

# A Randomized Controlled Trial of Muscle Strengthening versus Flexibility Training in Fibromyalgia

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**ABSTRACT.** *Objective.* To determine the effectiveness of a muscle strengthening program compared to a stretching program in women with fibromyalgia (FM).

*Methods.* Sixty-eight women with FM were randomly assigned to a 12 week, twice weekly exercise program consisting of either muscle strengthening or stretching. Outcome measures included muscle strength (main outcome variable), flexibility, weight, body fat, tender point count, and disease and symptom severity scales.

*Results.* No statistically significant differences between groups were found on independent t tests. Paired t tests revealed twice the number of significant improvements in the strengthening group compared to the stretching group. Effect size scores indicated that the magnitude of change was generally greater in the strengthening group than the stretching group.

*Conclusion.* Patients with FM can engage in a specially tailored muscle strengthening program and experience an improvement in overall disease activity, without a significant exercise induced flare in pain. Flexibility training alone also results in overall improvements, albeit of a lesser degree. (J Rheumatol 2002;29:1041–8)

*Key Indexing Terms:*

FIBROMYALGIA  
MUSCLE STRENGTHENING

EXERCISE  
FLEXIBILITY

Fibromyalgia (FM) is a common, costly, and debilitating syndrome with a high prevalence in both the general population and in rheumatology clinics<sup>1-3</sup>. Symptoms include localized pain, widespread pain, disrupted sleep, fatigue, visceral and other pain syndromes, neurological symptoms (e.g., dizziness, numbness, tingling), and exercise intolerance<sup>4,5</sup>. Pain in FM is hypothesized to be due to both peripheral and central mechanisms. The peripheral component involves nociceptive input from muscles; the central component is thought to involve abnormal sensory processing at the level of the spinal cord and brain<sup>6-8</sup>. These systems work

together to perpetuate pain and deconditioning. Objective as well as functional muscle strength and endurance have been shown to be lower in patients with FM than healthy age matched controls<sup>9,10</sup>. Deconditioned muscles are more likely to experience muscle microtrauma, which will cause more pain, often 2–5 days after activity<sup>11-13</sup>. Thus a cycle is established that produces microtrauma, increased local pain, and increased generalized pain<sup>14</sup>.

Clinical trials of mixed exercise (aerobic, muscle strengthening, and flexibility) offer evidence that FM patients who tolerate the interventions can improve their aerobic capacity and muscle strength and decrease their FM symptoms<sup>15-35</sup>. However, many of the earlier studies employed interventions geared to the general public, perhaps without recognizing the possible central and peripheral mechanisms of FM. Some of these studies suffered from dropout rates as high as 40 to 87%<sup>16,22,23</sup>, with some patients reporting that the intervention actually increased their FM symptoms<sup>23,34</sup>. Further, little attention has been given to examining the effect of individual components of fitness in FM (strength, stretching, or aerobics rather than a combination of the 3). Some researchers believe that if the cycle of deconditioning is to be broken, an exercise program that focuses on muscle strengthening might be a first logical step in preparing persons to engage successfully in future, more comprehensive exercise programs designed to improve muscle strength, flexibility, and aerobic

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capacity<sup>36,37</sup>. Thus, many believe that although exercise is essential in the treatment of FM, much work remains in designing and successfully implementing a program tailored to accommodate the special needs of people with FM<sup>38</sup>.

We compared 2 exercise interventions for women with FM. The experimental group received a novel muscle strengthening program designed to be sensitive to peripheral and central dysfunctions in FM. The control group received a flexibility program of stretching exercises commonly prescribed for FM.

## MATERIALS AND METHODS

*Design and patients.* Sixty-eight female patients with FM were recruited from a registry of FM patients who had been seen on referral to the rheumatology practice at a teaching university in the northwestern US. Participants were randomized to receive a twice weekly program of either muscle strengthening for 12 weeks or stretching for 12 weeks. Randomization was accomplished with a coin flip. Data were collected within 2 weeks before study entry (pre-test) and within 2 weeks after the final exercise class (post-test). Data were collected by an exercise science technician (strength and body fat) or the principal investigator (all other measures). Both were blinded to group assignment.

Patients were eligible for the study if they met the following inclusion and exclusion criteria. Inclusion criteria included (1) female; (2) 20–60 years of age; (3) a definitive diagnosis of FM based on the American College of Rheumatology (ACR) criteria<sup>39</sup>. Exclusion criteria included (1) current or past history of cardiovascular, pulmonary, neurological, endocrine, or renal disease that would preclude involvement in an exercise program; (2) current use of medications, such as moderate or high dose beta blockers, that would significantly affect normal physiological response to exercise; (3) current cigarette smoking; (4) score  $\geq 29$  on the Beck Depression Scale modified for FM; and (5) current participation in a regular exercise program.

A power calculation determined that a sample size of 30 per group would be sufficient to detect a significant between-group change in effect size in the main outcome variable, isokinetic muscle strength as measured by dynamometry.

*Intervention.* The muscle strengthening group received a supervised, classroom based, progressive physical training program (non-aerobic) with muscle strengthening exercises performed in the standing, sitting, and lying positions, without machine weights. The exercises minimized eccentric contractions and provided a 4-count pause between repetitions. Minimization of eccentric work was accomplished by (1) an increased ratio of contractions near the body midline compared to farther from midline, and (2) a slower rate of concentric contraction and faster rate of eccentric contraction. The 4-count pause was incorporated to allow the muscle to fully return to resting state given delays in return to baseline resting state described by Elert, *et al*<sup>40</sup>. As an alternative to the pause, sometimes the opposing limb was worked during the pause phase. Each class strengthened 12 muscle groups (gastrocnemius, tibialis anterior, quadriceps, hamstrings, gluteus, abdominals, erector spinae, pectorals, latissimus dorsi and rhomboids, deltoids, biceps and triceps) with single sets, initially with 4 to 5 repetitions and progressing to 12 repetitions by the end of the study. Participants were encouraged to increase resistance (muscle load) over the 12 week program with hand weights (1–3 pound) and/or surgical tubing (Therabands). Participants were instructed to have no tension in the bands at the end of the eccentric phase in an effort to promote complete muscle relaxation. Participants were encouraged to listen to their bodies and reduce training load (intensity of load or number of repetitions) on days they were experiencing a symptomatic flare. The intensity of exercises was low due to a recognition of baseline physical deconditioning in FM that predisposes patients to microtrauma, delayed muscle pain, and aggravation of FM

tender point areas. The intervention provided balance, body posture, and alternative exercises for transient low back, knee, and shoulder pain common in FM<sup>41,42</sup>. Because FM patients complain of perceived instability and lightheadedness with rapid position change, gradual position changes from standing to lying, and vice-versa, were incorporated between exercises. The program progressed from week to week with earlier sessions focusing on education, body mechanics, and some muscle strengthening exercises. Class sessions were 60 min long, twice per week for 12 weeks. Individual classes began with 5 min of warmup (marching and rhythmic dancing) and gentle stretching followed by 45 min of muscle strengthening, and concluded with 10 min cooldown and stretching.

The flexibility training group received a classroom based supervised stretching program with stretches performed in the standing, sitting, or lying positions. Stretches targeted the same 12 major muscle groups as the strengthening group. Stretches were (1) static rather than ballistic, (2) minimized in FM tender point locations, and (3) individualized to teach each participant to locate her stop point and avoid overstretching. One method of identifying a stop point was to stretch with eyes closed, thereby increasing the focus on her own body and reducing the likelihood of overstretching due to imitation of the instructor or classmates. Language was also carefully selected to assist participants in avoiding overstretching. For example, the statement, “let your head hang toward your chest,” was employed rather than “stretch your chin toward your chest.” Participants could elect to use a towel to maximize stretch in some muscle groups (e.g., side lying quadriceps stretch, sitting hamstring stretch). Supervised classes meet for 60 min twice per week for 12 weeks. Class began with a low intensity warmup of marching in place or rhythmic dance for 10 min, gentle stretching for 40 min, and guided imagery and relaxation for the concluding 10 min. Professionally made videotapes of the strengthening and flexibility exercises had been previously developed and were provided to the participants.

*Measures.* Muscle strength, the main outcome variable, was measured by testing maximum isokinetic strength of nondominant knee extension and flexion with a Cybex II isokinetic dynamometer (Cybex Inc.)<sup>43,44</sup>. Power output was measured at an angular velocity of 60° per second, in 135° to 0° flexion/extension<sup>36</sup>. The Cybex II was then reconfigured with manufacturer’s adapters to test shoulder internal and external rotation strength with power output measured at an angular velocity of 60° per second, in 90° to 70° abduction/adduction. The best of 5 attempts was recorded.

Flexibility of the shoulder was measured by a hand-to-neck and hand-to-scapula movement. Internal rotation was assessed by asking subjects to reach behind their head with one arm and as far beyond their neck as possible. External rotation was assessed by asking subjects to reach behind their backs with one arm and up toward their scapula as far as possible. Each of these 2 movements were scored on a 0 to 4 point scale, where 0 is normal range of motion and 4 is worst range of motion. Reliability has been reported in women with FM<sup>9</sup>.

Body fat was measured in 7 sites (chest, axilla, triceps, subscapula, abdomen, suprailiac, thigh) using a 2-prong spring loaded caliper (Harpenden) per anthropomorphic standardized guidelines<sup>45</sup>. Body weight was measured in kg using a calibrated standing model scale (Detecto).

Pain was measured with 3 tests: number of tender points in 18 sites as described in the ACR 1990 FM Criteria<sup>39</sup>, total myalgic score, and a visual analog scale (VAS) within the Fibromyalgia Impact Questionnaire (FIQ). For tender point assessment, the degree of tenderness at each site was elicited by patient report when the principal investigator applied pressure at 18 specific muscle tendon junctions. Pain was rated as 0 = no pain to 3 = withdrawal of the patient from the examiner. A cumulative myalgic score was then calculated for each patient by totaling tender point scores.

The effect of FM was measured by the FIQ, a 19 item instrument that measures physical functioning and symptoms of pain, fatigue, morning tiredness, stiffness, depression, and anxiety, along with job difficulty and overall well being in the past week. The instrument has been validated and has shown sensitivity to change as a result of treatment<sup>46</sup>. Individual scale

items and a total score can be calculated to determine FM impact on functioning<sup>47</sup>.

Anxiety, depression, and quality of life were measured because exercise has beneficial effects on these conditions and women with FM have impairment of mood and a low quality of life<sup>49-51</sup>. Three commonly used scales were employed: the Beck Depression, Beck Anxiety, and Quality of Life Scales. The Beck Depression Inventory is a well known, 21 item scale that measures mood and behaviors characteristic of depression<sup>48</sup>. This scale was selected because it has been adapted for use with FM patients by removing from the total score 3 items that are characteristic of all FM patients (fatigue, sleep difficulties, and effort required to get things done), and which, therefore, do not correlate well with major depressive disorder. This adaptation has better accuracy, sensitivity, and specificity in an FM population than the original<sup>49</sup>.

The Beck Anxiety Inventory is a 21 item instrument used to measure the severity of anxiety while discriminating anxiety from depression. Scores range from 0 to 63, with a higher score indicating more anxiety. A mean of 16 with a standard deviation of 10 has been found in patients with FM. In a 6 month multidisciplinary intervention of 104 women with FM, the Beck Anxiety Inventory was found to be sensitive to change as a result of treatment in FM populations<sup>46</sup>.

The Quality of Life Scale (QOLS) is a 16 item Likert-type scale that measures well being and satisfaction with multiple domains of life. Scores for each item range from 1 (terrible) to 7 (delighted). Possible scores range from 6 to 112, higher scores indicating better well being and quality of life. It has been validated in a FM sample and is sensitive to change<sup>50,51</sup>.

Self-efficacy was measured because it has been shown to be the strongest predictor of exercise initiation and maintenance in a myriad of chronic conditions including FM<sup>52,53</sup>. Self-efficacy was measured with the Arthritis Self-Efficacy Scale (ASES). The ASES is a 20 item scale rating an individual's certainty for performing a given task such as walking 100 ft on level ground in 20 seconds. Certainty is measured on a scale of 10 (very uncertain) to 100 (very certain) in 10 point increments. The scale contains 3 subscales: pain, function, and other symptoms. Higher scores indicate higher self-efficacy. The ASES has been shown to be reliable, valid, and sensitive to change in a variety of rheumatic populations<sup>54</sup>.

**Data analysis.** Data analysis included descriptive statistics, frequencies, and chi-squares to profile the sample. Independent group t tests were used to compare the 2 groups at pre-test and to assess for between-group changes at post-test. Paired t tests were used for within-group measurement of change significance. Effect size was calculated for within-group changes in order to assess the magnitude of change. The alpha level was set initially at  $p < 0.05$  for all tests. All data were stored and analyzed by SPSS Version 10. The proposed study was approved by the university's Institutional Review Board. All participants completed informed consent.

## RESULTS

The sample consisted of 68 women with FM. Demographic and pre-test data are reported on all subjects. Five subjects did not return for post-testing; 4 of these 5 attended 0 to 4 classes. Thus, post-intervention data were collected on 63 subjects. Class attendance records by the exercise instructor indicated that 85% of the participants ( $n = 58$ ) attended 13 or more classes. There were incomplete data on 2 cases, yielding the final number for statistical comparison of 56 with 28 subjects in each group.

Data analysis on subjects who did not return for post-intervention testing or who did not attend enough classes to be included in statistical analysis ( $n = 10$ ) yielded no statistically significant differences when compared to study completers. There were, however, some nonsignificant

differences between those who completed the study and those who dropped out that may have clinical implications. The mean age of dropout subjects was about 2.5 years older than those who completed the study. Strength scores at knee extension and flexion were slightly lower in participants who dropped out. Beck anxiety scores were somewhat higher in those who dropped out ( $22 \pm 13.8$ ) versus study completers ( $14.3 \pm 8.6$ ).

**Pre-test data.** Analysis by independent group t tests indicated there were no significant differences at pre-test between groups on any variables including demographics, medication or exercise history, and physiological or symptom self-report measures. Demographic data are presented in Table 1. Pre-test physiologic and symptom self-report measures are presented in Table 2. The mean age of participants was 47.8 years. The average number of years with FM was 7.4. The majority of the sample were married, Caucasian, and attended school beyond high school. A large majority of the sample were employed in occupations that did not require college or professional training.

The majority of the sample took on average one over-the-counter medication [most commonly acetaminophen (Tylenol)] and one prescription antidepressant [most commonly amitriptyline (Elavil) or a selective serotonin inhibitor] medication per day. Slightly less than half of the sample took a narcotic pain medication weekly or narcotic precursor medication [e.g., tramadol (Ultram)] daily. About 30% of the sample took a daily prescription nonsteroidal antiinflammatory [e.g., naproxen (Naprosyn)]

Table 1. Demographics.

Variable	Treatment Group, Mean (SD) n = 28	Control Group, Mean (SD) n = 28
Age	49.2 (6.36)	46.4 (8.56)
Years with FM	6.9 (6.6)	7.7 (5.5)
Marital status		
Married or living together	18	18
Divorced or single	10	10
Education		
High school graduate or less	5	3
Some college/trade school	7	13
College degree or graduate degree	16	12
Employed outside home		
Full time	18	16
Part time	2	4
Not employed	8	8
Occupation		
Executive/professional	10	7
Technical/semiprofessional or home based	6	10
Clerical/sales	7	7
Retired/homemaker	5	4
Ethnicity		
White	25	26
Non-White	3	2

Table 2. Paired t test results.

Variable	Paired t Tests					
	Strength, mean, Time 1, Standard Error (mean)	Strength, mean, Time 2, Standard Error (mean)	Effect Size	Stretch, mean, Time 1, Standard Error (mean)	Stretch, mean, Time 2, Standard Error (mean)	Effect Size
Total myalgic score	34.18 (1.42)	28.46 (1.47)**	0.75	32.14 (1.43)	27.82 (1.91) NS	0.49
No. of tender points	16.46 (0.33)	15.00 (0.57)**	0.61	15.68 (0.38)	14.68 (0.66) NS	0.36
Weight, kg	89.1 (8.09)	89.3 (7.81) NS	0.01	91.70 (9.54)	93.00 (9.57) NS	0.06
Percent body fat	35.81 (0.723)	36.66 (0.716)*	0.23	35.90 (0.904)	35.36 (0.826) NS	0.12
Knee strength, ft lbs						
Extension	71.71 (4.07)	86.18 (4.27)***	0.67	77.11 (4.10)	86.81 (3.85)***	0.47
Flexion	34.21 (1.95)	40.36 (1.98)***	0.59	36.26 (2.02)	40.04 (1.55)**	0.41
Shoulder strength, ft lbs						
Internal rotation	6.54 (1.10)	14.61 (1.27)***	1.29	6.82 (1.05)	14.71 (1.02)***	1.44
External rotation	6.21 (1.07)	11.71 (1.14)***	0.94	7.14 (1.11)	12.93 (0.86)***	1.12
Flexibility						
Hand-to-neck	0.068 (0.14)	0.018 (0.11)**	0.76	1.0 (0.16)	0.07 (0.15)***	1.48
Hand-to-scapula	1.64 (0.16)	0.49 (0.14)***	1.43	1.67 (0.19)	0.22 (0.15)***	1.92
Fibromyalgia impact questionnaire (FIQ)						
Total scale score	48.08 (2.9)	37.81 (3.2)**	0.80	47.14 (3.9)	43.36 (3.7) NS	0.27
FIQ pain, VAS	6.50 (0.39)	4.61 (0.39)***	0.91	6.15 (0.36)	5.14 (0.41) NS	0.51
FIQ fatigue, VAS	7.64 (0.28)	5.21 (0.39)***	1.37	7.68 (0.41)	7.0 (0.46) NS	0.30
FIQ sleep, VAS	7.74 (0.42)	5.44 (0.52)*	0.97	7.57 (0.50)	7.04 (0.45) NS	0.21
Beck depression	10.78 (1.33)	7.11 (1.12)***	0.58	10.64 (1.2)	8.8 (1.21) NS	0.29
Beck anxiety	14.39 (1.73)	11.89 (1.76)*	0.27	13.7 (1.48)	14.4 (2.02) NS	0.08
Quality of life	70.82 (3.85)	78.50 (3.61)***	0.39	72.14 (3.0)	76.43 (2.17) NS	0.31
Arthritis self-efficacy scale						
Pain	258.52 (16.07)	323.7 (19.7)**	0.72	273.21 (17.7)	308.21 (19.0) NS	0.36
Symptom	298.57 (21.4)	383.93 (22.0)***	0.75	323.79 (20.7)	366.55 (21.3)*	0.38
Function	682.59 (34.6)	717.04 (28.4) NS	0.21	656.4 (33.4)	722.5 (27.8) NS	0.41

VAS: Visual analog scale, NS: not significant. \*  $p < 0.05$ , \*\*  $p < 0.01$ , \*\*\*  $p < 0.001$ . All significant differences remained significant after Bonferroni correction.

or muscle relaxant medication [most commonly cyclobenzaprine (Flexeril)]. Less than 15% of the sample reported regular use of vitamin or herbal medications.

The majority of the sample either were completely sedentary (87%) or reported walking 2 or less times per week at an intensity not known to improve aerobic fitness. No subjects reported regular participation in muscle strengthening activities such as calisthenics, push-ups, weight lifting, or physical therapy.

Subjects demonstrated a high pre-test amount of pain according to the number of tender points (scale range 0–18; mean score 16.2) and total myalgic scores (scale range 0–54; mean score 33.8). The majority of the sample was overweight or obese according to weight (88.5 kg) and percentage body fat (mean 35.2%). Subjects demonstrated very low mean strength scores in knee extension and knee flexion. Even lower strength scores were demonstrated in the upper body during shoulder internal and external rotation. Hand-to-neck flexibility and hand-to-scapula flexibility scores indicated no significant limitations in range of motion/flexibility, as almost all participants could reach to the midline of their neck posteriorly and behind their back to their scapula.

The mean negative effect of FM was moderately high by FIQ scores. The mean revised Beck Depression Inventory and Beck Anxiety Inventory scores indicated moderate amounts of depression and/or anxiety at pre-test. No subject scored high enough on the Beck Depression Inventory to necessitate exclusion from the study. Quality of life scores were low at pre-test, indicating a poor perceived global quality of life. The mean scores for the Arthritis Self-Efficacy subscales for pain, function, and other symptoms were at or near the midpoint of the scale ranges.

*Post-test data.* Independent group t tests indicated that there were no significant differences between the treatment and control groups at post-test. There were, however, a number of significant within-group changes found on paired t tests. To control for multiple comparisons, a Bonferroni correction was done and alpha for significance was set at 0.003. The treatment group demonstrated statistically and clinically significant changes in 12 measures (total myalgic score, VAS for pain, knee strength at extension and flexion, shoulder strength at internal and external rotation, hand-to-neck and hand-to-scapula flexibility, FIQ score, Beck Depression Inventory questionnaire score, QOLS questionnaire score, and Self-Efficacy Scale score). The control

group demonstrated statistically significant changes in 6 measures (knee strength at extension, shoulder strength at internal and external rotation, hand-to-neck and hand-to-scapula flexibility, and Self-Efficacy for Symptom Scale score). Change scores indicated that on all measures that expect flexibility, the treatment group improved more than the control group. Effect sizes indicated that the magnitude of change was generally greater in the treatment group. Table 2 lists group means, paired t test scores for significance (p values), and effect size.

Six participants (3 per group) experienced a worsening of one or more of the following pain measures: FIQ VAS for pain, total myalgic score, and number of tender points. Scatterplots were made on these cases for all variables. No discernible patterns were uncovered, including likelihood to drop out.

## DISCUSSION

Our study revealed that female patients with FM can engage in a specially tailored muscle strengthening program and experience an improvement in overall disease activity, without a significant exercise induced flare in pain or increase in medication usage. Flexibility training alone also resulted in overall improvements.

A strength of the study was that it was a randomized, blinded design that isolated muscle strengthening and compared it to the standard of care, flexibility training. The majority of exercise studies in FM to date employed aerobic or mixed interventions (aerobic, strengthening, and flexibility). There are limited data in FM investigating these 3 components individually. Skeletal muscle has been postulated to act as a target organ in FM, but at the time of this study, muscle strength training had only been tested as an isolated therapy in one study<sup>55</sup>. That study provided encouraging results including increases in aerobic capacity in an aerobic-trained group, increases in strength in a strength-trained group, and moderate quality of life and pain improvements in both groups. Further investigation is needed to follow up Hannonen's seminal work as the study employed only 20 subjects in each group, had an 18% attrition rate, and was only published as an abstract, leaving future researchers limited information needed to replicate the study. Since Hannonen's study, several major health organizations have recognized the value of strength training in a variety of populations and published major consensus statements regarding strength training<sup>36,56,57</sup>.

Another strength of our study was the low attrition rate (9%). This may have been due in part to the multiple step recruitment process prior to consent. The study employed a 6 step recruitment program that required potential participants' response or attendance. This was seen as advantageous not only from a cost and utility standpoint, but from the potential negative psychological effects dropout may have on other group members. Perhaps research participants

who were motivated to complete all the screening steps were less likely to drop out after the intervention began. Other possible reasons for the low dropout rate could include: (1) the sensitivity and specificity of the exercises improved physiologic measures as well as symptomatic measures<sup>14</sup>; (2) personalization of exercise instruction given to members of both groups by an exercise physiologist with clinical and research experience in FM; (3) no adverse events or injuries during the intervention; (4) promotion to continue by the exercise instructor, who employed a number of games, rewards, and encouragement systems to encourage attendance in both groups<sup>58</sup>; (5) small class sizes (4 classes of 17 each); (6) equal attention to both groups; and (7) employment of self-efficacy as a guiding theoretical framework. A final factor that may have positively affected attrition was that all but 2 of the participants invited to enter the study lived within an 11 mile radius of the exercise facility. Both participants who lived more than 11 miles from the fitness center dropped out (one due to pneumonia; the other found that making the journey alone was not enjoyable).

Our study was unable to determine statistically significant between-group differences. Perhaps this was because the stretching intervention was more likely a light exercise group rather than a sedentary control group. The participants were so sedentary and deconditioned at baseline that adding any form of exercise may have contributed to strength gains. Also, successfully completing a program of exercise may have helped participants be less fearful of triggering pain with post-intervention strength testing in the laboratory as they learned that exercise can be well tolerated<sup>25,59</sup>.

Future studies could substitute a nonphysical modality such as education as a third group when comparing flexibility to muscle strengthening. Examples of less active control groups in the FM exercise literature include McCain<sup>15</sup> (flexibility), Mengshoel<sup>16</sup>, Wiggers<sup>21</sup>, King<sup>25</sup>, and Busch<sup>26</sup> (treatment as usual control), Isomeri<sup>18</sup> (amitriptyline only), Nichols<sup>19</sup> and Clark<sup>20</sup> (sedentary controls), Martin<sup>22</sup> (relaxation), Norregaard<sup>23</sup> (hot packs), and King<sup>25</sup> (education only and no treatment control). Among these studies, however, the 4 that measured muscle strength or flexibility failed to produce statistically significant between-group changes on those measures<sup>16,22,23,28</sup>. The lack of detectable change could have been due to attrition or lack of documentation regarding systematically increasing the intensity of the exercise group. A number of symptomatic variables (pain, fatigue, sleep) and aerobic markers (VO<sub>2</sub> max, 6 minute walk) were found to have significant between-group differences in these studies. Another possible reason there were no statistically significant differences between groups on strength in our study could have been that the strengthening intervention was not monitored to assure that subjects progressively increased the load throughout the 12 weeks. Instead, participants were encour-

aged to listen to their bodies and increase the intensity as they thought they could tolerate it. However, increasing load in interventions with FM patients may be problematic. For example, Norregaard, *et al*<sup>23</sup> attempted to progressively increase the training load during the muscle strengthening component of the aerobic exercise group, but found that “despite much effort by the physiotherapist this was very difficult to implement” (p. 76). Norregaard, *et al* report their study suffered from low rate of volunteers (only 13% invited to participate agreed) and poor compliance (60% attrition after consent). It is not surprising, therefore, that statistical significance was not found for change within or between-group on isokinetic dynamometry for quadriceps or biceps strength<sup>23</sup>. Martin, *et al*<sup>22</sup> substituted surgical tubing for a universal gym machine for patients who had difficulty (number not disclosed) with strength training exercises. Like Norregaard, *et al*, Martin, *et al* were unable to observe statistically significant strength differences on isokinetic dynamometry between their exercise group and the relaxation group. This could perhaps be due to the short duration of the intervention (6 weeks) or attrition (40% from exercise and 33% from relaxation)<sup>22</sup>.

A possible limitation of our study was that upper body strength measures were collected at a Cybex setting of 60° per second. This setting may have contributed to measurement bias (a floor effect in score distribution). Since no shoulder rotation strength measures from isokinetic dynamometry had been reported in the FM literature at the time this intervention took place, the standard strength measures were used for the Cybex. Future researchers could consider setting the shoulder speed for isokinetic dynamometry to 180° per second. At higher speeds, the isokinetic dynamometer would be easier to push, possibly yielding a greater spread of scores pre and post-intervention. Additionally, laboratory observations by the principal investigator revealed that many subjects had difficulty forming a 90° angle at the shoulder and elbow while lying supine and then generating enough strength to press the Cybex forward. An alternative suggestion for measuring upper body strength in people with FM would be to test biceps/triceps strength instead of shoulder rotation. Biceps/triceps strength testing would avoid the known tender point at the second rib anterior insertion near the sternum. The compensation for selecting biceps/triceps over the shoulder is that the shoulder girdle is implicated in a number of activities directly related to quality of life and activities of daily living in FM (e.g., washing hair, reaching high shelves). Adding additional flexibility measures in future studies may also yield information related to the ability to perform activities of daily living.

Another limitation of the study is use of the isokinetic dynamometer as the only measure of muscle strength. Isokinetic testing involves the assessment of muscle tension generated throughout a range of joint motion at a constant

angular velocity. We used equipment that allows control of the speed of joint rotation (degrees/second) as well as physical adjustability to test movement around various joints (e.g., knees, hip, shoulder, elbow). Such devices measure peak rotational force or torque defined as the measured ability of a rotation element to overcome resistance. However, strength, in its purest definition, is the maximum force a muscle or muscle group can generate. Muscle strength is therefore sometimes tested by measuring the amount of weight a participant can lift using correct form, breathing, and full range of motion during a single repetition (1 repetition maximum, RM). In muscle strengthening interventions, load is then progressively increased based on the percentage of 1 RM. The safety and reliability of 1 RM (chest press and leg press) testing for women with FM has recently been reported ( $r = 0.99$ )<sup>60</sup>, but data were not available during the course of our study. Since our study was completed, 2 exercise interventions in FM based on 1 RM loading have been reported<sup>27,61</sup>.

It would be interesting to examine the effectiveness of strength training prior to aerobic training. Perhaps the strength gains in the major muscle groups we observed would better prepare women with FM to successfully complete aerobic interventions. Aerobic activities are thought to catalyze a variety of positive health changes, including improvement of neurohormonal dysfunctions, that are postulated to mediate pain in FM. One recent example of impaired neurohormonal function in FM was reported by Paiva, *et al*, who demonstrated that untrained women with FM failed to release adequate growth hormone in response to single-bout treadmill exercise compared to age matched controls; growth hormone release to acute exercise was normalized in these same women when given an agent to decrease hypothalamic somatostatin tone (pyridostigmine bromide 30 mg po) 1 h prior to exercise<sup>62</sup>.

This study reports that female patients with FM can engage in a specially tailored muscle strengthening program and experience improvements in strength and overall disease activity, without a significant exercise induced flare in pain or increased reliance on pain medications. Flexibility training alone also resulted in overall improvements, albeit of a lesser degree.

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