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

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ABSTRACT. ***Objective.*** To examine the effectiveness of a supervised aerobic exercise program, a self-management education program, and the combination of exercise and education for women with fibromyalgia (FM).

Methods. One hundred fifty-two women were randomized into one of 4 groups: exercise-only, education-only, exercise and education, or control. The duration of the study was 12 weeks. All subjects were analyzed at 3 times: before study, immediately upon completion, and 3 months after completion of the intervention program on measures of disability, self-efficacy, fitness, tender point count, and tender point tenderness. Of the 152 women, complete data were available for 95 and 69 who complied with the protocol. In order to determine the group × time interaction, a 2 way analysis of variance with repeated measures was used for each measure.

Results. The only significant group × time interaction was reported with the compliance analysis for the Self-Efficacy Coping with Other Symptoms subscale and the Six Minute Walk. 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 improved in the 2 groups undergoing supervised aerobic exercise programs. However, the improvement in fitness was maintained at followup in the exercise-only group and not the combined group.

Conclusion. 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 followup in the exercise-only group. Results demonstrate the challenges with conducting exercise and education studies in persons with FM. (J Rheumatol 2002;29:2620–7

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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 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[1-4].

Research on aerobic exercise programs has demonstrated variable results in persons with FM[5-8]. Reductions in general pain, fatigue, number of tender points (TP), and total myalgic score have been reported[5-8]. However, no significant improvements on measures of psychosocial dimensions, such as influence of condition and self-efficacy, have been demonstrated. In addition, after study completion, either no followup 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. Educational studies have demonstrated reductions in pain and improvements in psychological and disability measures immediately upon completion of the program[9-14]. A group receiving exercise and education had greater changes in self-efficacy for coping with pain and other symptoms compared to a control group[1]. 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[2] 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 manage-

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ment group compared to the control group. Buckelew, *et al*[3] 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. A more recent study evaluating a 6 week program[4], however, reported no significant differences with respect to self-efficacy in the exercise and education group compared to the control group.

Trends toward baseline values have been reported in some studies (6 month followup)[9,11], while other studies have reported maintenance in post-program values upon 6 weeks to 4 years followup[2,4,12,14]. The combination groups were able to maintain improvements in TP index[3], self-efficacy for coping with pain, and other symptoms and life satisfaction[1]. In addition, Buckelew, *et al*[3] 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[1,3]. 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, or self-efficacy for functioning.

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[1,3]. The educational component may have focused only on relaxation or stress management[2,3] and not on skills to self-manage the condition. Control groups for comparison with the interventions were not included in other studies[12,14]. Further, the statistical analyses may have focused on the between- and within-group differences and not the interaction between group and time[1-3,12]. Finally, the reporting and/or examination of the compliance data may not have occurred.

We examined 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 effect of the condition, self-efficacy, physical fitness, and tender point assessment. It was also believed that the exercise-only and education-only groups would improve more than a control group on these same measures.

MATERIALS AND METHODS

Subjects. Subjects were women who met the American College of Rheumatology criteria for FM[15]. 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 that precluded ability to exercise (severe cardiac arrhythmia, dizziness, severe shortness of breath) or if they had an inflammatory arthritis, systemic lupus erythematosus, or rheumatoid arthritis. Persons involved in medicolegal cases were not excluded. Persons who had partaken in an education program similar to ours or who were currently following an exercise regimen were not excluded initially. These subjects underwent pre-testing and were randomized. Once randomized, a subject determined if she wanted to discontinue her exercise regimen and participate in the study or not. No subject randomized to the education part of the study had taken a program previously. Rheumatologists in the City of Edmonton were informed of an "exercise and education study" being run through the Faculty of Rehabilitation Medicine at the University of Alberta. With the consent of the subject, names and phone numbers of potential subjects were forwarded to the investigator who then contacted the person. If the person agreed to participate in the study, a date was set for the pre-test. Subjects that self-referred contacted the investigator. It was determined by telephone if she had been diagnosed by a rheumatologist and if she met the inclusion criteria. Inclusion criteria: women between ages of 18–65 years willing to meet 1 to 3 times per week for a 12 week period. The University of Alberta Faculty of Rehabilitation Medicine Ethics Committee approved procedures of 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[16]. 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, for a total of 120 subjects. To allow for the 30% attrition, a total of 170 women were recruited for the study by the end of the recruitment period. Demographic details are given in Table 1.

Design and data collection. This study was a randomized controlled trial with repeated measures design. The pre-test measures were completed on one visit. Informed consent was obtained from each subject prior to any testing. The medical history and TP assessment was completed by either a rheumatologist or a physical therapist. Employment status includes both part time and full time work, and compensation is the equivalent of disability payments.

The same examiner assessed the same subjects on subsequent visits. After physical assessment, self-report questionnaires and walking test were completed. So as to not influence the pre-test results, subjects were randomly assigned after pre-testing 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 blocks of 4 to 16 subjects. A list was prepared prior to start of study using a table of random numbers and subject ID number (order of admission to study). The investigator with the list who assigned subjects to groups was unaware of their baseline test results. 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 3 months later.

Outcome measures. Chronic Pain Self-Efficacy Scale (SE): 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[17]. Anderson, *et al*[17] based the scale on Lorig's Arthritis Self-Efficacy Scale[18] to measure the efficacy expectations for coping with the consequences of chronic pain. The only

Table 1. Demographic variables on all FM subjects (n = 170). Values are mean (SD) or percentages.

	Exercise, n = 46	Educations, n = 48	Exercise & Education, n = 37	Control, n = 39	F ratio or chi square (p)
Age, yrs	45.2 (9.4)	44.9 (10.0)	47.4 (9.0)	47.3 (7.3)	0.91 (0.440)
Height, cm	162.7 (7.3)	162.3 (6.2)	160.1 (4.9)	161.9 (6.8)	1.28 (0.282)
Weight, kg	74.0 (20.2)	75.8 (16.6)	82.1 (17.8)	76.8 (17.9)	1.43 (0.237)
Duration of symptoms, yrs	7.8 (6.1)	10.9 (10.7)	8.9 (7.3)	9.6 (7.9)	1.23 (0.299)
Marital status, %					
Married	63.0	64.6	62.2	64.1	
Single	8.7	14.6	21.6	12.8	4.21 (0.240)
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 (0.882)
Compensation					
% Yes	15.2	35.4	32.4	41.0	7.66 (0.054)
Litigation					
% Yes	6.5	6.3	8.3	7.7	0.15 (0.99)
Medications, %					
Antidepressants	52.2	72.9	64.9	41.0	6.0 (0.113)
Anxiolytics	6.5	8.3	2.7	2.6	6.22 (0.101)
Analgesics	45.7	35.4	35.1	38.5	3.56 (0.313)
NSAID	4.3	0	8.1	10.3	1.68 (0.431)
Muscle relaxants	17.4	20.8	10.8	15.4	4.85 (0.183)
Hypnotic	10.9	4.2	13.5	15.4	2.72 (0.436)
Anticonvulsants	6.5	14.6	5.4	5.1	2.86 (0.414)
Alternative	10.9	25.0	18.9	25.6	5.43 (0.143)
IBS	8.7	6.3	10.8	2.6	6.56 (0.087)
Thyroid	13.0	22.9	13.5	10.3	7.0 (0.072)
Estrogen	26.1	12.5	21.6	15.4	3.36 (0.339)
Gastrointestinal	21.6	12.5	13.5	5.1	3.26 (0.353)

NSAID: nonsteroidal antiinflammatory drugs. IBS: irritable bowel/bladder syndrome.

modification was made to the functioning subscale. A few questions regarding fine motor skills were replaced with questions pertaining to gross motor skills, determined to be more appropriate for a chronic pain population. For example, the original SE scale: "How certain are you that you can get out of an armless chair quickly, without using your hands for support?," versus the Chronic Pain SE scale: "How certain are you that you can perform your household chores?" A higher score indicates greater self-efficacy for the particular subscales.

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

Six Minute Walk (6MW): a field test developed from Cooper's 12 minute walk/run[20]. Subjects walked along a 40 meter, 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, subjects were informed of the time remaining in the walk. Encouragement and time remaining were standardized for all patients. The distance covered in meters was recorded. The reliability of the 6MW has been reported to be 0.73–0.89[21]. A correlation of 0.66 ($p = 0.001$) between the 6MW and peak oxygen consumption, a direct measure of fitness, has been demonstrated in the FM population[21]. The 6MW has been used in the FM research to evaluate fitness[1,12].

Tender Point Count and Total Survey Site Score: The 18 TP 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. The total number of positive TP is the TP count (ranging from 0 to 18). The self-report measure of pain severity that was used was the Total Survey Site Score[22]. Each time a TP is palpated, the subject rates the pain severity as 0 (no pain) to 10 (worst pain). The pain severity ratings that are 2 or more are considered positive TP. The scores for these positive TP are totalled, thus providing a Total Survey Site Score (ranging from 0 to 180).

Interventions. The intervention programs were based upon principles of self-management where the subjects, in collaboration with health care professionals, learn and adopt skills and behaviors to manage their condition[23]. For instance, the education program did not only provide information to passive recipients; it encouraged performance of new behaviors or skills. Self-management principles were taken from Bandura's social cognitive theory of enhancing self-efficacy beliefs as a mechanism underlying successful response to treatments[23].

Treatment programs ran simultaneously for 12 weeks. Due to the large number of subjects required, the programs were offered on 5 different occasions over a 2 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) recommendations on quantity and quality of exercise for maintaining and developing cardiorespiratory fitness in healthy adults[24]. However, subjects were instructed at the beginning of the exercise program to work at a level that was comfortable to them. For the duration of the study, subjects would increase the intensity and duration

of their sessions to meet the ACSM recommendations. The subjects met 3 times per week for a supervised exercise program. All instructors were certified fitness instructors with basic knowledge about the FM condition. In addition, a physical therapist experienced with exercise for FM attended every exercise session to modify activities for individuals when required. The therapist encouraged subjects when necessary.

Exercises were aerobic in nature and included activities such as walking, aquasize (deep and shallow water), or low impact aerobics. Depending on time of year and weather, subjects walked outside. All but 5 subjects participated in aquasize classes, held at 2 community pools during the winter study sessions. Water temperature was comfortable for the subjects. Subjects were integrated with non-FM persons in a "regular" aquasize class. At the beginning and end of each session mild stretches were included. Many aquasize activities in both shallow and deep water mimicked walking on land. There was no difference between exercise groups with respect to the number of subjects who participated in land- versus water-based exercise.

The majority of subjects were able to exercise comfortably at a heart rate (HR) based upon percentage of age predicted maximum HR (HRmax) (220 – age = HRmax)[25] (recommended range 60–75% HRmax); however, some subjects exercised at a HRmax a bit below 60%. At each session, HR was monitored with a Polar Accurex HRM. The HR information was downloaded into a computer, thus providing an average HR for the aerobic component of that exercise session. The accuracy of monitoring HR using the Polar Accurex HRM was no different on land or in the water. When a HR monitor was unavailable, HR was calculated by palpating the pulse for 15 seconds and then multiplied by 4. The average HR value was recorded at the middle and end of the aerobic session when the pulse was manually palpated. The rating of perceived exertion (RPE) was obtained for each subject at the end of the exercise session. Subjects recorded their perceived exertion based on the aerobic portion of the activity.

The duration of activity was 10–15 min at beginning of the program with gradually increasing duration throughout the study as subjects adapted to the activity. The average duration at the end was about 20–40 min.

Education group: This group met once a week for one and a half to 2 hours per session. The program was based upon principles of self-management. Topics included current information regarding potential cause of FM, goal setting with respect to a significant goal for the subject, maximizing energy for household chores or personal activities, pain or fatigue coping strategies, benefits of exercise, evaluating alternative therapies, and barriers to behavior change. Sessions were focused away from pain and other symptoms as much as possible and refocused on leading a well balanced life. 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 current knowledge about FM and answered subjects' questions. The psychologist compared a diagnosis of FM to a grieving cycle after the death of a loved one, because in a sense, a part of each subject had died when she developed FM. Subjects were also free to ask questions and discuss other issues with the psychologist. The dietician covered basic healthy eating, how to read labels and prepare nutritious meals with limited time and energy. Another session included family and/or friends of study participants, mainly to educate non-study participants about FM and how to assist someone with FM. Sessions required all subjects to be active participants. Subjects were encouraged to share solutions or provide suggestions for others' concerns/problems. The group leader introduced topics and facilitated discussions.

Exercise and education group: This group combined exercise and education programs. The educational component was the same as for the education-only group. The exercise-only group met twice per week and on the third day met for education and then exercise.

Control group: On the day of the initial assessment, subjects in the control group were given a page of instructions for basic stretches and 5 items related to general coping strategies. Control subjects also received this information. They were contacted once or twice throughout the 12 week period to ensure they were filling out their logbook and to answer any questions about their condition. Subjects from the control group were offered one of the intervention programs at the end of the followup period. Only 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 completed the study protocol, the education and exercise groups were too small at times, due to dropouts or poor attendance. Therefore, the exercise and education group was combined with the exercise-only group for the exercise portion and then combined with the education-only group for the education portion for subsequent programs.

Subjects were considered to be noncompliant 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., by beginning to exercise or participate in a FM education course) during the course of the study.

To monitor subjects' activities during the study, logbooks were provided for all subjects. Subjects recorded exercise sessions, visits to health care professionals (physicians, physical therapists, etc), visits for other treatments (i.e. acupuncture, acupressure, massage, etc), unusual problems or changes in medication, and weekly goals. Since goal setting was a component of the education section, logbooks for the education-only 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, investigators recognized the difficulty with enforcing such a stringent protocol over a 12 week period. Therefore, if participants documented any changes in their usual treatment and the change was not major, the subject remained an active participant.

Statistical analysis. Analyses of data included: (1) Intention to treat (ITT) analysis 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 completion of the study were asked to return for post-testing. When post-test data were missing, baseline scores were considered post-test scores. (2) Complete case analysis of subjects completing the 3 test sessions, regardless of attendance during the study. (3) Analysis of the subjects who complied with the study protocol.

Questionnaires, walking test, and TP data were analyzed using 2 way analysis of variance (ANOVA) with repeated measures (Group vs Time) (SPSS statistical package, version 10.0). Any significant group, time, or group versus time differences were examined using Tukey multiple comparisons. 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, and completers and non-completers. The significance level was set at $p < 0.01$ for all analyses.

RESULTS

Two hundred fifty-nine women were referred to the program or themselves contacted the investigators 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 pre-test session and were randomized into one of 4 groups. After randomization and before the first session, 26 subjects decided not to participate. Only the Six Minute Walk was significantly different ($p = 0.04$) between referral groups. The self-referred subjects walked significantly farther (499.5 ± 86.5 m) than the physician-referred (472.7 ± 85.2 m).

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 = 0.001), which was greater for the non-participants (547.7 ± 78.1 m vs 477.2 ± 87.0 m).

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 non-dropouts.

Intention to treat analysis. One hundred fifty-two subjects were included in the ITT analysis (Table 2). Baseline data were carried forward for 34 of the 152 subjects for the ITT analysis. There were no significant group versus time interactions. Significant main effects for time were found for self-efficacy — coping with pain and other symptoms, FIQ, 6MW, and number of TP. Examination of the means revealed improvements from pre-test to post-test.

Complete case analysis. Ninety-five of the original 170 subjects completed all 3 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 one way ANOVA between compliers and non-compliers on demographic and baseline measures revealed no significant differences between the 2 cohorts. One subject was unable to complete the 6MW at followup due to foot surgery; therefore n = 94 for this test.

Table 3 reports the means and standard deviations. No significant group versus time interactions were demonstrated. Significant main effects for time were demonstrated for the 3 self-efficacy scales, FIQ, 6MW, and number of TP. Improvements were demonstrated from pre- to post-test and from pre-test to followup for all measures, except 6MW. The distance walked significantly increased from pre- to post-test, but decreased from post-test to followup.

Compliers. The analyses were repeated using only subjects who complied with the study protocol, n = 69 [exercise-only: n = 21, education-only: n = 16, exercise and education: n = 15; control group (n = 17)(one subject in the control group was considered a noncomplier because she attended a FM self-management program offered by The Arthritis Society)]. The percentage of classes attended (mean ± standard deviation) for each group was as follows: Exercise 75.2 ± 21.0, education 83.3 ± 10.8, and exercise and education 71.2 ± 22.4. No significant difference was found among the groups. There were no significant differences between compliers and non-compliers on demographic and baseline data, except for age (compliers 48.6 yrs vs non-compliers 43.4 yrs) and marital status (compliers 4 single vs noncompliers 20 single people).

A significant interaction was revealed with self-efficacy-coping with other symptoms [F(6,65) = 3.48, p = 0.003] (Figure 1) and the 6MW [F(6,63) = 2.87, p = 0.012] (Figure 2). Post-hoc analyses revealed that the combined group increased their self-efficacy for coping with other symptoms from pre-test to post-test and followup 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 improvement at followup. FIQ and number of TP demonstrated significant main effects for time, with significant decreases from pre-test to post-test and pre-test to followup.

Logbook information. Information provided from the logbooks revealed that minor alterations in medications were recorded in the following percentage of subjects: exercise-only 25%; education-only 40%; exercise and education 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 (the majority of exercise was stretching) at least 2 times per week. The most popular form

Table 2. Intention to treat analysis (n = 152) at pretest (Pre) and post-test (Post). Values are mean (SD).

	Exercise, n = 42		Education, n = 41		Education & Exercise n = 35		Control, n = 34	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
FIQ	52.4 (12.7)	49.6 (14.7)	56.8 (10.7)	54.0 (14.8)	52.9 (10.7)	44.7 (18.6)	55.2 (11.8)	54.3 (12.6)
SE Pain	49.8 (21.2)	52.8 (20.4)	48.6 (21.2)	51.1 (22.0)	53.9 (20.2)	61.7 (24.5)	42.1 (21.1)	46.1 (21.3)
SE Function	62.9 (24.8)	64.9 (20.5)	56.0 (22.1)	60.3 (23.7)	60.8 (20.7)	65.1 (23.2)	52.7 (19.2)	53.3 (20.8)
SE Coping with symptoms	50.4 (19.8)	55.3 (18.8)	52.4 (20.6)	56.3 (19.7)	50.6 (17.0)	60.3 (22.0)	47.9 (17.8)	48.4 (20.5)
6MW	484.8 (94.3)	506.7 (91.1)	491.6 (76.8)	499.0 (89.8)	462.6 (78.0)	493.5 (78.0)	471.1 (95.7)	462.0 (105.5)
No. of TP	16.3 (2.0)	16.0 (2.4)	16.5 (1.9)	16.0 (2.1)	16.3 (1.9)	15.8 (3.1)	16.6 (1.8)	16.0 (2.3)
Total survey site score	105.3 (38.8)	107.5 (36.6)	106.0 (29.5)	102.4 (34.0)	97.7 (28.3)	94.5 (36.3)	101.1 (31.5)	95.1 (30.8)

SE: Self-Efficacy Scale; FIQ: FM Impact Questionnaire; 6MW: Six Minute Walk; TP: tender points.

Table 3. Complete case analysis (n = 96) at pre-test (Pre), post-test (Post), and followup (F/U). Values are mean (SD).

	Exercise, n = 30			Education, n = 21			Exercise & Education, n = 26			Control, n =18		
	Pre	Post	F/U	Pre	Post	F/U	Pre	Post	F/U	Pre	Post	F/U
FIQ*	49.0	46.9	47.5	54.7	50.3	50.7	53.2	41.6	46.6	54.7	50.4	51.5
	(12.4)	(15.0)	(14.0)	(10.1)	(16.5)	(16.4)	(10.5)	(19.6)	(15.7)	(13.0)	(13.9)	(13.1)
SE Pain	54.9	56.2	59.9	50.4	50.6	54.8	50.1	61.1	60.1	41.9	48.8	46.7
	(19.7)	(18.2)	(17.5)	(18.6)	(20.8)	(20.4)	(19.3)	(26.1)	(21.5)	(18.8)	(19.5)	(21.6)
SE Function	68.2	68.7	69.9	55.2	61.6	61.2	55.7	62.5	63.2	55.7	58.6	60.7
	(25.8)	(16.6)	(19.4)	(22.1)	(24.8)	(27.3)	(20.5)	(25.6)	(23.4)	(21.0)	(24.0)	(24.2)
SE Coping	53.2	58.0	62.2	52.9	56.6	53.7	48.8	63.4	60.8	53.0	57.5	55.4
with Symptoms*	(20.5)	(16.8)	(17.9)	(21.4)	(20.2)	(19.8)	(15.3)	(23.0)	(22.3)	(19.1)	(19.7)	(19.0)
6MW*	491.4	525.5	520.9	495.4	494.3	476.6	452.0	501.1	465.2	494.6	498.7	479.4
	(91.9)	(78.7)	(80.9)	(74.3)	(96.2)	(109.9)	(73.5)	(81.9)	(107.4)	(93.6)	(125.6)	(112.3)
No. of TP	16.8	15.8	15.0	17.4	16.6	16.2	15.8	14.6	15.4	16.3	15.0	15.0
	(1.8)	(2.8)	(3.0)	(1.3)	(2.4)	(3.6)	(2.5)	(4.0)	(2.9)	(1.6)	(3.4)	(5.4)
Total survey	104.2	104.7	93.6	114.4	112.5	107.1	91.6	80.9	86.9	91.3	80.1	96.8
site score	(49.5)	(40.9)	(44.8)	(25.7)	(35.0)	(37.5)	(26.6)	(35.5)	(28.9)	(32.5)	(35.9)	(46.3)

SE: Self-Efficacy Scale; FIQ: FM Impact Questionnaire; 6MW: Six Minute Walk, TP: tender points. * Significant main effect for Time for pooled data

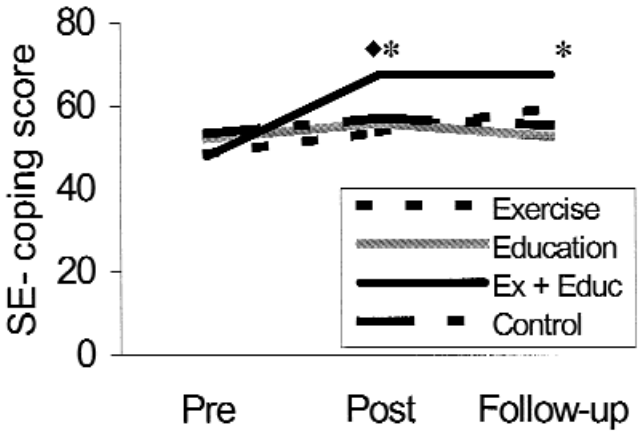

Figure 1. Self-efficacy coping with other symptoms score for compliance analysis. *Significant improvement from pre-test. ◆ Significant difference between exercise and education group and Control group.

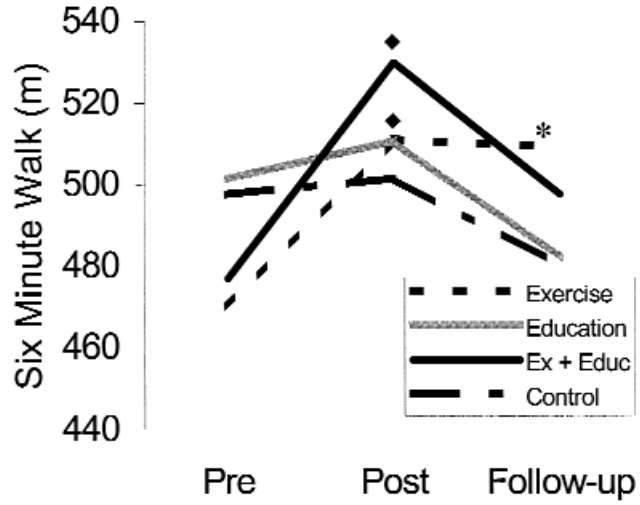

Figure 2. Six Minute Walk distance for compliance analysis. ◆ Significant improvement from pre- to post-test. *Significant improvement from pre-test to followup.

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, subjects sought alternative treatments more often than they did traditional treatments [mean number of visits 7.9 ± 9.0 (range 1–36) vs 5.6 ± 5.4 (range 1–19), respectively].

DISCUSSION

Results from our 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 2 groups undergoing supervised aerobic exercise programs. However, the improvement in fitness was maintained at followup in the exercise-only group and not the exercise and education group.

Previous randomized controlled trials investigating multidisciplinary treatment in persons with FM have reported varied results[1-4]. Significant differences were demonstrated between the intervention groups and control group on measures of self-efficacy and life satisfaction after 6 week programs[1,3]. However, a more recent study[4] found no significant differences pertaining to self-efficacy in the exercise and education group compared to the control group after a 6 week program. Overall, discrepancies between the results from our study and previous research with FM may be related to differences with analyses, program content, and/or program duration. Burckhardt, *et al*[1] measured between-group differences with a one-way ANOVA using a

change score for the FIQ. The within-group changes from the 3 testing periods were analyzed using paired t tests. Horven Wigers, *et al*[2] also used paired t tests to determine within-group differences. Due to skewed data, Buckelew, *et al*[3] analyzed their data using non-parametric methods. These analyses are limiting in that only the between- and within-differences were examined and not the group versus time interactions. This may explain some of the more positive findings in previous studies compared to our 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[1,3] may not be long enough to demonstrate a change in fitness or other behaviors; however, compliance levels may have been better.

The lack of significant group differences in our study may have resulted from a decrease in power due to the number of dropouts. In the education only and control groups over half 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, and were not pacified to learn they would receive an intervention of their choice at the completion of study. Thus many of the control subjects could not be reached or refused to return for testing. Perhaps if an attention control group had been offered instead of delayed treatment, a greater number of control subjects would have continued in the study. 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[2]. Reservations regarding exercise did not appear to have a negative effect on the treatment outcome in that study. It is unclear what effect pre-program beliefs regarding exercise and education had upon our results.

Another reason for the lack of group differences may relate to possible group contamination. Despite planning to keep different intervention groups separate, the exercise and education groups had to be combined part way through the study. This may have led to crossover between groups when the exercise and education group joined with the exercise-only and education-only groups, resulting in less difference among the groups. The authors recognized the potential effect combining groups could have on the results. However, it was determined that the effect of working together as a group was more important than maintaining separate intervention groups, if it meant that the intervention group would only have one to 3 individuals participating. The authors did encourage the exercise and education group to not discuss educational material with the exercise-only group to help minimize the effect of contamination.

Additionally, a formal measure examining previous exercise experience, as well as current duration and intensity of exercise, should have been utilized at the onset of the study. 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. Since it was believed to be unethical to ask the subjects to discontinue exercising, if randomized into a non-exercise group, a formal measure of current exercise intensity and duration may have allowed for stratification of subjects based on exercise levels for analysis purposes.

Another possible limitation was that no measure of depression was used in our 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*[1] 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.

Our 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 behavioral changes. It would also determine if impairment and functioning improved with the physical or behavioral changes. Third, 3 types of analyses were undertaken to determine the effect 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 provide descriptive data that may have explained some of the results.

The exercise component was also 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 was 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. During the winter months, 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 neighborhood once the study was finished.

The high dropout rate highlights the difficulty with compliance to treatment protocols that involve exercise and behavior modification for persons with FM. Attrition also affected the power to detect a difference among the groups. 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 enhanced treatment effectiveness. Testing a variety of theoretical models to understand and explain behavior would greatly assist in designing and evaluating treatment programs for persons with FM. Finally, perhaps an emphasis on adopting or enhancing a physically active or wellness lifestyle, instead of promoting "exercise" would be a more appropriate approach to treatment programs in this population.

Results from our study revealed that when subjects complied with the treatment protocol of both exercise and education their perceived ability to cope with other FM symptoms improved. In addition, a supervised exercise program increased walking distance at post-test, an increase that was maintained at followup in the exercise-only group. An education program alone did not provide benefits that were greater than those provided by the exercise and exercise plus education components.

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