exercise and education may not be very efficacious for the management of FM.

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List of Abbreviations

Adaptive Coper – AC

Arterio-venous Oxygen Difference – (a-v)O_2 diff

Cardiac Output - Q

Dysfunctional – Dys

Fear-Avoidance Beliefs Questionnaire - FAB

Fibromyalgia – FM

Heart Rate maximum - HRmax

Interpersonally Distressed – ID

Low Back Pain - LBP

Multidimensional Pain Inventory – MPI

Oxygen – O_2

Peak Oxygen consumption - pVO_2

Quality of Life Scale - QOL

Self-efficacy – SE

Six Minute Walk – 6MW

Stroke Volume - SV

Tender Points –TPs

Tender Point Survey Site – TSS

CHAPTER 1

Introduction

The management of fibromyalgia (FM) is a challenge for persons with the condition as well as health care professionals. Part of the difficulty with management is that the condition involves a variety of nonspecific symptoms such as pain, fatigue, sleep disturbance, numbness and irritable bowel (1, 2). The other management difficulty is that no clear physiological and/or psychological abnormalities have been identified. Unfortunately, research with this population has also failed to identify a clear treatment protocol. Medications, aerobic exercise and education have been identified as part of a treatment plan. However, most research has demonstrated only moderate success with decreasing pain and improving psychosocial measures. Perhaps the moderate treatment success is due to wide response variability in the FM population, suggesting that management programs be designed to accommodate different types of patients. Improvements in physical fitness have been reported following aerobic training, however it is unknown if they are related to improvements in psychosocial measures. There are also difficulties with respect to evaluating the change in disability or impairment. For these reasons, the management of FM is problematic for all concerned.

The prevalence of FM has been increasing over the past five years and FM is the only rheumatic disorder on the rise (3). Recently, the prevalence rate reported in men was 1.6% and in women was 4.9% (4). Moreover, it is reported that 50% of FM patients' symptoms worsen over five years (5). It has been discovered that two thirds of persons with FM are forced to reduce their work or school hours compared to persons with chronic pain and healthy controls (28.9% and 8.9%, respectively) (6). A large majority (87%) of persons with FM reported that their ability to work has been affected mainly due to the pain, fatigue, weakness and loss of memory/concentration (6). In addition, leisure and household activities are adversely affected in over 90% of persons with FM (5). They report lower quality of life (7, 8) compared to persons with other chronic

diseases, such as osteoarthritis, advanced cancer and chronic obstructive pulmonary disease. Even the family members of persons with FM report lower quality of life scores as compared to controls (9). The impact of FM is great with respect to quality of life and disability.

Management of FM

The current management of FM typically includes medication, aerobic exercise and some type of education program. The success of treatment programs involving exercise and/or education has been variable.

Aerobic Exercise

The concept of aerobic exercise as being beneficial for persons with FM originated with Moldofsky et al (10). These researchers demonstrated that normal healthy subjects deprived of stage IV sleep developed tender points similar to that seen in FM, while marathon runners did not. These results suggested that aerobic exercise would be beneficial for managing the symptoms of FM.

Research has demonstrated that aerobic exercise can improve measures of fitness and some physical symptoms without increasing symptoms in persons with FM (11-14). Investigators have reported significant decreases in number of tender points (TPs) (13) and myalgic scores (11, 13) compared to non-exercising groups. However, Mengshoel et al (14) reported that general pain and fatigue did not differ significantly between a group participating in aerobic exercise and a control group. Small sample sizes (n=11 exercise, n=14 control) may have contributed to the lack of difference between the two groups. Aerobic training has resulted in significant improvements in measures of fitness, such as peak work capacity, walking time on a treadmill, and steady state exercising heart rate (11, 13, 14).

Improvements on psychosocial measures have been limited after an exercise program in persons with FM. No significant differences between exercising and non-exercising groups on measures of pain coping and

assessment of multidimensional symptoms (Symptom Check List-90-revised) have been reported (11, 14). Nichols and Glenn (12) reported a significant improvement on pain perception, but not on a measure of psychosocial dimension for an aerobic walking group compared to a control group. A trend for improvements on measures of self-efficacy and impact of condition has been demonstrated in exercising versus non-exercising groups (13). Despite studies demonstrating improvements on physical components after an exercise program, improvements on psychosocial measures appear to be undetermined (11-14).

It appears that aerobic exercise is beneficial for improving fitness levels and some symptoms of persons with FM. Therefore guidelines for exercise prescription should be delineated if aerobic exercise is one of the main forms of management. To determine appropriate exercise levels, examination of the relationship between physiological and psychosocial change after an aerobic exercise program needs to be undertaken. In clinical and non-clinical populations, contradictory results have been reported regarding the relationship between improvements in physiological and psychological measures (15-20). However, well-controlled studies (17, 19) do not report a significant relationship between physiological and psychological changes. Determining if physiological measures improve after an aerobic exercise program and if the improvements are associated with changes in psychosocial measures may have implications for exercise prescription in persons with FM.

Multidisciplinary Treatment

Typical treatment programs for the management of FM involve multidisciplinary treatment. Uncontrolled studies reported in the literature were of varying lengths (4 weeks to 6 months) and did not involve formal exercise programs (21-23). Improvements were reported in depression, disability, quality of life, pain severity and life control (21, 23). A 10 week program included body awareness exercises and strengthening of the back and abdominal muscles in addition to the educational sessions (22). A significant reduction in pain intensity and total pain was demonstrated after the program. Bennett et al (21) and Turk

et al (23) reported that most of the improvements were maintained at a follow-up ranging from 6 months to 2 years. However, Mengshoel et al (22) reported that scores had almost returned to baseline at 6 months follow-up. The results from the study by Mengshoel et al (22) may not have been as favourable due to the small sample size (n=16 versus n=67 and n=104 in the other studies) as compared to the other studies. The results from these studies indicate that some variables may improve with multidisciplinary programs with some changes maintained at follow-up.

Previous randomized controlled trials have examined the efficacy of education (i.e. stress management, biofeedback/relaxation, self-management) compared to or in combination with supervised or unsupervised exercise programs (24-28). Studies examining a combination of exercise and education compared to a control group have demonstrated increases in self-efficacy, quality of life, sense of well-being and a decrease in fatigue, depression, pain and number of TPs (24-28). Exercise only groups have demonstrated a decrease in the number of TPs, lower pain distribution, improved self-efficacy and physical fitness compared to a control group (24, 27). In addition, Horven Wigers et al (27) reported a decrease in TP tenderness in the stress management group compared to control group. Improvements achieved after the programs were maintained mainly in the combination groups on measures of quality of life, self-efficacy (coping with pain and other symptoms), number of tender points, physical activity, depression at follow-ups ranging from 3 months to 1-2 years (24, 25). Buckelew et al (24) also reported improvements or maintenance of scores in the exercise group for pain severity, physical activity, self-efficacy (coping with pain and other symptoms and function). No significant differences between groups were seen among completers of a program at 4 year follow-up (27). Although the treatment groups have demonstrated improvements on a variety of measures, it has not been determined which intervention provides the greatest improvements overall. No study has examined exercise and education alone and in combination to determine which component is most effective in

managing symptoms of FM.

Adherence to Study Protocols

An additional problem with exercise and/or educational programs is the issue of adherence to the protocol and the impact on study results. In a pilot study, Mengshoel et al (22) reported difficulty with motivating the persons with FM to exercise 3 days per week, therefore 2 sessions per week were selected for the actual study. Moreover, it was even difficult for the subjects to practice the new skills and complete the assignments (27, 29). Attendance in studies involving education and/or exercise ranges from 63-92%. Subjects in an exercise group, who complied with the study protocol, decreased their pain distribution (area covered on a pain drawing) compared to a stress management group (27), a result that was not evident initially when the whole group was analyzed. High attrition rates in studies showing positive results may indicate that people who respond to the treatment continue to participate. On the other hand, this adherence problem may also indicate that efficacious programs exist, but the programs are not presented in a fashion that promotes compliance to the treatment over a period of time.

Adherence may also relate to differences within the FM population and/or the treatment program. Inconsistent results regarding attendance were reported between two studies involving only exercise (11, 13). McCain et al (11) reported 90% attendance compared to Martin et al (13) who reported 63% attendance. The subjects from the study by McCain et al (11) were all referred to an outpatient rheumatology clinic and were diagnosed according to Smythe criteria (30), whereas the FM subjects from the study by Martin et al (13) were referred by rheumatologists, family practitioners and from a local FM support group. In addition, these subjects were diagnosed with FM according to the American College of Rheumatology (ACR) criteria (2). The referral basis from the latter study would suggest a sample more representative of the actual FM population and not strictly persons currently seeking treatment. Moreover, the persons from

the two studies may actually be dissimilar due to the different criteria used for diagnosis. The time commitment due to the duration of the program [6 weeks (13) versus 20 weeks (11)] may also influence attendance rate in studies for persons with FM.

It should be noted that nonadherence with programs, especially exercise, is not unique to the FM population. In the healthy population, clinical and community based exercise programs have attrition rates as high as 50% within the first 3-6 months (31, 32). Therefore, it should not be surprising that in a population suffering from chronic pain and fatigue, maintenance of exercise behaviours is a problem.

Heterogeneous Population

The limited and varied success of interventions for persons with FM may be due to the fact that programs are designed for the 'typical' or 'average' person with FM. Subgroups of persons that differ on various measures have been identified in the low back pain, headache and temporomandibular populations (33, 34). Turk et al (35) have demonstrated this same heterogeneity in persons with FM. Subgroups were identified based upon a self-report measure examining interference of pain with their lives, the response of significant others to their pain and their level of general activity. It was reported that the FM subgroups displayed different levels of pain, disability, functioning and depression, as well as differential response to the same treatment program. Perhaps determining the characteristics of FM responders/nonresponders or identifying variables that would predict treatment success would assist program leaders in determining who will benefit from certain interventions.

Previous research has established that pain behaviours and/or beliefs adopted after onset of pain may become a major management problem (36, 37). For example, persons with low back pain may avoid activities following the pain episode. Those who continue with this avoidance behaviour have reported greater frequency and duration of pain, higher fear of pain and injury, increased

disability in daily living and more attention to their pain (38). Fear-avoidance beliefs correlated negatively to self-efficacy beliefs (-.62) and were among several psychological variables that predicted chronicity in persons with low back pain (39). Fear-avoidance beliefs have not been examined in a FM population. Studying this construct may help explain some of the disability associated with FM and may assist in determining characteristics of responders to interventions, perhaps leading to more effective treatment.

In addition to the psychological or emotional response to pain, sociodemographic variables, such as age, years of education and income, have been reported to influence clinical outcome or presentation of pain in chronic pain and arthritis populations (40-42). Lower education has been associated with higher mortality in rheumatoid arthritis (43) and with the development of FM (44). Research from the arthritis, low back and chronic pain fields has also identified sociodemographic, psychological and emotional response variables as potential predictors of success with intervention programs (40, 41, 45-47). If similar characteristics could predict treatment response in persons with FM, clinicians could optimize the use of available treatment resources.

Measurement Issues

The six minute walk (6MW) has been adopted by researchers to evaluate fitness and function in persons with FM (21, 25, 26). The 6MW was originally developed from Cooper's 12 minute walk/run test (48). Over the years, the 12 minute walk/run has been adopted by cardiopulmonary researchers (49, 50) and has evolved into the 6MW to assess both fitness and functional status.

The 6MW has been adopted as a measure of fitness and/or function in persons with FM, however there has been little testing of its psychometric properties (51) for this population. Additionally, most studies have used only one walk as the baseline measure to make comparisons. Research from the cardiopulmonary field (49, 50) suggested that the first walk may not be a reliable baseline measure and that the distance increases from time 1 to 3 and then

plateaus on the remaining walks. The validity of the 6MW has not been previously determined with respect to a direct measure of fitness or a measure of function.

Despite the recommendations for aerobic exercise, the actual cardiovascular and metabolic response to exercise has not been adequately measured in persons with FM. Studies that included aerobic exercise as a form of treatment for persons with FM, evaluated changes in fitness by using work capacity or walking tests (distance covered or duration of test). After exercise programs, improvements from initial baseline fitness values have been reported (11, 13, 14, 21). Cardiovascular or metabolic measures have been reported only as baseline data. Moreover, no study has reported the central (related to heart and lungs) and peripheral (intrinsic to the muscle) adaptations to aerobic exercise training in persons with FM.

Self-Management Programs

A common approach for managing chronic conditions is to place the control of the health care in the hands of the person with the condition, in other words self-management. In self-management, the subject is not a passive recipient of information, but an active participant collaborating with health care professionals to achieve optimal treatment. The goal for the client is not just to receive information, but also to perform new health promoting behaviours (52). Self-management involves a continual process of making behavioural choices and decisions in his/her environment (53).

Theoretical Framework of Self-Management Programs

The theoretical basis of the self-management program, including the programs in the current study, is Bandura's Self-Efficacy Theory (52, 54). Self-efficacy is defined as the belief that one is capable or not capable of performing a specific behaviour or a set of behaviours (55). It does not refer to the actual skills the person has, but rather with the belief of what he/she can do with the skills he/she possess. Self-efficacy influences all aspects of behaviour, including the

acquisition of new and the inhibition of existing behaviours. In addition, self-efficacy beliefs affect the choice of behavioural settings, the effort expended on tasks and the emotional reactions to these tasks.

There are three components to the theory. First, self-efficacy expectancies are the person's belief in his/her ability to perform a particular behaviour (situation specific). These beliefs vary on three dimensions: level or magnitude (simple to difficult tasks), strength (weak to strong beliefs) and generality (situation specific or transferable to other situations). The second component is outcome expectancy. This is the belief that a particular behaviour will or will not lead to a given outcome. The third component is outcome value. This was not part of the original self-efficacy theory and was a proposed addition by several researchers (56, 57). This component examines the importance of the outcome for the subject. The change and maintenance of behaviours is a function of these components (55).

Efficacy expectations are learned or determined from six sources (55). The first is performance accomplishments. This refers to the mastery of a task and the increased self-efficacy that accompanies it. The second source is vicarious experience. This refers to observing events or people and then modeling the observed behaviour. The third determinant of self-efficacy is imaginal experiences. Beliefs about personal efficacy or inefficacy can be created by people imagining themselves performing a behaviour successfully or unsuccessfully. The fourth source is verbal persuasion, which essentially is the attempt to encourage or persuade the person to change their behaviour. The fifth source is the physiological state of the person. This influences self-efficacy when aversive physiological arousal is associated with poor behavioural performance and perceived failure. The final source is the emotional state of the person. Self-efficacy is influenced by the person's mood and level of anxiety or depression.

At the centre of self-efficacy theory is the sense of personal control or mastery (personal efficacy) that is essential for psychological wellness and behavioural effectiveness (58). Self-efficacy theory maintains that all processes

of psychological and behavioural change operate through the alteration of an individual's sense of mastery or self-efficacy in specific situations (55). Since the goal behind self-management programs is to place the person in charge of his/her own health, enhancing self-efficacy appears to be the most effective means to achieve this goal. Self-efficacy is instrumental in altering psychological and behavioural action to bring about an enhanced quality of life.

It has been demonstrated that self-efficacy plays a key role in the perception and management of different types of chronic conditions. Self-efficacy was associated negatively with disability, symptoms (i.e. pain) in persons with chronic pain, rheumatoid arthritis and FM (59-62). Self-efficacy belief for scheduling time to exercise was a significant predictor of adoption of exercise in sedentary men and women (63). Moreover, self-efficacy beliefs for overcoming barriers and scheduling were significant predictors of the intention to exercise in novice women exercisers (64).

Research in various populations has demonstrated that after an education program the enhancement of self-efficacy beliefs were related to changes in positive health behaviours and well-being. A change in self-efficacy after self-management education programs was also related to a positive change in pain levels, number of exercise sessions and other activities to improve self-management skills in persons with arthritis (65, 66). Smarr et al (67) also reported a strong association between changes in self-efficacy and changes in other clinical measures in persons with rheumatoid arthritis. Furthermore, the enhancement of self-efficacy was related to a decrease in pain at 15 months follow-up (67). In persons with low back pain, a self-management program was efficacious in reducing worry, creating positive attitudes towards self-care and decreasing limitations with activities compared to a control group (68). An increase on a measure of self-efficacy after an education program in persons with low back pain also predicted the maintenance of improved functioning and decreased self-reported pain levels at 6 month follow-up (69). In persons with FM, a significant relationship between self-efficacy for physical functioning, pain

and symptom management and pain behaviours was reported (70). Moreover, self-efficacy was predictive of a positive treatment outcome in the same population.

Summary of Introduction

FM is a challenging condition to treat due to the lack of clear pathology, the unknown cause and the variety of treatment responses in this population. Moreover, it has a significant impact upon quality of life. FM affects not only the persons with the condition, but also their family and friends. Research has demonstrated that aerobic exercise improves their fitness levels and does not exacerbate their symptoms, although the changes with psychosocial measures are less consistent. There is uncertainty regarding the association between a change in physical fitness and improvements in psychosocial or functional measures. Current management of FM includes education and exercise programs. It has not been determined if it is the exercise or education component of the treatment programs that is crucial for eliciting changes in persons with FM. Perhaps it is the combination of both that creates the greatest enhancements that are maintained over the longer duration. A partial explanation for the limited success of various interventions is the heterogeneity of FM. Treatment may need to be designed for the subgroups of persons with FM. Identification of characteristics of persons with FM who are most likely to achieve success after an intervention would be beneficial in order to optimize treatment resources.

Statement of Purpose

The purpose of this study was to examine the management of FM using aerobic exercise and an education program. More specifically, the purpose is to differentiate which component, either exercise or education, or the combination of the two, would demonstrate the greatest improvements in measures of self-efficacy, disability, life satisfaction, fitness or pain.

Primary Hypotheses

1. It was hypothesized that any of the three interventions would be more efficacious than no intervention in managing FM.
2. It was hypothesized that a combination of aerobic exercise and a self-management education program would be more efficacious in the management of FM than either exercise or education alone.
3. It was hypothesized that the three intervention groups would all demonstrate an improvement in the self-efficacy measure compared to the control group. The groups involving exercise would demonstrate an improvement on disability, fitness and TP assessment. The groups involving education would demonstrate a decrease in disability scores. Since the control group was not receiving a specific intervention, no change in self-efficacy was anticipated; therefore the other measures would not change (see Figure 1.1).

   Specifically the groups would respond as follows:

Exercise only. Persons in the exercise only group would influence self-efficacy directly by means of performing the aerobic exercise, modeling of other FM participants, verbal persuasion/encouragement from the group leaders and experiencing positive physiological and emotional states. Impact of the condition would be influenced directly by exercise or be mediated through self-efficacy. Fitness levels would increase directly, due to the exercise program. Self-efficacy may contribute to the continuation of exercise by means of the positive experiences, modeling and verbal persuasion. The pain severity of the TPs would also improve directly due to the exercise. The decreased disability and pain severity and increased fitness levels may in turn influence each other. The final result would be an increase in life satisfaction.

Education only. Persons in the education only group would influence self-efficacy by means of modeling other FM participants, verbal persuasion/encouragement from the group leaders, mental imagery exercises

and perhaps experiencing positive emotional states. The enhanced self-efficacy would decrease disability. In addition, education would have a direct impact on decreasing the disability of FM due to information and coping strategies provided in the sessions. Fitness levels and TP assessment would not significantly change, but may be influenced by the decreased impact of FM. These changes would lead to an increase in life satisfaction.

Exercise and Education. Persons in the exercise and education group would influence self-efficacy by the same means as the other two groups, but the improvement would be maintained for a longer period due to the combined content. For example, the subjects not only learn about the health and psychological benefits of exercise they also participate in an actual exercise program, thereby reinforcing the behaviour. This would result in an even greater decrease in the impact of FM resulting in a greater change in life satisfaction than either exercise or education alone. The change in number of TPs and pain severity at the TPs would not be any greater than for exercise only, since no change is anticipated with the education group.

Secondary Hypotheses

1. Improvements in peak and submaximal physiological measures would occur after an aerobic exercise training program. No physiological changes would occur in the groups not receiving aerobic exercise. In addition, improvements in psychosocial and functional variables would occur in the intervention groups. Finally, the physiological improvements would be associated with the changes in psychosocial and functional variables.
2. Variables that predict success from a FM treatment program would be identified from baseline sociodemographic and psychosocial measures. It was hypothesized that subjects who were younger, had shorter duration of symptoms, had higher education, were married, were not undergoing litigation, were receiving compensation, had low fear-avoidance beliefs and

were coping well with FM would improve after an intervention designed for persons with FM.

This thesis was written in paper format and involves a study conducted during 1997-1999. The following six papers are derived from that study. Each paper contributes unique information to the FM literature. The first three papers use baseline data to examine the measurement of physical fitness in persons with FM (a field test and a direct measure) and to delineate subgroups of persons with FM and their differential responses to various psychosocial and functional measures. The remaining three papers directly address the study hypotheses. The general purpose of each paper is provided below.

Paper 1 Validity and Reliability of the Six Minute Walk in Persons with FM

Despite the adoption of the six minute walk (6MW) as a measure of fitness and/or function (21, 25, 26), there has been little testing of the psychometric properties of it for persons with FM (51). Additionally, most studies have used only one walk as the baseline measure to make comparisons. Research from the cardiopulmonary field (49, 50) suggested that the first walk may not be a reliable baseline measure because the distance increases from time 1 to 3 and then plateaus on the remaining walks. There has been no validation of the 6MW against a disease-specific functional measure for FM. The validity of the 6MW has not been previously determined with respect to a direct measure of fitness or a measure of function. It is expected that if the 6MW is a valid measure of fitness, it should be highly correlated with other measures of fitness and moderately correlated with measures of function.

Purpose:

1) To determine the construct validity of the 6MW by examining its correlation with peak oxygen consumption, and disability/impact of FM,

2) To determine the reliability of the 6MW.

Paper 2 Cardiac Output and Arteriovenous Oxygen Difference in Women with FM

It is well established that persons with FM have low peak or maximal oxygen consumption (VO_2) (71). However, van Denderen et al (72) reported that their heart rates (HR) were lower than sedentary controls for a given VO_2. This finding normally suggests a higher aerobic fitness level, but only if accompanied by an increase in stroke volume (SV). What is unclear is the reason for this decreased heart rate during submaximal exercise (71-73). Measuring cardiac function (cardiac output, stroke volume) and peripheral extraction of O_2 (arteriovenous oxygen difference) during an acute bout of exercise would assist in determining if there are central or peripheral physiological impairments in persons with FM as compared to healthy persons.

Purpose:

1) To describe the cardiac output, stroke volume and arteriovenous oxygen difference of FM subjects during submaximal exercise,
2) To compare the current results from persons with FM to data previously obtained in healthy samples.

Paper 3 Characteristics of Persons with FM Classified According to the Multidimensional Pain Inventory

Studies evaluating the effectiveness of treatments for FM have demonstrated only modest success. A possible explanation is that these interventions have examined persons with FM as a homogenous group, when really they should be treated as a more diverse group. Turk et al (23) reported that 87% of FM patients could be classified into one of the three main groups of the West Haven-Yale Multidimensional Pain Inventory (MPI). They also reported that patients grouped as Dysfunctional or Interpersonally Distressed had higher levels of pain, disability and depression than the Adaptive Copers.

Purpose:

1) To compare persons with FM grouped according to their scores on the West Haven-Yale Multidimensional Pain Inventory (MPI) on measures commonly used and validated in a FM population,
2) To determine if the construct, fear-avoidance, can distinguish the MPI groups and if pain related fear of physical activity and work should be further explored in the FM population.

Paper 4 The Effects of Exercise and Education, Individually or Combined, in Women with FM

Previous studies have examined the efficacy of exercise, and education and exercise, sometimes with or without a control group, in managing the symptoms of FM. What has not been determined is which component, either exercise or education or the combination of both, is most beneficial or essential for managing the condition.

Purpose:

1) To compare the effects of exercise, education, and a combination of exercise and education for persons with FM on measures of disability, self-efficacy, fitness, pain severity and life satisfaction.

Paper 5 Relationship Between Changes in Physiological and Psychosocial Variables in Persons with FM

Aerobic exercise has been recommended as part of a treatment program for persons with FM. Previous studies have determined that persons with FM have low peak oxygen consumption, which increases after an aerobic exercise program. In addition, pain severity and physical function appear to improve for some persons with FM. What has not been determined is whether an improvement in the physiological measures relates to improvements in measures of disability, self-efficacy or life satisfaction.

Purpose:

1) To evaluate changes in physiological response to exercise and determine if adaptations in central or peripheral factors occur after a training program,
2) To examine correlations between physiological changes and changes in disability, self-efficacy, quality of life, tender points and fitness.

Paper 6 **Predictors of Outcome Success in a Supervised Aerobic Exercise Program in Persons with FM**

The treatment success of persons with FM is variable and it is unknown what factors contribute to a favorable outcome. Identifying sociodemographic, psychological and behavioural characteristics of persons with FM that may predict a positive response to treatment on a variety of measures would be clinically useful. It has been reported that there are sub-groups of persons with FM that differ on their response to pain, response of significant others to their pain and their general activity level. However, it is not known whether this group assignment or other characteristics of persons with FM can predict response to an intervention program.

Purpose:

1) To determine the variables that will predict successful outcome in an aerobic exercise and/or education program for persons with FM.

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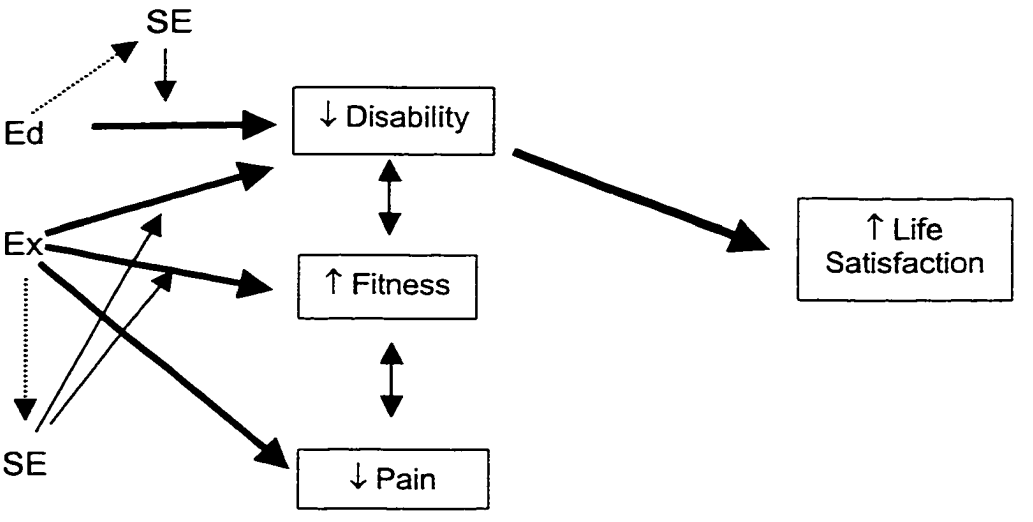

Figure 1.1. Overall model of management of FM hypothesized in current study. SE = self-efficacy, Ex = exercise and Ed = education. The arrows from SE to the larger arrows suggest that SE can influence the effect of Ex and Ed on outcome.

CHAPTER 2

Validity and Reliability of the Six Minute Walk in Persons with FM*

The Six Minute Walk (6MW) has been adopted by fibromyalgia (FM) researchers to assess fitness and function(1-5). However, its reliability and validity have not been adequately studied in this population. It is currently unknown whether the 6MW relates to other measures of function or fitness, in a population with FM, or if it even provides unique information that cannot be obtained through other means, such as a questionnaire.

The 6MW originated from Cooper (6), who developed a 12 minute walk/run test on young (mean age 22 years) healthy males. He was able to correlate the distance traveled with maximal oxygen consumption (VO_2max) and even created a table of estimated VO_2 values for a range of distances covered in 12 minutes. Butland et al (7) investigated walks of shorter duration to assess the exercise tolerance of patients with respiratory disease. They found high correlations (range 0.86-0.96) among the distances walked at 2, 6 and 12 minutes. From these results it was concluded that all 3 walk durations were measuring exercise tolerance, although no correlation with an actual measure of fitness was undertaken. The 6-minute test was chosen as the standard for cardiorespiratory patients because it was better able to discriminate among subjects (7) and was more responsive (8) than the 2-minute walk.

Much of the work on validity and reliability of the 6MW has been performed on cardiopulmonary patients (9-11). Guyatt and colleagues(8,12,13) found that when the 6MW was repeated, there was an increase in the distance covered from the first to third walks. They recommended that 2 practice walks be undertaken before the baseline measure to ensure reliability (8,12). They (8) also determined that performance improved when encouragement was provided at set intervals. Validity of the 6MW has been studied by examining its relationship with function and fitness measures. The correlation between 6MW distance and

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functional classification was fair for cardiac patients (r=-0.45), (12) but very low for pulmonary patients (14). Fair to moderate correlations have been reported between 6MW and maximum workload on a cycle ergometer in cardiac and respiratory patients (r=0.42 and r=0.57) (12). The correlation with a fitness measure, peak VO_2, in heart failure patients was greater (r=0.64) (10).

There has been little testing of the psychometric properties of the 6MW for patients with FM (3). The distance covered in a 12 minute walk has been correlated with VO_2max (r=0.64) and the Health Assessment Questionnaire (HAQ) (r=-0.48) in a mixed rheumatic disease sample that included persons with FM (5,15). After a 12 week interval, the 6MW was repeated in 12 persons with FM who had not changed their physical activity (5). The correlation was r= 0.78, but there was no report of the amount of change that occurred from time 1 to time 2 or whether it was a systematic change. Because of the time between tests, a large proportion of the variability could be due to real changes in the subjects rather than measurement error. There has been no validation of the 6MW against a disease-specific functional measure for FM.

The purpose of this study was to assess the reliability and construct validity of the 6MW in persons with FM and to determine an equation for predicting peak oxygen consumption (pVO_2) from the distance covered in 6 minutes.

MATERIALS AND METHODS

Subjects

Subjects were women who met the American College of Rheumatology criteria for FM (16). Each subject provided written informed consent. Exclusion criteria included any condition precluding the ability to exercise (i.e. severe cardiac arrhythmia, dizziness, severe shortness of breath). Persons with a systemic arthritis such as lupus or rheumatoid arthritis were also excluded. See Table 1 for subject characteristics.

Design

Ninety-six subjects, who were involved in a larger study, completed the 6MW and the FM Impact Questionnaire (FIQ). Within one week, a sub-group of 23 subjects who volunteered returned for the pVO_2 treadmill test. Validity was examined by determining the correlation of 6MW with measures of function (FIQ) and aerobic fitness (pVO_2). To determine reliability, 12 subjects from a hospital outpatient program repeated the walk 5 times over a 10 day period.

Testing

The 6MW protocol was identical for all subjects. The walk was completed along a 40 metre pre-measured unobstructed corridor. There was no warm-up included. The subjects were instructed to cover as much ground as they could in six minutes. Encouragement such as "good pace, keep it up" or "good work" was given at 2, 3, 4 and 5 minutes. At these same time intervals, the subjects were informed of the time remaining in the walk. Encouragement and time remaining were standardized for all patients. At the completion of the walk, the subjects rated their effort from Borg's scale, Rating of Perceived Exertion (RPE) (17). The distance the subjects walked was then measured and recorded. Each subject wore a heart rate monitor (Polar Accurex Plus HRM). The mean heart rate was obtained during two minutes of sitting rest and then during the walk. Rating of Perceived Exertion and HR were recorded as possible predictors of pVO_2 with the 6MW.

The FIQ was used for the measure of function. It is a brief questionnaire measuring physical function, work status, depression, anxiety, sleep, pain, stiffness, fatigue and well being. The FIQ has been correlated with the Arthritis Impact Measurement Scale (AIMS) lower extremity physical functioning scale to demonstrate construct validity (18). Both the total score and the physical disability subscale score of the FIQ were used in the analysis. The FIQ was scored according to the author's instructions (18).

For a measure of physical fitness, a pVO_2 test was used. The protocol was a symptom-limited treadmill test with the subject walking at a self-selected pace. The treadmill test was done only once. A brief practice period (1-2 minutes) was

included if the subject had never walked on a treadmill before. Once the subject was walking at a comfortable pace, the grade of the treadmill was increased by two percent every two minutes until she could no longer continue because of symptoms or exhaustion. Cardiorespiratory and metabolic measurements were continuously monitored using an automatic metabolic measurement cart (MMC 2900 Sensormedics Corporation, CA). The metabolic cart was calibrated using commercially available precision gases prior to and after each test to ensure accuracy of the data. Heart rate and RPE were recorded at the half -way point, to ensure a steady-state had been reached, during the two minute increments. Encouragement was provided throughout the test. The highest VO_2 achieved was used to calculate pVO_2 (ml/kg/min and ml/min).

Analysis

The reliability of the 6MW was analyzed with an Intraclass Correlation Coefficient (ICC) (1,1) determined from a repeated measures one way Analysis of Variance (ANOVA) of the five 6MW tests. Repeated measures ANOVAs were also run on the means for the HR and RPE to determine if these variables changed over the five walks. Newman-Keuls post hoc analyses were used to locate differences when the ANOVAs were significant ($p<.05$). To examine validity, pVO_2, FIQ Total and FIQ-Physical Disability were correlated with the 6MW distance using the Pearson Product Moment Correlation. Significance level for all tests was set at $p\leq.05$. Variables entered into a step-wise regression equation to predict pVO_2 were age, walking heart rate, body mass index (BMI) and 6MW distance. Step-wise regression analysis was performed using SPSS Statistical package version 8.0 and the default criteria (significance of $p<.05$ for entry and $p>.1$ for removal).

It was hypothesized that the distance covered during the 6 minutes would increase from Walk 1 to 3, but would level off at Walk 4 to 5, as seen in the cardiopulmonary field (8,12,13). The 6MW was expected to have a moderate to high correlation with measures of fitness, but a lower correlation with measures of function.

RESULTS

Reliability

Table 2.2 shows the means and standard deviations (SD) of all 5 walks. Analysis of Variance revealed a significant difference across time (F=8.45, p=.000). The post hoc analysis indicated that the difference was between Walk 1 and the remaining 4 walks. No significant difference was found among the last 4 walks (F-1.90, p=.148). For Walks 1 to 5, the ICC was 0.733, and for Walks 2 to 5, 0.885. The correlation between the first and second walks was r=0.72. The predictive equation determined from regression analysis was: Walk 2 Distance = 329.59 + 0.45 x Walk 1 distance (m).

The HR and RPE for each walk are provided in Table 2.2. ANOVA revealed a significant difference (F=4.40, p=.005) across trials for the HR data, but not the RPE data (F=1.59, p=.195). Again, the post hoc analysis located the difference between Walk 1 and the remaining 4 walks.

Validity

The means and standard deviations for pVO_2, 6MW and FIQ and the correlations between the 6MW and measures of physical fitness and function are reported in Table 2.3. Low correlations were found with the 6MW and measures of function, while moderate correlations were found between the 6MW and pVO_2. The Pearson Product Moment Correlation between the FIQ total score and RPE for the 96 subjects was r=.306 (p=.046). Correlations of the variables considered for the regression equation are in Table 2.4. Since HR and age were not significantly correlated with pVO_2, only BMI and 6MW distance met the criteria for entry into the regression equation to predict pVO_2. Figure 2.1 demonstrates the plot of the actual versus predicted pVO_2. The regression equation for predicting pVO_2 from BMI and distance was: $pVO_2 = 21.48 + (-.4316 \times BMI) + [.0304 \times distance(m)]$.

DISCUSSION

Reliability

Although there were only 12 subjects in the reliability study, the results indicated that the first walk may not be a stable baseline measure and that one practice walk should be undertaken before the actual distance is recorded. Previous research on cardiorespiratory patients demonstrated that the distance increases from the first to the third walk and then plateaus from the third walk to the fifth (12). Due to this increase, Guyatt (8) recommended that 2 walks be undertaken and if a 10% increase occurs between the first and second walk then a third walk should be done and used as the baseline measure. Although our results suggest that only one practice walk is necessary with persons with FM, our conclusion regarding the first walk as an unstable baseline measure concurs with Guyatt's work.

It is unclear whether this same pattern of change in distance across trials exists when the walk is repeated weeks or months later. Must subjects refamiliarize themselves with the test, therefore demonstrating this pattern, or is the distance traveled during the first walk the same as any immediate subsequent walks? Burckhardt et al (5) did report the test-retest reliability of the 12 minute walk in persons with FM, but the walk was performed only once at the beginning and once at the end of the 12 week period. Their reliability coefficient (r=0.78) was similar to the ICC found in this study for Walks 1-5.

An interesting finding was that the HR, but not the RPE, followed the same pattern as the distance with a significant increase from Walk 1 to Walk 2. The subjects performed more work in 6 minutes during times 2-5 than during time 1. Therefore, it would be expected that an increase in HR would reflect this increase in exercise intensity. Since RPE is a subjective measure, perhaps subjects' stress or uncertainty about the test influenced the higher rating of exertion (relative to the HR and exercise intensity) in session one. Alternatively, the RPE scale may not be sensitive enough to detect an increase in exertion in this population.

In a clinical setting, repeating the 6MW may be difficult, due to time constraints. The development of a predictive equation to determine the distance for the second walk would be beneficial. The development of a predictive equation to determine the distance for the second walk would be beneficial. In the present study, such an equation only predicted 52% of the variance. Perhaps another approach would be to identify the subjects whose 6MW might change in subsequent tests. An observation from the present study was that subjects (n=3) who walked very short distances (less than 350 m) on the first walk demonstrated an increase of over 100 m on subsequent walks. Further study is required to determine if such a distance cut-off could be used to discriminate reliable and unreliable results.

Validity

The correlations between the 6MW and the FIQ (total score and physical disability subscale) were very low, indicating that the 6MW cannot replace the FIQ as a measure of physical function. Moderate correlations were found with the pVO_2 test, indicating that the 6MW can evaluate some aspect of aerobic fitness in a clinical setting, but should not replace measures of oxygen consumption. Perhaps the differences between the function and fitness correlations with the 6MW are due to the fact that the measure of function (FIQ total and disability) is subjective. Both the 6MW and pVO_2 tests are objective measures of fitness, resulting in a stronger relationship between them. In addition, the correlation may be lower since function is only partially determined by physical abilities. For instance, psychosocial factors play a role in determining a person's physical capabilities.

The correlation with pVO_2 in the present study was lower than the correlations reported by Cooper (6) (r=0.90), but similar to results reported for cardiopulmonary and rheumatic disease patients (10,12,15). One of the potential reasons for the differences between healthy subjects and patients may be the difference in exercise mode to test VO_2. Cooper (6) used the treadmill, while most studies involving patients were done on the cycle ergometer. However, in

the present study, treadmill testing was used and the correlations were very close to those found in studies using ergometers. A second reason may be the low fitness level of the study sample and other patient populations. In comparing the pVO_2 results from the present study to a table of physical fitness values for women of similar age (20), the subjects with FM have very low fitness levels. Cooper (6) reported that his predictive equation was better able to estimate VO_2 for the subjects that were more fit. In a study on persons with rheumatoid arthritis and osteoarthritis (19), the correlation between VO_2max and 5 minute walk increased from r=0.71 to r=0.87 when 3 persons were excluded from the analysis. Two of these persons had very low VO_2max values.

For our predictive regression equation, we entered a number of variables, but found only BMI and 6MW distance to significantly predict pVO_2. Cooper's (6) original study predicted maximal oxygen consumption based on the 12-minute walk/run performance only. Cooper (6) also concluded from his research that any change in fitness level was reflected with an obvious change in the distance covered. It would be interesting to follow the FM subjects to determine if this same pattern is evident.

The 6MW can be affected by factors other than just fitness level. The correlation between 6MW and pVO_2 may have been influenced by inconsistent efforts in the 2 tests. This inconsistency may be related to concern about experiencing pain. Many subjects commented that they were hesitant to push themselves for fear of an increase in pain later. Subjects often report that at the time of exertion they feel fine and want to work harder, but experience has taught them that they will be in pain and discomfort later. Although not measured quantitatively, this feeling of hesitation was reported by many of the subjects during the treadmill test, and even the 6MW. The limitations for fitness tests may not be physiological, but rather motivational. A fear avoidance type behaviour may prevent full exertion in some subjects. Subjects with FM have expressed fear of physical activity when recording daily thoughts in journals (21). This observation is consistent with reports from the low back pain literature regarding

avoidance of physical activity due to fear of increased pain and disability (22). Future studies examining fitness in populations with FM might include questions regarding fear of exercise or exertion to further explore the effects of this fear on performance training.

Encouragement is another factor mentioned that can influence the 6MW. Guyatt (8,12,13) demonstrated that when encouragement was given, the distance covered was farther than when no encouragement was provided. As long as encouragement was standardized, it did not affect the reliability of the 6MW, even though variability was greater with encouragement for the 2 minute distance.

At a time when exercise is prescribed for the treatment of FM, the measurement of aerobic fitness or its change is extremely important. For this reason, aerobic fitness should be obtained by the most direct means, that is, by measuring aerobic capacity. In a clinical setting, however, access to advanced technical equipment to measure physiological variables may not be possible. Even if the equipment is accessible, occasions may arise where a patient with compromised physical abilities has no desire or is unable to participate in a maximal physical exertion test. In these instances, the 6MW appears to be an adequate substitute. There needs to be at least one practice walk and the instructions and encouragement must be standardized between and within subjects. Once these criteria have been met, then it can be ascertained that stable baseline measures have been achieved and true comparisons between walks and patients can be made.

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Table 2.1. Subject characteristics (mean ± standard deviation).

CHARACTERISTICS	RELIABILITY	VALIDITY**	
	n=12*	n=96	n=23+
Age (years)	46.3±11.9	46.0 ± 8.7	46.3 ± 9.6
Duration of Symptoms (years)	9.9 ± 9.0	8.9 ± 9.2	10.9 ±12.9
Employment status (%)			
Yes	41.7	45.4	45.5
Disability	16.7	1.1	0
Tender Points (n)	14.8± 4.0	16.4 ± 1.8	16.4 ± 1.8
BMI (kg/m^2)	30.5± 7.5	29.6 ± 7.2	31.4 ± 7.4

* subjects used to determine reliability
**subjects tested for both FIQ and 6MW
+ subset of subjects tested for pVO_2
BMI = Body Mass Index

Table 2.2. Distance, heart rate and rating of perceived exertion for repeated walks (mean ± standard deviation) (n=12).

WALK	Distance (m)	HR (beats/min)	RPE
1	488.8±115.14*	106.8± 17.5*	13.3± 2.1
2	545.9± 81.6	114.9± 11.4	13.3± 2.6
3	550.0± 72.3	112.8± 11.4	13.5± 2.2
4	555.7± 79.6	112.9± 11.5	14.3± 2.5
5	569.6± 82.1	113.5± 10.6	13.9± 2.3

* significantly different from Walks 2-5.

HR=heart rate (average heart rate recorded during the Six Minute Walk)
RPE=rating of perceived exertion

Table 2.3. Correlation of Six Minute Walk distance (6MW) with peak oxygen consumption (pVO_2) and scores of the Fibromyalgia Impact Questionnaire (FIQ). Mean and standard deviation (SD) of each variable included.

Variable	Mean ± SD	Correlation with 6MW
6MW (m)		
n=96	481.1± 94.5	
n=23	456.3± 116.4	
Peak VO_2 (n=23)		
(ml/min)	1727.1± 459.3	0.628 (p=.001)
(ml/kg/min)	21.8± 7.6	0.657 (p=.001)
FIQ-Total		
n=96	53.5± 12.8	-0.325 (p=.001)
n=23	53.4± 9.7	
FIQ-Physical Disabilities		
n=96	1.3± 0.6	-0.187 (p=.068)
n=23	1.2± 0.5	

Table 2.4. Correlations of variables considered for regression equation (n=23).

	6MW*	Age	HR	BMI*
Age	-.044 p=.843			
HR	388 p=.068	-.464 p=.026		
BMI	-.452 p=.030	.107 p=.628	.024 p=.914	
pVO_2	.657 p=.001	-.066 p=.764	.178 p=.418	-.631 p=.001

*criteria for entry and removal were met.

HR=heart rate

BMI=body mass index

pVO_2 =peak oxygen consumption

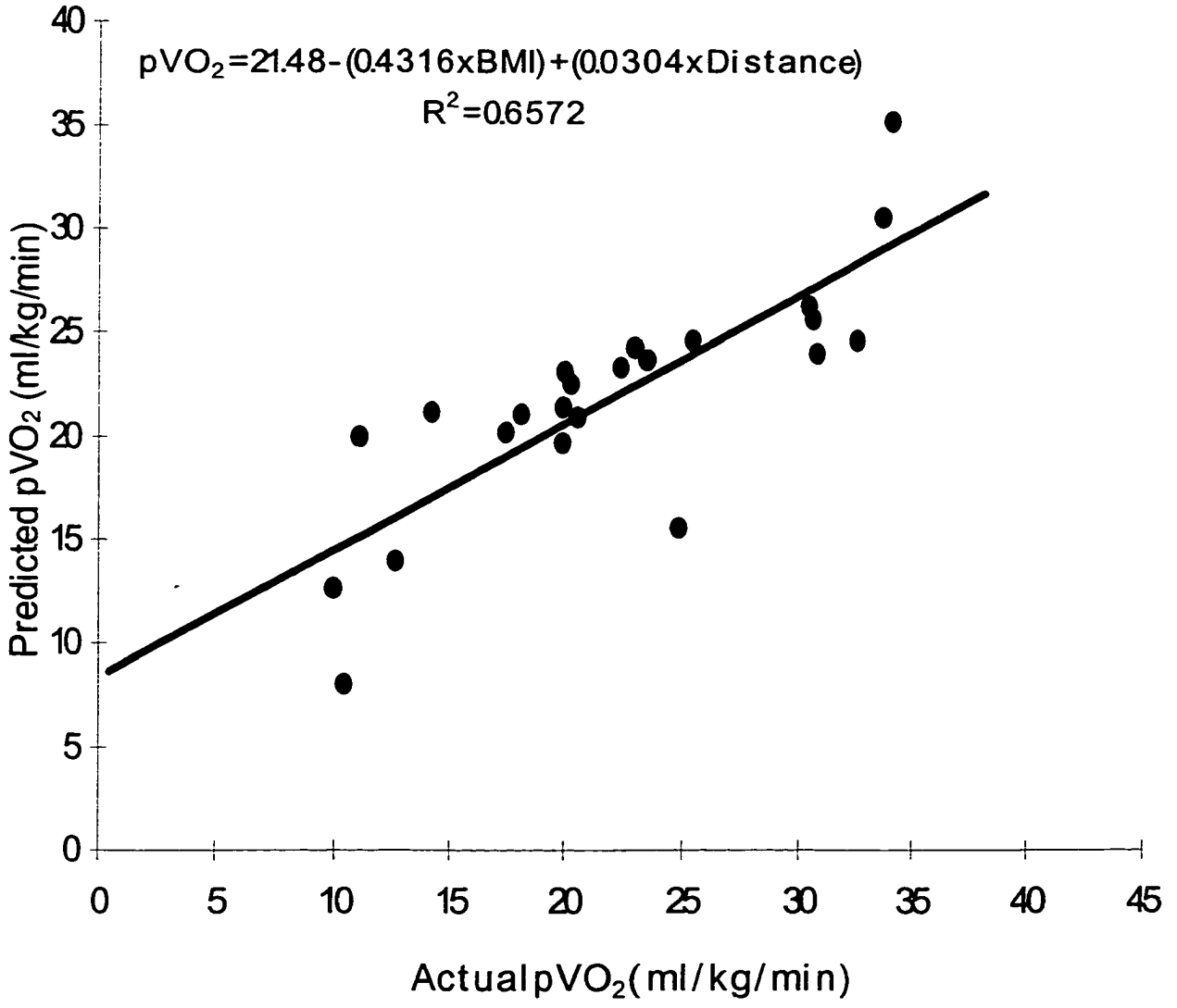

Figure 2.1. Correlation of actual peak oxygen consumption (ml/kg/min) values versus predicted peak oxygen consumption values (Adjusted R^2=.566, Standard Error of the Estimate=5.31, Six Minute Walk β=.469. and Body Mass Index β=-.485).

CHAPTER 3

Cardiac Output and Arteriovenous Oxygen Difference in Women with FM*

FM is a condition of chronic widespread pain predominately affecting women. Persons with FM experience extreme fatigue and muscle stiffness, among other symptoms (1). They also have low aerobic fitness levels (2-5), which may be due to deconditioning and/or some aspect of the disease process (e.g. an abnormal physiological response to exercise).

The lower maximal oxygen consumption (VO_2) in persons with FM has been documented previously (4,5). Van Denderen (6) has also reported that their heart rates (HR) are lower than sedentary controls for a given workload. However, their oxygen (O_2) consumption increased with increasing intensity of exercise in a manner similar to that of healthy sedentary subjects (5). If persons with FM have 'normal' O_2 consumption rates during exercise, in spite of lower HRs, then they must also have a proportionally greater stroke volume (SV) or greater arterio-venous O_2 difference [(a-v)O_2 diff] (peripheral extraction of O_2) compared to healthy sedentary subjects. To date, cardiac output (Q), SV and (a-v)O_2 diff have not been measured in FM subjects during exercise. Since O_2 consumption is determined by Q (product of HR and SV) and extraction of O_2 by active muscle [(a-v)O_2 diff] (Fick equation), determining these components of VO_2 is important to fully understand the cardiovascular and metabolic characteristics of persons with FM.

The equipment to determine Q is quite specialized, and the protocol is often difficult to tolerate for some subjects since the spontaneous ventilation is interrupted momentarily. For these reasons, a simpler method to determine SV, in order to calculate Q, is desirable. One such method for estimation is by calculating O_2 pulse. Oxygen pulse, calculated by VO_2/HR, represents the amount of O_2 extracted by the tissues of the body from the O_2 carried in each SV (7). A high O_2 pulse demonstrates efficient cardiorespiratory function. Previous

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research has demonstrated that SV can be estimated from O_2 pulse (8,9). In addition, regression equations for estimating SV and (a-v)O_2 diff have been developed from O_2 pulse for healthy women (9). Determining if the same O_2 pulse, SV and (a-v)O_2 diff relationship exists for persons with FM would eliminate the necessity of performing a test that is stressful for them. In addition, this information would allow for more complete analysis of the integrity of their cardiovascular system.

The purposes of this study were to: 1) describe the peak physiological responses during symptom limited treadmill exercise in women with FM; 2) describe Q, SV and (a-v)O_2 diff during submaximal exercise in this population; 3) determine whether O_2 pulse can predict SV and (a-v)O_2 diff.

MATERIALS AND METHODS

Subjects

Thirty-six women with a diagnosis of FM, according to the American College of Rheumatology criteria (1), provided written informed consent and volunteered to undergo physiological testing. Subject characteristics are reported in Table 3.1. The subjects used the following medications: anti-depressant (60%), non-steroidal anti-inflammatory/analgesic (40%) and thyroid replacement (40%). Exclusion criteria were any musculoskeletal or cardiopulmonary disorders that precluded the ability to exercise. The University of Alberta Faculty of Rehabilitation Medicine Ethics Committee approved the procedures undertaken in this study.

Design

This was a descriptive study of baseline physiological data from women who were part of a larger FM exercise study. All women were tested on one occasion for physiological responses during a continuous treadmill test. Because the larger study did not include other chronic pain or healthy control groups, comparisons were made with physiological values from the literature for healthy sedentary women of similar age.

Testing

To determine submaximal Q and the peak VO_2 (pVO_2), subjects performed an incremental treadmill test. Cardiorespiratory and metabolic measurements were continuously monitored using an automated metabolic measurement cart (MMC 2900, Sensormedics Corporation, CA). The metabolic cart was calibrated using commercially available precision gases (16% O_2, 4% CO_2, balance N_2, and 26% O_2, balance N_2) prior to and after each test to ensure accuracy of the data. The software used was the Advanced Exercise Testing Program (Sensormedics Corporation, California). Heart rate was recorded using a wireless monitor (Polar Accurex Plus HRM, Washington).

The subjects walked at a self-selected pace on the treadmill, and once the VO_2 values reached a steady state (i.e. VO_2 did not fluctuate more than 100ml/min), the re-breathing maneuver was initiated. Steady state for the re-breathing was usually achieved within 3-5 minutes from beginning the treadmill walk. After completion of the CO_2 re-breathing maneuver, the treadmill grade was increased by 2% every 2 minutes. Heart rate and Borg's rating of perceived exertion (10) were recorded during the last 30 seconds of the 2-minute increments. The test was terminated once the subjects determined they could not tolerate the pain or fatigue any longer. The subjects were encouraged to put as much effort into the walk as they possibly could. The highest VO_2 achieved over a 20 second interval was considered the pVO_2 (ml/kg/min and L/min).

Typically, the criteria to determine if maximal VO_2 is achieved are 1) plateau of VO_2 with increasing treadmill grade; 2) respiratory exchange ratio $\geq$ 1.10; and 3) age predicted HR maximum (HRmax) [calculated as 220 minus age in years] (11). The generally accepted rating of perceived exertion criterion is 18 to 20 for true maximal exercise responses in healthy subjects (10). The above criteria were not used to terminate the test due to the potential of significant stress on the subjects. However, the authors did examine the number of subjects that did meet the criteria.

The Collier CO_2 re-breathing technique (12) was used to measure Q during submaximal exercise. It is an indirect, noninvasive measure that is highly

correlated (r=0.94) with direct measurements of Q using the direct Fick equation (13,14). The test-retest reliability coefficient for the CO_2 re-breathing maneuver in this laboratory has been previously determined to be 0.89 in healthy males (15). The re-breathing technique utilizes the following assumptions as outlined in Jones (16): 1) an arterial pH of 7.4 and hemoglobin concentration of 13.9g/100ml; 2) arterial and venous O_2 saturation levels of 95% and 100%, respectively during re-breathing; and 3) conversion of the arterial and venous CO_2 pressures (PCO_2) into concentrations using the equation: $\log_c$ concentration $CO_2 = (0.396 \times \log_c PCO_2) + 2.38$.

The CO_2 re-breathing maneuver involves the subjects taking quick, deep breaths for approximately 12-15 seconds into a 5 litre anaesthesia bag containing premixed levels of either 8% or 11% CO_2 and balance O_2 until an equilibrium is achieved between the gas in the lungs and the bag. The gas concentration is based on the VO_2 and end-tidal CO_2 criteria available in Jones (16). The end-tidal CO_2 tension is considered to be reflective of arterial CO_2 pressure, whereas the bag CO_2 is assumed to be indicative of venous CO_2 pressure. A 'downstream' correction factor is applied to increase the validity of the latter assumption. The computer program assumes equilibrium of pressure of CO_2 between the bag and the lungs when there is less than 1 mm Hg pressure over a 5 second interval. The value of Q is determined from the average of the two VCO_2 values obtained immediately before the re-breathing maneuver and the estimated difference in the venous and arterial CO_2 concentrations under steady-state exercise conditions values (indirect Fick equation). All the subjects were able to perform the CO_2 re-breathing maneuver, but in some cases they experienced difficulty while breathing out of the bag. In instances where this occurred, the subject was asked to repeat the maneuver after a sufficient wash out period.

Analysis

The following variables were calculated: SV (ml/beat) = Q/HR; $(a\text{-}v)O_2$ diff (ml/100ml of blood) = VO_2(ml/min)/Q; and O_2 pulse (ml/beat)=VO_2(ml/min)/HR.

Means and standard deviations were determined for Q, pVO_2, HR, SV, $(a\text{-}v)O_2$ diff and O_2 pulse. Pearson Product Moment correlations were used to examine the relationship of O_2 pulse with SV and $(a\text{-}v)O_2$ diff. Regression equations to predict SV and $(a\text{-}v)O_2$ diff from O_2 pulse were also determined using the forced-entry regression analysis (SPSS statistical package 8.0) (significance of $p<.05$ for entry and $p>.1$ for removal).

Additional variables were recorded or calculated to indicate intensity of exercise during testing. These included ventilation, ventilatory equivalent for O_2, and Respiratory Exchange Ratio.

RESULTS

The peak physiological responses of the subjects are presented in Table 3.2. The average self-selected treadmill walking pace was 2.01±0.85 mph. The majority of the subjects did not meet the maximal VO_2 criteria. The age predicted HRmax and the percentage of age predicted HRmax achieved were determined for each subject. The achieved peak HR values corresponded to 82% of the subjects' age predicted HRmax (mean 173.2±9.4beats/min), and only 6 met the criteria for HRmax. Only 6 subjects had an Respiratory Exchange Ratio > 1.1, and these subjects failed to reach a plateau in their VO_2. In addition, only 11 of the 36 subjects reported an rating of perceived exertion > 17 at their peak exercise.

The submaximal physiological responses are reported in Table 3.3. The VO_2 and HR during the physiological steady state at the self-selected walking velocity corresponded to 54% and 77% of the FM subjects' respective peak values observed during the symptom-limited test. The rating of perceived exertion was 13.4, which corresponded to "somewhat hard" on the rating of perceived exertion scale. Data from a study on healthy sedentary women are included for comparison (17). Although the age (range of 17-40 years) and weight (range of 53.1-57.7 kg) did not match exactly, the study by Miles et al (17) was selected because they reported submaximal values for Q (obtained using a CO_2 re-breathing maneuver), SV and $(a\text{-}v)O_2$ diff, as well as the metabolic

values. In addition, the subjects were predominately sedentary women tested on a treadmill.

Figures 3.1 and 3.2 illustrate the significant relationships of O_2 pulse with the SV and (a-v)O_2 diff. The O_2 pulse was more closely related to the (a-v)O_2 diff ($r=0.76$, $p=0.000$) than to the stroke volume ($r=0.49$, $p=0.002$).

DISCUSSION

The peak physiological responses of the women in this study are consistent with values reported by others (4,5) for FM subjects, but lower than those reported for healthy sedentary women (9,17-21). For persons with FM, Bennett et al (4) and Sietsema et al (5) reported pVO_2 mean values of 21.5±1.1 and 21.1±8.9 ml/kg/min respectively during cycling. Their subjects also did not reach their age predicted HRmax. Bennett et al (4) reported a peak HR of 91% HRmax and Sietsema et al (5) reported a range of 60-95% HRmax. To illustrate the differences between the peak physiological values of women with and without FM, Table 3.4 includes results from studies of healthy women (9,17-21). As can be seen in the table, healthy sedentary women have higher pVO_2 values and tend to achieve peak HR very close to their age-predicted maximum. The acceptable range for determining if HRmax has been achieved is a HR within ±10 beats of the age predicted maximum (7). The low peak HR results obtained by the FM subjects would suggest that their pVO_2 was low because they did not exercise to their physiological maximum.

Failure to achieve age predicted HRmax values may have been due to the onset of symptoms or a fear of later symptoms, since symptoms rather than physiological measures were used to terminate the test session. Reasons for stopping the test ranged from increased fatigue, knee or hip pain to a 'dry mouth' or 'sore jaw'. Once the slightest discomfort was experienced, some subjects stated they terminated the test for fear of aggravating their symptoms. Sietsema et al (5) reported that 3 of their 14 subjects terminated the test early in case their symptoms increased. In addition, many of their subjects commented on their unwillingness to exert a maximal effort due to the pain they would or may

experience after the test. A practice session may have eliminated early termination due to minor discomfort, such as a dry mouth, because they would have been more familiar with the equipment. However, a practice session may also have resulted in high dropouts since some subjects did report an increase in symptoms for a few days to a few weeks following the test. For persons with FM, the fear of aggravating their symptoms may result in avoidance of any form of physical exertion.

Body weight was another factor contributing to the lower relative pVO_2 values in the FM group compared to the healthy women. Based on body mass index values from Stone (22), 75% of the subjects from the current study could be classified as mildly (n=14, 25-30 kg/m^2), moderately (n=5, 30-35 kg/m^2) or severely (n=8, > 35 kg/m^2) obese. The absolute VO_2 (L/min) values of the FM subjects and the healthy comparison groups in Table 3.4 are similar. However, the relative VO_2 (ml/kg/min) values indicate a definite decrease in the exercise capacity of the FM subjects. As for all obese persons, the absolute metabolic cost of moving will be high for the FM subjects. The fact that they have a low relative pVO_2 suggests that even their daily activities may be limited by their aerobic capacity.

Although there was no healthy comparison group in the present study, the data of Miles et al (17) (age range of 17-40 years and weight range of 53.1-57.7kg) provided the authors with some idea of the "normalness" of the submaximal exercise response of persons with FM. Absolute VO_2, $\%pVO_2$ and O_2 pulse had to be calculated from mean values of other variables reported in their paper (see legend of Table 3.3 for details). It appears from Table 3.3 that the physiological response of persons with FM at a given submaximal load is similar to that of healthy sedentary women.

The current results do not support the suggestion of abnormal muscle metabolism and reduced blood flow in persons with FM. Previous research has demonstrated decreased levels of adenosine triphosphate, phosphoryl creatine, ADP and increased levels of creatine in muscle biopsies of persons with FM compared to sedentary controls (23-24). More recently, no difference in muscle

metabolism, as revealed by the inorganic phosphate/phosphocreatine ratio, between subjects with FM and normal controls during exercise was reported (25-26). In addition, Bennett et al (4) have reported decreased blood flow in the exercising anterior tibialis muscle in persons with FM. However, due to the overlap of values between the FM and sedentary control subjects, Bennett et al (4) suggested the reduced blood flow was characteristic of sedentary detrained persons and not unique to FM. In fact, the (a-v)O_2 diff results from the present study would suggest similar or higher blood flow in FM tissue at submaximal exercise. Although muscle metabolism and blood flow were not directly measured in the current study, the submaximal results suggest that if these abnormalities exist they do not appear to affect the physiological variables as measured during exercise.

The current study indicated that O_2 pulse was significantly related to both SV and (a-v)O_2 diff in the FM patients. This observation is contrary to those of Bhambhani et al (9,15) who reported that the O_2 pulse was significantly related only to the SV ($r=0.78$) but not the (a-v)O_2 diff ($r=0.26$) during submaximal exercise in healthy men and women. The reversed O_2 pulse relationship with SV and (a-v)O_2 diff suggests an alteration in the manner in which the VO_2 is attained during exercise in persons with FM. It has been demonstrated that despite lower HRs at a similar workload, the rate of O_2 consumption at increasing exercise intensity in persons with FM is the same as sedentary controls (6). This finding and the results from the current study suggest that in order to maintain the same O_2 consumption, a greater extraction of O_2 from the tissue may occur. Although a high correlation does not infer causation, it does suggest that O_2 consumption may rely more on a wider (a-v)O_2 diff (greater peripheral extraction) than SV in persons with FM. Consequently, SV cannot be estimated from O_2 pulse in this population.

Although invasive measures were not used in the present study to determine Q, the technique used should not be viewed as a limitation. As mentioned previously, the re-breathing maneuver used in this study is highly correlated with the direct Fick method. Still, indirect measures can under and

overestimate the actual Q values (13,27), depending upon the protocol. Marks et al (27) reported less than 12% difference between direct and indirect methods for obtaining Q and a slight overestimation (mean differences ranging from 0.26-0.63 L/min) using the same re-breathing maneuver as the current study. The re-breathing maneuver used by Miles et al (17) has similar validity and reliability as the technique used in the current study. Therefore any overestimation in measurement should be similar in the two studies. Furthermore, the study (9) used to compare the correlation coefficients of O_2 pulse with SV and (a-v)O_2 diff, utilized the same protocol for the re-breathing maneuver as in the present study. Although direct measures for determining Q are the gold standard and can be utilized during exercise, it appears unnecessary to have the FM subjects endure such invasive techniques when reliable and valid noninvasive measures are available.

It is also important to highlight the use of medications and the effect they might have had on the results. A majority of the subjects were taking low doses of anti-depressants and 40% were on thyroid replacement therapy, medications that may have influenced the results by increasing the HR (28). Although the dosages for the medications were all fairly low, it is impossible to rule out a potential effect on Q and SV in this study.

A limitation with the submaximal testing protocol was that Q was only measured at one level of exercise for each subject. An improved design would have been to measure Q at increasing intensities of exercise. This may have proved extremely difficult because some subjects found the re-breathing maneuver to be uncomfortable and would not have tolerated the procedure more than once. In addition, the researchers were uncertain as to the tolerance of the FM subjects to this particular protocol.

The major limitation of the current study was the lack of an age, gender, and activity matched control group. The data were collected as part of a larger study involving exercise in persons with FM and were intended to be descriptive only. Comparisons with results from the literature are difficult due to differences in test protocols, reporting of data, and subject characteristics. However limited,

data from sedentary women of a similar age were available in the literature and enabled some comparisons to the current results.

The current results indicate that women with FM have lower pVO_2 values and peak HR, compared to healthy sedentary women of similar age. However, the two groups have similar Q, SV and $(a\text{-}v)O_2$ diff when exercising at a similar submaximal VO_2.The results suggest that peak exercise performance is not limited by the cardiovascular system in FM, but more likely by symptoms or fear of developing symptoms.

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Table 3.1. Subject characteristics (n=36).

Variables	Mean±Standard Deviation
Age (yr)	46.3±9.6
Duration of symptoms (yr)	10.9±12.9
Height (cm)	162.7±6.9
Weight (kg)	83.2±18.3
Body Mass Index (kg/m^2)	30.6±7.9

Table 3.2. Physiological variables at peak exercise for women with FM - current study and study by Bennett et al

Variable	Current study Mean(Standard Deviation) (range of values)	Bennett et al (4) Mean (Standard Deviation)
pVO_2 (L/min)	1.7(0.4) (.78-2.65)	1.5^
pVO_2 (ml/kg/min)	22.6(7.3) (9.1-36.1)	21.5(1.1)
HR (beats/min)	141.8(22.6) (87-185)	162.0^
O_2 pulse (ml/beat)	12.3(3.7) (1.3-13.4)	9.0^
Ventilation (L/min)	55.1(14.6) (20.9-140.0)	-
Ventilatory Equivalent (L/min)	32.5(6.3) (25.5-54.7)	-
Respiratory Exchange Ratio	1.02(0.13) (.82-1.4)	1.28(0.12)
Rating of Perceived Exertion	16.6(2.4) (6-20)	7.9(1.8)**

Weight originally in lbs, converted to kgs (150 lbs = 68kg).
^. pVO_2 (L/min)=21.5 (ml/kg/min) x average weight (68kg)/1000
^. HR (beats/min): 220-average age (41.9 years) = predicted HRmax (178.1beats/min); 91% of predicted HRmax=178.1 beats/min x .91
^. O_2 pulse (ml/beat)= pVO_2 (1462 ml/min)/average HR (162beats/min)
-: values could not be estimated.
**modified Borg scale (0-10); equal to 'very strong'
pVO_2=peak oxygen consumption, HR=heart rate, O_2 pulse=oxygen pulse

Table 3.3. Physiological results at submaximal exercise for current study and a healthy cohort of women.

Variable	Current Study Mean(Standard Deviation) (range of values)	Miles et al (18) Mean (Standard Deviation)
VO_2 (L/min)	0.91(0.26) (0.52-1.7)	0.72^
VO_2 (ml/kg/min)	10.9(3.2) (6.7-17.1)	12.8(2.1)
%pVO_2	54 (29-95)	37^
Cardiac Output (L/min)	8.0(1.7) (3.0-13.1)	8.2(2.0)
Stroke Volume (ml/beat)	72.5(16.4) (27.6-99.7)	74.5(23.7)
HR (beats/min)	109.4(15.7) (76-147)	113.0(4.0)
arteriovenous oxygen difference (ml/100ml)	11.6(2.5) (5.1-17.3)	8.9(2.0) 6.4^
O_2pulse (ml/beat)	8.6(2.2) (4.0-13.4)	

^. VO_2 (L/min)=12.8 ml/kg/min x average weight [55.89 Kg] / 1000;
^. %pVO_2 =[submaximal VO_2 (12.8 ml/kg/min)/34.9 ml/kg/min] x 100;
^. O_2pulse (ml/beat)= VO_2 (720 ml/min)/average HR (113.0 beats/min).
VO_2=oxygen consumption, %pVO_2 =percentage of peak oxygen consumption, HR=heart rate, O_2pulse=oxygen pulse

Table 3.4. Summary of current study and published VO_2, HR, RPE and RER data for women during peak exercise

Variables	Current study	Kilbom, 1971 (26)	Miles, 1980 (18)	Bhambhani, 1995 (9)	Fitzgerald et al, 1997 (meta-analysis) (27)	Tanaka et al, 1997 (meta-analysis) (28)	Proctor et al, 1998 (29)
Training Status/ Mode	sedentary/ treadmill	sedentary/ cycle	sedentary, moderately active/ treadmill	moderately active/ cycle	sedentary/ cycle, treadmill	sedentary/cycle, treadmill	endurance trained/ cycle
Age (yrs)	46.3 (9.6)	44 (range 37-48)	(range 17-40)	32.1 (7.7)	40.5 (19.4)	45.0 (1.0)	61.0 (3.0)
Weight (kg)	83.2 (18.3)	63.8 (2.7)	-	59.5 (6.0)	60.8 (5.5)	66.0 (3.0)	58.1 (2.3)
VO_2 (ml/kg/min)	22.6 (7.3)	31.0 (1.7)	34.9 (4.2)	36.6 (7.1)	29.7 (7.8)	27.0 (1.2)	35.1 (1.6)
VO_2 (L/min)	1.7 (0.4)	2.0 (0.1)	1.9 (0.2)	2.2 (0.4)	1.8 (0.1)	1.7 (0.1)	2.0 (0.1)
Heart Rate (beats/min)	142 (22.6)	177 (2)	184 (8.5)	183 (12)	177 (17)	179 (2)	165 (4)
% age predicted HR max	82	101	96	97	99	102	103
Rating of Perceived Exertion	16.6 (2.4)	18.1 (0.3)	-	-	-	19.0 (0.3)	18
Respiratory Exchange Ratio	1.02 (0.13)	1.04 (0.02)	1.15 (0.11)	1.33 (0.07)	-	1.19 (0.02)	1.15 (0.05)

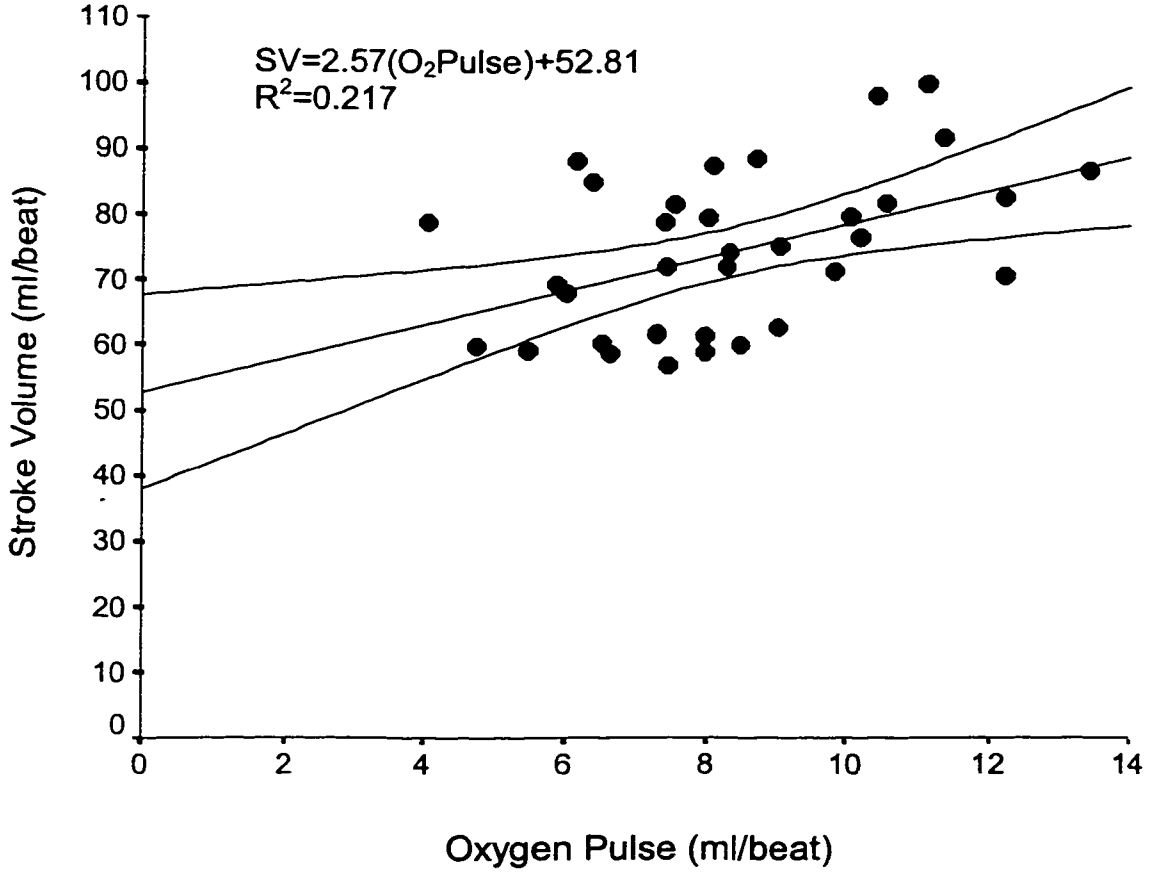

Figure 3.1. Pearson Product Moment Correlation of O_2 Pulse with Stroke Volume for FM subjects (Adjusted R^2=.222, Standard Error of the Estimate=10.83, β=.494).

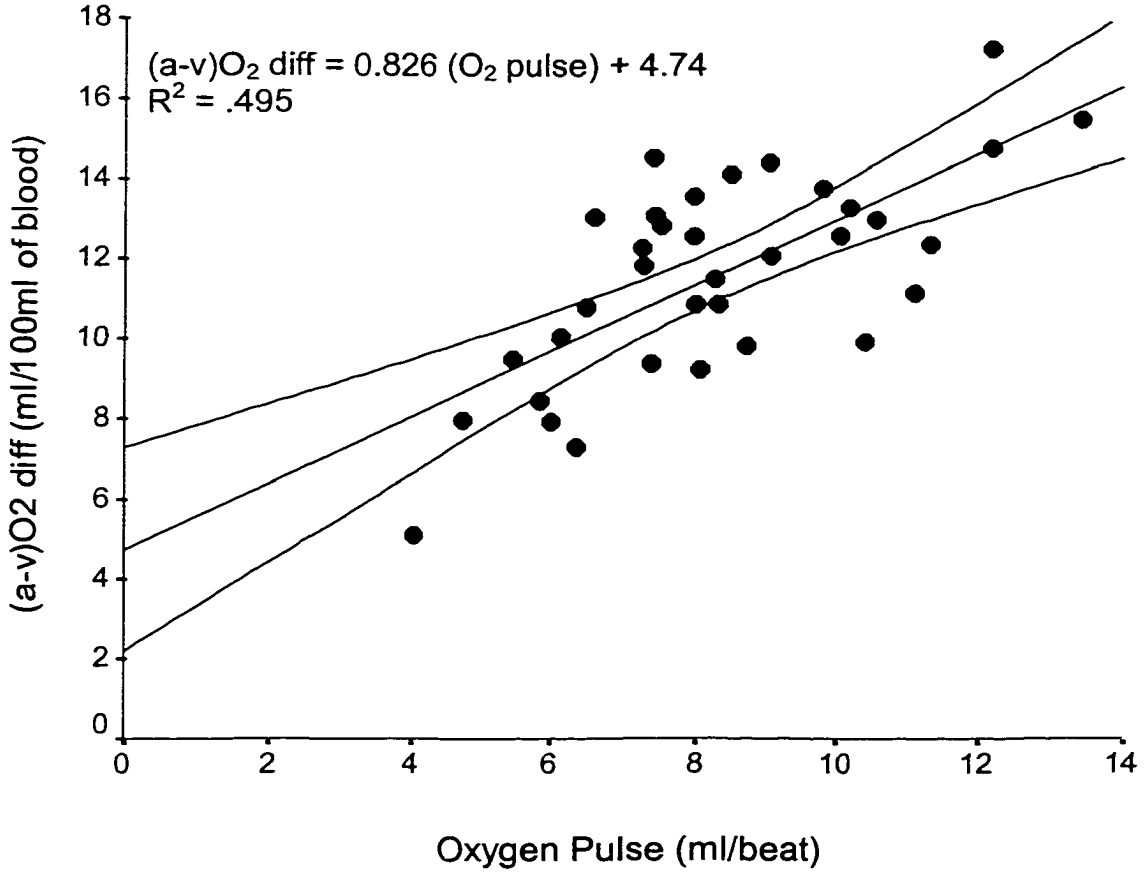

Figure 3.2. Pearson Product Moment -Correlation of O_2 Pulse with arteriovenous oxygen difference for FM subjects (Adjusted R^2=.571, Standard Error of the Estimate=1.67, β=.764).

CHAPTER 4

Characteristics of Persons with FM Classified According to the Multidimensional Pain Inventory*

Persons with FM (FM) have chronic, disabling pain and fatigue that usually respond poorly to treatment (1-5). Turk et al (6) have suggested that the apparent failure of interventions for FM may be related to the heterogeneous nature of the condition. The West-Haven Yale Multidimensional Pain Inventory (MPI) was developed to classify chronic pain patients (7-10). It has been used since to investigate the multiple facets of chronic pain and the treatment response in persons with FM (11).

The MPI is a self-report questionnaire that examines the impact of pain on a person's life, the responses of others to the communication of pain and the extent to which the person participates in common daily activities (7). More than 90% of chronic pain patients (low back pain, headache and temporomandibular disorder) have been classified into one of three main groups; Adaptive Coper (AC), Interpersonally Distressed (ID) and Dysfunctional (Dys) (8-10). The AC is characterized by lower levels of pain, life interference and emotional distress, and higher levels of general activity and life control. The Dys is the opposite of the AC on all of the above scales. The ID perceives his/her significant other to provide more punishing responses and fewer supportive responses than the AC or Dys groups. When compared on psychosocial, pain, and behavior measures, these groups were different on pain severity, pain-specific fear-avoidance behavior, marital satisfaction, depression, and daily hassles (8-10,12). These findings support the validity of the MPI as a tool that can classify chronic pain based on multiple dimensions.

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* A version of this paper was submitted to Arthritis Care and Research, SJ King, J Wessel, D Sholter, W Maksymowych

Similar work has been conducted in persons with FM (6). The majority were classified by the MPI into one of the three major groups. These groups also showed differences in constructs that appear linked to the theoretical basis of the MPI. These included: depression, disability, pain severity, ability to perform common physical activities, and marital satisfaction. The authors concluded that these findings illustrated the construct validity of the MPI for use with FM.

A significant limitation of the previous study with FM (6) was that many of the outcome measures used in the validation of the MPI had not been previously validated themselves on a FM population. For example, pain and physical functioning were measured using the Jan van Breeman Institute Quantification of Pain and Physical Functioning, a measure that appears more appropriate for spinal conditions. In addition, disability was measured using the Oswestry Disability Inventory, a measure designed for and validated on patients with low back pain (13).

It may be further argued that the severity of the condition might affect the MPI classification. That is, if pain is more severe, persons with FM will more likely be in the Dys group and have greater disability. Pain severity is, in fact different in the three main MPI groups (6,8), supporting the hypothesis that the worse the condition the greater the psychosocial problems. On the other hand, duration of pain, number of symptoms and spinal mobility (i.e. lumbar flexion/extension, lateral bending, and cervical range of motion), do not appear to be different in the MPI groups (6).

The present study was designed to further investigate the MPI classification of persons with FM using outcome measures that have been validated or frequently used for persons with this condition. In addition, fear-avoidance beliefs (14) were measured. Although this questionnaire has not been previously validated on this population, it was included to determine if persons with FM possess beliefs pertaining to the fear of increasing pain due to physical activity or work leading to avoidance of these activities. Moreover, could a

distinction be made among MPI groups based on the fear-avoidance results. Fear-avoidance beliefs have been examined in chronic low back pain patients and were found to be one of several psychological variables predicting the initiation of chronic pain, as well as a risk factor for its maintenance (15-16). If the MPI were a multidimensional measure of pain in FM, one would expect differences among the groups with respect to disability, impact of the disease, self-efficacy, quality of life, fear-avoidance beliefs and physical fitness. If the severity of pain in FM were the main factor determining MPI classification, then it should be more severe in the Dys group than the other two, and show correlations with other outcome measures. Therefore the purposes of this study were to: 1) confirm the ability of the MPI to classify a large cohort of patients with FM, 2) compare these groups on measures commonly used to measure outcome of FM, and 3) examine correlations between scores on the various outcome measures and pain severity.

METHODS

Design

The data for this study were obtained from baseline measurements of persons with FM who participated in a controlled trial examining the effects of exercise and education. Each subject completed all questionnaires and the Six Minute Walk (6MW) at one visit. Tender points (TPs) were assessed first, followed by commencement of the questionnaires and the walking test. The subjects were allowed as much time as necessary to complete the questionnaires with breaks as required. The University of Alberta Faculty of Rehabilitation Medicine Ethics Committee approved the procedures undertaken in this study.

Subjects

Subjects were 195 women and 8 men who met American College of Rheumatology criteria for FM (17). They were either referred by rheumatologists

or self-referred, but all diagnoses were confirmed by a rheumatologist. Potential subjects were excluded if they had any conditions which precluded the ability to exercise (severe cardiac arrhythmia, dizziness, severe shortness of breath) or if they had an inflammatory arthritis systemic lupus or rheumatoid arthritis. Persons involved in medico-legal cases were not excluded. Participants were not questioned about their exercise activities at the entry of the study.

Instruments

West Haven-Yale Multidimensional Pain Inventory (MPI) - has 52 items (version 1) (7) divided into 3 sections. Section one evaluates subjects' reports of pain severity, perceived life interference by pain, sense of control over their lives, affective distress and perceived level of social support. Section two assesses behavioural responses exhibited by patients' significant others in response to pain complaints. Section three assesses levels of engagement in various activities: social, household chores, outdoor activities and activities away from home. The MPI is made up of 9 scales (there are 13 original scales, but four activity scales are combined to obtain a general activity scale), derived from the questions in all three sections. The responses to these scales are used to classify the subject.

In addition to the three main classifications (AC, ID and Dys), there are anomalous, hybrid and unanalyzable profiles. An anomalous profile is considered an exaggerated type of dysfunctional profile and is highly unusual. Persons are categorized as hybrid when the scores represent aspects of more than one of the three main profiles. An unanalyzable profile occurs when two or more of the nine scales are missing data and the program cannot classify the patient. The internal consistency of the MPI has been reported to be 0.70-0.90, and reliability 0.62-0.91 (9).

Fibromyalgia Impact Questionnaire (FIQ) - is a brief 10 item survey measuring physical functioning, work status, depression, anxiety, sleep, pain, stiffness, fatigue and well being in persons with FM (18). Construct validity has been

demonstrated by a moderate correlation (r=.67) with the lower extremity physical functioning subscale of the Arthritis Impact Measurement Scale (AIMS) (18). The total FIQ score was calculated according to Burckhardt et al (18). The range of scores is 0-70 with a higher score indicating greater impact of the condition on the person's life.

Quality of Life Scale (QOL) - is a 16 item questionnaire dealing with satisfaction with various aspects of life, such as health/physical activity, raising or having children, independence, learning or attending school (19). The quality of life of persons with FM was found to be lower, compared to other rheumatic and nonrheumatic diseases, although there was substantial overlap in the range of scores for the FM, chronic obstructive pulmonary disease and diabetes patients in the sample (20). Scoring is based upon a Likert scale ranging from 1 (terrible) to 7 (delighted). A total satisfaction score is obtained by summing all 16 items with total scores ranging from 16-112. A higher score indicates greater satisfaction with life.

Chronic Pain Self-Efficacy Scale (SES) - is a 20 item scale divided into 3 subscales (pain, functioning and coping with other symptoms), measuring subjects' beliefs in their ability to perform specific tasks and control symptoms of their condition (21). It was modified from Lorig's Arthritis Self-Efficacy Scale to measure the efficacy expectations for coping with the consequences of chronic pain (21). For each subscale a total score is calculated and then these three scores are combined to create the SES total score. Both subscale scores and the total score were used in this study. A higher score indicates greater self-efficacy.

Fear-Avoidance Beliefs Questionnaire (FABQ) - is a 16 item scale examining patients' previous experience regarding fear of pain and the avoidance of certain behaviours (14). The questionnaire is divided into two fear-avoidance subscales pertaining to beliefs about work and physical activity. It was originally designed for patients with chronic low back pain and has not been validated on patients with FM. Scoring consists of a Likert-type scale with ranges of 0 (completely disagree) and 6 (completely agree). A separate score is calculated for each subscale and then combined for a total score. Scores may range from 0-24 for

physical activity and 0-42 for work. A higher score indicates greater fear-avoidance beliefs.

Tender Point Count and Total Survey Site Score - the 18 TPs were examined according to the manual TP survey protocol of Okifuji et al (22). This protocol outlines examiner and subject positioning, order of examination and pressure application technique. Additionally, the Total Survey Site Score was used as a self-report measure of pain severity (22). Okifuji and colleagues (22) concluded that the range of severity scores obtained from the Total Survey Site Score would allow for a detection of change over time and a decrease in TP pain after treatment. A self-report measure of pain severity was selected, rather than physician observation or interpretation, due to the subjective nature of pain. The total number of positive TPs is the TP count (ranging from 0-18). Each time a TP is palpated, the subject rates the pain severity as 0 (no pain) - 10 (worst pain). The pain severity ratings that are 2 or more are considered positive TPs. The scores for these positive TPs are totaled, thus providing a Total Survey Site Score (ranging from 0-180).

Six Minute Walk (6MW) - is a field test developed from Cooper's 12 minute walk/run (23). Subjects were instructed to "cover as much ground as possible in 6 minutes". Encouragement such as "good pace, keep it up" or "good work" was given at 2, 3, 4 and 5 minutes. At these same time intervals, the subjects were informed of the time remaining in the walk. Encouragement and time remaining were standardized for all patients. The 6MW has been used in the FM research to evaluate fitness. Research has demonstrated a correlation of 0.66 (p=.001) between the 6MW and peak oxygen consumption, a direct measure of fitness (24). The distance covered in metres was recorded.

Data Reduction and Analyses

The MPI questionnaire data were entered into the Multiaxial Assessment of Pain MPI taxonomy system (Pain Evaluation and Treatment Institute, University of Pittsburgh School of Medicine, 1987) for assessment and profile

outcome. The three main groups, as determined by the MPI, were compared on each of the variables by means of one way analyses of variance (ANOVA). When there was a significant difference, a Tukey post hoc analysis was done to determine where the difference arose. Except for subject demographics, data were not analyzed for subjects who did not fall into one of the three main classifications. One-way ANOVAs and Chi square were used to compare demographics of the 3 MPI groups and those not classified [Miscellaneous (MISC)]. Significance was set at $p<.01$.

RESULTS

Demographic variables of the subjects are summarized in Table 4.1. The majority (73.4%) of the subjects were classified into one of the three main MPI groups: 27.6% AC, 27.6% ID and 18.2% Dys. The remaining subjects were classified as anomalous (6.4%), hybrid (8.4%) or unanalyzable (11.8%). Due to the small number of subjects, these remaining groups were then combined and termed MISC in order for a comparison of demographics with each of the three main groups. The MISC group was not included in the remaining analysis.

An ANOVA demonstrated a significant difference among the groups in symptom duration. Post hoc analysis revealed the ID group to have had symptoms for a significantly longer period than either the AC or Dys groups. Onset of FM was considered traumatic when symptoms began after a motor vehicle accident (i.e. whiplash), surgery or another identifiable incident that may have caused insult to the body. There was no significant difference among the groups with respect to precipitating traumatic events. Chi square analysis revealed significant differences with respect to marital status. However, once the MISC group was removed from the analysis, these differences were no longer significant. Employment status was also significantly different among the groups. The Dys group had the lowest percentage of patients employed compared to the AC, ID and MISC group. In addition, significant differences were noted amongst

those receiving compensation. The Dys had the highest percentage of subjects receiving some form of compensation compared to AC, ID and MISC groups. Although not significant, a greater majority of the AC group had some university or college education, compared to the ID, Dys and MISC group.

Means and standard deviations of the outcome measures for the groups are presented in Table 4.2. The ANOVAs and post hoc analyses revealed significant differences between the AC group and both the ID and Dys groups on all psychosocial and physical fitness measures (Table 4.2). The AC group scored better than the other two groups on almost all outcome measures. The ID group scored significantly better than the Dys group on SES coping, function and FABQ for work. The number of TPs and the Total Survey Site Score were not significantly different across the three groups, despite the major differences in the other outcome measures.

To examine the question as to whether the MPI is indeed multidimensional, the relationship among all the outcome measures was examined by Pearson product moment correlations (Table 4.3). Most correlations were low to moderate demonstrating that the variables are related in some aspects, but are still measuring different components of the person's psychosocial phenotype. If correlations between the measures were all very high, the measures would likely have all been measuring the same construct. Thus, differences between the MPI groups on every measure would be expected, because these measures may not be examining anything unique. This finding provides support for the multidimensional nature of the MPI and further evidence for the unique characteristics of each MPI group. Due to the multiple comparisons, a Bonferroni correction factor was applied and the significance level adjusted to $p<0.007$.

DISCUSSION

The current study demonstrates that the AC group had better scores than both the ID and Dys groups on all psychosocial and physical fitness measures, demonstrating the AC's ability to manage with FM. The ID and Dys groups scored similarly on all measures with the exception that the Dys group demonstrated lower self-efficacy and greater fear-avoidance beliefs pertaining to work. These results indicate that the ID group perceive that they have the ability to function and cope better than the Dys group, but this perception is not reflected in a greater quality of life or lower impact of the condition. Perhaps this is due to the lack of positive social support, and that without the required support, self-efficacy may not alter their general satisfaction with life. Despite the distinctions among the groups on measures of self-efficacy, satisfaction, function and fitness, there were no differences with measures of pain severity, specifically the number of TPs and the Total Survey Site Score, reinforcing the multidimensional aspects of the MPI.

The current results, specifically the questionnaire responses, are consistent with the conclusions of Turk et al (6), in that persons with FM can be classified into the 3 major MPI groups, and that these groups have different characteristics. However, a finding that appears to contradict Turk et al (6) relates to the pain intensity among the groups. Turk et al (6) reported that pain intensity was greater in the Dys group and lowest in the AC group in their FM sample. In contrast, the findings from the present study demonstrated no difference among the groups with respect to pain intensity, as measured by tenderness. It appears that the difference between the two studies is related to the actual measurement of pain. Turk et al (6) recorded pain intensity during activities using the Jan van Breeman Institute Quantification of Pain and Physical Functioning, rather than pain on palpation. To further examine the relationship between TPs and pain severity in the current study, the correlation between the Total Survey Site Score and the FIQ visual analogue subscale for pain was

determined to be 0.328 (p=.000). An ANOVA and post hoc analyses were run to determine if the groups differed by FIQ pain. The AC group experienced the least amount of pain (5.6 ±2.3cm) compared to the other two groups (ID 7.7±1.6, Dys 8.2±1.5). Therefore, the current data are indeed consistent with the results of Turk et al (6) in that the three groups have distinct characteristics and levels of pain, as measured by self-report rather than degree of tenderness.

The range of values for the number of TPs was narrow demonstrating its lack of discriminating ability. Although the Total Survey Site Score displayed a wider range of values, there was still no significant difference among the groups. It is evident that the number and severity of TPs, do not discriminate between a person with FM who functions well and one who does not. These findings support the view that TPs are unrelated to the severity of the condition and serve no clinical purpose beyond diagnosis of FM.

The percentage of subjects classified into the 3 groups and the proportion of subjects in each group was comparable to another study of FM (6), leaving close to 30% of the FM study population that did not fit into one of the main groups. However, for other chronic pain populations (chronic low back pain, headache and temporomandibular disorders), the percentage of subjects classified (over 90%), and the proportion of subjects classified as Dys (range of 43-62%) were higher (8-10,25) than in the FM groups. One would have expected that FM should have had at least as many Dys subjects as those in other chronic pain conditions. The reasons for the differences in proportions between FM and other chronic pain conditions are unknown. It does not appear to be due to the lack of visible pathology and unpredictability of symptoms, as all types of chronic pain have these characteristics. Perhaps scepticism in the medical community regarding the nature of FM promotes the adoption of certain coping mechanisms that contribute to the lower percentage of Dys patients. Other chronic pain conditions may appear to be more legitimate or valid than FM, thereby eliminating the need to 'prove' the existence of pain. Even gender does not

definitively explain these observed differences between the chronic pain groups. It has been demonstrated that men exhibit more psychological distress than women when coping with chronic pain (26). Conceivably, this could account for a lower proportion of Dys in the FM cohort when compared to low back pain (more men than women suffer with low back pain). However it does not account for the higher proportion of Dys in headache and temporomandibular disorders (more women than men suffering) (27).

Symptom duration, employment and compensation were the only demographic variables that were different among the MPI groups. Having FM symptoms for longer may create a greater strain on relationships, thereby contributing to or resulting in the ID classification. Since the Dys group report the greatest interference in their lives due to pain, one would expect them to work less and receive more compensation than the other groups. Although not significant, the AC group had the highest percentage of individuals with some college or university training, indicating that higher education results in better coping. This finding would concur with work demonstrating that more years of formal education was one of the factors that improved the survival rate of persons with rheumatoid arthritis (28).

A unique addition to the usual questionnaires used with FM, was the use of the FABQ. The fear of activity/movement leading to avoidance behaviours has been examined extensively in the chronic low back pain population (14-16). The exploration of this construct was undertaken to further investigate the psychosocial phenotype of persons with FM. The FABQ was, in fact, different among the groups and the results seem appropriate if the chronic low back pain and fear-avoidance behaviour literature is examined (15, 16). The higher FAB-work score of the Dys group indicates that they believe work activities will make their pain worse. This result appears consistent with the demographic findings of a lower percentage of employed and increased compensation in this group. Further exploration of the fear-avoidance construct would assist in delineating

differences in beliefs and behaviours in persons with FM.

One limitation with this study was it's cross-sectional nature. In this study design, causation cannot be inferred. At present, it is still uncertain if the pre-morbid personality of the individual with FM predicts disease outcome or whether a poor outcome contributes to a dysfunctional or interpersonally distressed profile. No evidence was provided regarding the ability of the MPI to predict treatment outcome. However, a recent study (11) suggests that there is a differential response to treatment among the groups in persons with FM and that some are able to change from their original group to another after treatment. Those patients that do not change from their initial Dys or ID classification need to be examined more closely to determine the best course of action for their treatment.

An additional limitation was that the symptoms that were examined included only pain. Potentially, the number of symptoms may determine or contribute to the MPI categorization. However, common symptoms of temporomandibular disorders were not significantly different among the MPI groups (10). Future research could examine symptoms more extensively to determine if a relationship exists between current/past medical history, MPI classification and FM.

The current study supports the use of the MPI as a multidimensional tool to categorize FM. The majority of the subjects were classified into one of the three main groups, which were different on both psychosocial and physical function measures.

The clinical implications of this study are three-fold. First, the heterogeneous nature of FM was highlighted in this study. Secondly, using a classification system, such as the MPI, may be a more rationale approach to the evaluation of therapeutic agents/programs in FM. Perhaps the success rate of treatment programs would improve and treatment effects would be maintained longer if an 'individualized' approach was adopted based on the MPI

classification system. Finally, the study results bring into question the relevance of TP assessments in clinical practice, other than for diagnosis. As was demonstrated, the number of TPs do not add any value to the overall assessment, nor do they relate to the patient's current functional or coping ability.

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Table 4.1. Demographic variables for the MPI groups [mean (standard deviation)].

Demographic	AC (n=56)	ID (n=56)	Dys (n=37)	MISC (n=54)
Age (yrs)	45.9 (8.8)	48.4 (9.1)	45.4 (8.7)	43.7 (10.7)
Gender (F:M)	54:2	52:4	35:2	51:3
Symptom duration (yrs)*	6.8 (5.9)	11.1 (9.7)	6.3 (5.1)	7.8 (7.4)
Onset of FM symptoms(%)				
idiopathic	80.4	76.8	70.3	75.9
traumatic	19.6	23.2	29.7	24.1
Marital status (%)*				
single	13.3	6.5	10.7	37.2
married/common law	84.4	80.4	71.4	34.9
divorced/separated	2.2	13.0	17.9	27.9
Education (%)				
< high school	25.0	12.5	29.7	28.3
high school graduate	14.3	39.3	27.0	26.4
university/college	60.7	48.2	43.2	45.3
Employed (%)*				
yes	50.1	37	10.8	43.4
Compensation (%)*				
yes	26.8	39.3	56.8	44.4

* significant difference between groups.

Table 4.2. Comparison of MPI groups on FIQ, QOL, SES, FAB, 6MW, number of TPs and Total Survey Site Score [mean (SD)].

Variable	AC (n=56) (27.6%)	ID (n=56) (27.6%)	Dys (n=37) (18.2%)	Sign. levels (p value)
FIQ	43.97 (10.29)*†	58.05 (11.73)	61.38 (8.54)	.000
QOL	80.21 (10.08)*†	65.07 (16.34)	63.16 (12.89)	.000
SES total	189.70 (39.68)*†	157.98 (52.78)†	129.38 (43.95)	.000
coping	60.06 (15.11)*†	50.12 (18.68)†	40.32 (15.70)	.000
function	71.92 (19.98)*†	59.15 (21.94)†	45.50 (16.15)	.000
pain	57.71 (16.96)*†	43.57 (22.27)	48.71 (20.50)	.003
FAB- total	24.46 (12.04)*†	33.43 (13.26)†	41.73 (10.60)	.000
p.a.^	9.45 (4.23)†	11.57 (5.42)	13.89 (5.00)	.000
work	15.05 (10.50)*†	21.80 (10.37)†	27.57 (10.05)	.000
6MW (m)	505.32 (82.37)*†	457.04 (96.23)	449.66 (78.65)	.003
#TPs	15.55 (3.06)	15.49 (2.78)	16.28 (2.44)	.376
Total Survey Site Score	97.80 (32.23)	98.88 (35.10)	109.52 (29.25)	.277

From Tukey post hoc analyses: * significantly different from ID; † significantly different from Dys. FIQ=FM Impact Questionnaire, QOL=Quality of Life Questionnaire, SES=Self-Efficacy Scale, FAB=Fear-Avoidance Beliefs, 6MW=Six Minute Walk, TPs= Tender Points. ^ physical activity

Table 4.3. Pearson Product Moment correlations of all outcome measures for the entire sample (n=203).

	*FIQ	QOL	SES total	coping	Func	pain	FAB	p. activity	work	6MW	#TPs
QOL	-.505*										
SES total	-.558*	.542*									
coping	-.493*	.516*	.872*								
function	-.508*	.502*	.839*	.611*							
pain	-.420*	.366*	.840*	.644*	.503*						
FAB	.453*	-.476*	-.543*	-.423*	-.573*	-.366*					
p. activity	.291*	-.317*	-.553*	-.425*	-.500*	-.468*	.635*				
work	.411*	-.428*	-.398*	-.311*	-.462*	-.251*	.930*	.311*			
6MW	-.316*	.190*	.400*	.319*	.487*	.203*	-.243*	-.243*	-.206*		
#TPs	.157	-.140	-.198	-.148	-.181	-.173	.161	.043	.179	-.127	
Total Survey Site Score	.310*	-.132	-.168	-.124	-.198	-.101	.190	.069	.197	-.314*	.563*

* significant at p=.007

CHAPTER 5

The Effects of Exercise and Education, Individually or Combined, in Women with Fibromyalgia

Fibromyalgia (FM) is a puzzling and challenging chronic widespread pain condition. It is puzzling due to the lack of a clear pathology and challenging because well defined treatment to manage the symptoms eludes clinicians and clients alike. At present, the most beneficial treatment appears to be the management of symptoms by means of a multidisciplinary approach involving education and aerobic exercise.

Research with aerobic exercise programs has demonstrated variable results in persons with FM (1-4). Reductions in general pain, fatigue, number of tender points (TPs) and total myalgic score have been reported (1-4). However, no significant improvements on measures of psychosocial dimensions, such as impact of condition and self-efficacy, have been demonstrated. In addition, after study completion, either no follow-up was undertaken or very few subjects continued to exercise.

The efficacy of education, alone or combined with exercise has been examined and/or compared to a control group. The content of the educational programs has included information on FM, stress management and coping strategies. The educational studies have demonstrated reductions in pain and improvements in psychological and disability measures immediately upon completion of the program (5-10). A group receiving exercise and education had greater changes in self-efficacy for coping with pain and other symptoms compared to a control group (11). Compared to the control group, the education only and the combined groups also demonstrated enhanced life satisfaction and self-efficacy for functioning on pre to post-test change scores. Another study (12) reported significant differences on measures of self-report pain distribution and TP tenderness in the exercise only group and reduced TP tenderness in the stress management group compared to the control group. Buckelew et al (13)

reported improvements in the exercise and combination (biofeedback/relaxation and exercise) groups on measures of self-efficacy for function and physical activity. Their biofeedback/relaxation group appeared least effective in demonstrating a change in measures of disability, impairment or function.

Trends toward baseline values have been reported in some studies (6 months follow-up) (5, 7), while other studies have reported maintenance in post program values upon 6 weeks to 4 years follow-up (8, 10, 12). The combination groups were able to maintain improvements in TP index (13), self-efficacy for coping with pain and other symptoms and life satisfaction (11). In addition, Buckelew et al (13) reported that the exercise and the combined groups maintained the improvements on measures of physical activity and self-efficacy for functioning.

Despite previous research examining exercise and/or education interventions, the differential effect of exercise or education in improving impairment and functional measures in persons with FM is still unknown. Would either component be equally effective in reducing the impact of FM or would the combination of both be necessary for the enhanced management of FM? Previous studies suggest that the combination of exercise and education may improve and maintain improvements reported after an intervention better than either component on its own (11, 13). However, it has not been equivocally determined if the combination is necessary to demonstrate a change in disability, fitness, self-efficacy for coping with pain and other symptoms, self-efficacy for functioning, or life satisfaction.

Other concerns with previous research include methodological issues or the content of the treatment programs. Some exercise programs involved mainly stretching, postural training or range of motion exercises rather than aerobic training. In others the intensity of the 'aerobic' exercise was not monitored (11, 13). The educational component may have focused on just relaxation or stress management (12, 13) and not on skills to self manage the condition. Control groups for comparison with the interventions were not included in other studies

(8, 10). Furthermore, the statistical analyses may have focused on the between and within group differences and not the interaction between group and time. Finally, the reporting and/or examination of the compliance data may not have occurred.

The purpose of this study was to examine the effectiveness of a supervised aerobic exercise program, a self-management education program and the combination of exercise and education for persons with FM. It was hypothesized that the group receiving exercise and education would demonstrate the greatest improvements on the impact of the condition, self-efficacy, life satisfaction, physical fitness and tender point assessment. In addition, it was believed that the exercise only and education only groups would improve more than a control group on these same measures.

METHODS AND MATERIALS

Subjects

Subjects were women who met the American College of Rheumatology criteria for FM (14). They were either referred by rheumatologists or self-referred, but all diagnoses were confirmed by a rheumatologist. Potential subjects were excluded if they had any conditions, which precluded the ability to exercise (severe cardiac arrhythmia, dizziness, severe shortness of breath) or if they had an inflammatory arthritis systemic lupus or rheumatoid arthritis. Persons involved in medico-legal cases were not excluded. Rheumatologists in the city of Edmonton were informed of an 'exercise and education study' being run through the Faculty of Rehabilitaiton Medicine at the University of Alberta. Names and phone numbers of potential subjects were then forwarded to the investigator in order to contact the person. If the person agreed to participate in the study, a date was set for the pretest. Subjects that self-referred contacted the investigator. It was determined over the telephone if she met the inclusion criteria and if she had been diagnosed by a rheumatologist. Inclusion criteria were: women between the ages of 18-65 years with a willingness to meet 1-3 times per

week for a 12 week period. The University of Alberta Faculty of Rehabilitation Medicine Ethics Committee approved the procedures undertaken in this study. To determine an adequate number of subjects to detect a significant interaction effect, a power analysis was calculated using an effect size of 0.25 for the questionnaires with a power of 0.8 and alpha level of 0.01 (15). In order to detect a significant difference at least 26 subjects per group were required. Due to the potential for high dropouts with this population, it was determined that at least 30 subjects per group should be recruited totaling 120 subjects. By the completion of the recruitment period, a total of 170 women had volunteered for the study.

Design and Data Collection

This study was a randomized controlled trial with repeated measures design. The pre-test measures were completed on one visit. The medical history and tender point assessment was completed by either a rheumatologist or a physical therapist. During the medical history, the subjects were asked if they could identify an incident that initiated their symptoms (traumatic) or if their symptoms began gradually (idiopathic). Moreover, employment status includes both part-time and full-time work.

The same examiner assessed the same subjects on subsequent visits. After the physical assessment, the self-report questionnaires and the walking test were completed. Following the pre-test, subjects were randomly assigned to one of the following groups: exercise only, education only, exercise and education or a delayed treatment control group. Random assignment of subjects to groups was done in uneven blocks ranging from 4 to 16 subjects. The list was prepared prior to the commencement of the study using a table of random numbers and the subject ID number (order of admission to the study). The individual with the list and assigning subjects to groups was unaware of the baseline test results of any of the subjects. Both assessors were blinded to the subject's group randomization on subsequent visits. A post-test was done immediately after completion of the program and again three months later.

Outcome Measures

For each outcome measure, complete validity and reliability values are reported in Appendix C.

Chronic Pain Self-Efficacy Scale (SE) - is a 20-item scale divided into 3 subscales (pain coping, functioning and coping with other symptoms), measuring subjects' beliefs in their ability to perform specific tasks and control symptoms of their condition (16). It was modified from Lorig's Arthritis Self-Efficacy Scale (17) to measure the efficacy expectations for coping with the consequences of chronic pain. A higher score indicates greater self-efficacy for the particular subscales.

FM Impact Questionnaire (FIQ) - is a brief 19-item survey measuring physical functioning, work status, depression, anxiety, sleep, pain, stiffness, fatigue and well being in persons with FM (18). The total FIQ score was calculated according to Burckhardt et al (18). Scores range from 0-80 with a higher score indicating greater impact of the condition on the person's life.

Six Minute Walk (6MW) - is a field test developed from Cooper's 12 minute walk/run (19). Subjects walked along a 40-metre, level corridor and were instructed to "cover as much ground as possible in 6 minutes". Encouragement such as "good pace, keep it up" or "good work" was given at 2, 3, 4 and 5 minutes. At these same time intervals, the subjects were informed of the time remaining in the walk. Encouragement and time remaining were standardized for all patients. The distance covered in metres was recorded. The 6MW has been used in the FM research to evaluate fitness (8, 11).

Quality of Life Scale (QOL) - is a 16-item questionnaire dealing with satisfaction with various aspects of life, such as health/physical activity, raising or having children, independence, learning or attending school (20). Each item is rated on a Likert scale ranging from 1 (terrible) to 7 (delighted). A total satisfaction score is obtained by summing all 16 items with total scores ranging from 16-112. A higher score indicates greater satisfaction with life.

Tender Point Count and Total Survey Site Score - the 18 TPs were examined according to the manual TP survey protocol of Okifuji et al (21). This protocol

outlines examiner and subject positioning, order of examination and pressure application technique. The total number of positive TPs is the TP count (ranging from 0-18). The self-report measure of pain severity that was used was the Total Survey Site Score (21). Each time a TP is palpated, the subject rates the pain severity as 0 (no pain) - 10 (worst pain). The pain severity ratings that are 2 or more are considered positive TPs. The scores for these positive TPs are totaled, thus providing a Total Survey Site Score (ranging from 0-180).

Interventions

The programs were based upon principles of self-management where the subjects, in collaboration with health care professionals, learn and adopt skills and behaviours to manage their condition (22). For instance, the education program did not just provide information to passive recipients. It encouraged the performance of new behaviours or skills. Self-management principles were taken from Bandura's social cognitive theory in which it is hypothesized that enhancing self-efficacy beliefs is the mechanism underlying successful response to treatments (22).

The treatment programs ran simultaneously for twelve weeks. Due to the large number of subjects required, the programs were offered on five different occasions over a two-year period (winter-spring once, fall-winter and spring-summer twice each).

Exercise group – The program was based upon the 1990 American College of Sports Medicine (ACSM) position stand on the recommended quantity and quality of exercise for maintaining and developing cardiorespiratory fitness in healthy adults (23). However, the subjects were instructed at the beginning of the exercise program to work at a level that was comfortable to them. Throughout the duration of the study, the subjects would increase the intensity and duration of their sessions to meet the ACSM recommendations. The subjects met three times per week for the supervised exercise program. All instructors were certified fitness instructors with basic knowledge about the FM condition. In addition, a

physical therapist experienced with exercise and FM attended every exercise session to assist with modifications of the activities for individuals when required. The therapist offered encouragement to the subjects when necessary.
The exercise was aerobic in nature and included activities such as walking, aquasize (deep and shallow water), or low impact aerobics. Depending on the time of year and weather permitting, the subjects walked outside. All subjects, except 5, were able to participate in the aquasize classes. The aquasize classes took place at two community pools. The study subjects were integrated with nonFM persons in a 'regular' aquasize class. At the beginning and end of each session mild stretches were included.

The majority of the subjects were able to exercise comfortably at a heart rate based upon the percentage of age predicted maximum HR (HRmax) (recommended range of 60-75% HRmax), although some subjects exercised at a HRmax a bit below 60%. At each session, heart rate was monitored with a Polar Accurex HRM (Washington). The HR information was downloaded into a computer, thus providing an average HR for the aerobic component of that exercise session. When a HR monitor was unavailable, HR was calculated by palpating the pulse. The average HR value was recorded at the middle and end of aerobic session.

The duration of activity was 10-15 minutes at the beginning of the program with gradually increasing duration throughout the study as the subjects adapted. The average duration at the end was approximately 20-40 minutes.
Education group – This group met once a week for 1.5-2 hours per session. The program was based upon principles of self-management. Topics included goal setting, problem solving, time/stress management, coping strategies, benefits of exercise, evaluating alternative therapies and barriers to behaviour change. Sessions were focused away from pain and other symptoms as much as possible and refocused on leading a well-balanced life. The group leader introduced topics and facilitated discussions. Subjects discussed solutions to problems or strategies to deal with difficulties they experienced. Guest speakers

included a rheumatologist, psychologist, registered dietician and other health and fitness experts (i.e. yoga master, tai chi instructor). The rheumatologist covered some basic information regarding the current knowledge about FM and then answered questions from the subjects. The psychologist compared the classification of FM to a grieving cycle after a death of a loved one. In a sense, a part of them had died. The dietician covered basic healthy eating, how to read labels and prepare nutritious meals with limited time and energy._ Another session included the family and/or friends of study participants. It was designed mainly for the non-study participants to learn more about FM and how they could assist someone with the condition. The sessions required all subjects to be active participants. Subjects were encouraged to share solutions or provide suggestions for others' concerns/problems.

Exercise and Education group - This group was a combination of both the exercise and education programs. The educational component was the same as for the education only group. The exercise group met 2 times per week and on the 3rd day met for education and then exercise.

Control group - On the day of the initial assessment, the subjects in the control group were given two pages of information on stretches and general coping strategies. They were contacted once or twice throughout the 12 week period to see how they were managing. The subjects from the control group were offered one of the intervention programs at the end of the follow-up period. Only the data collected during the control period was included in the current analysis.

Originally, the study was designed so that the different treatment groups would not interact with each other. However, the first time a cohort of subjects went through the study protocol, the education and exercise groups were too small at times due to dropouts or poor attendance. Therefore, despite the fear of contamination among groups the exercise and education group was combined with the exercise group for the exercise portion and then combined with the education group for the education portion for subsequent programs.

Subjects were considered to be non-compliant if they missed 3 exercise

sessions in a row or a total of 12 of 36 exercise sessions and 6 of 14 education sessions. Control subjects were considered to have complied if they did not alter their lifestyle (i.e. begin to exercise or participate in a FM education course) during the course of the study.

To assist with monitoring subjects' activities during the study, logbooks were provided for all subjects. The subjects recorded their exercise sessions, visits to health care professionals (physicians, physical therapists, etc), visits for other treatments (i.e. accupuncture, accupressure, massage, etc), unusual problems or changes in medication and weekly goals. Since goal setting was a component of the education section, the logbooks for the education and combination groups placed goal setting at the beginning of the books for emphasis. Subjects were instructed not to change their present treatment (i.e. medications) for the duration of the study. However, the investigators recognized the difficulty with enforcing such a stringent protocol over a 12 week period. Therefore, as long as participants documented any changes in their usual treatment the subject was still enrolled as an active participant.

Statistical Analysis

Three types of analyses were done on the data. First, an intention to treat (ITT) analysis was done on the pre and post data only. A subject was considered a study participant if she attended at least one treatment session. Subjects who dropped out before the completion of the study were asked to return for the post-testing. When post-test data were missing, baseline scores were then considered post-test scores. Secondly, a complete case analysis was done on subjects that completed the three test sessions. Finally, an analysis of the subjects who complied with the study protocol was done.

Questionnaires, walking test and TP data were analyzed using two-way analyses of variance (ANOVA) with repeated measures (Group vs Time) (SPSS statistical package, version 8.0). Any significant group, time, or group vs time differences were examined using Tukey multiple comparisons. In addition,

independent t-tests and Chi square tests were used to compare demographic and baseline variables in self- and physician-referred subjects, participants and non-participants, completers and non-completers. Significance level was set at $p<.01$ for all analyses.

RESULTS

Two hundred fifty-nine women were referred to the program or contacted the investigators themselves to participate. Seventeen subjects were ineligible to participate because they did not fit the inclusion criteria. Of the 242 subjects that were left, 46 could not be contacted or refused to participate. One hundred ninety-six women attended the pretest session and were randomized into one of four groups. After randomization and before the first session, 26 subjects decided not to participate. Only the Six Minute Walk was significantly different ($p=.04$) between referral groups. The self-referred subjects walked significantly farther (499.5 ± 86.5m) than the physician-referred (472.7 ± 85.2m).

The number of non-participants for each group was: exercise only - 3; education only - 11; exercise and education - 5; and control - 7. Reasons for not participating included lack of time (n=6), sessions conflicted with previous commitments (n=5), distance to travel (n=2), moved out of country (n=1), and unknown (n=12). Independent t-tests were run between the study participants and non-participants on demographic and baseline variables. The only significant difference between participants and non-participants was with the Six Minute Walk ($p=.001$), which was greater for the non-participants (547.7 ± 78.1m versus 477.2 ± 87.0m).

The reasons that subjects dropped out after attending at least one session were: lack of time (n=11), sessions conflicted with previous commitments (n=1), family health/personal problems (n=8), felt program would not help (n=5) or they could not be reached or refused to return for testing (n=9). No significant differences with any of the variables were demonstrated between dropouts and nondropouts.

Intention to Treat Analysis

One hundred fifty-two subjects were included in the ITT analysis. Baseline data were carried forward for 34 of the 152 subjects for the ITT analysis. Table 5.2 summarizes the power and ANOVA results for the ITT analysis. There were no significant group vs time interactions. Significant main effects for time were found for SE – coping with pain and other symptoms, FIQ, 6MW and number of TPs (Figures 5.1-5.3). Examination of the means revealed improvements from pre-test to post-test. The SE – function subscale was almost significant (Table 5.5).

Complete Case Analysis

Ninety-five of the original 170 subjects completed all three parts of the study (exercise only n=30; education only n=21; exercise and education n=26; and control n=18). Fifty –two subjects either dropped out before the first session or attended at least one session and 23 subjects refused to return for testing. A comparison by means of a one way ANOVA between the compliers and non-compliers on the demographic and baseline measures revealed no significant differences between the two cohorts. One subject was unable to complete the 6MW at follow-up due to foot surgery; therefore n=94 for this test.

Table 5.6 provides the summary of the power and ANOVA results for the subjects at all three test sessions. A significant interaction was almost demonstrated for the 6MW (p=.015) (Figure 5.5). Significant main effects for time were demonstrated for the three SE scales, FIQ, 6MW and number of TPs (Figures 5.6-5.10). Improvements were demonstrated from pre to post-test and from pre-test to follow-up for all measures, except the 6MW. The distance walked significantly increased from pre to post-test, but decreased from post-test to follow-up.

Compliers

The analyses were repeated using only the subjects that complied with the study protocol. The number of subjects who complied with the protocol were n=69: exercise only: n=21; education only: n=16 and exercise and education: n=15. One subject in the control group (n=17) was considered a noncomplier because she attended a FM Self-Management program offered by the Arthritis Society. There were no significant differences between compliers and noncompliers on demographic and baseline data, except for age (compliers 48.6 years vs noncompliers 43.4 years) and marital status (compliers had 4 single people vs noncompliers with 20 single people).

Table 5.7 summarizes the power and ANOVA results. A significant interaction was revealed with SE-coping with other symptoms (Figure 5.12) and the 6MW (Figure 5.13). Post hoc analyses revealed that the combined group increased their self-efficacy for coping with other symptoms from pre-test to post-test and follow-up compared to the control group. The exercise groups significantly improved their 6MW distance from pre-test to post-test. The exercise only group also maintained the improvement at follow-up.

The FIQ and number of TPs demonstrated significant main effects for time (Figure 5.14 and 5.15) with significant decreases from pre-test to post-test and pre-test to follow-up. The SE-coping with pain and functioning subscales were close to demonstrating a significant main effect for time (Figures 5.16 and 5.17).

Logbook Information

Information provided from the logbooks revealed that minor alterations in medications were recorded in the following percentage of subjects: exercise 25%; education 40%; combined 50%; control 38%. These alterations included slight increases/decreases in dosage or the addition/deletion of a drug. It was also discovered that 60% of the subjects in the education only and 73% of the subjects in the control group reported that they exercised (this included stretching) at least 2 times per week. The most popular form of exercise was

walking. There were no significant differences among the groups for number of visits for traditional treatments (e.g. physician, physical therapist, psychologist), nor for number of visits for alternative treatments. The number of subjects who reported seeking alternative type treatments was less than the number who reported seeking traditional treatments. However, the subjects sought alternative treatments more often than they did traditional treatments (mean number of visits 7.9±9.0; range of 1-36 versus 5.6± 5.4; range of 1-19, respectively).

DISCUSSION

Results from the current study revealed that only when compliance with the study protocol was taken into account did a significant difference among groups arise. If the program was followed, the combination of a supervised exercise program and group education provided persons with FM with a better sense of control over their symptoms. Fitness was also improved in the two groups undergoing supervised aerobic exercise programs. However, the improvement in fitness was maintained at follow-up in the exercise only group and not the combined group.

The 6MW results from the present study revealed that a supervised exercise program increased fitness, a change that was maintained at 3 months follow-up for the exercise only group. These results are contrary to Burckhardt et al (11) who did not find an improvement in the 6MW with their group involving exercise. The differences between studies may be due to the content and format of the exercise programs. The current study incorporated a supervised group aerobic exercise program that monitored exercise intensity and duration for each subject at every session. The study by Burckhardt et al (11) used physical training, which involved stretching, range of motion and time to develop an individual exercise program. Unfortunately, no details regarding intensity, supervision or format of exercise (group versus individual) were provided. Buckelew et al (13) provided information regarding exercise intensity, however

details regarding format and monitoring of intensity and duration of activity were lacking. In groups involving exercise, improvements were reported on the physical activity scale of a self-report questionnaire and not an actual measure of fitness (13). The results from the current study suggest that in order to create a change in fitness, a supervised group aerobic exercise program that monitored exercise intensity and duration, offered three days per week, was necessary.

Surprisingly, at follow-up the improvements in 6MW distance were maintained in the exercise only group, but not the combined group. A possible explanation may relate to the coping strategies used by the two groups. The combined group was taught a variety of methods for coping with FM, not just exercise. The exercise only group was not taught any additional coping strategies and may have only had experience with exercise in order to manage FM. The combined group may not have relied on exercise as much as the exercise only group to manage FM, therefore the distance walked at follow-up decreased.

It was interesting that QOL did not improve in any of the groups during the study period (Table 5.8). A change was anticipated after the 12 week program, since a previous study reported a significant change in intervention groups after only 6 weeks (11). In the current study, little variability among groups was revealed and lower baseline scores were found compared to the study by Burckhardt et al (11). Perhaps subjects from the current study did not have a full comprehension as to how the questionnaire was to be answered. For example, some subjects did not understand that even if they did not participate in an activity they could still be satisfied with that aspect of their lives.

In the current study, the number of TPs decreased over time with no significant change in Total Survey Site Score. These results indicate that despite the decrease in the number of TPs, the pain severity was rated higher at each positive site after the 12 weeks. Moreover, the results were similar for all 4 groups. Although two trained examiners assessed the TPs of the same subject

at each test session, no reliability checks were done. However, the TP assessment protocol was standardized according to previously published criteria (21). This finding is contrary to previous research that reported a reduction in myalgic scores after exercise (1-4). The difference in results may relate to the scale used for the subject to assess pain severity. In the present study, the TP assessment protocol utilizes a pain severity scale with a range of 0-10 for each TP; whereas the scale used in previous research ranges from 0-3. The lack of significant change with TP pain severity may indicate that very little fluctuations occur over time with this measure. Recently it has been reported in persons with FM that TP pain scores were associated with generalized pain and pain behaviours (24). Perhaps substantial changes in pain levels need to occur for the TP pain severity to be altered.

Previous randomized controlled trials investigating multidisciplinary treatment in persons with FM have reported varied results (11-13, 25). Significant differences were demonstrated between the intervention groups and control group on measures of self-efficacy and life satisfaction after 6 week programs (11, 13). However, a more recent study (25) found no significant differences pertaining to self-efficacy in the exercise and education group compared to the control group after a 6 week program. The lack of consistent results suggests that exercise and education may not be efficacious for the management of FM.

Overall, discrepancies between the results from the current study and previous research with FM may be related to differences with analyses, program content and/or program duration. Although the analyses employed by previous researchers (11-13) were adequate, they did not determine group versus time interactions. These analyses are limiting in that only the between and within differences were examined. This may explain some of the more positive findings in previous studies compared to the current results. Variability in educational content and type of exercise also may contribute to the differences among the studies. In addition, programs of only 6 weeks duration (11, 13) may not be long

enough to demonstrate a change in fitness or other behaviours, however compliance levels may have been better.

The lack of significant group differences in the current study may have resulted from the number of dropouts. In the education only and control groups over half of the subjects dropped out. It became clear when the subjects were randomized that some had a strong desire to be in a specific group. For example, some expressed the opinion that they already knew enough about FM and they did not need to attend an education class. Others were either anxious to be in an exercise group or did not want to participate in exercise at all. A few subjects expressed disappointment for ending up in the control group. They were not pacified with the knowledge that they would receive an intervention of their choice at the completion of the study. Due to this, many of the control subjects could not be reached or refused to return for testing. Previous research has reported that prior to treatment, 30% of subjects with FM were certain that aerobic exercise would make them worse and only half thought they would improve from the exercise (12). The reservations regarding exercise did not appear to have a negative impact on the treatment outcome in that study. It is unclear the impact that pre-program beliefs regarding exercise and education had upon the current results.

Lack of time was another reason some subjects cited for not continuing with the study. The time commitment for the subjects in the exercise only and combined groups was large. However, in order to determine if a training effect occurred, the subjects needed to exercise at least 3 days per week. A previous study (3) reported that in pilot work, the number of exercise sessions per week had to be reduced from 3 to 2, due to the number of dropouts and non-compliers. The number of dropouts in the previous study compared to the current study may have been reduced due to fewer exercise sessions. However fewer exercise sessions did not translate into increased fitness levels compared to the control group.

Previous investigators have suggested that the interventions were not

powerful enough to create a difference among the intervention groups (6, 11). These authors concluded that the superficial education programs were not aggressive enough to actually alter behaviours; hence the lack of significant differences among groups. However, these conclusions may actually suggest that the treatments examined were not efficacious in managing FM. The lack of significant interactions in the current study would support this statement. Perhaps the use of exercise and education for the treatment of FM needs to be reassessed.

Limitations

There were also some limitations with the current study. Firstly, as mentioned previously, the number of dropouts was a concern and did influence the power to detect a difference between groups. The dropouts from the control group may have decreased if an attention control group had been offered instead of delayed treatment. It also may have appeased some of the subjects who were unhappy with the outcome of randomization. Secondly, despite originally planning to keep the different intervention groups separate, the exercise and education groups had to be combined part way through the study. This potentially may have led to crossover between groups when the combined group joined with the exercise and education groups. Finally, a majority of the subjects from the education and control groups were already exercising on their own at the commencement of the study. This may have contributed to the lack of significant differences among groups. However, it was believed to be unethical to ask the subjects to discontinue exercising if randomized into a non-exercise group.

Another possible limitation was that no measure of depression was used in the present study. Varying levels of anxiety and depression have been reported in the literature for persons with FM (26-28). It has been reported that the frequency of depression and anxiety disorders are higher in persons with FM as compared to rheumatoid arthritis and osteoarthritis (29). Burckhardt et al (11)

reported that 25% of their subjects with FM were severely depressed. Although it has not been determined which came first, the depression or the FM, research suggests that physical functioning does relate to current emotional states (30). Perhaps identifying high depression levels by means of an interview/questionnaire and controlling for it in the analysis by using an analysis of covariance may have resulted in greater group differences.

The current study expanded or improved upon previous work in a number of areas. First, the study design was such that the differential effects of exercise and education in persons with FM could be determined. Second, the duration of the study was 12 weeks, which should have allowed for an adequate training period to induce any physical improvements or behavioural changes. It would also determine if impairment and functioning improved with the physical or behavioural changes. Third, three types of analyses, were undertaken to determine the impact of attendance and compliance on the treatment outcome. Finally, logbooks were given to every subject, including the control group, to monitor medication changes, exercise and visits to health care professionals or alternative treatments. This would enable comparisons among the groups, as well as descriptive data that may have explained some of the results.

The referral sources were also different than the majority of studies. Although all subjects were volunteers and may have been seeking treatment of some kind, referrals did not just come from rheumatologists. Subjects were self-referred once they had heard about the research project. This may have resulted in a wider variety of subjects perhaps more representative of the general FM population.

The exercise component was also quite unique compared to previous studies involving exercise in persons with FM. The exercise was supervised by a physical therapist 3 times per week. Exercise intensity was monitored by both HR and RPE at every session. The duration of the exercise sessions were also recorded for each person at every session. The subjects exercised as a group, but the intensity was individualized and subjects were encouraged to work at

their own pace with modifications to activities when necessary. Part way through the study, the exercise sessions were held with regular aquasize classes at community pools. By holding the exercise classes in community facilities it was hoped that the subjects would continue exercising at a facility in their neighbourhood once the study was finished.

Conclusions

Results from the current study revealed that the subjects receiving the combination of exercise and education and who complied with the treatment protocol improved their perceived ability to cope with other symptoms. In addition, a supervised exercise program increased walking distance at post-test, an increase that was maintained at follow-up in the exercise only group. Education alone did not provide benefits that were greater than those provided by the exercise and exercise plus education components. Overall, the results do not provide strong support for the use of exercise and education in managing FM. The high dropout rate highlights the difficulty with compliance to treatment protocols, such as exercise and education, for persons with FM. Perhaps future research with the FM population needs to focus on not only treatment efficacy, but also on strategies to encourage and promote compliance with any prescribed treatment plan. Detailed examination of the reasons for non-compliance with treatment programs in persons with FM may contribute to an enhanced treatment effectiveness.

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Table 5.1. Demographic variables on all FM subjects

	Exercise n=46	Education n=48	Exercise & Education n=37	Control n=39	F ratio or Chi^2 (p value)
Age (yrs)	45.2 (9.4)	44.9 (10.0)	47.4 (9.0)	47.3 (7.3)	0.91(.440)
Height (cm)	162.7 (7.3)	162.3(6.2)	160.1 (4.9)	161.9 (6.8)	1.28(.282)
Weight (kg)	74.0(20.2)	75.8(16.6)	82.1(17.8)	76.8(17.9)	1.43(.237)
Duration of symptoms (yrs)	7.8 (6.1)	10.9(10.7)	8.9 (7.3)	9.6 (7.9)	1.23(.299)
Onset of symptoms (% Yes)					
Idiopathic	82.6	68.8	67.6	71.8	3.15 (.368)
Traumatic	17.4	31.2	32.4	28.2	
Marital Status (%)					
Married	63.0	64.6	62.2	64.1	
Single	8.7	14.6	21.6	12.8	4.21 (.240)
Divorced/ separated	15.2	14.6	16.2	15.4	
Common-law	6.5	6.3	0	5.1	
Widowed	6.5	0	0	2.6	
Employed (% Yes)	47.8	47.9	40.5	46.2	0.66 (.882)
Compensation (% Yes)	15.2	35.4	32.4	41.0	7.66 (.054)

Table 5.1 Continued

Litigation (% Yes)	6.5	6.3	8.3	7.7	0.15 (.99)
# of Tender Points	16.3 (2.0)	16.5 (1.9)	16.3 (2.0)	16.6 (1.5)	0.40 (.751)
Medications (%)					
anti-depressants	52.2	72.9	64.9	41.0	6.0 (.113)
anxiolytics	6.5	8.3	2.7	2.6	6.22 (.101)
analgesics	45.7	35.4	35.1	38.5	3.56 (.313)
NSAIDS	4.3	0	8.1	10.3	1.68 (.431)
muscle relaxants	17.4	20.8	10.8	15.4	4.85 (.183)
hypnotic	10.9	4.2	13.5	15.4	2.72 (.436)
anti-convulsants	6.5	14.6	5.4	5.1	2.86 (.414)
alternative	10.9	25.0	18.9	25.6	5.43 (.143)
IBS	8.7	6.3	10.8	2.6	6.56 (.087)
thyroid	13.0	22.9	13.5	10.3	7.0 (.072)
estrogen	26.1	12.5	21.6	15.4	3.36 (.339)
gastric	21.6	12.5	13.5	5.1	3.26 (.353)

Table 5.2. Analysis of Variance summary table for ITT analysis (n=152).

	SE pain	SE function	SE coping	FIQ	6MW	QOL	#TPs	Total Survey Site Score
Group	F(3,161)=3.04	F(3,161)=2.40	F(3,161)=1.22	F(3,161)=2.42	F(3,158)=1.13	F(3,160)=0.24	F(3,160)=.194	F(3,160)=1.04
	p=0.031*	p=0.070	p=0.303	p=0.068	p=0.340	p=0.867	p=.900	p=.375
	power=.706	power=.592	power=.324	power=.595	power=.300	power=.095	power=.086	power=.279
Time	F(1,161)=9.41	F(1,161)=5.86	F(1,161)=12.6	F(1,161)=17.4	F(1,158)=7.44	F(1,160)=2.96	F(1,160)=10.84	F(1,160)=1.69
	p=0.003**	p=0.017*	p=0.001***	p=0.000***	p=0.007**	p=0.087	p=.001***	p=.195
	power=.862	power=.672	power=.941	power=.986	power=.774	power=.402	power=.253	power=.253
Group	F(3,161)=0.65	F(3,161)=0.57	F(3,161)=1.79	F(3,161)=2.85	F(3,158)=3.25	F(3,160)=1.41	F(3,160)=.199	F(3,160)=.748
x Time	p=0.582	p=0.636	p=0.151	p=0.039*	p=0.023*	p=0.242	p=.897	p=.525
	power=.185	power=.166	power=.460	power=.675	power=.738	power=.675	power=.087	power=.208

* significant at p<0.05

** significant at p<0.01

***significant at p<0.001

SE=Self-Efficacy Scale, FIQ=FM Impact Questionnaire, 6MW=Six Minute Walk, QOL=Quality of Life Scale, #TPs=number of tender points

Table 5.3. Self-efficacy -Pain score for ITT analysis [Mean (SD)].

	Pre*	Post
Exercise	49.8 (21.2)	52.8 (20.4)
Education	48.6 (21.2)	51.1 (22.0)
Ex & Educ	53.9 (20.2)	61.7 (24.5)
Control	42.1 (21.1)	46.1 (21.3)

* significant time effect

Table 5.4. Self-efficacy -Coping with Other Symptoms score for ITT analysis [Mean (SD)].

	Pre*	Post
Exercise	50 4 (19.8)	55.3 (18.8)
Education	52.4 (20.6)	56.3 (19.7)
Ex & Educ	50.6 (17.0)	60.3 (22.0)
Control	47.9 (17.8)	48.4 (20.5)

* significant time effect

Table 5.5. Self-efficacy - Function score for ITT analysis [Mean (SD)].

	Pre*	Post
Exercise	62.9 (24.8)	64.9 (20.5)
Education	56.0 (22.1)	60.3 (23.7)
Ex & Educ	60.8 (20.7)	65.1 (23.2)
Control	52.7 (19.2)	53.3 (20.8)

* significant time effect

Table 5.6. Analysis of Variance summary table for complete case analysis (n=95).

	SE Pain	SE Function	SE Coping with Symptoms	FIQ	6MW	QOL	#TPs	Total Survey Site Score
Group	F(3,91)=2.04	F(3,91)=1.43	F(3,91)=0.24	F(3,91)=0.99	F(3,90)=1.02	F(3,91)=0.09	F(3,76)=.966	F(3,76)=1.50
	p=0.114	p=0.240	p=0.871	p=0.399	p=0.386	p=0.967	p=.413	p=.222
	power=.507	power=.367	power=.093	power=.263	power=.270	power=.065	power=.254	power=.381
Time	F(2,91)=5.61	F(2,91)=4.92	F(2,91)=9.57	F(2,91)=10.77	F(2,90)=6.69	F(2,91)=2.96	F(2,152)=7.82	F(2,152)=1.55
	p=0.004**	p=0.008**	p=0.000***	p=0.000***	P=0.002**	p=0.055	p=.001**	p=.215
	power=.854	power=.802	power=.980	power=.989	power=.911	power=.571	power=.949	power=.326
Group	F(6,91)=1.04	F(6,91)=0.52	F(6,91)=2.01	F(6,91)=1.72	F(6,90)=2.72	F(6,91)=0.71	F(6,152)=.921	F(6,152)=1.67
x Time	p=0.400	p=0.794	p=0.067	p=0.119	p=0.015*	p=0.638	p=.482	p=.132
	power=.405	power=.206	power=.722	power=.642	power=.863	power=.279	power=.356	power=.623

* significant at p<0.05

** significant at p<0.01

*** significant at p<0.001

SE=Self-Efficacy Scale, FIQ=FM Impact Questionnaire, 6MW=Six Minute Walk, QOL=Quality of Life Scale, #TPs=number of tender points

Table 5.7. Analysis of Variance summary table for subjects' who complied with the study protocol (n=69).

	SE Pain	SE Function	SE Coping with Symptoms	FIQ	6MW	QOL	#TPs	Total Survey Site Score
Group	F(3,65)=1.65	F(3,65)=0.62	F(3,65)=0.60	F(3,65)=0.75	F(3,63)=0.01	F(3,65)=0.521	F(3,60)=1.05	F(3,60)=1.78
	p=0.188	p=0.608	p=0.618	p=0.529	p=0.998	p=0.669	p=.377	p=.161
	power=.412	power=.171	power=.168	power=.201	power=.052	power=.151	power=.270	power=.440
Time	F(2,65)=3.79	F(2,65)=4.00	F(2,65)=12.92	F(2,65)=7.98	F(2,63)=8.27	F(2,65)=0.660	F(2,60)=6.23	F(2,60)=.992
	p=0.025*	P=0.021*	p=0.000***	P=0.001***	P=0.000***	p=0.519	p=.003**	p=.374
	power=.682	power=.707	power=.997	power=.950	power=.958	power=.159	power=.886	power=.219
Group	F(6,65)=1.52	F(6,65)=0.82	F(6,65)=3.48	F(6,65)=1.17	F(6,63)=2.87	F(6,65)=1.04	F(6.60)=.485	F(6,60)=1.06
x Time	p=0.178	p=0.556	p=0.003**	p=0.327	p=0.012**	p=0.400	p=.818	p=.389
	power=.570	power=.315	power=.939	power=.448	power=.878	power=.401	power=.191	power=.405

* significant at p<0.05

** significant at p<0.01

*** significant at p<0.001

SE=Self-Efficacy Scale, FIQ=FM Impact Questionnaire, 6MW=Six Minute Walk, QOL=Quality of Life Scale, #TPs=number of tender points

Table 5.8. Quality of life scores for each analyses [Mean (SD)].

	ITT		Complete Case			Compliers		
	n=152		n=95			n=69		
Group	Pre	Post	Pre	Post	Follow-up	Pre	Post	Follow-up
Exercise	70.0 (15.3)	72.3 (15.5)	71.9 (16.8)	74.3 (15.5)	72.9 (15.8)	68.8 (17.5)	70.4 (15.6)	70.6 (16.7)
Education	67.7 (16.5)	69.5 (16.7)	72.1 (17.1)	73.2 (17.4)	72.0 (15.8)	75.3 (17.1)	73.6 (14.7)	71.9 (14.9)
Ex & Educ	69.4 (13.5)	72.3 (14.9)	70.3 (12.4)	75.1 (14.5)	75.7 (14.7)	71.9 (12.8)	75.3 (13.1)	76.8 (13.4)
Control	70.8 (15.7)	69.4 (17.5)	73.5 (14.8)	75.2 (18.3)	75.2 (14.3)	74.5 (14.7)	75.6 (18.7)	75.6 (14.6)

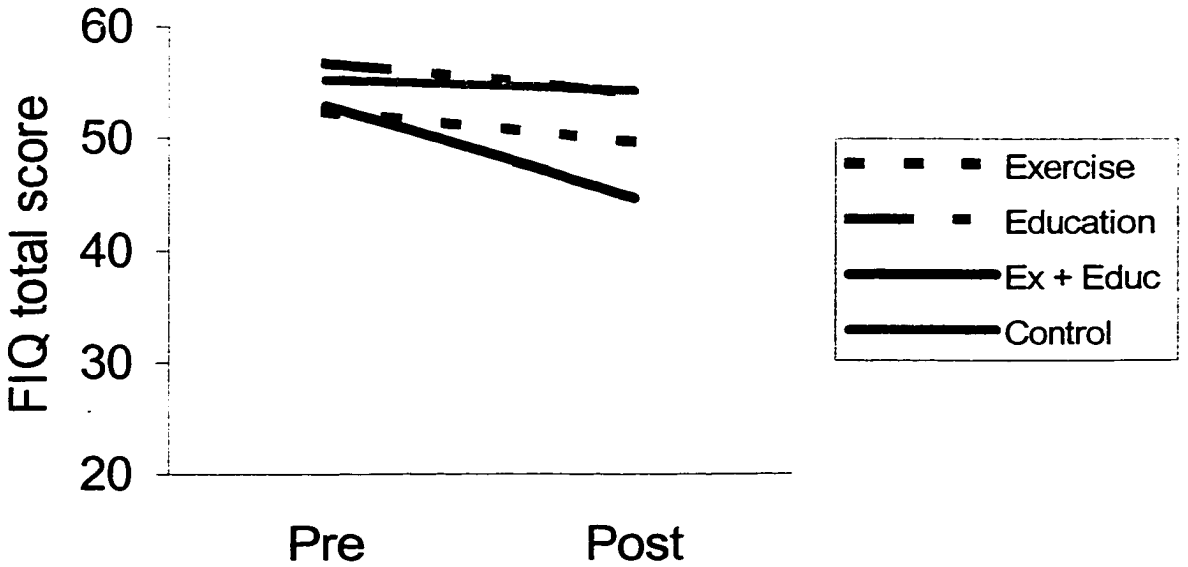

Figure 5.1. Fibromyalgia Impact Questionnaire total score (ITT analysis). Combined group significantly decreased score at posttest.

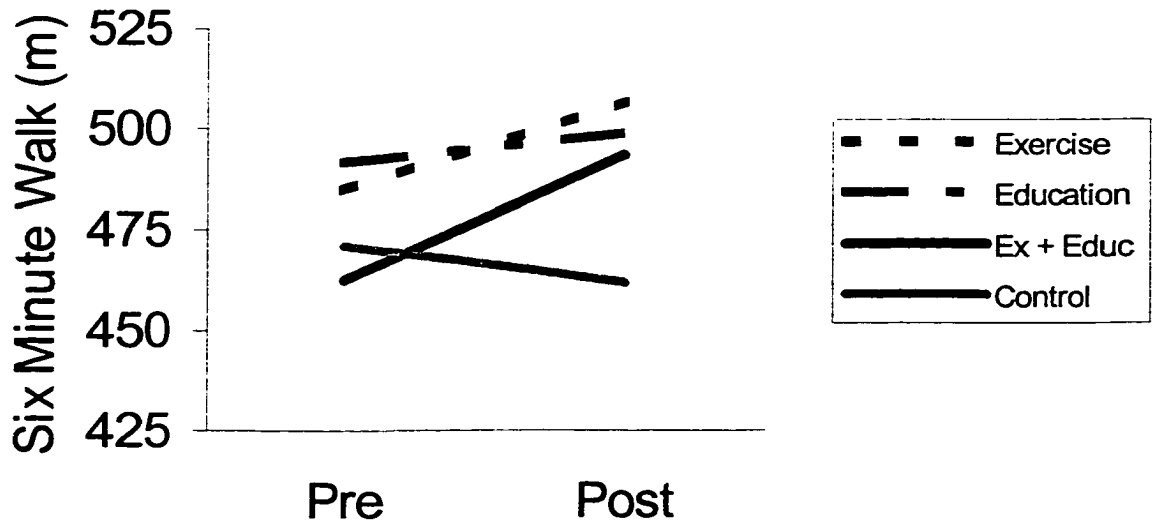

Figure 5.2. Six Minute Walk distance (ITT analysis). Exercise only and combination groups significantly improved distance at posttest.

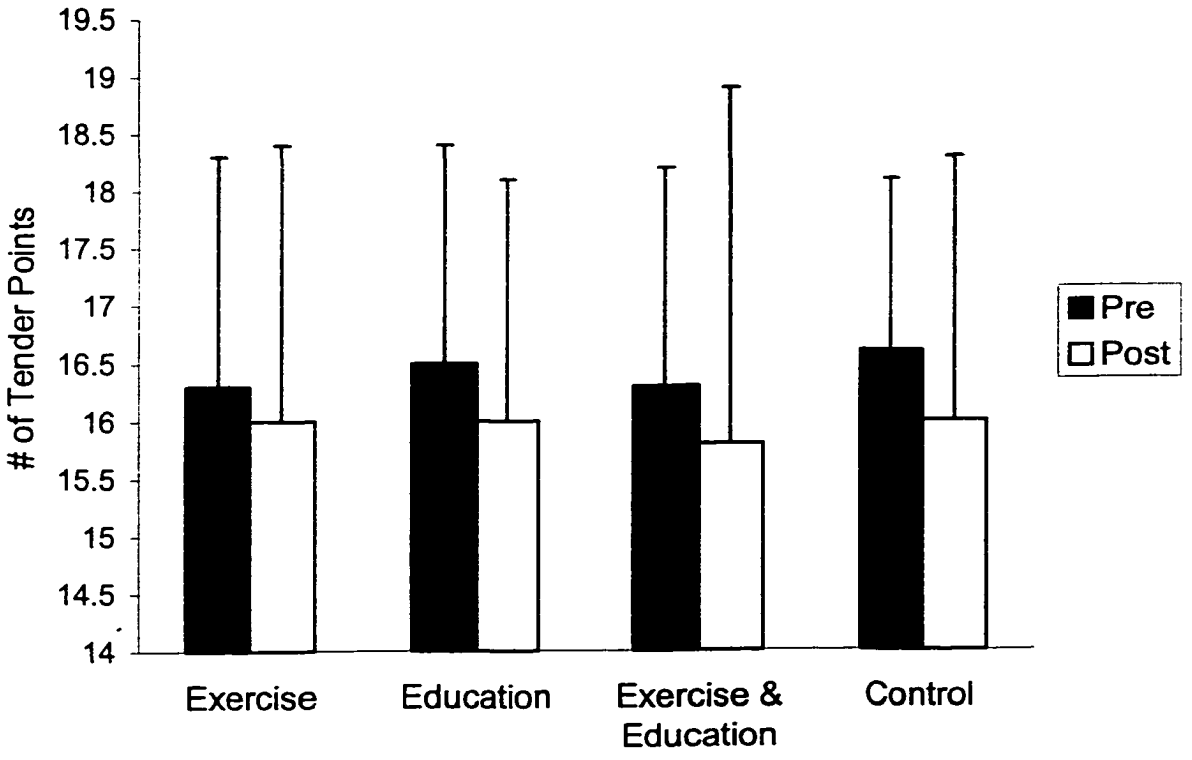

Figure 5.3. Number of Tender Points for ITT Analysis (values 0-18). Significant time effect.

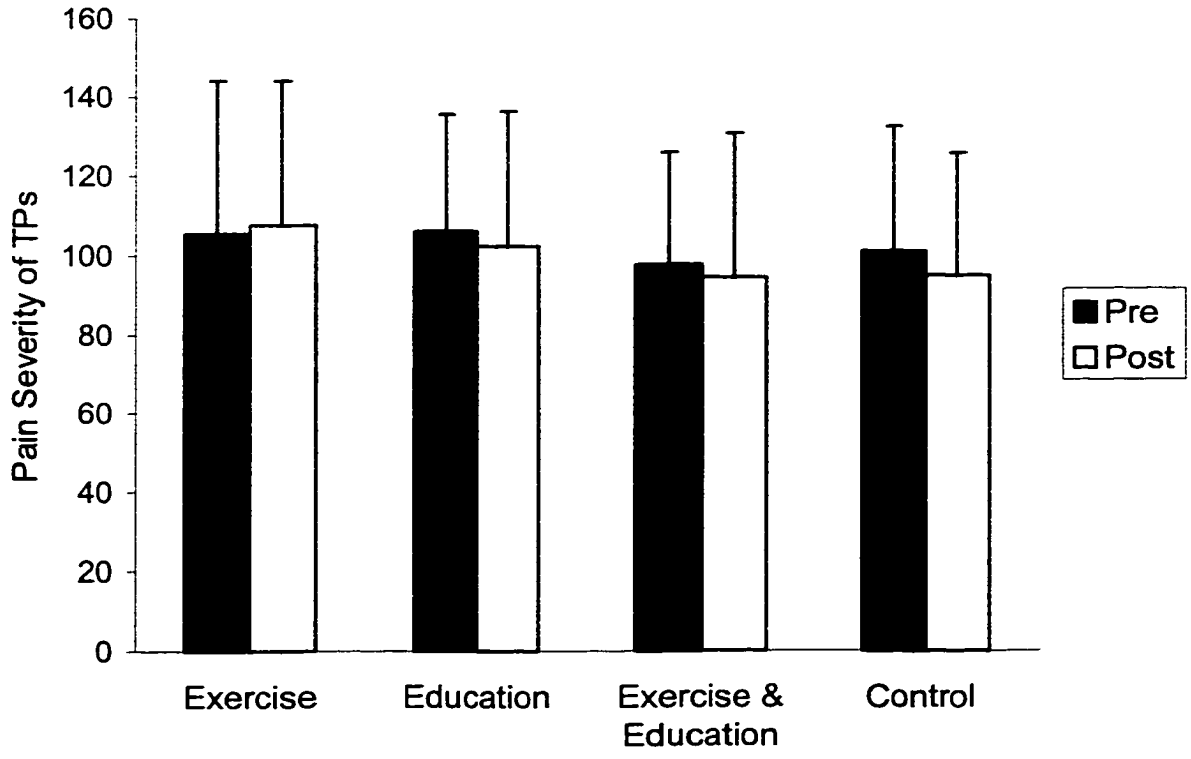

Figure 5.4. Pain Severity of Tender Points for ITT Analysis (values 36-180).

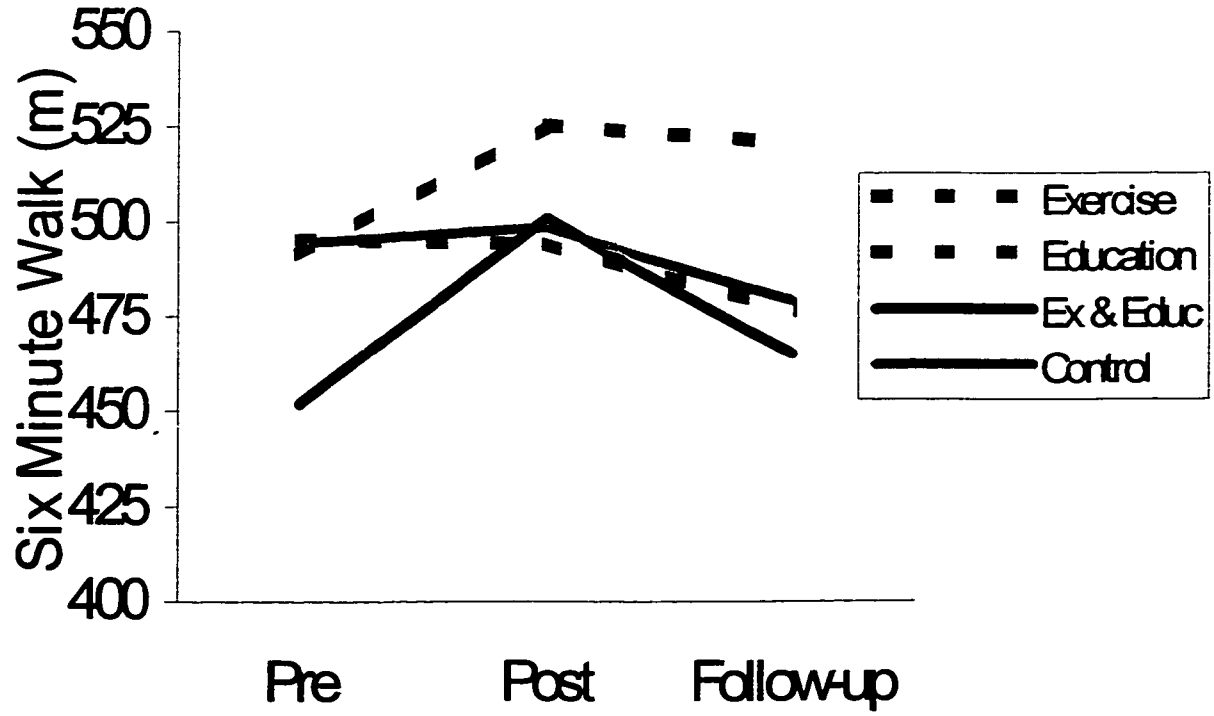

Figure 5.5. Six Minute Walk results for complete case analysis. Significant increase for exercise only (pretest<posttest and pretest<follow-up).

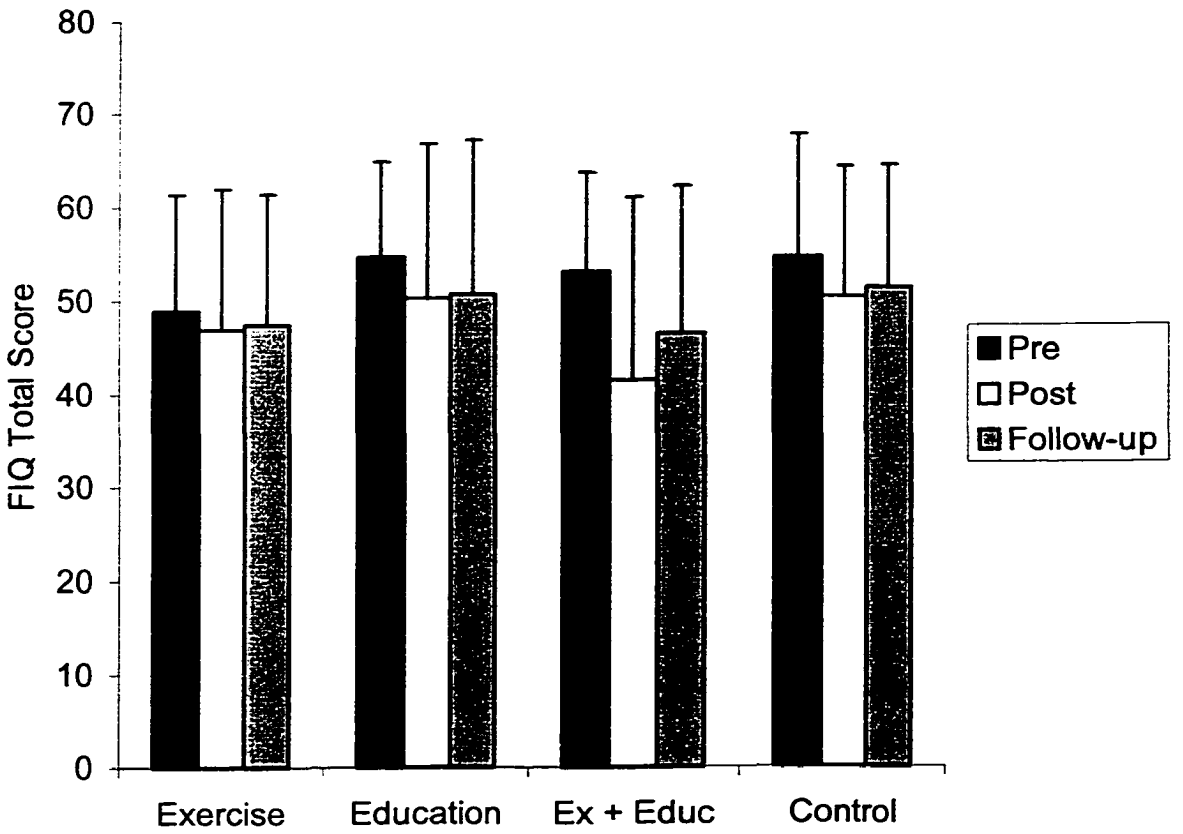

Figure 5.6. FM Impact Questionnaire total score for complete case analysis. Significant time effect (pre> post and pre>follow-up).

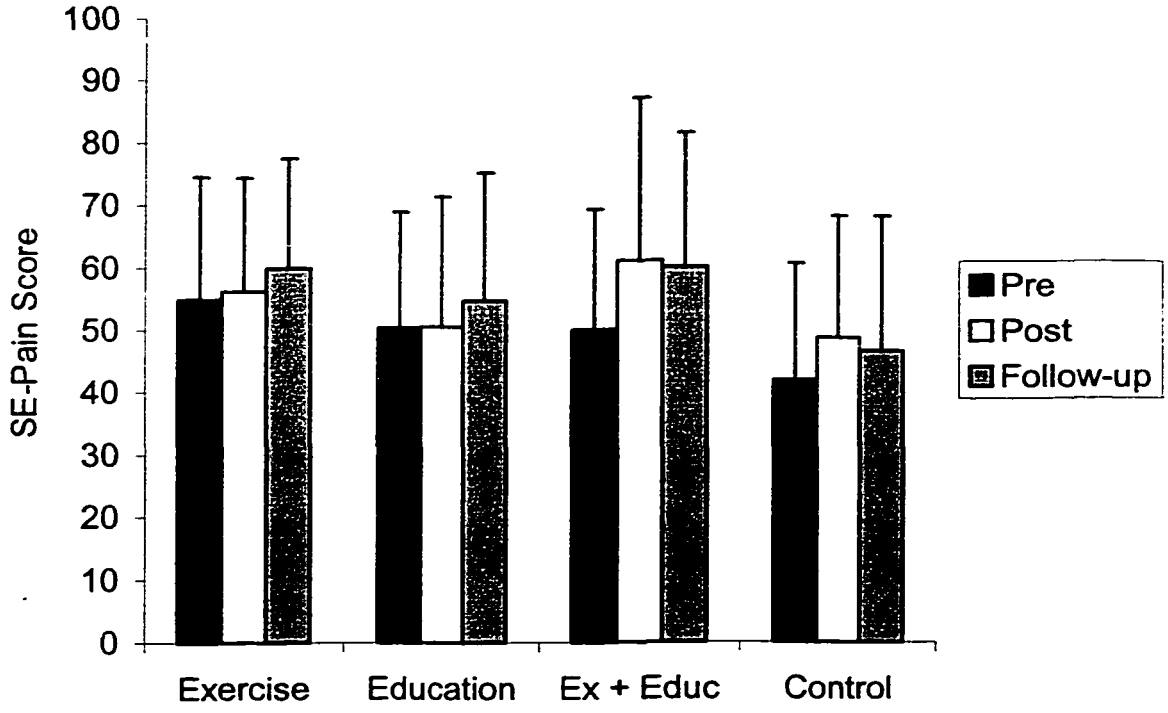

Figure 5.7. Self-Efficacy for coping with pain subscale for complete case analysis. Significant time effect (pre<post and pre<follow-up).

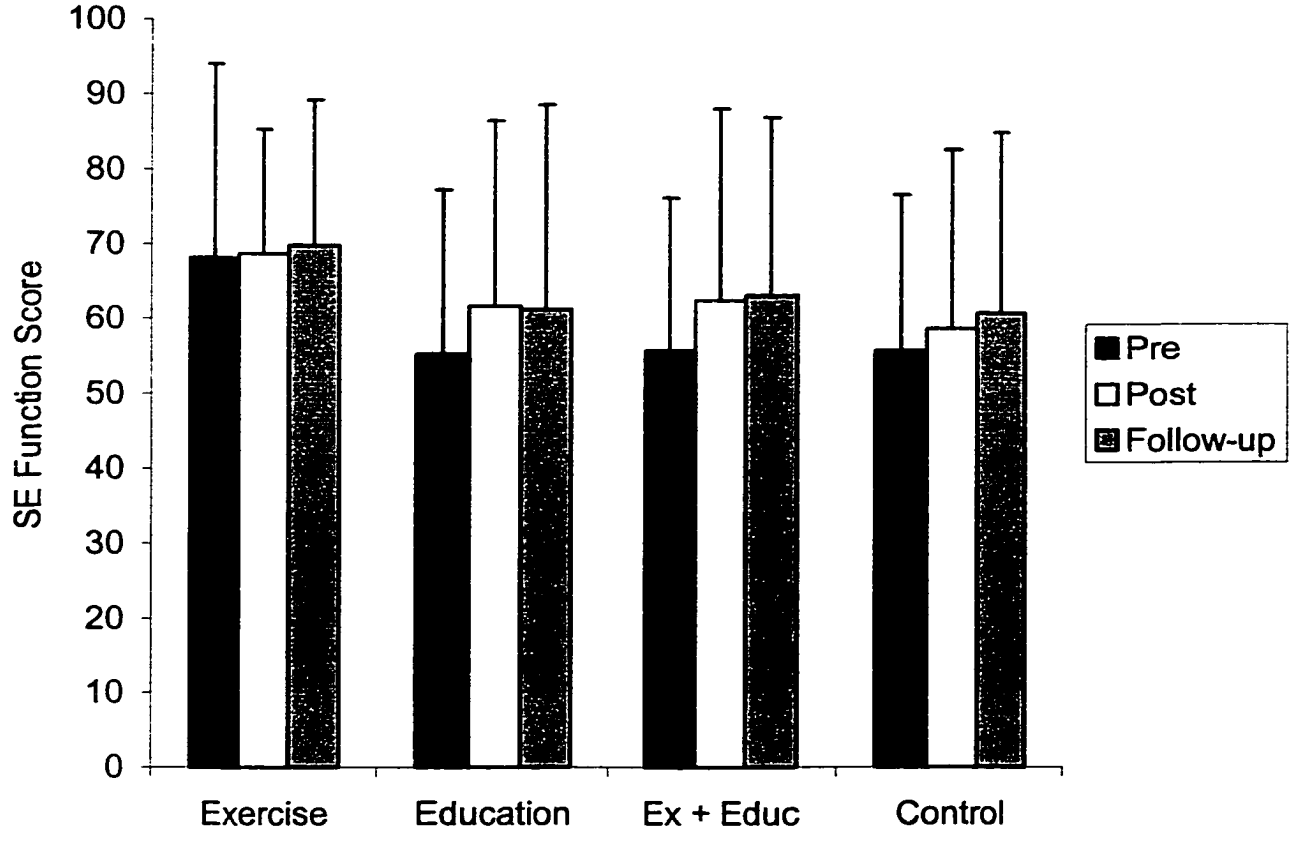

Figure 5.8. Self-Efficacy for function subscale for complete case analysis.

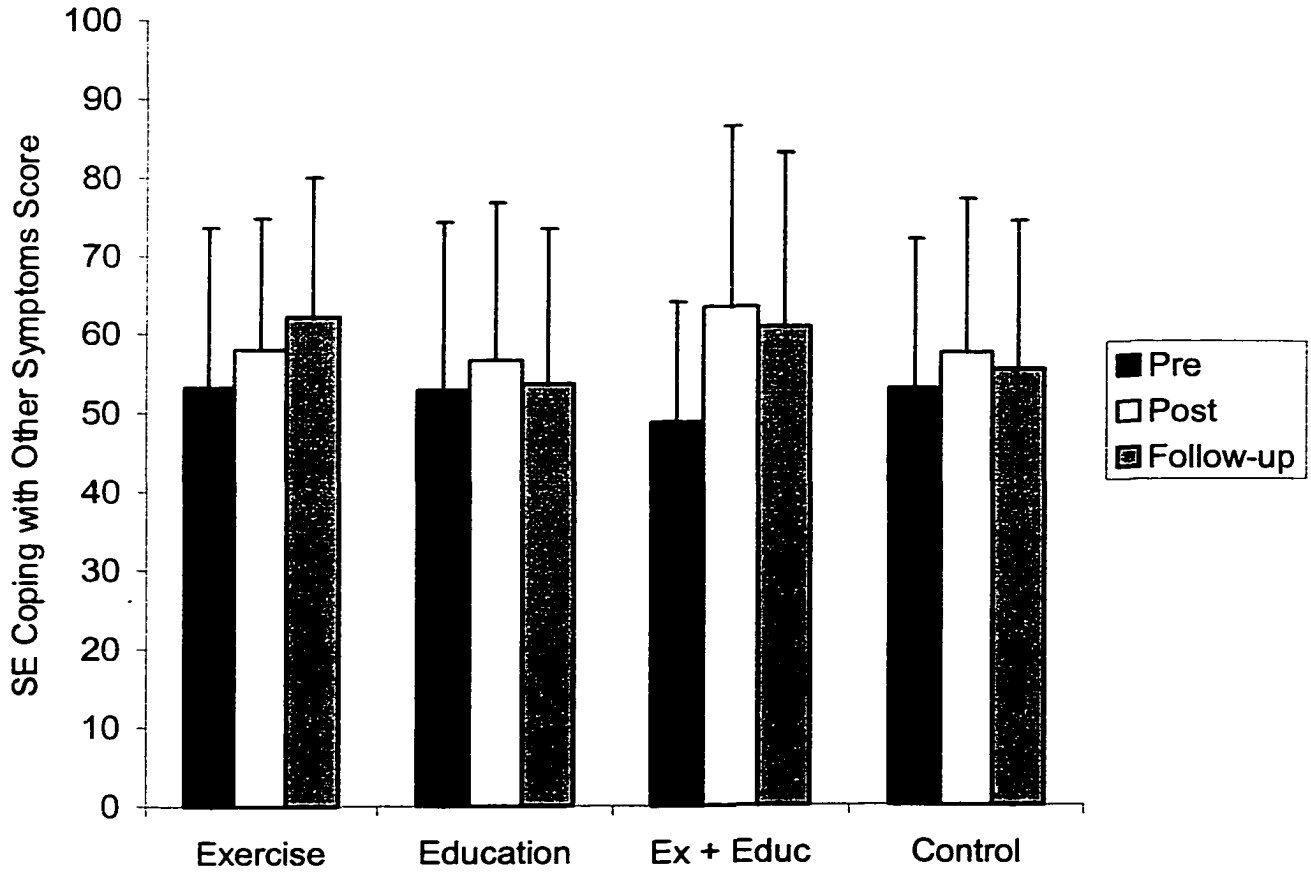

Figure 5.9. Self-Efficacy for coping with other symptoms subscale for complete case analysis. Significant time effect (pre<post and pre<follow-up).

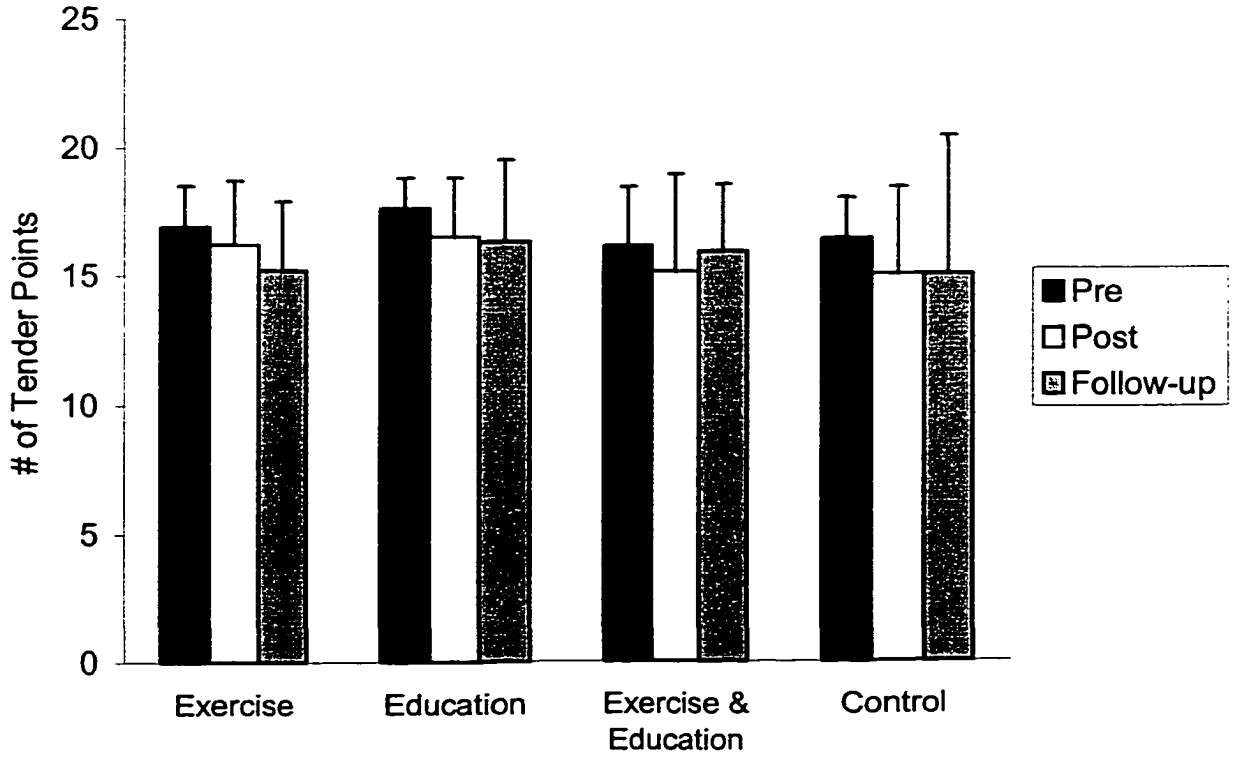

Figure 5.10. Number of Tender Points for complete case analysis (values 0-18). Significant time effect (pre<posttest).

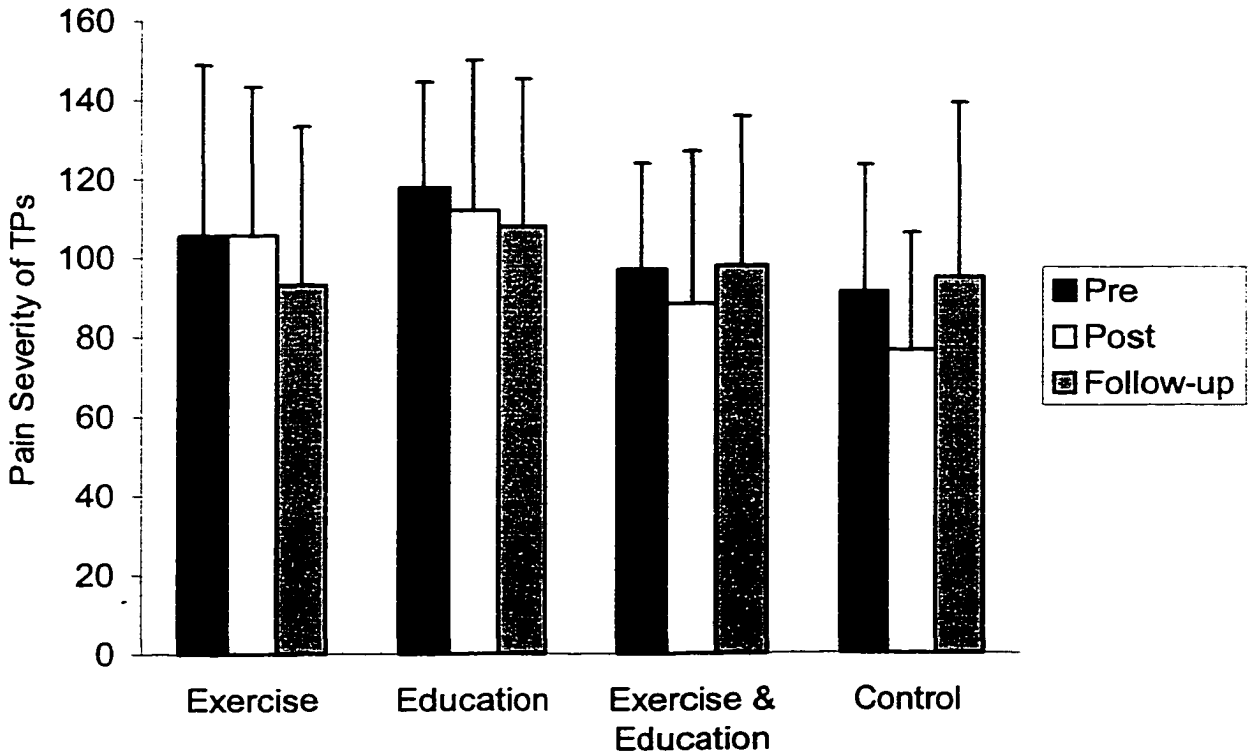

Figure 5.11. Pain Severity of Tender Points for Complete Case Analysis (values 36-180).

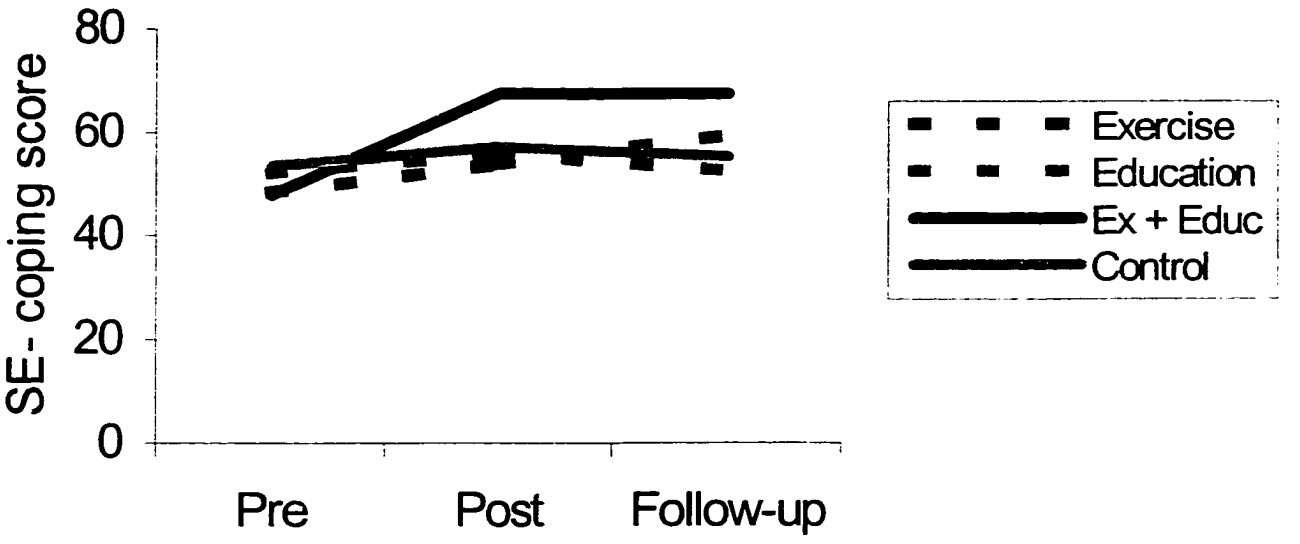

Figure 5.12. SE coping with other symptoms score for compliance analysis. Significant improvement for Ex and Educ group (pre<post and pre<follow-up; Ex and Educ group > Control group).

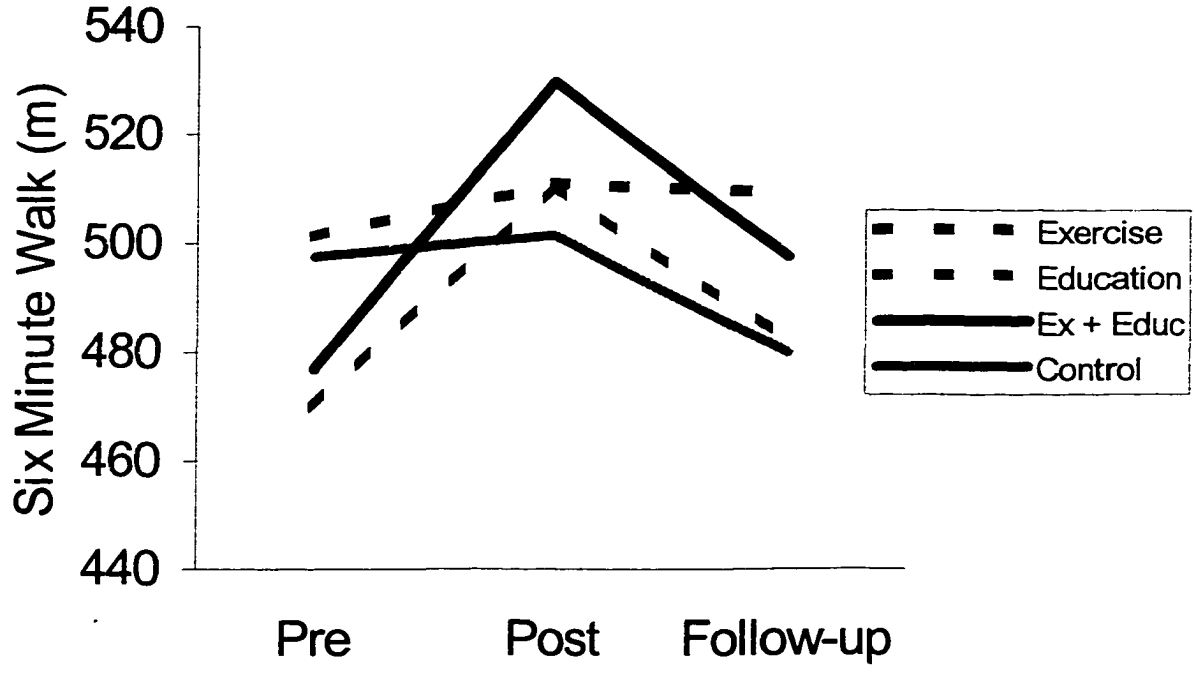

Figure 5.13. Six Minute Walk distance for compliance analysis. Significant improvement for Exercise only group (pre<post and pre<follow-up) and Exercise and Education group (pre<post).

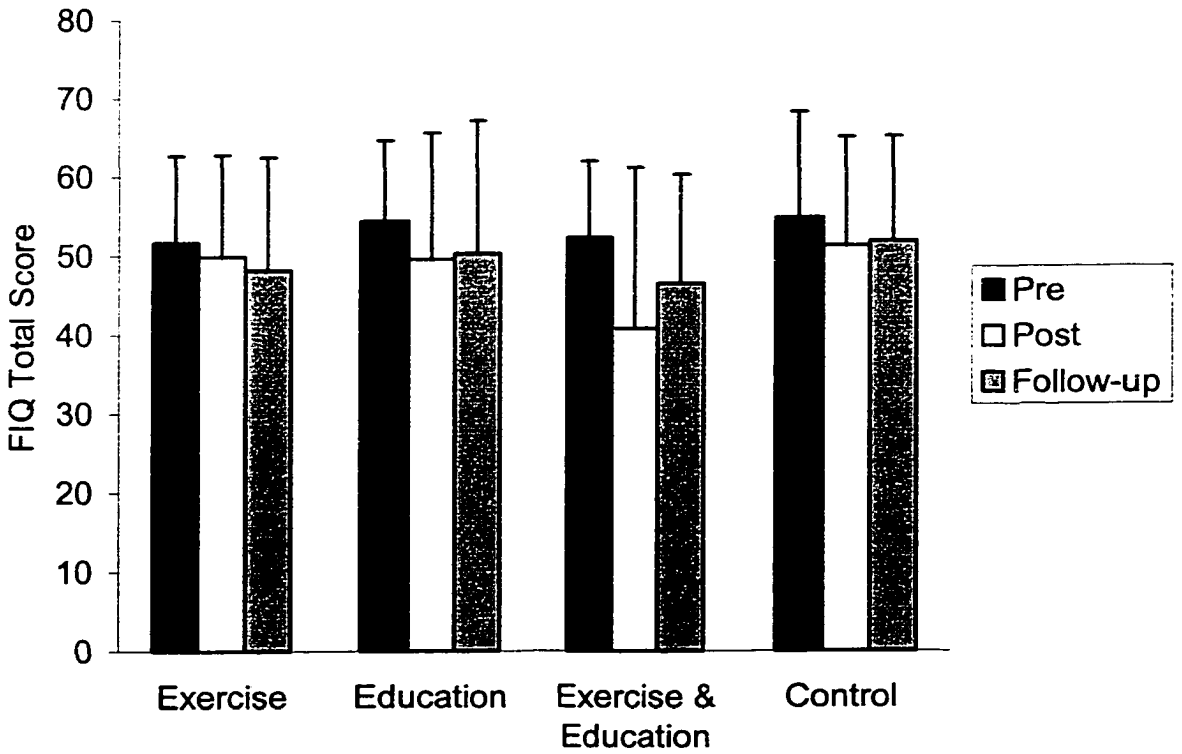

Figure 5.14. FM Impact Questionnaire total score for compliance analysis. Significant time effect (pre>post and pre>follow-up).

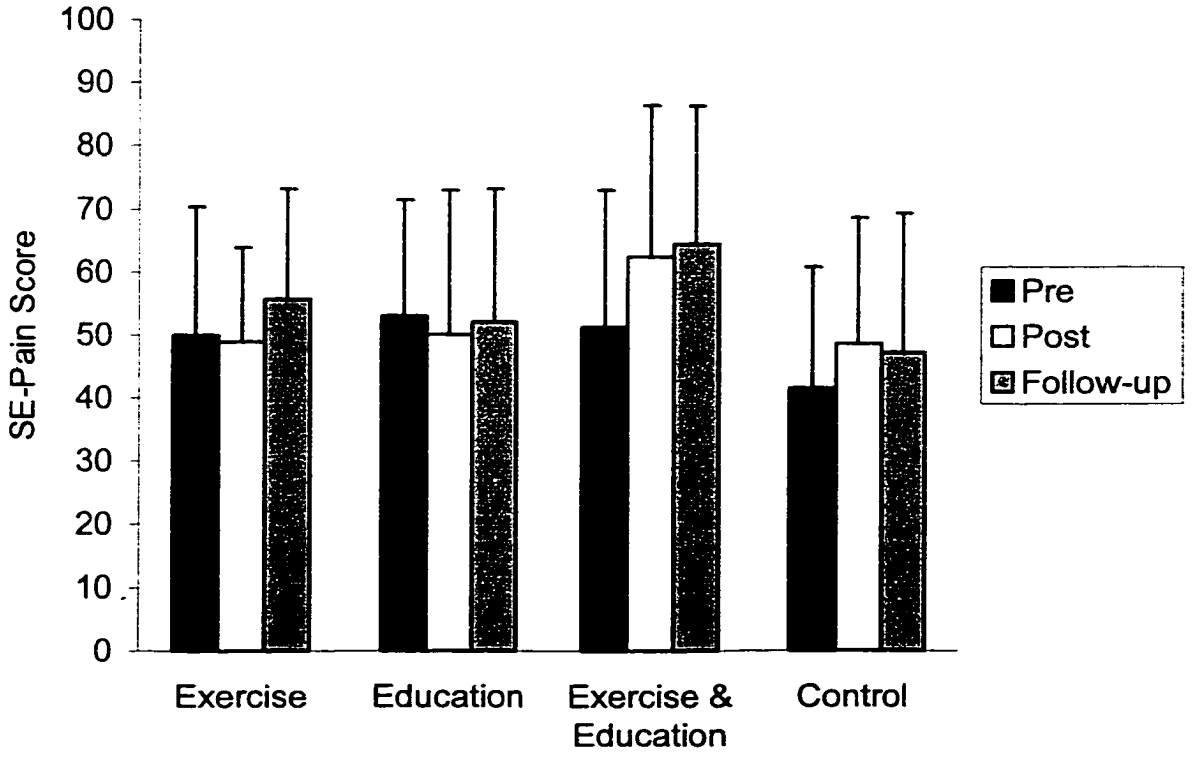

Figure 5.15. Self-efficacy for coping with pain subscale score for compliance analysis.

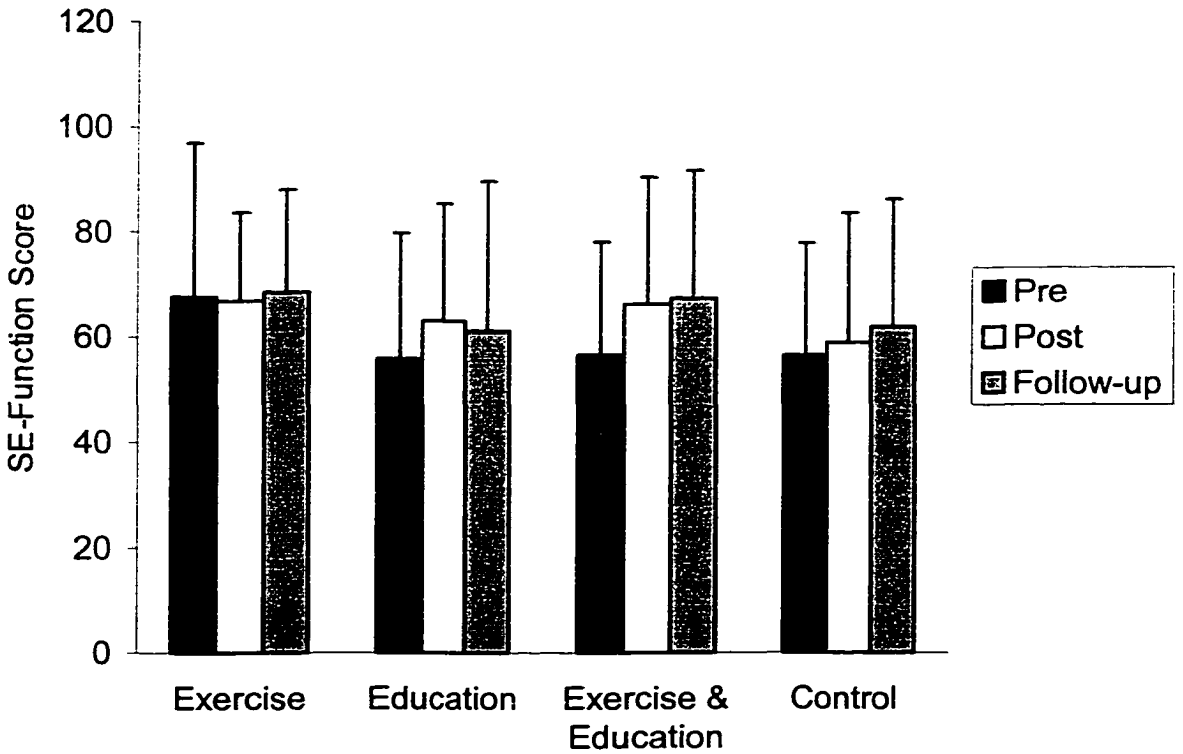

Figure 5.16. Self-efficacy for function subscale score for compliance analysis.

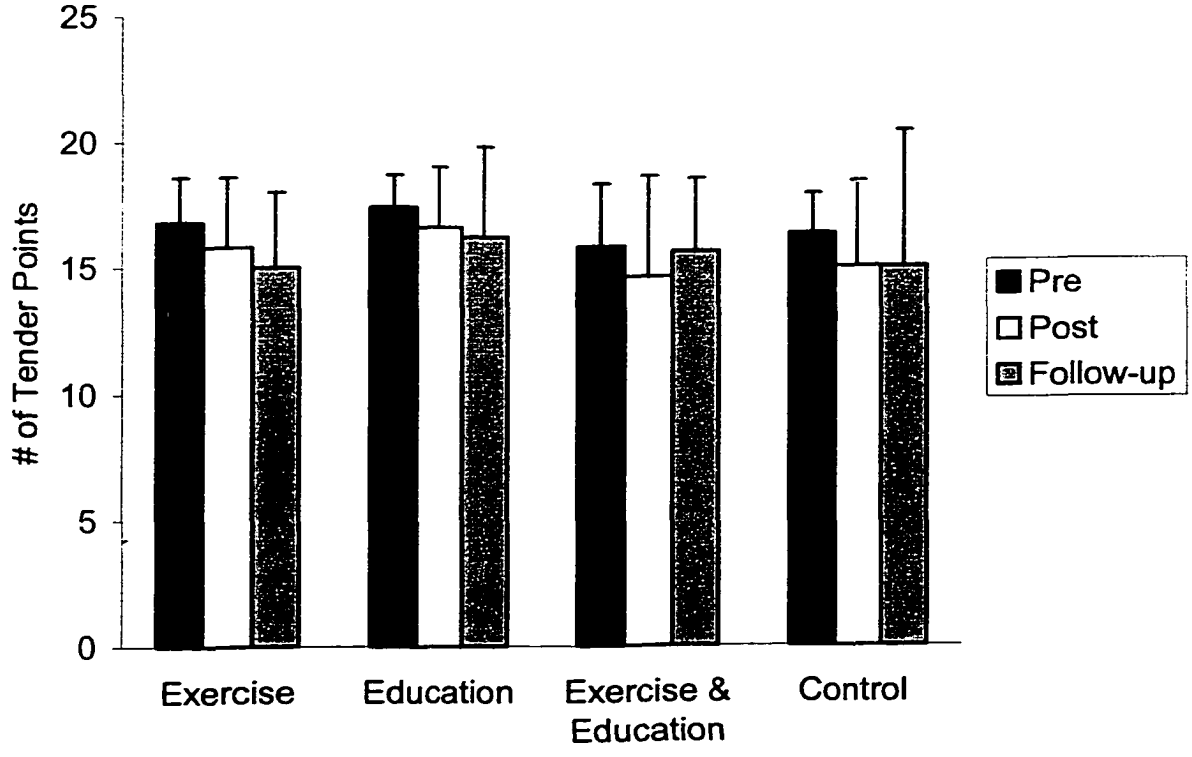

Figure 5.17. Number of Tender Points for compliance analysis (values 0-18). Significant time effect (pre<post and pre<follow-up).

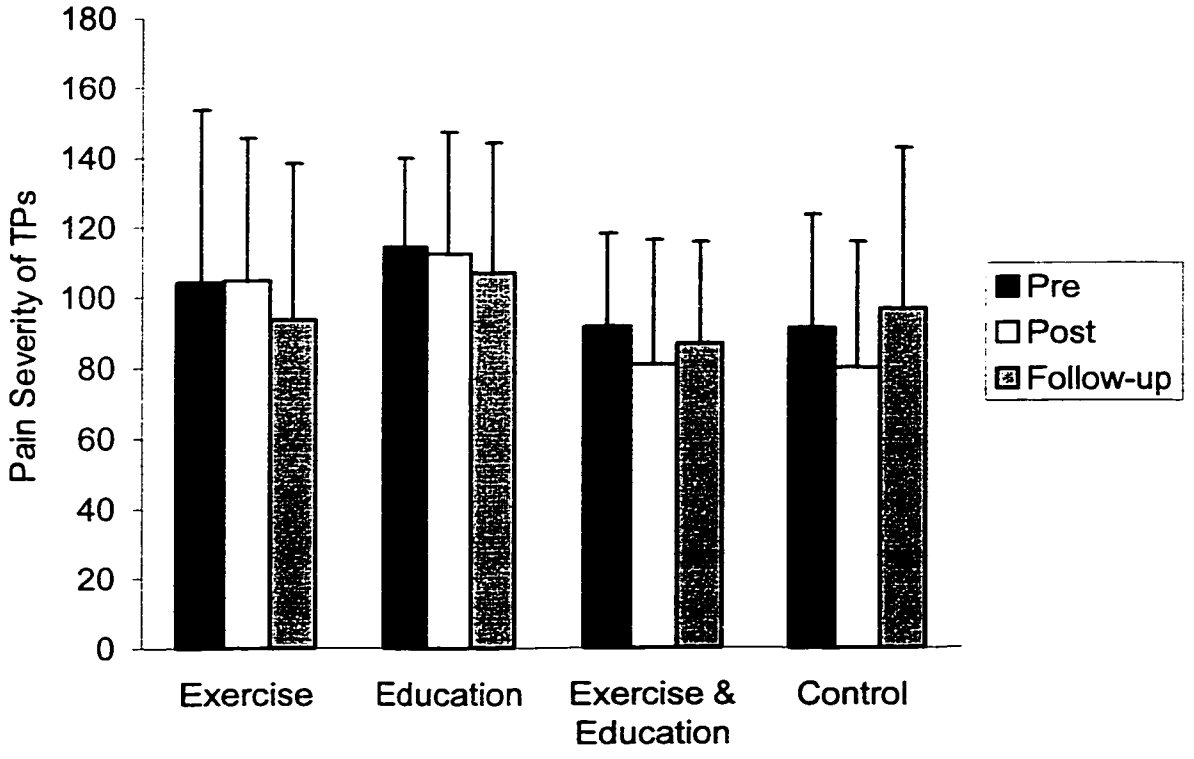

Figure 5.18. Pain Severity of Tender Points for compliance analysis (values 36-180).

CHAPTER 6
Relationship Between Change in Physiological and Psychosocial and Functional Measures in Women with FM

Regular physical activity is an important factor for maintaining and improving health and wellness. The physical and mental health benefits of physical activity are well reported in healthy populations (1-4), as well as in persons with chronic diseases (5-7). Since it was reported that tender points (TPs) developed after sleep deprivation in healthy persons, but not marathon runners (8), aerobic exercise has been examined and recommended as an adjunct to other treatments for managing symptoms of FM (FM), a chronic pain condition (9-12).

Despite the recommendations for regular aerobic exercise, the actual cardiovascular and metabolic responses to exercise have not been adequately measured in persons with FM. Studies that included aerobic exercise as a form of treatment for persons with FM evaluated changes in fitness by using work capacity or walking tests (distance covered or duration of test). After exercise programs, improvements from initial baseline fitness values have been reported (9, 10, 12, 13). Cardiovascular or metabolic measures have been reported only as baseline data. Oxygen consumption (VO_2) is determined by cardiac output (Q) [product of heart rate (HR) and stroke volume (SV)] and the extraction of O_2 by active muscle [arteriovenous oxygen difference ($(a\text{-}v)O_2$ diff)]. Measuring these components in persons with FM would help determine if any central (SV) or peripheral [$(a\text{-}v)O_2$ diff] adaptations occur with aerobic training.

In addition to reported improvements in fitness, changes with physical findings and psychosocial measures have been demonstrated in persons with FM after an exercise intervention. Improvements in the number of tender points (TPs), total myalgic scores, self-efficacy, impact of condition and overall well-being have been demonstrated in some persons with FM involved in exercise programs (12, 13).

To date, research that has examined the relationship between changes in fitness and improvements in measures of psychosocial or functional outcomes in

persons with FM has not been conducted. In clinical and non-clinical populations, contradictory results have been reported regarding the relationship between improvements in physiological and psychological measures (4, 14-18). However, the well-controlled studies do not report a significant relationship between physiological and psychological changes. Determining if cardiovascular and metabolic measures improve after an aerobic exercise program and if the improvements are associated with changes in psychosocial measures may influence exercise prescription for persons with FM.

Therefore, the purposes of this study were threefold. The first objective was to determine if maximal and submaximal cardiovascular and metabolic variables improve in persons with FM after an aerobic exercise program. The second objective was to determine that if improvements do occur, do differences exist in the subjects receiving exercise, education or the combined exercise and education. The final objective was to determine if a change in peak oxygen consumption (VO_2) is associated with psychosocial and functional changes in persons with FM. It is hypothesized that cardiovascular and metabolic measures will improve significantly after the exercise program, but that these improvements will not be related to improvements in psychosocial and functional measures, just as previous research suggests (4,14).

METHODS AND MATERIALS

Subjects

Subjects were women between the ages of 18 and 65 years with a diagnosis of FM, according to the American College of Rheumatology 1990 criteria (19). They were referred by rheumatologists and general practitioners, or recruited through a local support group. A rheumatologist examined any subject not initially diagnosed with FM by a rheumatologist. Exclusion criteria were any musculoskeletal or cardiopulmonary condition precluding the ability to exercise, and any systemic inflammatory condition such as rheumatoid arthritis and systemic lupus. The University of Alberta's Faculty of Rehabilitation Medicine Ethics Committee approved the procedures undertaken in this study.

A power analysis was calculated to determine the number of subjects required in each group to detect a significant difference. Assuming an effect size of 0.4 for the cardiac output, a power of 0.8, and an alpha of 0.01, 11 subjects from each group were required to demonstrate a group x time interaction (20). To compensate for potential dropouts, it was determined that 13 subjects per group would be randomly selected from the entire sample for a total of 52 subjects. In pilot work with the physiological testing, it was determined that some persons randomly selected refused to undergo the testing. Therefore, instead of random selection, all of the subjects who were participants of the larger study were asked to undergo the physiological test on a treadmill. From the 170 subjects, 43 agreed to complete the physiological testing.

Methodology

On the first visit, all subjects completed a physical examination, questionnaires and a walking test. Once the tests had been completed, the subjects were randomized into one of four intervention groups. The subjects who volunteered were tested a few days later. Subjects were examined again on all of the measures immediately after the program was completed and at 3 months follow-up.

Testing

Physiological

To determine submaximal Q and the pVO_2, subjects performed an incremental treadmill test. Cardiorespiratory and metabolic measurements were continuously monitored using an automated metabolic measurement cart (MMC 2900, Sensormedics Corporation, CA). The metabolic cart was calibrated using commercially available precision gases (16% O_2, 4% CO_2, balance N_2, and 26% O_2, balance N_2) prior to and after each test to ensure accuracy of the data. The software used was the Advanced Exercise Testing Program (Sensormedics Corporation, California). Heart rate was recorded using a wireless monitor (Polar Accurex Plus HRM, Washington).

The subjects walked at a self-selected pace on the treadmill, and once the VO_2 values reached a steady state (i.e. VO_2 did not fluctuate more than 100ml/min), the maneuver to determine Q was initiated. Steady state for the re-breathing was usually achieved within 3-5 minutes from beginning the treadmill walk. After completion of the re-breathing maneuver, the treadmill grade was increased by 2% every 2 minutes. Heart rate and Borg's rating of perceived exertion (21) were recorded during the last 30 seconds of the 2-minute increments. The test was terminated once the subjects determined they could not tolerate the pain or fatigue any longer. The highest VO_2 achieved over a 20 second interval was considered the peakVO_2 (ml/kg/min and L/min).

The Collier carbon dioxide (CO_2) re-breathing technique (22), which is based on the indirect Fick principle, was used to measure Q during submaximal exercise. It is an indirect, noninvasive method that is highly correlated (r=0.94) with direct measurements of Q using the Fick technique (23, 24). The test-retest reliability coefficient of 0.89 has been published for the CO_2 re-breathing maneuver during upright cycling exercise in healthy males (25). The re-breathing technique utilizes the following assumptions as outlined in Jones (26): 1) an arterial pH of 7.4 and hemoglobin concentration of 13.9g/100ml; 2) arterial and venous O_2 saturation levels of 95% and 100%, respectively during re-breathing; and 3) conversion of the arterial and venous CO_2 pressures (PCO_2) into concentrations using the equation: $\log_c$ concentration $CO_2 = (0.396 \times \log_c PCO_2) + 2.38$.

The CO_2 re-breathing maneuver involves the subjects taking quick, deep breaths for approximately 12-15 seconds from a 5 litre anaesthesia bag containing premixed levels of either 8% or 11% CO_2 and balance O_2 until an equilibrium is achieved between the gas in the lungs and the bag. The gas concentration was based on the VO_2 and end-tidal CO_2 criteria available in Jones (26). The end-tidal CO_2 tension was considered to be reflective of arterial CO_2 pressure, whereas the bag CO_2 was assumed to be indicative of venous CO_2 pressure. A 'downstream' correction factor was applied to increase the validity of the latter assumption. The computer program assumes equilibrium of pressure of CO_2 between the bag and

the lungs when there was less than 1 mm Hg pressure over a 5 second interval. The average of the two carbon dioxide (VCO_2) values obtained immediately before the re-breathing maneuver were used to calculate Q. All the subjects were able to perform the CO_2 re-breathing maneuver, but in some cases they experienced difficulty while breathing out of the bag. In instances where this occurred, the subject was asked to repeat the maneuver after a sufficient wash out period.

The same treadmill speed and procedures from pre-test were used again at post-test and follow-up. This allowed for a comparison between the initial physiological values and the values after program completion.

The following cardiorespiratory variables were calculated: SV (ml/beat) = Q/HR; (a-v)O_2 diff (ml/100ml of blood) = VO_2(ml/min)/Q; and O_2 pulse (ml/beat)=VO_2(ml/min)/HR. The pVO_2 values (ml/kg/min) were converted into metabolic equivalents (METs) (1 MET = resting O_2 consumption or 3.5ml/kg/min) as another means of expressing energy expenditure. Variables that also indicate intensity of exercise during testing included ventilation (V_E), ventilatory equivalent for O_2 (V_E/VO_2), and respiratory exchange ratio (RER) (VCO_2/VO_2).

Psychosocial and Functional

The following measures were used to examine psychosocial and functional variables before and after the program:

Chronic Pain Self-Efficacy Scale (SE) - is a 20-item scale divided into 3 subscales (pain coping, functioning and coping with other symptoms), measuring subjects' beliefs in their ability to perform specific tasks and control symptoms of their condition (27). It was modified from Lorig's Arthritis Self-Efficacy Scale (28) to measure the efficacy expectations for coping with the consequences of chronic pain (27). A higher score indicates greater self-efficacy.

FM Impact Questionnaire (FIQ)- is a brief 19-item survey measuring physical functioning, work status, depression, anxiety, sleep, pain, stiffness, fatigue and well being in persons with FM (29). The total FIQ score was calculated according to Burckhardt et al (29). The range of scores is 0-80 with a higher score indicating greater impact of the condition on the person's life.

Quality of Life Scale (QOL) - is a 16-item questionnaire dealing with satisfaction with various aspects of life, such as health/physical activity, raising or having children, independence, learning or attending school (30). Each item is rated on a Likert scale ranging from 1 (terrible) to 7 (delighted). A total satisfaction score is obtained by summing all 16 items with total scores ranging from 16-112. A higher score indicates greater satisfaction with life.

Six Minute Walk Test (6MW) - is a field test developed from Cooper's 12-minute walk/run (31). Subjects walked along a flat 40-metre corridor and were instructed to "cover as much ground as possible in 6 minutes". Encouragement such as "good pace, keep it up" or "good work" was given at 2, 3, 4 and 5 minutes. At these same time intervals, the subjects were informed of the time remaining in the walk. Encouragement and time remaining were standardized for all patients. The distance covered in metres was recorded. The 6MW has been used in the FM research to evaluate fitness. Research has demonstrated a correlation of 0.66 ($p=.001$) between the 6MW and pVO_2, a direct measure of fitness (32).

Number of Tender Points (TPs) and Total Survey Site - the 18 TPs were examined according to an established manual TP survey protocol. (33). This protocol outlines examiner and subject positioning, order of examination and pressure application technique. Each time a TP is palpated, the subject rates the pain severity as 0 (no pain) - 10 (worst pain). The pain severity ratings that are 2 or more are considered positive TPs. The scores for these positive TPs are totaled, thus providing a Total Survey Site Score (ranging from 0-180).

Intervention

The intervention was 12 weeks in duration. The exercise program was based upon the 1990 American College of Sports Medicine (ACSM) position stand on the recommended quantity and quality of exercise for maintaining and developing cardiorespiratory fitness in healthy adults (23). However, the subjects were instructed at the beginning of the exercise program to work at a level that was comfortable to them. Throughout the duration of the study, the subjects increased the intensity and duration of their sessions to meet the ACSM

recommendations. The subjects met three times per week for the supervised exercise program. All instructors were certified fitness instructors with basic knowledge about the FM condition. In addition, a physical therapist experienced with exercise and FM attended every exercise session to assist with modifications of the activities for individuals when required. The therapist offered encouragement to the subjects when necessary.

The exercise was aerobic in nature and included activities such as walking, aquasize (deep and shallow water), or low impact aerobics. Depending on the time of year and weather permitting, the subjects could walk outside. All subjects, except 5, were able to participate in the aquasize classes. The aquasize classes took place at two community pools. The study subjects were integrated with nonFM persons in a 'regular' aquasize class. At the beginning and end of each session mild stretches were included.

The majority of the subjects were able to exercise comfortably at a heart rate based upon the percentage of age predicted maximum HR (HRmax) (recommended range of 60-75% HRmax), although some subjects exercised at a HRmax a bit below 60%. At each session, heart rate was monitored with a Polar Accurex HRM (Washington). The HR information was downloaded into a computer, thus providing an average HR for the aerobic component of that exercise session. When a HR monitor was unavailable, HR was calculated by palpating the pulse. The average HR value was recorded at the middle and end of aerobic session. The duration of activity was 10-15 minutes at the beginning of the program with gradually increasing duration throughout the study as the subjects adapted. The duration at the end was approximately 20-40 minutes.

The education group met once a week for 1.5-2 hours per session. The program was based upon principles of self-management. Topics included goal setting, problem solving, time/stress management, coping strategies, benefits of exercise, evaluating alternative therapies and barriers to behaviour change. Sessions were focused away from pain and other symptoms as much as possible and refocused on leading a well-balanced life. The group leader introduced topics and facilitated discussions. Subjects discussed solutions to problems or strategies

to deal with difficulties they experienced. Guest speakers included a rheumatologist, psychologist, registered dietician and other health and fitness experts (i.e. yoga master, tai chi instructor). The rheumatologist covered some basic information regarding the current knowledge about FM and then answered questions from the subjects. The psychologist compared the classification of FM to a grieving cycle after a death of a loved one. In a sense, a part of them had died. The dietician covered basic healthy eating, how to read labels and prepare nutritious meals with limited time and energy. Another session included the family and/or friends who were invited to learn more about FM and how they could help their friend or family member. The sessions required all subjects to be active participants. Subjects were encouraged to share solutions or provide suggestions for others' concerns/problems.

The exercise and education group was a combination of both the exercise and education programs. The educational component was the same as for the education only group. The exercise group met 2 times per week and on the 3rd day met for education and then exercise.

Statistical Analysis

Means and standard deviations were determined for physiological and psychosocial/functional measures. A two-way analysis of variance (ANOVA) (Group vs Time) was used to determine differences after the training program and at follow-up for physiological, psychosocial and functional measures. A positive change score was created for all measures by subtracting the pre program score from the post program score. In addition, the pre program scores were subtracted from the follow-up scores for all variables. The only exceptions were the FIQ, number of TPs and Total Survey Site Score where a lower score was more positive. For these variables the post program and follow-up scores were subtracted from the pre program score. Pearson Product Moment Correlations were used to determine the relationship between pVO_2 and psychosocial and functional change scores. The significance level was set at $p<0.01$.

RESULTS

The demographic variables for all subjects involved in the physiological testing are presented in Table 6.1. A one-way ANOVA revealed no significant differences on demographic or baseline measures between the subjects who volunteered to undergo the physiological testing and those who declined . There were 43 subjects that underwent the physiological testing at pre-test: exercise, n=17, exercise and education, n=12, education, n=7, control, n=7. Only 12 subjects participated in the post-test: exercise, n=6, exercise and education, n= 4, education, n=2, and 7 in the follow-up test: exercise, n=3, exercise and education, n=4. The main reason for not participating after the first test was the degree to which symptoms increased. Due to the large number of dropouts at post-testing and follow-up, no between group analysis (exercise versus no exercise) was possible. The groups involving exercise were combined and the education and control group subjects were excluded. Therefore, at pre-test n=29 and at post-test n=10.

Since between group analyses were not possible, a paired t-test determined the pre to post program differences for the physiological, psychosocial and functional measures. The significance level was adjusted to $p<0.05$ due to the decreased power. No significant differences were demonstrated with the demographic variables between subjects who completed both pre and post physiological tests and those who did not.

The percentage of HRmax that all of the subjects exercised at over the study period ranged from 65.4-69% (67.8 ±1.2%) (Figure 6.1). The average duration of the sessions ranged from 21.8 to 34.4 minutes (29.1±3.6 minutes) (Figure 6.2). During the follow-up period of 12 weeks, all subjects recorded in their logbooks any exercise sessions they completed. All of the subjects that underwent physiological testing continued to exercise during the follow-up period. The subjects exercised 2-4 times per week for a duration ranging from 25-40 minutes during the follow-up period. The main activity was walking.

Pre-test and post-test scores and significance levels for the physiological variables are presented in Table 6.2. Peak VO_2 (ml/kg/min and L/min), METs and

O_2 pulse increased significantly from pre to post-test. Heart rate, V_E and ventilatory equivalent (V_E/VO_2 ratio) did not change significantly. Body weight decreased, although not significantly, from 83.0 ± 22.6kg to 79.8 ± 20.4kg in the subjects. This change contributed to some of the improvement in the relative VO_2.

No significant improvements were demonstrated in any of the measures at submaximal exercise. Absolute VO_2 was almost significantly different at post-test (p=.058).

Table 6.3 outlines the pre-test and post-test scores and significance levels for the psychosocial/functional measures. Self-efficacy for function, coping with pain and coping with other symptoms, the FIQ, number of TPs and Total Survey Site Score significantly improved at post-test. No change was found with the QOL scale. The distance walked in 6 minutes increased by 9%, but was not statistically significant.

Correlations between the change scores of pVO_2 and the psychosocial/functional measures are presented in Table 6.4. No correlations were significant.

Only 7 subjects agreed to undergo the physiological testing at follow-up. Statistical comparisons were not done and only mean values are reported for these 7 subjects. Peak VO_2 (ml/kg/min) decreased slightly from post-test (Figure 6.3). Peak HR at follow-up was lower than at pre-test, but higher than at post-test. (pre-test 141.4±23.3 bpm vs post-test 126.8±13.1 bpm vs follow-up 133.9±30.2 bpm). Body weight slightly increased at follow-up compared to pre-test, but was the same as at post-test (pre-test 66.7±11.9kg vs post-test 68.4±11.9kg vs follow-up 68.4±11.2kg).

DISCUSSION

Exercise training in this study resulted in changes in pVO_2, disability, perceived ability to cope with pain, symptoms and functioning, number of TPs, and pain severity at the TPs. The increase in V_E and slight decrease in V_E/VO_2 ratio, although not significant, were in the expected direction. Despite the improvements in pVO_2 and psychosocial and functional measures, no significant relationships

between the changes in the measures were demonstrated.

In the literature there is an absence of studies examining the metabolic and cardiovascular response to aerobic exercise training for persons with FM and sedentary middle-aged women. Therefore, comparisons were made with results from older women (age ranging from 50 to 75 years). The results from the current study suggest that although the values are lower, the subjects with FM responded normally to aerobic training when maximal exercise values were examined. DeVito et al (35) reported an increase in VO_2 max (24.3±3 vs 25.0±2 ml/kg/min), HRmax (152±11vs 155±12 beats/min) and V_E (50±10 vs 56.6±13 L/min) in healthy older subjects (mean age 60 years; 3 men, 8 women) after an aerobic training program. Seals et al (36) found increases of 7-29% for VO_2 max values in a cohort (7 men; 4 women) of older (mean age 63±2 years) low or high endurance trained subjects. The response to aerobic training in the current study was consistent with the physiological responses reported in the literature for older sedentary healthy women indicating that the metabolic system in women with FM was adaptable after aerobic training.

Despite the significant improvement in pVO_2 and O_2 pulse after aerobic training, virtually no change in peakHR was demonstrated. Typically, an increase in pVO_2 should be accompanied by an increase in peakHR. Since O_2 pulse is mathematically related to both SV and (a-v)O_2 diff, in order to maintain the same O_2 consumption, either a greater volume of blood was pumped through each heart beat or a greater amount of O_2 was extracted from the tissue in the periphery. Previous research in healthy women has reported a significant relationship between O_2 pulse and SV, but not O_2 pulse and (a-v)O_2 diff at ventilatory threshold (34). Although not measured at peak exercise in the current study, perhaps the increase in VO_2 and O_2 pulse was due to an adaptation in SV after the aerobic training.

It was difficult to determine unequivocally that the physiological changes at maximal exercise were a direct result of the exercise program and not due to familiarity with the test procedures. None of the subjects had ever undergone a test of this nature. A few subjects had never walked on a treadmill before.

However, sedentary older women inexperienced with physiological testing showed a mean difference of 0.8 ml/kg/min between two VO_2max treadmill tests (37). Previous research evaluating aerobic fitness has used an increase of >15% to indicate a true change in aerobic fitness (17, 18). The current results revealed a 15.6% increase in pVO_2. In addition, peakHR should have changed if the increase in VO_2 had been due to a familiarity with the test alone. Despite this increase in pVO_2 and the reliability of physiological testing in sedentary women, familiarity with the test protocol may have contributed in part to the change in peak exercise values.

The submaximal response to aerobic training for persons with FM, although not significant, was in the anticipated direction and was similar to that of older sedentary women. The typical responses in older women are a relatively unchanged VO_2 and SV, decreased HR and Q, and increased $(a\text{-}v)O_2$ diff (38). Although a slight decrease in $(a\text{-}v)O_2$ diff was demonstrated at post-test, 50% of the subjects responded in the expected direction. The lack of significant changes with respect to the cardiovascular measures [Q, SV and $(a\text{-}v)O_2$ diff], suggest that neither central nor peripheral adaptations occurred at submaximal exercise after the aerobic training.

In the FM literature, exercise consistently decreased physical symptoms of the condition, such as number of TPs, total myalgic score and pain severity at the TPs, even when compared to a control group (9,12,13). However, the results with psychosocial measures in persons with FM after exercise have varied. Bennett et al (13) reported improvements with psychosocial measures including disability, self-efficacy and life satisfaction in a FM cohort that exercised in addition to receiving an education program. The anxiety and depression subscales from the FIQ also significantly improved in the same cohort (13). Studies involving exercise alone compared to a control group found only trends in improvements with psychosocial measures (9, 12). The current study reported improvements in disability, self-efficacy (function and coping with pain and other symptoms) in a cohort who received exercise, some of whom also received education. Psychosocial variables measured after an exercise program may be influenced by

the intensity of exercise, group versus individual activity or the amount of individual control within the exercise program. Moreover, previous research with FM and the current findings would suggest that the addition of an educational component may positively influence psychosocial and psychological factors.

The results suggest that improving physiological capacity alone does not ensure an increased well-being in persons with FM. They also indicate that persons with FM can improve on measures of disability and pain without a change physiologically. These results would support results found in healthy and chronically ill adults (4, 14, 16) in that despite improvements in psychological measures such as mood, anxiety, and depression, these changes were not related to improvements in VO_2 after exercise programs. Although no significant relationships with pVO_2 were demonstrated, the two psychosocial measures with the greatest change, FIQ and SE-coping with other symptoms, were also the two most highly correlated with the change in pVO_2. The moderate correlations indicate that improved fitness does relate in some part to reducing disability and improving perceived ability to cope with symptoms of FM.

The improvements demonstrated in psychosocial measures may be due to 'secondary' changes and/or the exercise environment and not exercise alone. King et al (4) reported that a small change in body weight was related to the change in some of the psychological measures. In addition, exercise environment (group versus individual or community versus home based exercise) may influence psychological improvements due to the amount of social support provided (4, 14). In the current study, 'secondary' changes also may have contributed to the psychosocial changes. Although not directly measured, some subjects commented that their clothes fit better or they felt they were sleeping better since beginning the exercise program. Many also commented on their ability to perform activities of daily living with greater ease after beginning the exercise program. Probably the most commonly heard comment was regarding the social aspect of the exercise program. These comments suggest that other benefits of exercise do play a role in psychosocial and functional improvements after exercise in persons with FM.

The lack of association between changes in physiological and psychosocial

measures raises the question of exercise prescription for persons with FM. Research has demonstrated that moderate physical activity lowers mortality, whereas physical inactivity and excess body weight increases mortality (3). Similar reductions in coronary heart disease were demonstrated in women who walked and those who vigorously exercised (40). Lan et al (41) reported significant increases in VO_2max in an elderly cohort of men and women participating in a tai chi program compared to controls. These results suggest that low to moderate intensity of physical activity does improve health and reduce the risk of mortality. In addition, low to moderate intensity exercise will more likely be adhered to than a high intensity program (42). The current recommendation for physical activity for all persons is the accumulation of 30 minutes or more of moderate intensity physical activity on most, if not all, days of the week (43, 44). It appears that this recommendation for physical activity would be appropriate for the FM population to promote a physically active lifestyle.

Limitations with the present study relate to the protocol and equipment of the physiological tests and how they may have influenced the dropout rate. In order to decrease the stress of the test a symptom-limited protocol was used instead of following the criteria for achieving VO_2max. However, the subjects may have discontinued walking at the slightest discomfort, thereby not achieving a true maximal value. In addition, the headgear worn by the subjects was heavy and may have increased the neck and jaw strain, thereby eliciting pain and irritation. Perhaps using headgear that was lighter would have increased the test duration and a closer to maximal value may have been achieved. Lighter headgear may also have lessened the physical strain resulting in a higher return in subjects at post-test. Either due to the equipment and/or test, symptoms were severely increased for a few days and/or weeks in some subjects. The increase in symptoms resulted in many subjects refusing to return for the physiological testing. Due to the dropouts, it was not possible to compare exercising and non-exercising groups to determine the training effect. The dropout rate highlights the difficulty with physiological testing for persons with FM. Alternatives to physiological testing should be further explored for this population. For example, the 6MW correlated

significantly with pVO_2 ($r=.66$, $p<.001$) in persons with FM (32). A better measure may be the shuttle walk test, which was significantly correlated with pVO_2 ($r=.83$, $p<.001$) in persons with chronic heart failure (45). Perhaps the shuttle walk or other field tests can be adopted and examined as a means of measuring fitness in persons with FM.

Results from this study indicated that persons with FM improved their metabolic, but not cardiovascular fitness after an aerobic exercise program. In addition, disability, self-efficacy for coping with pain and FM symptoms and functioning, number of TPs and total myalgic score improved. However, the metabolic and psychosocial improvements were not related. Unfortunately, the high number of dropouts prevented stronger conclusions being drawn from the results. Despite the lack of association between an increase in fitness and improvement in psychosocial or functional measures, physical activity remains important for overall well being, especially in a population where inactivity or bedrest can be very prevalent. Future research should focus on ways to encourage the adoption and maintenance of a physically active lifestyle in persons with FM.

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Table 6.1. Demographic variables for the subjects who were in exercise groups and underwent physiological testing (n=29).

Variable	Mean (SD) or Percentage
Age (years)	46.3 (9.3)
Duration of Symptoms (years)	8.2 (8.1)
Onset of Symptoms (%)	
traumatic	37.9
idiopathic	62.1
Height (cm)	162.6 (6.4)
Weight (kg)	83.0 (22.6)
Body Mass Index (kg/m^2)	33.8 (8.3)
Marital Status (%)	
single	10.3
married/common law	75.9
divorced	13.8
Employed (% yes)	37.9
Education (%)	
< high school	13.8
high school	31.0
college/university	55.2
Compensation (% yes)	34.5
Litigation (% yes)	13.8

Table 6.2. Pre-post analysis of physiological measures at maximal and submaximal exercise [Mean(standard deviation)](n=10).

Variable	Pre	Post	p value
Peak Exercise			
peakVO_2 (ml/kg/min)	18.1 (4.8)	21.4 (6.0)	**.010**
peakVO_2 (L/min)	1.54 (0.4)	1.81 (0.6)	**.020**
HR (beats/min)	131.9(12.1)	133.7(13.4)	.478
V_E (L/min)	51.6(15.9)	59.7(19.8)	.107
V_E/VO_2	34.1 (8.9)	33.3 (3.4)	.728
O_2 pulse (ml/beat)	11.7 (3.2)	13.4 (3.8)	**.036**
RER	1.01 (0.1)	0.92 (0.1)	.149
RPE	16.9 (2.4)	16.8 (2.9)	.906
METs	5.2 (1.4)	6.1 (1.7)	**.010**
Submaximal Exercise			
VO_2 (ml/kg/min)	10.8 (3.2)	9.8 (4.0)	.119
VO_2 (L/min)	0.92 (0.2)	0.82 (0.3)	.058
HR (beats/min)	109.0(15.7)	102.5(11.6)	.088
Q (L/min)	7.3 (1.7)	6.9 (1.8)	.109
O_2 pulse (ml/beat)	8.5 (2.3)	8.0 (2.9)	.382
SV (L/min)	68.2 (15.2)	67.2(15.8)	.783
(a-v)O_2 diff (ml/100ml blood)	12.5 (2.4)	11.1 (4.1)	.244
V_E (L/min)	30.2 (6.7)	28.7 (8.6)	.154
RPE	9.7 (2.4)	9.3 (3.2)	.763
METs	3.1 (0.9)	2.8 (1.1)	.119

HR=heart rate, V_E=ventilation rate, V_E/VO_2=ventilatory equivalent, RER=respiratory exchange ratio, RPE=rating of perceived exertion, SV=stroke volume, (a-v)O_2 diff=arteriovenous O_2 difference

Table 6.3. Pre-post analysis of psychosocial and functional variables [Mean(standard deviation)](n=10).

Variable	Pre	Post	p value
SES - pain	53.2 (18.5)	68.5 (19.9)	**.039**
SES - function	62.6 (26.7)	72.4 (20.0)	**.047**
SES - coping	54.0 (25.7)	67.9 (17.6)	**.000**
FIQ	55.9 (9.2)	41.3 (15.1)	**.005**
QOL	75.0 (15.3)	75.4 (13.3)	.916
6MW (m)	441.8(136.0)	481.8 (91.1)	.091
# Tender Points	16.8 (2.1)	14.8 (3.7)	**.011**
Total Survey Site Score	117.6(28.5)	94.9 (38.5)	**.022**

SES=Self-Efficacy Scale, FIQ=Fibromyalgia Impact Questionnaire, QOL=Quality of Life Scale, 6MW=Six Minute Walk

Table 6.4. Correlations between changes in peak VO_2 (ml/kg/min) and changes in psychosocial and functional measures (n=10).

Variable	r	p value
FIQ	-.259	.417
QOL	-.119	.714
SES - pain	.163	.612
SES - function	.098	.762
SES - coping	.350	.265
6MW (m)	-.034	.916
# Tender Points	-.021	.949
Total Survery Site Score	-.119	.713

FIQ=Fibromyalgia Impact Questionnaire, QOL=Quality of Life Scale
SES=Self-Efficacy Scale, 6MW=Six Minute Walk

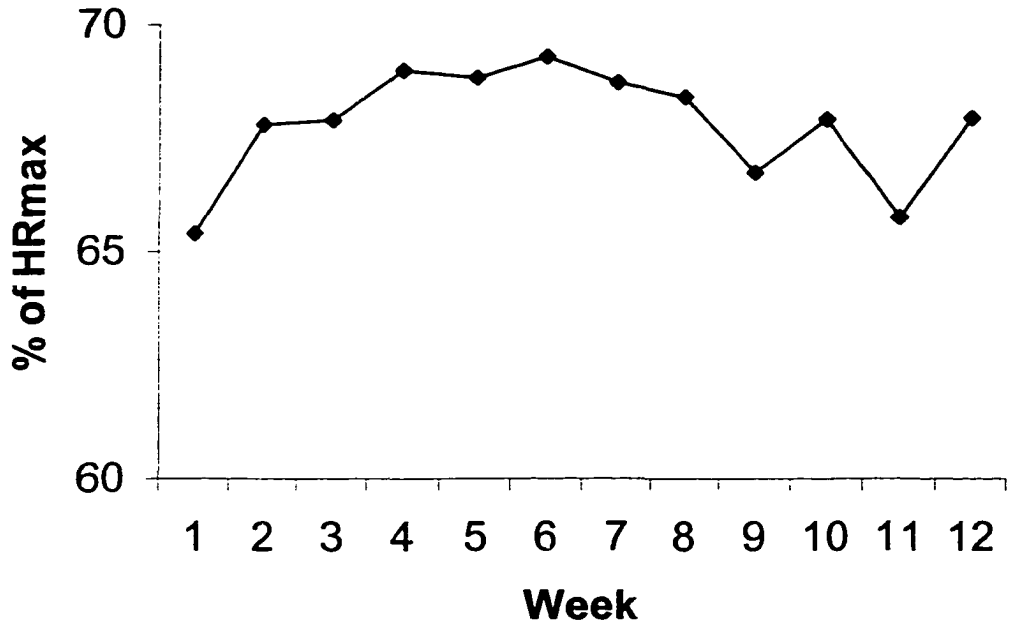

Figure 6.1. Mean exercise intensity (% HRmax) of subjects (n=10) over 12 weeks.

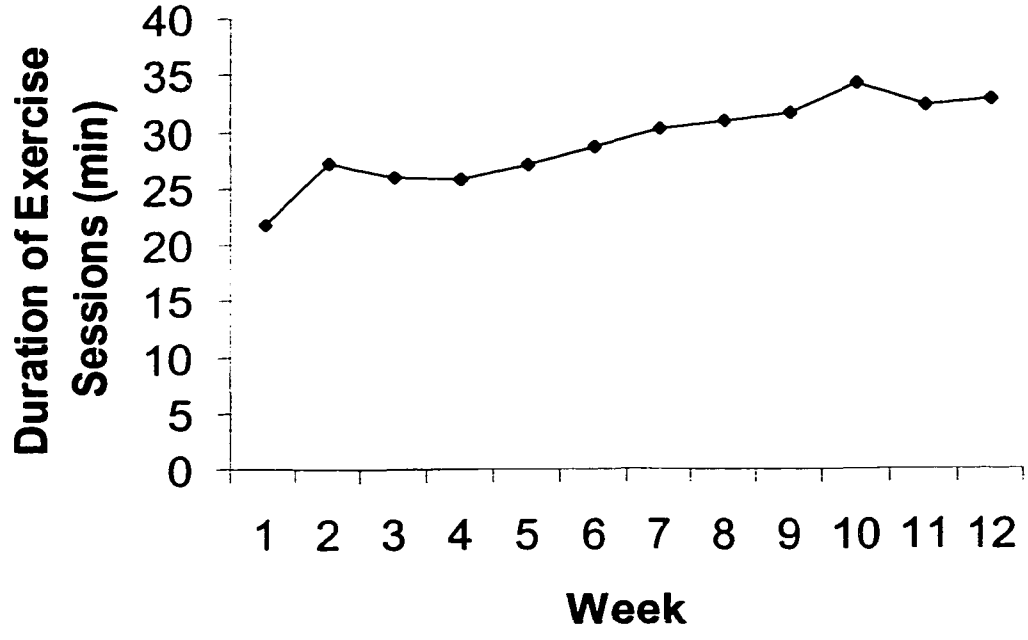

Figure 6.2. Mean duration of exercise sessions of subjects (n=10) over 12 weeks.

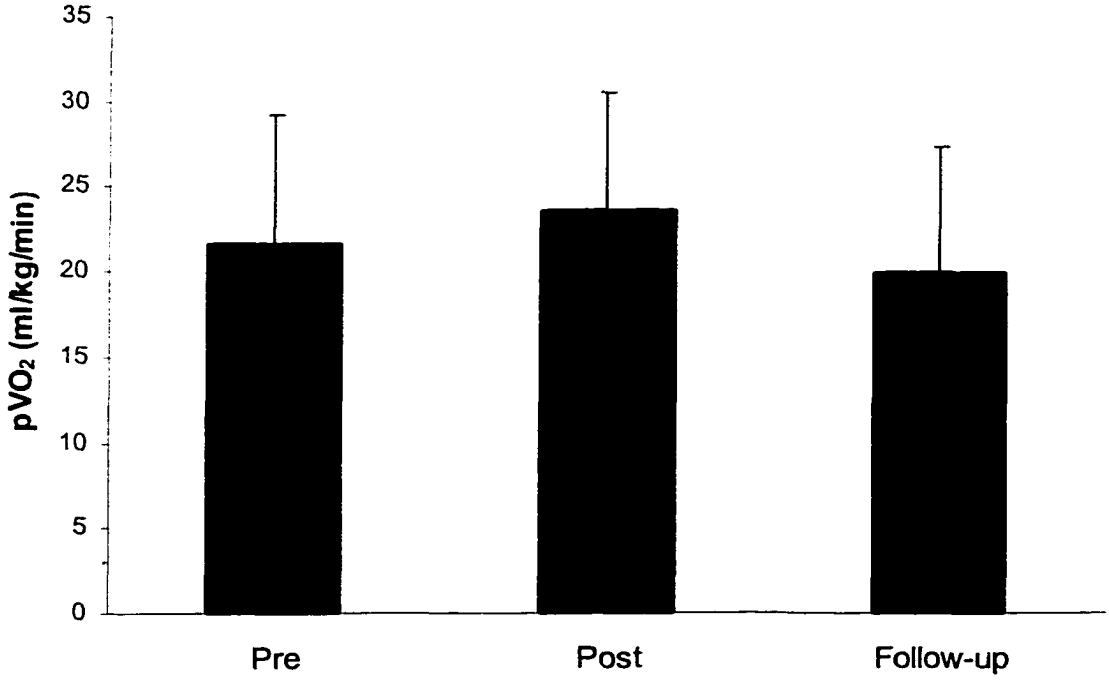

Figure 6.3. Peak VO_2 (ml/kg/min) [means and standard deviations] for the 7 subjects completing the physiological tests at three test sessions.

CHAPTER 7

Predictors of Success of Intervention Programs for Persons with FM

Fibromyalgia (FM) is a difficult condition to manage. Moreover, in the current healthcare environment, treatment resources are slim. Previous research has determined the heterogeneous nature of FM using a multidimensional tool, the Multidimensional Pain Inventory (MPI) (1). The subgroups that were identified responded differently to the same treatment program, suggesting that one standard program may not effectively manage the condition (2). Unfortunately, no analysis was done to identify sociodemographic or other psychosocial variables that may have predicted improvements after treatment. Research from the arthritis, low back and chronic pain fields has identified sociodemographic, psychological and emotional response variables as potential predictors of success with intervention programs (3-7). If similar characteristics could predict treatment response in persons with FM, clinicians could optimize the use of available treatment resources.

Sociodemographic variables, such as age, years of education and income, have been reported to influence clinical outcome or presentation of pain in chronic pain and arthritis populations (3, 4, 8). Lower education has been associated with higher mortality in rheumatoid arthritis (9) and with the development of FM (10). However, Klapow et al (4) reported that sociodemographic variables alone were less accurate than psychosocial variables (52% vs 63% accuracy) at discriminating the clinical subgroups (subgroups: chronic pain syndrome, positive adaptation to pain and good pain control) in persons with chronic back pain.

Subjects' beliefs or emotional responses to pain and others' response to them may have an affect on treatment success. In low back pain, the emotional response to pain has been examined by evaluating fear-avoidance beliefs (11). According to the Fear-Avoidance Model (11, 12), a strong fear of

pain results in the avoidance of activities the person feels will exacerbate his/her pain. At the other end of the continuum, pain still exists, but the person is less afraid that activity will increase pain, so he/she still participates in activities. Research has demonstrated that the expected increase in pain with activity, rather than the actual pain experienced, was a significant predictor of poor performance on behavioural tasks (13). Avoidance behaviours were also a risk factor for the development and maintenance of chronic LBP (13, 14).

Perhaps other determinants of treatment success may be identified by examining responders to treatment in the subgroups of persons with FM. The MPI has classified the majority of persons with FM into categories based upon their perception of the impact of the condition, others' response to them and their activity level (1). Turk et al (15) compared the three main subgroups of the MPI for the number of treatment responders as determined by the Reliability of Change Index (RC) (index that determines the proportion of responders/nonresponders to treatment) (16). They (15) determined that approximately 40% of the subjects responded to the standard treatment on a measure of pain severity. Unfortunately, it was not determined if subjects responded to the treatment on measures of disability, coping, or general life satisfaction. It is also unknown if the subgroups of subjects respond differently to different types of interventions. Would a greater proportion of subjects from one subgroup respond more than another subgroup regardless of the intervention?

The purposes of this study were two-fold. The first objective was to determine which sociodemographic, psychological and behavioural characteristics of persons with FM will predict a positive response to treatment on measures of disability, life satisfaction, self-efficacy, fitness, number of tender points and pain severity. The second objective was to identify the proportion of responders/nonresponders for each MPI subgroup in order to determine if they responded differently to the interventions, as measured by various outcomes. It was hypothesized that a positive response to treatment

would be identified in persons with FM with the following characteristics: 1) sociodemographics: younger, married, shorter duration of symptoms, higher education, employed, not undergoing litigation or receiving compensation, and 2) psychosocial: lower fear-avoidance beliefs, levels of pain, life interference and emotional distress, and higher activity levels, and perceived ability to function and cope with pain and other symptoms.

METHODS AND MATERIALS

Subjects

One hundred seventy-four women with FM underwent baseline testing. Subjects were referred from rheumatologists or general practitioners (n=99) or self-referred from the community (n=75). All subjects were diagnosed with FM according to the American College of Rheumatology 1990 criteria (17). A rheumatologist involved with the study examined any subject not initially diagnosed with FM by a rheumatologist. Inclusion criteria were: women between the ages of 18 and 65 years with a willingness to meet 1-3 times per week for a 12 week period. Exclusion criteria included any systemic inflammatory disease, such as rheumatoid arthritis or systemic lupus, any condition precluding the ability to exercise (i.e. severe osteoarthritis or cardiac condition). The University of Alberta Faculty of Rehabilitation Medicine Ethics Committee approved the procedures undertaken in this study.

Design and Data Collection

The general design was a prospective cohort design. Subjects completed a physical examination, all questionnaires and the walking test at an initial visit. Upon completion, they were randomized into one of 3 interventions (exercise only, education only or combination of exercise and education) or a control group. Detailed information of the different groups is provided in Appendix D. After the 12 week program, subjects were reexamined on the same measures as at pretest.

Independent Variables

The independent variables (16 variables) collected were the following:

1) Age - measured in years
2) Duration of symptoms – measured in months
3) Marital status – divided into categories: single, married/common-law and divorced/separated. The variables were divided into 2 dichotomies or dummy variables (one less the number of categories). One variable was married/common-law versus other and the second was divorced/separated versus other. The dummy variables were coded as 1=yes, 0=no.
4) Employment status – coded as 1=yes, 0=no. Part-time work was considered as employed.
5) Level of education – original data was categorized as: less than high school (no high school diploma), high school (have a diploma) and more than high school (some college/university). The categories were divided into 2 dummy variables. One variable was less than high school versus other and the second was greater than high school versus other. The dummy variables were coded as 1=yes, 0=no.
6) Receiving compensation – coded as 1=yes, 0=no
7) Undergoing litigation – coded as 1=yes, 0=no
8) Intervention – subjects were randomized into one of four groups (3 interventions, 1 control group). Two categories were created: exercise versus no exercise and education versus no education. Categories coded as 1=yes, 0=no.
9) West Haven-Yale Multidimensional Pain Inventory (MPI) (18)– questionnaire that classifies subjects according to their response to pain, response of significant others to them and their general activity level. Subjects classified into one of six categories: Adaptive Coper (AC), Interpersonally Distressed (ID), Dysfunctional (Dys), Unanalyzable, Hybrid, or Anomolous. The last three categories were combined and

called Other. Lower levels of pain, life interference and emotional distress and higher levels of activity characterize Adaptive Copers. Subjects classified as Dys are the opposite of the AC on all of the scales. The variables used were AC vs other and Dys vs other. They were coded as 1=yes, 0=no.

10) Fear-Avoidance Beliefs Questionnaire (FAB) (19)– examines patients' beliefs about the avoidance of behaviours due to a fear of increasing pain levels. Two subscales, physical activity and work, are delineated in the questionnaire. The subscales are continuous variables. A higher score indicates greater fear-avoidance beliefs.
11) Chronic Pain Self-Efficacy total score (SE) (20)– is a 20-item scale divided into 3 subscales (pain coping, functioning and coping with other symptoms). The scales measure subjects' beliefs in their ability to perform specific tasks and control symptoms of their condition. By adding the subscales together, a SE Total score is obtained. A higher score indicates greater self-efficacy. It is a continuous variable. It was entered into the regression analyses for all dependent variables.

All independent variables were recorded as the subject's status at the time of entry to the study and not previous status. For instance, if she had received compensation for a period of time, but currently was not receiving any, then she would be coded as a no.

Dependent Variables

The dependent variables included in the analysis were a change in:

1) Fibromyalgia Impact Questionnaire (FIQ) - is a brief 19-item survey measuring physical functioning, work status, depression, anxiety, sleep, pain, stiffness, fatigue and well being in persons with FM (21). The total FIQ score was calculated according to Burckhardt et al (21). The range of scores is 0-80 with a higher score indicating greater impact of the condition on the person's life.

2) Quality of Life Questionnaire (QOL) - is a 16-item questionnaire dealing with satisfaction with various aspects of life, such as health/physical activity, raising or having children, independence, learning or attending school (22). Each item is rated on a Likert scale ranging from 1 (terrible) to 7 (delighted). A total satisfaction score is obtained by summing all 16 items with total scores ranging from 16-112. A higher score indicates greater satisfaction with life.
3) Self-Efficacy – pain coping (SE-pain) – subscale from SE total score. Examines perceived ability to cope with pain
4) Self-Efficacy – function (SE-function) – subscale from SE total score. Examines perceived ability to perform certain functional activities.
5) Self-Efficacy – coping with other symptoms (SE-cope) – subscale from SE total score. Examines perceived ability to cope with other symptoms of chronic pain.
6) Six Minute Walk (6MW) - is a field test developed from Cooper's 12-minute walk/run (23). Subjects walked along a level 40-metre corridor and were instructed to "cover as much ground as possible in 6 minutes". Encouragement such as "good pace, keep it up" or "good work" was given at 2, 3, 4 and 5 minutes. At these same time intervals, the subjects were informed of the time remaining in the walk. Encouragement and time remaining were standardized for all patients. The distance covered was measured in metres. The 6MW has been used in the FM research to evaluate fitness (24-26).
7) Number of Tender Points (#TPs) - the 18 TPs were examined according to an established manual TP survey protocol. (27). This protocol outlines examiner and subject positioning, order of examination and pressure application technique. The total number of painful TPs was the TP count (ranging from 0-18).
8) Pain Severity at Tender Points - was used as a self-report measure of pain severity (27). Each time a TP was palpated, the subject rated the

pain severity as 0 (no pain) - 10 (worst pain). The pain severity ratings that were 2 or more were considered positive TPs. The scores for these positive TPs were totaled, thus providing a Total Survey Site score (ranging from 0-180).

The dependent variables were selected because they were reliable measures that had been previously utilized with persons with FM. Detailed descriptions of the questionnaires and MPI classifications are provided in Appendix C.

Statistical Analysis

The continuous variables were summarized by means and standard deviations. The categorical data were summarized by frequencies. The change scores were calculated from measures taken before and immediately following an intervention. The post score was subtracted from the pre score for all variables except the FIQ, #TPs and Total Survey Site Score, where a lower post score indicated an improvement in that measure. The pre score was subtracted from the post score for these variables. A higher, positive change score indicated greater improvement in that variable at the end of the 12 weeks.

Pearson Product Moment correlations were calculated to determine significant relationships between the independent and dependent variables. All of the independent variables were forced into the regression analyses (forced-entry) to determine the relative influence of a set of independent variables on the dependent variable. This allows for an examination of the raw score regression weights to determine the influence of each independent variable on the dependent variable while the other independent variables are held constant. Forward-entry stepwise regression analyses were conducted to determine the influence of the independent variables on a dependent variable in order of decreasing influence. Step-wise regression analysis was performed using SPSS version 8.0 and the default criteria (significance of $p<.05$ and $p>.1$ for removal).

To determine the proportion of responders/nonresponders for the subjects classified according to the MPI, a reliability of change (RC) index was calculated (16) for each subject with each measure. A responder is a person with a RC index greater than 1.96. This indicates that the magnitude of the change can be considered more than that which occurs with the normal measurement fluctuations from repeated measures. A RC index of less than 1.96 indicates a nonresponder. A negative RC index indicates a decline in scores or a worsening of the score.

This index is determined by the following equation:

$$RC = \frac{x_2 - x_1}{s_1\sqrt{1-r_{xx}}},$$

where x_1 is the subject's pre-test score, x_2 is the subject's post-test score, s_1 is the standard deviation of the pre-scores and r_{xx} is the test-retest reliability of the measure. The test-retest reliability scores (r_{xx}) used to calculate each RC index were as follows: FIQ .56 and .95 (21), QOL .76 and .84 (22), SE-pain coping .88, SE function .87, SE-coping with symptoms .90 (20) and 6MW .73 and .89 (28). For the variables with two published reliability coefficients from the literature, two RC indexes were calculated. The values used for the calculations are reported in Appendix E. Kruskal-Wallis tests (non-parametric test) were done to determine if significant differences existed among the MPI groups and number of responders for each variable.

RESULTS

Of the 174 subjects recruited at baseline, 128 returned for post-testing and were included in the analyses. There were 4 subjects who did not continue with the program, but did return for the post-testing. They were included in the analyses. Table 7.1 provides demographic information only for the subjects included in the analyses. A one-way analysis of variance for the continuous variables and Chi^2 analysis were used to determine if any significant differences were present between the dropouts and completers on all of the baseline

measures. The only significant difference between the dropouts and completers was education level (p=.029). The subjects with higher education levels (some college or university education) were more likely to dropout than subjects with high school or less education.

The data were examined to check the assumptions of linear regression [linearity, normality and homoscedasticity (standard deviations of errors of prediction are approximately equal for all predicted dependent variables)]. Violations to the assumptions were not revealed therefore transformations of the data were not necessary. Change scores for the dependent variables are presented in Table 7.2. Correlations between the independent and dependent variables are provided in Appendix F. Due to lack of significant correlations with any of the dependent variables, age, employment status, compensation and litigation were removed from the list of independent variables for the forced-entry and step-wise regression. This increased the ratio of cases to independent variables, thereby improving the power.

Forced-Entry

The forced-entry regression results (significance level and raw score regression weights) for the dependent variables are shown in Tables 7.3-7.10. The only significant independent variables were FAB-work, participation in an exercise group, SE Total score and Dys classification.

SE Total score and FAB-work were significant predictors of change in SE-coping with pain (p=.000 and .050, respectively) (Table 7.5). Self-Efficacy Total score was a significant predictor of change in SE-coping with other symptoms (p=.000) (Table 7.7) and number of TPs (p=.040) (Table 7.9). Inclusion in an exercise group versus a non-exercise group and a MPI classification other than Dys were both significant predictor variables for change in 6MW (p=.023 and p=.048, respectively) (Table 7.8). No significant independent variables predicted change in FIQ, QOL, SE-function and Total Survey Site Score.

Step-Wise Regression

Results from the step-wise regression analyses are provided in Tables 7.11-7.17. Significant predictor variables for change were revealed for all dependent variables except the FIQ. Regression equations for predicting the change in dependent variables from significant independent variables are reported at the bottom of each table. The percentages of the variance in the change scores explained by the independent variables ranged from 4-15%. The predictor that appeared most often in the regression results was duration of symptoms. It predicted a change in SE-function, 6MW and Total Survey Site Score. A classification as Dys, SE total score and greater than high school education were all significant predictors for two dependent variables.

Responders/Nonresponders

Table 7.18 outlines the responders to an intervention program in subjects grouped according to the MPI. The 128 subjects that completed pre and post-testing were classified into 1 of the 4 MPI categories. There were a few more subjects classified as AC and ID than Dys and Other. Of the subjects that dropped out, there was a fairly equal distribution among the MPI subgroups (AC=9, ID=16, Dys=10 and Other=14). The non-parametric tests indicated that no group responded more than another group on any of the measures.

DISCUSSION

The results from the current study indicated that select sociodemographic and psychosocial variables, and type of intervention were significant, but not strong predictors of improvement in a variety of measures after a treatment program. The main independent variables that predicted a positive change in dependent variables were a higher education, longer duration of symptoms, lower perceived abilities to cope and function with FM, and MPI classification other than Dys. Additionally, when the MPI subgroups were examined, no one group demonstrated a greater proportion of responders/nonresponders

compared to another group.

Having more than a high school education was a predictor of a positive response of life satisfaction, perceived ability to cope with symptoms and number of TPs. These results are in agreement with results from the arthritis and low back pain literature. Lower formal education was one of the variables predicting mortality over 5 years in persons with rheumatoid arthritis (9). Numerous other studies have identified the significant role that level of education plays in the reporting and long-term outcome of arthritis and low back pain (3, 8, 29, 30). Perhaps persons with a lower education need a specific or specialized type of intervention in order to demonstrate improvements after treatment. Results from previous research and the current study stress the importance of the level of formal education in managing a chronic condition.

Results also demonstrated that a longer duration of symptoms predicted a positive change in fitness and perceived ability to function, whereas a shorter duration of symptoms predicted a positive change with pain severity. This finding was surprising since it was hypothesized that a longer duration of symptoms would have a negative effect on the change of all variables. However, BenDebba et al (31) reported that persons who experienced low back pain for 6 months or more scored the same as healthy adults on psychological measures. These authors suggested that a longer duration of symptoms might have a negative effect on a subgroup of subjects, but not the entire low back pain population. The results from the present study suggest that functional measures can improve despite having the symptoms for a long time. Therefore, referrals to treatment programs should not be discouraged for persons who have experienced FM symptoms for a long period of time. However, if strictly wanting to reduce pain levels, one would expect more of a reduction in persons with shorter duration of symptoms.

The combined variables that predicted the highest percentage of variance of the change were SE total score, Dys classification and FAB-physical activity. It was hypothesized that a higher SE total score, classification other than Dys

and lower FAB score would result in a greater change after the interventions. The hypothesized relationships were demonstrated, except for SE total score. The current study indicated a negative relationship between the initial SE total score and the change in SE coping with pain and other symptoms. This finding suggests that a ceiling effect may have been present. Although fear-avoidance beliefs have not been examined previously in persons with FM, persons with low back pain demonstrating higher avoidance of activities reported a greater frequency and duration of pain and increased disability (32). This finding appears to be in agreement with the findings from the current study. Moreover, as hypothesized, the change in perceived ability to cope with pain was greater if classified as other than Dys. In contrast, Turk et al (2) reported that persons with FM classified as Dys achieved the greatest benefits compared to the AC and ID groups on measures of depression, perceived disability and adverse impact of FM symptoms after a multidisciplinary intervention program. The difference between the two studies may be due to the use of self-efficacy versus describing function or disability (2). The inclusion of the above psychosocial predictors supports the current suggestions to incorporate a multidisciplinary treatment team that involves sessions with a psychologist in order to assess and alter the cognitions of persons with FM (33).

Surprisingly, neither self-efficacy total score nor fear-avoidance beliefs for work/physical activity predicted a change in perceived ability to function. This finding is contrary to results from the literature. In persons with low back and chronic pain, higher fear-avoidance beliefs were related to lower self-efficacy for functioning (34, 35). The differences may be due to the measurement of functional self-efficacy. The current study examined functional self-efficacy for basic homecare needs using a questionnaire designed for persons with arthritis. Lackner et al (34) used a scale that focused on physical requirements in an occupational setting (lifting, carrying, pushing, pulling) and would be used to assess readiness to return to work for persons with low back pain. The above differences suggests that self-efficacy and fear-avoidance beliefs may play a

greater role in occupational settings than at home.

A significant change (increase) in distance walked was predicted from a classification other than Dys and inclusion in an exercise group. Perhaps for persons with high pain severity and life interference and low life control and activity levels, fitness may not improve even after an exercise intervention. Previous research with healthy populations has demonstrated self-efficacy as a significant predictor of exercise adoption and even maintenance (to a lesser extent) (36, 37). These findings highlight the importance of psychosocial and cognitive factors in relation to improving and maintaining fitness levels. The importance of addressing psychosocial and cognitive concerns first before physical interventions, such as exercise, will hopefully lead to improved fitness or function later.

The independent variables that surprisingly did not demonstrate significant correlations with any dependent variables were employment status, compensation and litigation. In the current study, only 9 subjects were undergoing litigation at the time of their involvement, thus one reason that litigation was not a significant predictor. Previous research has demonstrated that employment status and economic rewards (litigation and compensation) were important factors in emotional distress, depression and illness behaviours, such as inactivity, work and domestic disability in persons with chronic pain (38). Furthermore, these relationships may not be direct, but rather mediated by other factors such as job satisfaction or financial strain (39, 40). Perhaps because the employment, compensation and litigation variables were dichotomous the relationship with the change in dependent measures was not captured. A direct relationship between these independent variables and the dependent variables may not have been demonstrated due to other factors, such as job satisfaction, social contact at work, the amount of control in the workplace and financial strain mediating the relationship. Although the relationships may not be the same in persons with FM as with chronic pain, the complex interactions of employment, compensation and litigation may need to be examined further.

The percentage of responders for the MPI subgroups combined and individually was very low. When total subject response was examined for all of the variables, only 12-37% of the subjects responded after the 12 weeks. Turk et al (15) examined the number of responders on a measure of pain severity and reported that only 39.3% or 22 of their 56 subjects responded after an intervention. Vlaeyen et al (41) also reported low percentages of responders in two treatment groups (6.4 and 18.4%) in persons with FM. The absence of clinically significant changes would suggest that the subjects did not respond regardless of the intervention they received. The low percentage of responders from previous research and from the current study suggest that there is still a large portion of the FM population that does not benefit from the treatment programs currently offered.

The highest percentages of responders for all groups combined were demonstrated with the self-efficacy subscales. This finding indicates that perhaps the self-efficacy scale was a very sensitive measure. It also may indicate that persons with FM perceive themselves to be coping better, but this is not translated into improved function or reduced disability. Perhaps self-management programs, designed to enhance self-efficacy in this population do not provide the necessary skills to actually enhance functioning and overall well-being. Factors related to their environment (social and work) may influence their behaviour to the extent that certain programs do not alter behaviours.

Despite the identification of significant independent variables, they were not strong predictors of change in the measures employed. In fact, the best predictive model only explained 15% of the variance in the change of SE-coping with pain (Table 7.12). The other independent variables explained less than 13% of the variance in the change score of the dependent variables. The low percentage of explained variance in the change scores suggests that either the heterogeneous nature of FM precludes the identification of predictor variables and/or the independent variables selected were not appropriate predictors of treatment success.

Other constructs or combination of variables may be better predictors of change after treatment and have not been identified in persons with FM. In a FM population, type of coping style (catastrophizer) was able to explain a significant amount of variance in psychosocial disability scores after controlling for demographic and clinical variables and disease severity (42). McCracken (43) reported that greater acceptance of chronic pain was associated with lower pain intensity, less pain related anxiety and avoidance and less depression in a chronic pain population. Social support has emerged as an important factor in the management of chronic pain conditions (4) and would perhaps be crucial in the management of FM. Other demographic, psychosocial or psychological variables may be more important than the variables utilized in the current study for predicting success from a treatment program in persons with FM. Although the previous studies did not predict changes after treatment, they did identify variables that could potentially be investigated as contributing to changes after treatment.

Although the rates of depression may vary widely in persons with FM (44), the impact of depression in the management of FM has been identified previously (15, 25). Turk et al (15) reported that depression was a factor discriminating between responders and nonresponders to treatment. In the current study, level of depression may have been identified as a variable predicting the change in one or more of the dependent variables. Future research should include a measure of depression to assist in clarifying its role in the management of FM.

A limitation of the current study was the measure of success that was utilized. A change score (post-pre-test difference) was used to define improvement after an intervention, where a larger positive difference indicated greater improvement from the intervention. One concern with the use of a change score is the potential for regression towards the mean on post-test. In an attempt to minimize the effect of regression to the mean, only reliable measures that had been used with persons with FM previously were utilized.

The results from the current study indicate that higher education, longer duration of symptoms, lower fear-avoidance beliefs for physical activity and self-efficacy beliefs and classification other than Dys were the main predictors of treatment success after a 12 week intervention. However, these variables were able to explain only a small portion of the variance indicating that more important predictors may exist. The low percentage of explained variance with the change scores may also be due to the heterogeneity of FM. In addition, the poor percentage of responders suggests that current forms of treatment are not effective for a large portion of the FM population. Therefore, health care professionals need to reassess the present course of management for persons with FM.

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Table 7.1. Demographic variables for the cohort (n=128).

Variable	Mean± Standard Deviation* (Range)
Age (years)	46.8± 8.7 (18-64)
Height (cm)	162.0±6.1 (144-177)
Weight (kg)	77.9±18.4 (45-142)
Duration of Symptoms (years)	9.2± 8.0 (4-40)
Onset of Symptoms (%)	
Idiopathic	73.4 (n=94)
Traumatic	26.6 (n=34)
Marital Status (%)	
Single	15.6 (n=20)
Married/Common-law	69.5 (n=89)
Divorced	14.8 (n=19)
Education (%)	
< high school	16.4 (n=21)
high school diploma	29.7 (n=38)
college/university	53.9 (n=69)
Employed (full and part-time) (% yes)	43.8 (n=56)
Litigation (% yes)	9.3 (n=12)
Compensation (% yes)	32.0 (n=41)
# TPs	16.5±1.8 (11-18)
Pain severity at TPs (0-180)	103.0±32.8 (2-176)

* Mean ± Standard Deviation unless otherwise stated

Table 7.2. Mean change scores for each dependent variable used in regression analysis. A positive value indicates an improvement.

	Mean change score (Standard Deviation)	Range of change scores
FIQ	4.3 (12.5)	-25.3 – 42.2
QOL	2.0 (11.1)	-23.0 – 46.0
SE-pain	5.1 (19.2)	-38.0 – 60.0
SE-function	3.4 (16.4)	-64.4 – 78.9
SE-symptoms	5.9 (18.6)	-48.3 – 56.7
6MW	16.5 (66.2)	-134.0 – 209.0
# TPs	.80 (2.4)	-9.0 – 5.0
Total Survey Site Score	4.3 (33.0)	-91.0 – 97.0

FIQ=Fibromyalgia Impact Questionnaire, QOL=Quality of Life Scale, SE=Self-Efficacy, 6MW=Six Minute Walk, #TPs=Number of Tender Points

Table 7.3. Significance of independent variables and raw regression weights from the forced regression analysis to predict the change in Fibromyalgia Impact Questionnaire in persons with Fibromyalgia.

Variable	Significance	Weight
Education group	.058	4.46
Exercise group	.115	3.80
Dysfunctional	.459	2.49
SES-total	.518	.002
Married	.691	-1.67
FAB-physical activity	.822	-.006
< High School	.829	-.763
FAB-work	.906	.001
Adaptive Coper	.920	.271
Divorced	.932	.274
> High School	.972	.010
Duration of symptoms	.990	.002

*SES=Self-Efficacy Scale, FAB=Fear-Avoidance Beliefs

Table 7.4. Significance of independent variables and raw regression weights from the forced regression analysis to predict the change in Quality of Life Questionnaire in persons with Fibromyalgia.

Variable	Significance	Weight
< High School	.086	-5.24
Exercise Group	.106	3.33
Divorced	.186	3.65
Dysfunctional	.290	3.04
FAB-physical activity	.310	-.225
Education group	.314	2.01
> High School	.353	2.15
SES-total	.361	-.002
Adaptive Coper	.395	-1.97
FAB-work	.408	.009
Duration of symptoms	.623	-.005
Married	.667	1.54

FAB=Fear-Avoidance Beliefs, SES=Self-Efficacy Scale

Table 7.5. Significance of independent variables and raw regression weights from the forced regression analysis to predict the change in Self-Efficacy-Coping with Pain score in persons with Fibromyalgia.

Variable	Significance	Weight
SES Total	.000	-.168
FAB-work	.022	-.395
FAB-physical activity	.100	-.600
Dysfunctional	.104	-7.68
< High School	.109	-8.01
Exercise group	.325	3.31
Divorced	.420	-3.64
Education group	.534	2.03
Adaptive Coper	.595	-2.01
> High School	.614	-1.91
Married	.618	2.93
Duration of symptoms	.897	-.002

FAB=Fear-Avoidance Beliefs, SES=Self-Efficacy Scale

Table 7.6. Significance of independent variables and raw regression weights from the forced regression analysis to predict the change in Self-Efficacy-Function score in persons with Fibromyalgia.

Variable	Significance	Weight
Duration of symptoms	.071	.003
SES Total	.144	-.006
Education group	.267	3.38
Exercise group	.571	1.77
Adaptive Coper	.660	- 1.55
> High School	.783	.973
< High School	.801	-1.16
Dysfunctional	.804	-1.08
FAB-work	.830	-.003
Married	.873	-.875
Divorced	.985	- .008
FAB-physical activity	.999	-.000

FAB=Fear-Avoidance Beliefs, SES=Self-Efficacy Scale

Table 7.7. Significance of independent variables and raw regression weights from the forced regression analysis to predict the change in Self-Efficacy-Coping with Other Symptoms score in persons with Fibromyalgia.

Variable	Significance	Weight
SES Total	.000	-.152
Exercise group	.028	7.40
Education group	.068	5.95
> High School	.076	6.74
FAB-work	.083	-.296
Divorced	.208	5.67
Married	.273	6.94
< High School	.541	-3.02
Duration of symptoms	.609	-.009
FAB-physical activity	.627	-.175
Adaptive Coper	.671	1.60
Dysfunctional	.894	-.619

FAB=Fear-Avoidance Beliefs, SES=Self-Efficacy Scale

Table 7.8. Significance of independent variables and raw regression weights from the forced regression analysis to predict the change in Six Minute Walk distance in persons with Fibromyalgia.

Variable	Significance	Weight
Exercise group	.021	28.94
Dysfunctional	.036	-36.41
Duration of symptoms	.074	.116
Adaptive Coper	.178	-18.84
FAB-physical activity	.227	-1.61
Education group	.419	9.73
< High School	.728	-6.41
FAB-work	.781	- .174
SES-total	.812	-.004
Divorced	.819	3.86
Married	.842	-4.33
> High School	.926	-1.28

FAB=Fear-Avoidance Beliefs, SES=Self-Efficacy Scale

Table 7.9. Significance of independent variables and raw regression weights from the forced regression analysis to predict the change in Number of Tender Points in persons with Fibromyalgia.

Variable	Significance	Weight
SES-total	.043	.001
> High School	.066	.997
FAB-physical activity	.082	.009
Divorced	.216	-.790
Adaptive Coper	.339	.501
Exercise group	.394	-.403
Married	.479	-.596
Duration of symptoms	.503	-.002
Education group	.696	.182
< High School	.759	-.220
Dysfunctional	.858	.123
FAB-work	.958	- .001

FAB=Fear-Avoidance Beliefs, SES=Self-Efficacy Scale

Table 7.10. Significance of independent variables and raw regression weights from the forced regression analysis to predict the change in Total Survey Site Score (pain severity of tender points) in persons with Fibromyalgia.

Variable	Significance	Weight
Duration of symptoms	.044	-.007
Adaptive Coper	.119	11.20
Exercise group	.222	-7.90
SES-total	.225	.009
FAB-physical activity	.589	.390
Divorced	.637	-4.09
FAB-work	.652	.157
< High School	.764	2.94
Dysfunctional	.861	-1.65
Married	.869	-1.90
Education group	.879	.969
> High School	.963	.344

FAB=Fear-Avoidance Beliefs, SES=Self-Efficacy Scale

Table 7.11. Results of step-wise regression analysis used to predict change in Quality of Life score.

Independent variable	Multiple R	R^2	Adjusted R^2	β	Sig.	Standard Error of the Estimate
1. < High School	.215	.046	.044	-.227	.016	11.00

QOL change = less than high school education(-6.58) + 3.03

Table 7.12. Results of step-wise regression analysis used to predict change in SE-coping with pain score.

Independent variable	Multiple R	R^2	Adjusted R^2	β	Sig.	Standard Error of the Estimate
1. SES Total	.233	.054	.045	-.233	.009	18.77
2. Dys	.342	.117	.112	-.300	.001	18.21
3. FAB-phys. activity	.391	.153	.137	-.177	.000	17.91

SE-coping with pain change = SE Total (-.16) + Dys (-11.01) + FAB-phys. activity (-.790)+ 41.81

Table 7.13. Results of step-wise regression analysis used to predict change in SE- function score.

Independent variable	Multiple R	R^2	Adjusted R^2	β	Sig.	Standard Error of the Estimate
1. Dur symp	.200	.040	.028	.187	.025	16.17

SE-function change = Duration of symptoms(.034) + (-.433)

Table 7.14. Results of step-wise regression analysis used to predict change in SE- coping with other symptoms score.

Independent variable	Multiple R	R^2	Adjusted R^2	β	Sig.	Standard Error of the Estimate
1. SES Total	.214	.046	.042	-.221	.016	18.25
2. > High School	.288	.083	.074	.204	.005	17.97

SE-coping with other symptoms = SE Total(-.092) + > High School(7.33) + + 16.48

Table 7.15. Results of step-wise regression analysis used to predict change in Six Minute Walk distance.

Independent variable	Multiple R	R^2	Adjusted R^2	β	Sig.	Standard Error of the Estimate
1. Dys	.253	.064	.059	-.257	.005	65.87
2. Exerc grp	.308	.095	.088	.191	.002	65.04
3. Dur symp	.355	.126	.111	.174	.001	64.18

6 minute walk change = Dysfunctional(-35.78) + Exercise group(28.01) + Duration of symptoms(.13) + (-6.50)

Table 7.16. Results of step-wise regression analysis used to predict change in Number of Tender Points.

Independent variable	Multiple R	R^2	Adjusted R^2	β	Sig.	Standard Error of the Estimate
1. > High School	.210	.044	.033	.203	.028	2.29

# of TPs change = greater than high school education(.98) + .35

Table 7.17. Results of step-wise regression analysis used to predict change in Pain Severity at Tender Points.

Independent variable	Multiple R	R^2	Adjusted R^2	β	Sig.	Standard Error of the Estimate
1. Dur symp	.228	.052	.043	-.227	.017	30.53

Pain severity at the TPs change = Duration of symptoms(-.072) + 13.75

Table 7.18. The number of responders versus non-responders in subjects classified according to MPI.

	AC* n=39	ID n=35	Dys n=25	Other n=28	Total Group
	Number of Responders (% responded)				
FIQ**	6 (15.4)	7 (20.0)	5 (20.0)	7 (25.0)	25 (18.7)
	15 (38.5)	17 (48.6)	8 (32.0)	9 (32.1)	49 (36.6)
QOL**	4 (10.3)	2 (5.7)	5 (20.0)	5 (17.9)	16 (11.9)
	4 (10.3)	2 (5.7)	7 (28.0)	6 (21.4)	19 (14.2)
SE pain	9 (23.1)	11 (31.4)	6 (24.0)	11 (39.3)	37 (27.6)
SE function	7 (17.9)	7 (20.0)	7 (28.0)	11 (39.3)	32 (23.9)
SE coping	13 (33.3)	16 (45.7)	10 (40.0)	10 (35.7)	49 (36.6)
6MW**	2 (5.1)	8 (22.9)	0 (0.0)	6 (21.4)	16 (12.1)
	9 (23.1)	10 (28.6)	1 (4.0)	10 (35.7)	30 (22.7)

* For the 6MW group sizes are: AC n=39, ID n=37, Dys n=28 and Other n=28

** two sets of responder values are reported due to two different reliability scores (see Appendix E).

CHAPTER 8
General Discussion and Conclusions

The main purpose of this study was to evaluate the efficacy of aerobic exercise and education for the management of FM. Previous research in persons with FM has demonstrated limited success with programs involving exercise alone, education alone and/or a combination of both (1-4). The previous research has been unable to differentiate the effect of exercise and education individually on the management of FM. It has also not been determined if both components are necessary to invoke the greatest improvements in the management of FM. Despite the support for inclusion of aerobic exercise as part of the management of FM, exercise recommendations based on research have been lacking. Even appropriate measurements of fitness are difficult to attain in this population. It has not been determined if metabolic or cardiovascular changes occur after an aerobic training program or if they are related to improvements with psychosocial measures. Finally, it has been suggested that the limited success of treatment programs may relate to the heterogeneous nature of FM (5, 6). The identification of certain characteristics that predict treatment success in persons with FM would assist in optimizing treatment resources. The specific hypotheses of the study were to test if in persons with FM:

1) the combination of exercise and education was more efficacious than either exercise alone or education alone;
2) any intervention was superior to no intervention;
3) improvements in physiological measures were related to improvements in psychosocial and functional measures; and
4) treatment success could be predicted from baseline sociodemographic and/or psychosocial measures.

The overall hypothesized model of response to treatment in persons with FM (Figure 1.1, Chapter 1), was altered based on the results of this study (Figure

8.1). The results indicated that both exercise and education were required to elicit an improvement in self-efficacy for coping with other symptoms, and a supervised exercise program was required to elicit an improvement in fitness. However, these improvements occurred only in subjects who adhered to the protocol. Despite these improvements, an enhanced life satisfaction did not occur. Education alone did not improve any of the measures. Overall, the results suggest limited efficacy of exercise and the combination of exercise and education for the management of FM.

The improvements with metabolic measures after aerobic training were not associated with improvements on psychosocial and functional measures in persons with FM. This finding concurs with the results from the literature in healthy and diseased persons (7-9). It suggests that another mechanism may be responsible for the beneficial effects of exercise and not just changes in peak oxygen consumption.

The analysis revealed that duration of symptoms, education, dysfunctional classification [according to the Multidimensional Pain Inventory (MPI)] self-efficacy and fear-avoidance beliefs for physical activity were identified as predictors of change in life satisfaction, self-efficacy for functioning, coping with pain and other symptoms, fitness, and pain severity. However, the significant independent variables were only able to explain 3.5-16% of the variance in the changes of the dependent variables.

Only 12-37% of all subjects responded to the treatment interventions. The MPI classifications did not differ with response rate on the dependent variables. This indicates that the MPI classification could not predict the response to treatment. The low percentage of responders also suggests that the current treatment for FM needs to be re-evaluated.

A major limitation with the current study was the number of dropouts and noncompliers. Despite requesting that the subjects telephone if they could not attend and the investigators telephoning due to an absence of a program or test

session, adherence to both the exercise and educational aspects of the study may have been improved by a more stringent follow-up and documentation of absent subjects. Moreover, a reasonable effort was made to have a central location in the city for the exercise and education sessions, easy access to free parking or reimbursements if only paid parking was available and a convenient time of day. In spite of these considerations, not all subjects were satisfied and discontinued participation for at least one of the above reasons. Perhaps a home based exercise program or exercising at their chosen location, would have improved the chances of retaining some of these subjects. Finally, pilot testing of a smaller sample of subjects at the proposed study session locations may have eliminated some of these difficulties in the larger study. However, even a study designed to take the above issues into account may not have precluded the number of dropouts.

Recommendations for Future Research

The management of FM continues to be a complex issue. The results from the current study showed that some persons with FM improved after the different interventions. This does not suggest that exercise and education should be discarded altogether, but it does indicate that adjustments to the present treatment programs are necessary. The current study highlights some areas for application of the results and future research.

In the current study, it was proposed that self-efficacy would influence the effect of exercise and education on outcome. The model proposed in Chapter 1 (Figure 1.1) did not fit the result after the interventions. However, self-efficacy was the measure that improved most frequently for all subjects. This suggests that by attempting to enhance self-efficacy, disability and life satisfaction may not be influenced or improved. Possible reasons for the discrepancy between the model and response with self-efficacy may relate to the impact of certain symptoms on self-efficacy. Two sources of self-efficacy are the physiological and

emotional state of the person (10). Fatigue, memory impairments, anxiety and depression (11, 12) have been reported in persons with FM, but their influence on self-efficacy has not been examined fully. Perhaps by determining the impact these factors have on self-efficacy would assist in designing programs to address these issues thereby enhancing treatment efficacy.

In order to properly assess a change in health status or life satisfaction, quality of life needs to be explored in greater detail in the FM population. A measure of quality of life that can be easily filled out by the subject in a clinical or research setting would greatly assist in determining the impact of treatments. In addition, an in depth examination of the various aspects of quality of life in persons with FM is essential to understand how this condition impacts the social, physical and psychological dimensions of their lives.

Treatment programs may not be efficacious, especially over the long term if the family dynamics are not examined in conjunction with traditional management programs. Previous research in both adults and children suggested that the family environment and parental pain history were related to how children cope with juvenile FM (13). The family unit plays a key role in the management and presentation of FM in both adults and children with FM (13-15). The direct or indirect impact of the family on the reaction to the condition and ability to cope with it in persons with FM suggests that perhaps treatment should occur with the entire family unit and not just the person with FM. Treatment programs designed to actively involve the family unit in the management may provide greater benefit to persons with FM.

The influence of social support and social control (interactions that involve influence and regulation) in relation to health behaviours and overall well-being in persons with FM needs more in depth examination. Research with persons with rheumatoid arthritis determined that an avoidance type of coping encouraged others to be nonsupportive or critical of the person, which led to decreased well-being (16). In persons with end-stage joint disease, it was determined that low

and high levels of emotional support (receiving love, trust, understanding, and approval from significant others) enhanced the negative effects of functional limitations and depression (17). Lewis and Rook (18) examined the impact of social control on health behaviours and psychological distress in health persons and highlighted the impact of the overall social network versus the impact by a specific social network member. Worse, rather than better health practices were associated with greater social control when the overall social network was assessed. However, positive behaviour changes were associated with social control when assessed in terms of the influence of a particular network member. In addition, more intense social control was associated with more psychological distress. The above studies emphasize the need to examine in detail the type of social support network, not just the presence or absence of one, as well social control within those networks.

A relationship that has not been examined previously in persons with FM is the relationship with health care professionals and the ultimate effect on the management of the condition. It is not uncommon for persons with FM to see multiple specialists before a diagnosis of FM ever occurs. Many physicians and health care professionals even doubt the existence of this condition. Not surprisingly, this experience can leave many persons frustrated and angry. A recent study examining quality of life issues in persons with FM (19) reported that patients want more empathy and listening from health care professionals. In addition, better educated health care professionals was requested from over 50% of the subjects and one third just wanted health professionals to believe that the condition exists. Is the management of FM partially impeded due to the commonly negative experience in the health care system and the constant need for validation of symptoms? Understanding the attitudes of health professionals towards persons with FM and the impact of these attitudes on the management of the condition may predict their response to treatment. Identification of these predictors eventually should lead to the development of more effective treatment

programs. Issues may be identified that once addressed at the beginning of a program would lead to improvements in function and overall quality of life.

The moderate success of interventions suggests that different theoretical frameworks be employed to improve the understanding of the adoption of health promoting or coping behaviours in persons with FM. Perhaps self-efficacy theory can only partially explain or assist with explaining these behaviours resulting in better management of FM. Other theoretical models such as transtheoretical model and the stages of change (20), theory of planned behaviour (21) and theory of reasoned action (22) have been beneficial in the understanding of the adoption of health behaviours in a variety of populations (23-26). For example, determining the readiness to adopt new or maintain current behaviours by using the stages of change model may allow for programs to be designed for each specific stage. The response to treatment may increase if persons are placed into specific programs based on the stage they are in presently. Another model, the elaboration likelihood model of attitude change (27) has been recently applied to health promotion with respect to communications tailored towards people who do not have a favourable attitude towards exercise (28). Exploring different theoretical frameworks may assist with explaining and understanding behaviour, thereby leading to the improved management of FM.

Some of the results from this study should provide the basis for the development and examination of exercise prescription guidelines for persons with FM. Anecdotally, it was noted in the current study that persons working at an age predicted HRmax above 75% experienced an increase in symptoms. This increase was alleviated once their exercise intensity dropped below 70-75% age predicted HRmax. Aerobic exercise may not be the key to the management for some persons with FM, however a physically active lifestyle is important for everyone to enhance and maintain proper health and well-being (29, 30). Therefore, determining if physical activity accumulated throughout the day provides greater benefits and is adhered to more than continuous aerobic

exercise would greatly impact exercise recommendations. Home based versus group exercise programs should be compared to determine if differences in adherence or treatment outcomes exist. Examining the benefits of nontraditional types of activities (i.e. yoga, tai chi) in persons with FM may lead to improved exercise prescription. In addition, to determine if a relationship between intensity of exercise and symptoms exists, varying intensities of aerobic exercise could be examined.

Issues identified in this and other studies with persons with FM are adherence and relapse prevention (31-34). In the current study, attrition was a problem, not just with exercise, but also with the education program. Unfortunately, many factors influence the large number of dropouts. The role of fatigue has not been adequately examined with respect to the impact it has on the management of FM. Possibly, fluctuations in symptoms prevent continued participation in an ongoing treatment program. Subjects may also judge the treatment to be ineffective, therefore they dropout. Perhaps they relapse after treatment concludes because they were not satisfied with the outcome of treatment or maybe they never altered their behaviour in the first place (35). Previous research in healthy and diseased populations has focused on adherence and relapse prevention issues and strategies (23, 36-41). Booster sessions or periodic updates have sustained improvements in other populations after treatment (42, 43). In the FM population, determining factors related to nonadherence during treatment and issues surrounding relapses after treatment may result in the improved management of FM. In addition, perhaps identifying characteristics of persons with FM who are at "high risk" for relapse would help maintain improvements over time.

FM is a challenging condition to treat. Currently, exercise and education do not appear very beneficial in managing the condition due to the lack of response to treatment in a majority of persons with FM. This does not suggest the abandonment of exercise and education for all persons with FM, but it does

suggest a departure from the standard treatment recommendations to explore alternative methods for managing this puzzling condition.

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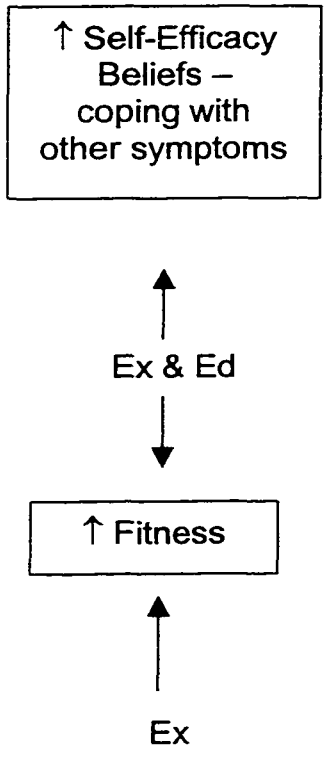


Figure 8.1. Overall model of effect of exercise and education on the management of Fibromyalgia.

APPENDIX A

Definition of Terms/Abbreviations

*Physiological**

Maximal oxygen consumption (VO_2max)(ml/min, L/min or ml/kg/min)– the maximal oxygen uptake obtainable for a given form of ergometry despite further work rate increases and effort by the subject. It provides a quantitative statement of a person's capacity for aerobic energy transfer. (VO_2=Q x (a-v)O_2 diff)

Peak oxygen consumption (pVO_2) (ml/min, L/min or ml/kg/min) – the highest, yet not maximal, oxygen uptake obtainable for a given form of ergometry despite further work rate increases and effort by the subject. It provides a quantitative statement of a person's capacity for aerobic energy transfer. (VO_2=Q x (a-v)O_2 diff)

Heart Rate (HR) (beats/min) –the number of times the heart pumps blood (ventricular contractions) in one minute.

Cardiac output (Q)(L/min) – the flow of blood ejected per unit time from the heart in a particular period of time. It is the product of the average stroke volume per beat (ml/beat) and the heart rate (number of beats per minute). (Q=HR x SV)

Stroke volume (SV) (ml/beat)– volume of blood ejected from either ventricle of the heart in a single beat. (SV=Q/HR)

Arterio-venous oxygen difference [(a-v)O_2 diff] (ml/100ml of blood)– the difference in the oxygen content of the arterial and mixed venous blood. [(a-v)O_2 diff= VO_2(ml/min)/Q]

Oxygen pulse (O_2 pulse)(ml/beat) – the ratio of VO_2 to HR. The amount of oxygen extracted by the tissues of the body from the oxygen carried in each stroke volume. [O_2 pulse= VO_2 (ml/min)/HR]

Respiratory exchange ratio (RER) – the ratio of carbon dioxide production to oxygen consumption. The ratio reflects the metabolic exchange of the gases in the lungs. ($RER=VCO_2/VO_2$)

* taken from Wasserman et al

(Wasserman K, Hansen JE, Sue DY, Whipp BJ, Casaburi R. Principles of Exercise Testing and Interpretation. 2nd ed. Philadelphia: Lea & Febiger, 1994.)

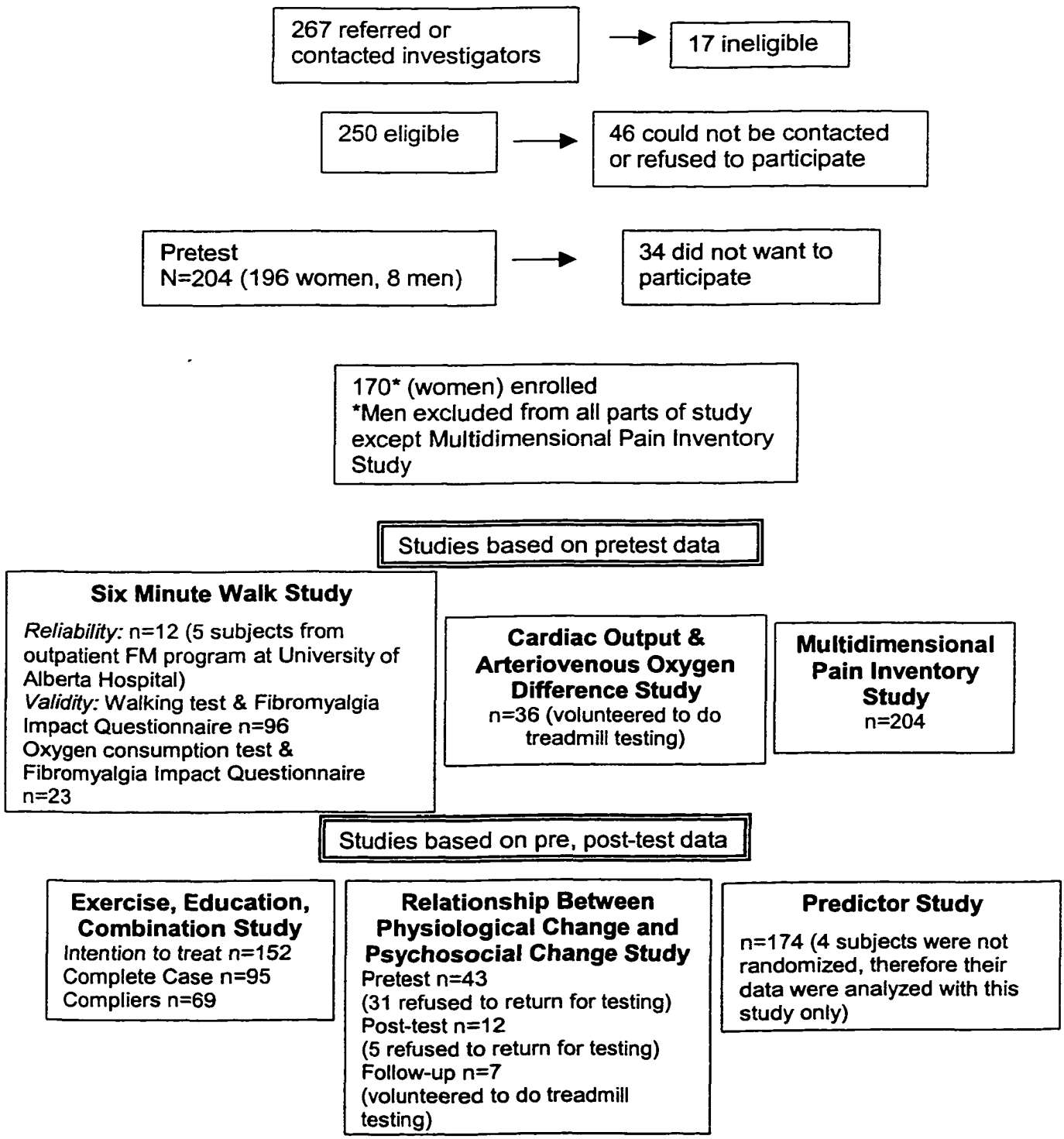
Psychosocial

Self-efficacy (SE) – one's own perceived ability that he/she is capable of performing a specific behaviour or a set of behaviours.

Fear-avoidance beliefs (FAB) – strongly held feelings (negative feelings) or a fear of the consequences of certain activities on his/her functioning, therefore these activities are avoided. For example, a strong fear of pain results in the avoidance of activities the person feels will exacerbate his/her pain.

APPENDIX B

Number of Subjects for Each Aspect of the Study



APPENDIX C

Descriptions of Questionnaires

Chronic Pain Self-Efficacy Scale (SES) - is a 20-item scale divided into 3 subscales (pain coping, functioning and coping with other symptoms), measuring subjects' beliefs in their ability to perform specific tasks and control symptoms of their condition (1). The scale is similar to Lorig's Arthritis Self-Efficacy Scale, however the Function subscale was altered to measure the efficacy expectations for functioning with the consequences of chronic pain (2). When the SES was compared to the Beck Depression Inventory and Beck Hopelessness Scale, the chronic pain subjects with higher self-efficacy reported more positive mood, fewer symptoms of depression and less hopelessness (significant correlations ranging from 0.44-0.50). A higher score indicates greater self-efficacy.

Fibromyalgia Impact Questionnaire (FIQ) - is a brief 19-item survey measuring physical functioning, work status, depression, anxiety, sleep, pain, stiffness, fatigue and well being in persons with FM (3). Construct validity has been demonstrated by a moderate correlation (r=.67) with the lower extremity physical functioning subscale of the Arthritis Impact Measurement Scale (AIMS) (3). The total FIQ score was calculated according to Burckhardt et al (3). The range of scores is 0-70 with a higher score indicating greater impact of the condition on the person's life.

Six Minute Walk (6MW) - is a field test developed from Cooper's 12 minute walk/run (4). Subjects walked along a 40 metre level corridor and were instructed to "cover as much ground as possible in 6 minutes". Encouragement such as "good pace, keep it up" or "good work" was given at 2, 3, 4 and 5 minutes. At these same time intervals, the subjects were informed of the time remaining in the walk. Encouragement and time remaining were standardized for all patients.

Resting heart rate was monitored for 2 minutes (sitting) and for the duration of the test. Borg's rating of perceived exertion was recorded at the end of the walk (5). The 6MW has been used in the FM research to evaluate fitness. Research has demonstrated a correlation of 0.66 (p=.001) between the 6MW and peak oxygen consumption, a direct measure of fitness (6). The reliability of the 6MW has been reported to be 0.73-0.89 (6). The distance covered in metres was recorded.

Quality of Life Scale (QOL) - is a 16-item questionnaire dealing with satisfaction with various aspects of life, such as health/physical activity, raising or having children, independence, learning or attending school (7). Test-retest reliability coefficients ranged from 0.76-0.84 with a population of rheumatoid arthritis, osteoarthritis and other chronic illness patients (7). Validity on chronic illness patients was demonstrated by the correlations obtained with other health and satisfaction indices (7). Scoring is based upon a Likert scale ranging from 1 (terrible) to 7 (delighted). A total satisfaction score is obtained by summing all 16 items with total scores ranging from 16-112. A higher score indicates greater satisfaction with life. The quality of life of persons with FM was found to be lower, compared to other rheumatic and nonrheumatic diseases, although there was substantial overlap in the range of scores for the FM, chronic obstructive pulmonary disease and diabetes patients in the sample (8).

Tender Point Count and Total Survey Site Score - the 18 TPs were examined according to the manual TP survey protocol of Okifuji et al (9). This protocol outlines examiner and subject positioning, order of examination and pressure application technique. Additionally, the Total Survey Site Score was used as a self-report measure of pain severity (9). Okifuji and colleagues (9) concluded that the range of severity scores obtained from the Total Survey Site Score would allow for a detection of change over time and a decrease in TP pain after

treatment. A self-report measure of pain severity was selected, rather than physician observation or interpretation, due to the subjective nature of pain. The total number of positive TPs is the TP count (ranging from 0-18). Each time a TP is palpated, the subject rates the pain severity as 0 (no pain) - 10 (worst pain). The pain severity ratings that are 2 or more are considered positive TPs. The scores for these positive TPs are totaled, thus providing a Total Survey Site Score (ranging from 0-180). The TP criterion from the study by Okifuji et al (9) was 88.6% sensitive and 71.4% specific with the TP criteria developed by the American College of Rheumatology multicentre study (10).

West Haven-Yale Multidimensional Pain Inventory (MPI) - has 52-items (version 1) (11) divided into 3 sections. Section one evaluates subjects' reports of pain severity, perceived life interference by pain, sense of control over their lives, affective distress and perceived level of social support. Section two assesses behavioural responses exhibited by patients' significant others in response to pain complaints. Section three assesses levels of engagement in various activities: social, household chores, outdoor activities and activities away from home. The MPI is made up of 9 scales (there are 13 original scales, but four activity scales are combined to obtain a general activity scale), derived from the questions in all three sections. The responses to these scales are used to classify the subject.

In addition to the three main classifications (AC, ID and Dys), there are anomalous, hybrid and unanalyzable profiles. An anomalous profile is considered an exaggerated type of dysfunctional profile and is highly unusual. Persons are categorized as hybrid when the scores represent aspects of more than one of the three main profiles. An unanalyzable profile occurs when more than two or more of the nine scales are missing data and the program cannot classify the patient. The internal consistency of the MPI has been reported to be 0.70-0.90, and reliability 0.62-0.91 (12).

Fear-Avoidance Beliefs Questionnaire - is a 16-item scale examining patients' previous experience regarding fear of pain and the avoidance of certain behaviours (13). The questionnaire is divided into two fear-avoidance subscales pertaining to beliefs about work and physical activity. It was originally designed for patients with chronic low back pain and has not been validated on patients with FM. Scoring consists of a Likert-type scale with ranges of 0 (completely disagree) and 6 (completely agree). A separate score is calculated for each subscale and then combined for a total score. Scores may range from 0-24 for physical activity and 0-42 for work. A higher score indicates greater fear-avoidance beliefs. The average kappa level for all items was .74 (12)

THE WEST HAVEN-YALE MULTIDIMENSIONAL PAIN INVENTORY

SECTION 1

In the following 20 questions, you will be asked to describe your pain and how it affects your life. Under each question is a scale to record your answer. Read each question carefully and then *circle* a number on the scale under that question to indicate how that specific question applies to you.

1. Rate the level of your pain at the present moment.

0	1	2	3	4	5	6
No pain						Very intense pain

2. In general, how much does your pain problem interfere with your day to day activities?

0	1	2	3	4	5	6
No interference						Extreme interference

3. Since the time you developed a pain problem, how much has your pain changed your ability to work?

0	1	2	3	4	5	6
No change						Extreme change

4. How much has your pain changed the amount of satisfaction or enjoyment you get from participating in social and recreational activities?

0	1	2	3	4	5	6
No change						Extreme change

5. How supportive or helpful is your spouse (significant other) to you in relation to your pain?

0	1	2	3	4	5	6
Not at all supportive						Extremely supportive

6. Rate your overall mood during the *past week.*

0	1	2	3	4	5	6
Extremely low mood						Extremely high mood

7. On the average, how severe has your pain been during the *last week?*

0	1	2	3	4	5	6
Not at all severe						Extremely severe

8. How much has your pain changed your ability to participate in recreational and other social activities?

0	1	2	3	4	5	6
No change						Extreme change

9. How much has your pain changed the amount of satisfaction you get from family-related activities?

0	1	2	3	4	5	6
No change						Extreme change

10. How worried is your spouse (significant other) about you in relation to your pain problems?

0	1	2	3	4	5	6
Not at all worried						Extremely worried

11. During the *past week* how much control do you feel that you have had over your life?

0	1	2	3	4	5	6
No control						Extremely in control

12. How much *suffering* do you experience because of your pain?

0	1	2	3	4	5	6
No suffering						Extreme suffering

13. How much has your pain changed your marriage and other family relationships?

0	1	2	3	4	5	6
No change						Extreme change

14. How much has your pain changed the amount of satisfaction or enjoyment you get from work?

0	1	2	3	4	5	6
No change						Extreme change

_____ Check here, if you are not presently working

15. How attentive is your spouse (significant other) to your pain problem?

0	1	2	3	4	5	6
Not at all attentive						Extremely attentive

16. During the past week how much do you feel that you've been able to deal with your problems?

0	1	2	3	4	5	6
Never						Very often

17. How much has your pain changed your ability to do household chores?

0	1	2	3	4	5	6
No change						Extreme change

18. During the past week how irritable have you been?

0	1	2	3	4	5	6
Not at all irritable						Extremely irritable

19. How much has your pain changed your friendship with people other than your family?

0	1	2	3	4	5	6
No change						Extreme change

20. During the past week how tense or anxious have you been?

0	1	2	3	4	5	6
Not at all tense or anxious						Extremely tense or anxious

SECTION 2

In this section, we are interested in knowing how your spouse (or significant other) responds to you when he or she knows that you are in pain. On the scale listed below each question, *circle* a number to indicate *how often* your spouse (or significant other) generally responds to you in that particular way *when you are in pain*. Please answer *all* of the 14 questions.
***Please identify the relationship between you and the person you are thinking of.

1. Ignores me

0	1	2	3	4	5	6
Never						Very often

2. Asks me what he/she can do to help

0	1	2	3	4	5	6
Never						Very often

3. Reads to me

0	1	2	3	4	5	6
Never						Very often

4. Expresses irritation to me

0	1	2	3	4	5	6
Never						Very often

5. Takes over my jobs or duties

0	1	2	3	4	5	6
Never						Very often

6. Talks to me about something else to take my mind off the pain

0	1	2	3	4	5	6
Never						Very often

7. Expresses frustration at me

0	1	2	3	4	5	6
Never						Very often

8. Tries to get me to rest

0	1	2	3	4	5	6
Never						Very often

9. Tries to involve me in some activity

0	1	2	3	4	5	6
Never						Very often

10. Expresses anger at me

0	1	2	3	4	5	6
Never						Very often

11. Gets me some pain medication

0	1	2	3	4	5	6
Never						Very often

12. Encourages me to work on a hobby

0	1	2	3	4	5	6
Never						Very often

13. Gets me something to eat or drink

0	1	2	3	4	5	6
Never						Very often

14. Turns on the T.V. to take my mind off my pain

0	1	2	3	4	5	6
Never						Very often

SECTION 3

Listed below are 18 common daily activities. Please indicate *how often* you do each of these activities by *circling* a number on the scale listed below each activity. Please complete *all* 18 questions.

1. Wash dishes

0	1	2	3	4	5	6
Never						Very often

2. Mow the lawn

0	1	2	3	4	5	6
Never						Very often

3. Go out to eat

0	1	2	3	4	5	6
Never						Very often

4. Play cards or other games

0	1	2	3	4	5	6
Never						Very often

5. Go grocery shopping

0	1	2	3	4	5	6
Never						Very often

6. Work in the garden

0	1	2	3	4	5	6
Never						Very often

7. Go to a movie

0	1	2	3	4	5	6
Never						Very often

8. Visit friends

0	1	2	3	4	5	6
Never						Very often

9. Help with the house cleaning

0	1	2	3	4	5	6
Never						Very often

10. Work on the car

0	1	2	3	4	5	6
Never						Very often

11. Take a ride in a car

0	1	2	3	4	5	6
Never						Very often

12. Visit relatives

0	1	2	3	4	5	6
Never						Very often

13. Prepare a meal

0	1	2	3	4	5	6
Never						Very often

14. Wash the car

0	1	2	3	4	5	6
Never						Very often

15. Take a trip

0	1	2	3	4	5	6
Never						Very often

16. Go to a park or beach

0	1	2	3	4	5	6
Never						Very often

17. Do a load of laundry

0	1	2	3	4	5	6
Never						Very often

18. Work on a needed house repair

0	1	2	3	4	5	6
Never						Very often

SELF-EFFICACY SCALE

Self-efficacy pain subscale

In the following questions, we'd like to know how your pain affects you. For each of the following questions, please circle the number which corresponds to your certainty that you can now perform the following tasks.

1. How certain are you that you can decrease your pain quite a bit?

10 20 30 40 50 60 70 80 90 100
Very uncertain — Moderately uncertain — Very certain

2. How certain are you that you can continue most of your daily activities?

10 20 30 40 50 60 70 80 90 100
Very uncertain — Moderately uncertain — Very certain

3. How certain are you that you can keep pain from interfering with your sleep?

10 20 30 40 50 60 70 80 90 100
Very uncertain — Moderately uncertain — Very certain

4. How certain are you that you can make a small-to-moderate reduction in your pain by using methods other than taking extra medication?

10 20 30 40 50 60 70 80 90 100
Very uncertain — Moderately uncertain — Very certain

5. How certain are you that you can make a large reduction in your pain by using methods other than taking extra medication?

---

10 20 30 40 50 60 70 80 90 100
Very uncertain — Moderately uncertain — Very certain

Self-efficacy function subscale

We would like to know how confident you are in performing certain daily activities. For each of the following questions, please circle the number which corresponds to your certainty that you can perform the tasks as of now, without assistive devices or help from another person. Please consider what you routinely can do, not what would require a single extraordinary effort.

AS OF NOW, HOW CERTAIN ARE YOU THAT YOU CAN:

1. Walk ½ mile on flat ground?

---

10 20 30 40 50 60 70 80 90 100
Very uncertain — Moderately uncertain — Very certain

2. Lift a 10 pound box?

---

10 20 30 40 50 60 70 80 90 100
Very uncertain — Moderately uncertain — Very certain

3. Perform a daily home exercise program?

---

10 20 30 40 50 60 70 80 90 100
Very uncertain — Moderately uncertain — Very certain

4. Perform your household chores?

10 20 30 40 50 60 70 80 90 100
Very uncertain — Moderately uncertain — Very certain

5. Shop for groceries or clothes?

10 20 30 40 50 60 70 80 90 100
Very uncertain — Moderately uncertain — Very certain

6. Engage in social activities?

10 20 30 40 50 60 70 80 90 100
Very uncertain — Moderately uncertain — Very certain

7. Engage in hobbies or recreational activities?

10 20 30 40 50 60 70 80 90 100
Very uncertain — Moderately uncertain — Very certain

8. Engage in family activities?

10 20 30 40 50 60 70 80 90 100
Very uncertain — Moderately uncertain — Very certain

9. Perform the work duties you had prior to the onset of chronic pain? (For homemakers, please consider your household activities as your work duties)

10 20 30 40 50 60 70 80 90 100
Very uncertain — Moderately uncertain — Very certain

Self-efficacy other symptoms subscale (coping with symptoms)
In the following questions, we'd like to know how you feel about your ability to control your pain. For each of the following questions, please circle the number which corresponds to the certainty that you can now perform the following activities or tasks.

1. How certain are you that you can control your fatigue?

10 20 30 40 50 60 70 80 90 100
Very uncertain — Moderately uncertain — Very certain

2. How certain are you that you can regulate your activity so as to be active without aggravating your pain?

10 20 30 40 50 60 70 80 90 100
Very uncertain — Moderately uncertain — Very certain

3. How certain are you that you can do something to help yourself feel better if you are feeling blue?

10 20 30 40 50 60 70 80 90 100
Very uncertain — Moderately uncertain — Very certain

4. As compared with other people with pain like yours, how certain are you that you can manage pain during your daily activities?

---

10 20 30 40 50 60 70 80 90 100
Very uncertain — Moderately uncertain — Very certain

5. How certain are you that you can manage your symptoms so that you can do the things you enjoy doing?

---

10 20 30 40 50 60 70 80 90 100
Very uncertain — Moderately uncertain — Very certain

6. How certain are you that you can deal with the frustration of pain?

---

10 20 30 40 50 60 70 80 90 100
Very uncertain — Moderately uncertain — Very certain

FIBROMAYLGIA IMPACT QUESTIONNAIRE (FIQ)

Directions: for questions 1 through 10, 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 times	Occasionally	Never
Do shopping?	0	1	2	3
Do laundry with a washer and dryer	0	1	2	3
Prepare meals?	0	1	2	3
Wash dishes/cooking utensils by hand?	0	1	2	3
Vacuum rug?	0	1	2	3
Make beds?	0	1	2	3
Walk several blocks?	0	1	2	3
Visit friends or relatives?	0	1	2	3
Do yard work?	0	1	2	3
Drive a car?	0	1	2	3

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

0 1 2 3 4 5 6 7

How many days last week did you miss work because of your FM? If you don't have a job outside the home, leave this item blank.

0 1 2 3 4 5 6 7

Directions: For the remaining items, place a mark like this | at the point on the line that best indicates how you felt overall for the past week.

When you did work, how much did pain or other symptoms of your FM interfere with your ability to do your job?

No problem with work	Great difficulty with work

How bad has your pain been?

No pain	Very severe pain

How tired have you been?

No tiredness	Very tired

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

Awoke refreshed	Awoke very tired

How bad has your stiffness been?

No stiffness	Very stiff

How nervous or anxious have you felt?

Not anxious	Very anxious

How depressed or blue have you felt?

Not depressed	Very depressed

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	Satisfied	Mixed	Mostly Dissatisfied	Unhappy	Mostly 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
6. 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

QUALITY OF LIFE QUESTIONNAIRE cont'd

	Delighted	Pleased	Satisfied	Mixed	Mostly Dissatisfied	Unhappy	Mostly Terrible
9. Learning - attending school, improving understanding, getting additional knowledge	7	6	5	4	3	2	1
10. Understanding yourself - knowing your assets 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

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FEAR AVOIDANCE BELIEFS QUESTIONNAIRE

Here are some of the things which other patients have told us about their pain. For each statement please circle any number from 0 to 6 to say how much physical activities such as bending, lifting, walking or driving affect or would affect your pain.

	Completely disagree			Unsure			Completely agree
1. My pain was caused by physical activity	0	1	2	3	4	5	6
2. Physical activity makes my pain worse	0	1	2	3	4	5	6
3. Physical activity might harm my muscles	0	1	2	3	4	5	6
4. I should not do physical activities which (might) make my pain worse	0	1	2	3	4	5	6
5. I cannot do physical activities which (might) make my pain worse	0	1	2	3	4	5	6

The following statements are about how your normal work affects or would affect your pain

6. My pain was caused by my work or by an accident at work	0	1	2	3	4	5	6
7. My work aggravated my pain	0	1	2	3	4	5	6
8. I have a claim for compensation for my pain	0	1	2	3	4	5	6
9. My work is too heavy for me	0	1	2	3	4	5	6
10. My work makes or would make my pain worse	0	1	2	3	4	5	6
11. My work might harm my body	0	1	2	3	4	5	6
12. I should not do my normal work with my present pain	0	1	2	3	4	5	6
13. I cannot do my normal work with my present pain	0	1	2	3	4	5	6
14. I cannot do my normal work till my pain is treated	0	1	2	3	4	5	6
15. I do not think that I will be back to my normal work within 3 months	0	1	2	3	4	5	6
16. I do not think that I will ever be able to go back to that work	0	1	2	3	4	5	6

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APPENDIX D

Treatment Programs

Exercise only - met three times per week to exercise as a group. The exercise was all aerobic in nature and included activities such as walking, aquasize (deep and shallow water), or aerobics. A physical therapist experienced in exercise therapy for persons with FM was present at each session. Modifications to activities were made on an individual basis with the help of the physical therapist. The subjects were instructed to exercise at a level that was comfortable for them. At each session, heart rate was monitored with a Polar Accurex HRM (Washington). Average exertion for the session was assessed by Borg's Rating of Perceived Exertion (RPE) (1). When a heart rate monitor was not available, the subjects' pulse was palpated and heart rate was calculated. Guidelines regarding heart rate were provided based on a percentage of age predicted maximum HR (maxHR). The duration of activity was 10-15 minutes at the beginning of the program. By the end of the program, some subjects were exercising for 30-50 minutes.

Education only - met once, sometimes twice a week, for 1.5-2 hours per session. The basis of the program was a self-management program. Topics included goal setting, problem solving, time/stress management, benefits of exercise, evaluating alternative therapies. Guest speakers included a rheumatologist, psychologist, registered dietician and other health and fitness experts (i.e. yoga master, tai chi instructor). One session included the family and/or friends of study participants. This session was designed mainly for the non-study participants in order for them to learn more about the condition and ways that they could assist the person they knew with FM. Two scenarios were presented (one from the FM person's viewpoint and the other from the FM person's spouse), which the group discussed in order to find some resolutions to the issues.

Exercise and Education - this group was a combination of both the exercise and education programs. Typically, after the educational group would meet on their appointed day, the subjects in the combined program would exercise.

Control group - on the day of the initial assessment, the subjects in the control group were given two pages of information on stretches and general coping strategies. They were contacted once or twice throughout the 12 week period to see how they were managing. At the end of the follow-up period, the control subjects were offered a program of exercise, education or the combination. Only their control period data was analyzed.

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APPENDIX E

Reliability of Change Index

Values for Calculations

FIQ

SD=12.55
test-retest reliability (r_{xx}) = .56 and .95 (1)
Standard Error=8.32, 2.81

QOL

SD=15.61
test-retest reliability (r_{xx}) = .76 and .84 (2)
Standard Error=7.65, 6.24

SE-coping with pain

SD=20.78
test-retest reliability (r_{xx}) =.88 (3)
Standard Error=7.20

SE-function

SD=22.00
test-retest reliability (r_{xx}) = .87 (3)
Standard Error=7.93

SE-coping with symptoms

SD=18.64
test-retest reliability (r_{xx}) = .90 (3)
Standard Error=5.89

6MW

SD=87.12
test-retest reliability (r_{xx}) = .733 and .885 (4)
Standard Error=45.02, 29.54

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APPENDIX F

Correlations of Independent and Dependent Variables

Table 1. Pearson Product Moment correlations of FIQ change scores with independent variables used to predict this change in persons with FM.

Independent Variable	Pearson r	Significance
Age	.083	.338
Married/common-law	.036	.684
Divorced	-.061	.485
Duration of symptoms	-.021	.809
Compensation	-.108	.213
Litigation	-.046	.601
Employed	.023	.789
< High school	-.020	.818
> High school	.042	.633
Adaptive Coper	.007	.933
Dysfunctional	.045	.605
Fear Avoidance - physical activity	-.054	.539
Fear Avoidance - work	-.014	.874
SES – Total	.076	.380
Education Group	.163	.060
Exercise Group	.118	.175

Bold denotes significant at p<.05

Table 2. Pearson Product Moment correlations of QOL change scores with independent variables used to predict this change in persons with FM.

Independent Variable	Pearson r	Significance
Age	-.009	.922
Married/common-law	.046	.595
Divorced	.009	.918
Duration of symptoms	-.021	.808
Compensation	-.062	.480
Litigation	.107	.220
Employed	.062	.477
< High school	-.228	**.008**
> High school	.195	**.024**
Adaptive Coper	-.117	.180
Dysfunctional	.115	.186
Fear Avoidance - physical activity	-.022	.800
Fear Avoidance - work	.100	.250
SES – Total	-.032	.712
Education Group	.088	.312
Exercise Group	.113	.194

Bold denotes significant at p<.05

Table 3. Pearson Product Moment correlations of SE-coping with pain change scores with independent variables used to predict this change in persons with FM.

Independent Variable	Pearson r	Significance
Age	.085	.329
Married/common-law	-.175	**.043**
Divorced	.162	.062
Duration of symptoms	.076	.383
Compensation	-.088	.312
Litigation	.035	.691
Employed	.038	.667
< High school	-.073	.404
> High school	-.028	.752
Adaptive Coper	-.066	.446
Dysfunctional	-.136	.117
Fear Avoidance - physical activity	-.025	.778
Fear Avoidance - work	-.141	.105
SES - Total	-.232	**.007**
Education Group	.047	.590
Exercise Group	.026	.767

Bold denotes significant at p<.05

Table 4. Pearson Product Moment correlations of SE-function change scores with independent variables used to predict this change in persons with FM.

Independent Variable	Pearson r	Significance
Age	.097	.264
Married/common-law	-.023	.795
Divorced	.013	.877
Duration of symptoms	.188	**.030**
Compensation	.092	.291
Litigation	-.087	.322
Employed	-.060	.491
< High school	-.042	.628
> High school	.006	.941
Adaptive Coper	-.082	.349
Dysfunctional	.007	.936
Fear Avoidance - physical activity	.073	.403
Fear Avoidance - work	.032	.714
SES - Total	-.170	**.049**
Education Group	.108	.213
Exercise Group	-.006	.947

Bold denotes significant at p<.05

Table 5. Pearson Product Moment correlations of SE-coping with other symptoms change scores with independent variables used to predict this change in persons with FM.

Independent Variable	Pearson r	Significance
Age	.015	.861
Married/common-law	.006	.941
Divorced	.054	.537
Duration of symptoms	.003	.976
Compensation	-.091	.297
Litigation	.062	.479
Employed	.095	.275
< High school	-.086	.320
> High school	.143	.099
Adaptive Coper	-.008	.928
Dysfunctional	-.001	.993
Fear Avoidance - physical activity	.053	.545
Fear Avoidance – work	-.051	.560
SES – Total	-.220	**.011**
Education Group	.114	.189
Exercise Group	.122	.162

Bold denotes significant at p<.05

Table 6. Pearson Product Moment correlations of Six Minute Walk change scores with independent variables used to predict this change in persons with FM.

Independent Variable	Pearson r	Significance
Age	.058	.510
Married/common-law	-.008	.924
Divorced	.008	.931
Duration of symptoms	.153	.080
Compensation	-.093	.290
Litigation	-.008	.932
Employed	-.026	.769
< High school	.067	.448
> High school	.032	.714
Adaptive Coper	-.047	.596
Dysfunctional	-.257	**.003**
Fear Avoidance – physical activity	-.185	**.035**
Fear Avoidance - work	-.104	.237
SES - Total	.112	.201
Education Group	.085	.332
Exercise Group	.220	**.011**

Bold denotes significant at p<.05

Table 7. Pearson Product Moment correlations of number of tender points change scores with independent variables used to predict this change in persons with FM.

Independent Variable	Pearson r	Significance
Age	-.062	.502
Married/common-law	-.016	.863
Divorced	-.070	.449
Duration of symptoms	-.088	.342
Compensation	.144	.121
Litigation	-.012	.898
Employed	.038	.681
< High school	-.099	.288
> High school	.178	**.054**
Adaptive Coper	.127	.172
Dysfunctional	.001	.993
Fear Avoidance - physical activity	-.007	.937
Fear Avoidance - work	-.046	.621
SES - Total	.154	.097
Education Group	.017	.852
Exercise Group	-.064	.493

Bold denotes significant at p<.05

Table 8. Pearson Product Moment correlations of Total Survey Site change score with independent variables used to predict this change in persons with FM.

Independent Variable	Pearson r	Significance
Age	-.080	.387
Married/common-law	.028	.760
Divorced	-.062	.504
Duration of symptoms	-.201	**.029**
Compensation	.156	.091
Litigation	-.021	.821
Employed	.039	.674
< High school	.054	.564
> High school	-.050	.588
Adaptive Coper	.185	**.045**
Dysfunctional	.000	.999
Fear Avoidance - physical activity	.016	.864
Fear Avoidance - work	-.033	.721
SES - Total	.085	.360
Education Group	.007	.940
Exercise Group	-.102	.270

Bold denotes significant at p<.05

APPENDIX G

Consent Form

An Evaluation of the Effect of Exercise and Education for Women with Fibromyalgia

Investigators: Dr. Jean Wessel, Dr. Yagesh Bhambhani, Sharla King
Faculty of Rehabilitation Medicine
University of Alberta
Edmonton, AB, T6G 2G4
Ph: J Wessel 492-2812, Y Bhambhani 492-7248,
Sharla King 492-7336

I, _____, agree to participate in the above named study being conducted by Sharla King, PhD student, Jean Wessel, Associate Professor and Yagesh Bhambhani, Professor in the Faculty of Rehabilitation Medicine.

The purpose of the study is to evaluate the effects of a special program designed for persons with fibromyalgia. The program will include information on the condition, its management and specific strategies to deal with the pain and impact of the disease. By volunteering to be in the study, I realize that I may be assigned by chance to one of four groups. One of the groups will receive information, but not attend regularly for weekly treatment sessions. If I am in one of the three groups that attends special sessions, I will be required to come to the University of Alberta 2-3 times per week for 12 weeks for sessions lasting 60-90 minutes each.

I realize that no matter what group I am in, I will attend testing sessions in which I will complete questionnaires about my pain and the impact of my condition on everyday life and on work. I will also be tested for my fitness level. This test will involve my walking for one mile on a track. A heart rate monitor will be strapped to my chest (under my clothing) to record my heart rate during this activity. I understand that these tests will all occur in one session that will take approximately 60-90 minutes.

I may also be requested to participate in some additional tests on fitness. These tests will require one extra test session both at the beginning and at the end of the study. If I perform this test, I will walk on a treadmill with electrodes on my chest to record heart rate, and I will breath through a mouthpiece so that a machine can record how much oxygen I am consuming during exercise. Once I have reached a steady level of exercise, I will be required to breath rapidly for 20 seconds in and out of a gas sampling bag containing a mixture of carbon dioxide and oxygen. I will also be requested to walk at a faster and faster pace until I feel

I have reached by maximal effort. This extra session will take no longer than 60 minutes.

It is possible that I could experience symptoms such as nausea and dizziness during the breathing into a bag and muscle soreness during or after any of the exercise tests. I understand that if I experience such discomfort at any time, I will be free to terminate the test.

The information that has been obtained in this study will be seen only by the investigators and their assistants. In order to ensure confidentiality, all data will be recorded with a code number rather than my name. The list linking names to codes will be kept in a locked cupboard in Dr Wessel's laboratory in the Faculty of Rehabilitation Medicine. Any information that is shown to others, published or presented at conferences will not refer to me by name, but only by number and only when necessary.

I understand that the investigators and their assistants will be pleased to answer any of my questions concerning the study and my participation in it. I may decline to enter the study or I may withdraw from the study at any time without prejudice.

With my signature below, I indicate that I understand all that is required of me in this study, and I acknowledge receipt of a copy of this consent form.

_____	_____	_____
Subjects signature	Witness's signature	Investigator's signature

_____

Date