Feasibility and Effectiveness of an Aerobic Exercise Program in Children With Fibromyalgia: Results of a Randomized Controlled Pilot Trial

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Objective. To determine the feasibility of conducting a randomized controlled trial of a 12-week exercise intervention in children with fibromyalgia (FM) and to explore the effectiveness of aerobic exercise on physical fitness, function, pain, FM symptoms, and quality of life (QOL).

Methods. FM patients ages 8–18 years were randomized to a 12-week exercise intervention of either aerobics or qigong. Both groups participated in 3 weekly training sessions. Program adherence and safety were monitored at each session. Data were collected at 3 testing sessions, 2 prior to and 1 after the intervention, and included FM symptoms, function, pain, QOL, and fitness measures.

Results. Thirty patients participated in the trial. Twenty-four patients completed the program; 4 patients dropped out prior to training and 2 dropped out of the aerobics program. Better adherence was reported in the aerobics group than in the qigong group (67% versus 61%). Significant improvements in physical function, functional capacity, QOL, and fatigue were observed in the aerobics group. Anaerobic function, tender point count, pain, and symptom severity improved similarly in both groups.

Conclusion. It is feasible to conduct an exercise intervention trial in children with FM. Children with FM tolerate moderate-intensity exercise without exacerbation of their disease. Significant improvements in physical function, FM symptoms, QOL, and pain were demonstrated in both exercise groups; the aerobics group performed better in several measures compared with the qigong group. Future studies may need larger sample sizes to confirm clinical improvement and to detect differences in fitness in childhood FM.

INTRODUCTION

Childhood fibromyalgia (FM) is a chronic disease of unknown etiology characterized by widespread pain, and has a reported prevalence of 2–7.5% in North America and Europe (1–5). Childhood FM is not well understood. Studies have suggested that children, like adults with FM, have increased pain and fatigue, decreased quality of life (QOL), and reduced self-efficacy in comparison with healthy controls and other patients with rheumatic disease (2,6–8).
Symptoms of FM (e.g., pain and fatigue) are commonly reported to affect physical function and participation in daily living activities, thus influencing QOL in patients with FM (2,6).

Studies suggest that adults diagnosed with FM are deconditioned. In adult women with FM, measures of cardiorespiratory fitness, including peak oxygen consumption ($V_{O2peak}$) and anaerobic threshold, are significantly reduced when compared with normal values (9). Measures of workload during maximal cycle tasks have also been reported to be significantly lower in adult FM patients when compared with healthy controls (10). Other measures of fitness such as flexibility scores, strength, and walking distances also appear to be significantly lower in FM patients when compared with historic norms and age-sex-matched controls (11). Chronic deconditioning leading to decreased physical activity participation has been suggested to contribute to the severity of symptoms and functional disability commonly reported in FM (2,8,9,12–14).

Exercise interventions in adults with FM have been successful in improving physical fitness, reducing pain and fatigue, and improving overall QOL (15). Valim et al compared the effect of 2 exercise programs (stretching and aerobic fitness training) on function, pain, QOL, depression, and anxiety in 76 women with FM (12). Patients were randomized to either a stretching program or aerobic walking program over a 20-week period. Patients in the aerobic group significantly improved their cardiorespiratory fitness, depression, anxiety, and pain scores in comparison with those in the stretching group (12). A comprehensive review of 46 exercise studies conducted from 1988 to 1995 in adults with FM suggests that aerobic exercise is beneficial in improving cardiorespiratory fitness and symptoms of FM (15). These findings are further supported by a recent meta-analysis of 4 aerobic exercise interventions suggesting that patients who participated in 6 to 23 weeks of exercise had improvements in global well-being and objectively-measured physical function (16).

To date, exercise interventions have not been formally studied in children with FM. Preliminary data from a retrospective study of 50 children with FM found a significant relationship between patient reports of disease improvement and exercise program participation (17). Evidence from exercise clinical trials in children with other rheumatic diseases such as juvenile arthritis suggests that exercise is safe and possibly effective in improving physical function and QOL (18). A strong role for exercise as a component of therapy in adults with FM in addition to preliminary evidence in children lends support for the need to determine the role of exercise in the treatment of children with FM (15,17,19,20). The primary purpose of this trial was to determine the feasibility of performing a randomized clinical trial to study the effects of an aerobic fitness program; feasibility was defined by program adherence and recruitment ability. Our secondary purpose was to determine the effect of aerobic training on physical fitness (as defined by peak aerobic capacity, muscular power, and metabolic efficiency), FM symptoms, and overall physical function in children with FM. We hypothesized that it would be possible to recruit and retain 30 children with FM with high compliance rates. We also hypothesized that the aerobic exercise program would result in greater improvement in measures of physical fitness, FM symptoms, and overall physical function when compared with a controlled, low-intensity, exercise program.

**PATIENTS AND METHODS**

**Patients.** Children ages 8–18 years diagnosed with FM were recruited from rheumatology and pain clinics located at The Hospital for Sick Children or Bloorview Kids Rehab in Toronto, Ontario, Canada. FM was confirmed by the patient’s attending rheumatologist and was based on the criteria set by the American College of Rheumatology (ACR) (21). Children with FM often have fewer tender points than adults; therefore, the minimum tender point count for a diagnosis of FM was reduced to 5 (5). Patients with a comorbid condition (cardiopulmonary disease), engaged in 3 or more hours of physical activity per week, receiving an unstable dose of medication, or unable to cooperate with testing procedures were excluded from the trial.

This study was approved by the Research Ethics Boards at The Hospital for Sick Children and Bloorview Kids Rehab. All patients were enrolled only after fully informed written consent was obtained from the parent and the child.

**Allocation.** Block randomization balanced for pubertal stage (less than or equal to Tanner stage 2 versus greater than Tanner stage 2) and sex was used to account for independent factors known to influence fitness measures. The concealed allocation scheme involved sequential opaque envelopes in blocks of 2–4. Those doing the fitness testing were blinded to treatment group allocation.

**Intervention.** Patients participated in a 12-week exercise intervention of an aerobics or qigong program consisting of a once-weekly supervised session and twice-weekly unsupervised sessions. Trained instructors led both exercise programs in 1 of 5 different centers located across the greater Toronto area. A small-group format was used, with an instructor to patient ratio of 1:4 to ensure adequate attention.

**Experimental group.** The aerobics program (experimental) consisted of a structured 30-minute aerobic program of cardio-dance and boxing movements. Each session commenced with a 10-minute warm-up routine of gentle movement exercises incorporating all major upper and lower body muscles. Trained instructors then led patients through a range of low-impact movements drawn from dance and aerobics (cardio-boxing), with the goal of progressing to 30 minutes of continuous activity at or above a heart rate of 70% of their individual heart rate maximum (HRM), determined from their $V_{O2peak}$ exercise test at enrollment. The intensity of the program was monitored by heart rate with a heart rate monitor (Polar 650i; Polar Instruments, Kempele, Finland) or by taking a manual count for 15 seconds at the carotid artery. In addition,
patients were asked to rate the intensity of the program using the Children’s OMNI scale of perceived exertion (RPE) (22). A 10-minute session of gentle passive stretching of all major upper and lower extremity muscles concluded the session.

Control group. The qigong program consisted of an 18-posture routine. Qigong is a traditional Chinese exercise method characterized by gentle flowing motions combined with isometric holds to promote blood flow and flexibility (23). Qigong training sessions were held at the same location as the experimental program but took place at different times. Instructors trained in qigong led the patients through the 18 postures. Each posture was repeated 8 times on each side of the body and the exercise took ~30 minutes to complete. A 5-minute cool-down completed the session. Instructors encouraged the children to maintain a heart rate of <70% of their HRM, determined from their V02peak exercise test at enrollment.

Unsupervised sessions. Patients were asked to participate in twice-weekly home sessions that mimicked their in-class exercise using a video program. Patients who missed a supervised session were also encouraged to make it up with an additional session at home.

Outcomes. Adherence. Adherence was measured by the combination of heart rate monitor recordings and diary entries. Adherence rates were determined from diary records kept by the patient as well as attendance records kept by the fitness instructors. The study coordinator and instructors maintained frequent contact with the patients and phoned families to motivate the children and solve potential impediments to participation. Each child kept a study diary and recorded details of both the supervised and home sessions, including heart rate, RPE, and pain. Children were rewarded with a sticker for each completed exercise session and were able to trade them for small token incentives. Finally, on a rotating basis for a week at a time, each child was given a heart rate monitor for home use.

Safety monitoring. Safety was monitored by diary ratings of pain from a 10-cm visual analog scale (VAS), filled in at each exercise session by the patients. Patients were asked each week by their instructors if there were any complications that arose from the home or subsequent supervised sessions. Symptoms of syncope, injury, neurologic, or psychological distress and any significant cardiopulmonary events were considered adverse events. These were either recorded in the study diary or reported to the study staff; in addition, study diaries were monitored for adverse events by the study coordinator and the fitness instructor.

Cardiorespiratory fitness. Patients participated in 3 exercise testing sessions to determine cardiorespiratory fitness, lasting 2.5 hours each in the cardiopulmonary exercise testing lab at The Hospital for Sick Children in Toronto. Testing sessions occurred on weekday evenings or on the weekend. Patients underwent a familiarization session that was held at the time of enrollment to familiarize the patients with testing procedures. The testing procedures were then repeated 2 to 6 weeks later and patients were then allocated to their intervention program. Finally, posttesting was held within 2 weeks of the completion of the intervention program.

At each session, height (Harpenden Stadiometer, London, UK) and weight (SR555 Stand-on Scale System; SR Instruments, Tonawanda, NY) were taken to the nearest 0.1 cm and 0.1 kg, respectively, in patients wearing light clothing but no shoes. Body fat percentage was determined by taking skin-fold measurements at the biceps, triceps, supraspinatus, and suprailiac sites and by entering the average of 3 trials into equations by Slaughter et al (24). Tender points were assessed as described by the ACR criteria (21).

Spirometry, including forced vital capacity, forced expiratory volume in 1 second, and maximum ventilatory volume, was performed using standard practices and techniques with the best of 3 trials recorded (Vmax Series, V6200 Autobox, and Vmax Series Software; SensorMedics, Yorba Linda, CA) (25).

Economy of walking (V02submax) was measured by a treadmill walking task at 3.0 km/hour and a self-selected comfortable walking speed (CWS) for 5 minutes each. CWS was determined by conducting a timed 20-meter walk in which patients were instructed to walk at their comfortable pace. The average speed was determined from 4 separate trials and used as the CWS for the treadmill walking task. Expired gases were collected continuously, with ventilatory equivalent, V02, VCO2, and the respiratory exchange ratio recorded at 20-second intervals (PhysioDyne Max-II metabolic cart; PhysioDyne Instruments, Quogue, NY). Heart rate was monitored continuously using a 4-lead electrocardiogram system (GE Case 8000; General Electric Medical Systems, Milwaukee, WI). Steady state was recorded as the average of the last 3 minutes of V02 (ml/kg/minute) measurements.

Peak aerobic capacity (V02peak) was assessed through a graded cycle test to the point of volitional fatigue. An individualized test format was used, with V02peak achieved through gradual increases in workload of 10 to 15 watts every minute. Criteria used to determine an acceptable V02peak performance included obtaining peak HRM values >185 beats per minute and a respiratory exchange ratio of ~1.1. Expired gases and heart rate were recorded as described above.

Anaerobic muscle endurance and strength (peak power) were assessed by a modified Wingate Anaerobic Test protocol using an isokinetic cycle ergometer (Biodex lower body cycle; Biodex Medical Systems, Shirley, NY) (26). Patients were given a 2-minute warm-up and then instructed to peddle “as fast as you can” for 10- and 30-second periods. Patients pedaled at 90 revolutions per minute; the highest wattage obtained was recorded as peak power and the score at the completion of the task was recorded as end power.

Psychological, functional, and activity outcomes. During each testing session, patients completed the Childhood Health Assessment Questionnaire (C-HAQ) (27), the Quality of Life (QOML) scale, the Pediatric Quality of Life Inventory (PedsQL) fatigue and pain score (28), the Functional Status and Symptom Questionnaire (FSSQ), the Fibromyalgia Impact Questionnaire (FIQ) (29), the Child-
The Childhood Depression Inventory (CDI) (30,31), and the Habitual Activity Estimation Scale (HAES) (32–35) with the assistance of the research coordinator. The research coordinator provided a detailed explanation of how to fill in each questionnaire and was also available to read the questions to the participant if necessary.

The C-HAQ provides a summary score based on 8 functional activity domains, and is rated on a scale of 0–3, where 0 indicates no limitations and 3 indicates severe limitations. The severity of illness, pain severity, and the overall well-being of the patient over the past week is also measured by 10-cm VAS (27).

Overall QOL and health-related quality of life (HRQOL) were measured by the QOML scale on separate 10-cm VAS, with lower scores indicating worse QOL/HRQOL and higher scores indicating better QOL/HRQOL (36).

The modified FIQ is a health status questionnaire that was validated for use in children and teenagers with FM (28,37). A summary score is given for 3 fatigue domains and is rated on a 5-point ordinal scale (where 0 indicates never and 4 indicates almost always). Higher scores indicate better outcomes. The modified FIQ includes 9 scales measuring present pain and the worst pain experienced by the patient in the past week, with higher scores indicating worse pain.

The FSSQ was developed to evaluate change in FM symptoms and to determine the impact of FM symptoms on activities of daily living (Wright V: unpublished observations). Degree of difficulty is rated by a 4-point ordinal scale (where 0 indicates unable to do and 3 indicates no difficulty). FM symptom severity is given for each task by marking a 10-cm VAS. A mean symptom severity score is given.

The modified FIQ is a health status questionnaire that was modified from the adult version (FIQ) for children with FM. The modified FIQ includes 9 scales measuring function, depression, anxiety, pain, stiffness, fatigue, and sleep quality (29).

The CDI is a depression symptom scale validated for use in children ages 7–17 years (31). The index consists of 27 items pertaining to different aspects of depressive symptoms. The items are scored on a 3-point scale (0–2), where higher scores indicate worse depression.

The HAES questionnaire is a physical activity questionnaire in which children are asked to recall physical activity on a typical weekday and weekend day during the past 2 weeks. Total activity hours (somewhat active plus active) and total active hours scores are calculated separately for weekdays and weekend days (32–35).

**Statistical analysis.** A convenience sample of 30 participants was used for this pilot study and was determined to be adequate for determining the feasibility aims of the study. The main outcome, feasibility, was determined by the recruitment and adherence rates of the patients in the exercise intervention program. An intent-to-treat analysis was used with session compliance calculated for all patients, regardless of their original treatment allocation. The proportion of sessions completed by each patient was determined by taking the fraction of reported supervised sessions divided by total possible supervised sessions. This process was repeated for unsupervised sessions and for the combination of supervised and unsupervised sessions.

An exploratory analysis was conducted using an intent-to-treat analysis to determine the change in the secondary outcomes physical function, cardiorespiratory fitness, FM symptoms, and QOL, with patients analyzed based on their original group allocation regardless of program adherence. A repeated-measures analysis of variance using a general linear model approach was used to compare the rates of change between the groups in the exploratory analysis of secondary outcome measures (SAS version 9.1, SAS Institute, Cary, NC).

**RESULTS**

Thirty children diagnosed with FM were recruited from The Hospital for Sick Children and Bloorview Kids Rehab in Toronto, Ontario, Canada between October 2005 and April 2007. Demographic data are shown in Table 1. The blocking factors age and sex were evenly distributed among the groups.

**Feasibility: recruitment and adherence rates.** A total of 537 patients were located from an initial search of the division of rheumatology patient database: 392 were ineligible, 78 declined, 37 were not contactable, and 30 participated in the trial (21% of all eligible, 28% of eligible patients who could be contacted). Twenty-four (80%) patients completed the entire program; 3 dropped out after test 1, one dropped out after test 2, and 2 dropped out from the aerobics program before completing the final testing (Figure 1). One patient reported a dislike of the testing procedure, 1 patient lost their transportation to the training program, 1 patient did not like the aerobic classes, and the other patients reported a lack of time as their reason for dropping out of the study.

**Patient adherence.** There was an overall adherence rate of 64% in the unsupervised and supervised sessions for both training groups combined. Patients reported a better adherence with the video program: 72% versus a 48% overall adherence rate with the supervised sessions. Patients in the aerobics group took part in an average of 1.8
sessions per week and the qigong group participated in an average of 1.5 sessions per week. Patients reached 70% of their HRM (determined from VO2peak test at baseline) in 50% of the sessions for the aerobics group and in 11% of the qigong training sessions. A significant difference in RPE was evident between the aerobics and qigong groups, with an average rating of 4.4 and 2.2, respectively (F[1,665] = 12.71, P = 0.002). Program adherence by treatment group is shown in Table 2.

Safety. There were no adverse events reported during the testing or training sessions. In addition, pain was not exacerbated in either group as determined from weekly pain ratings in the patient’s diary. Pain ratings taken from diary records of supervised and unsupervised exercise sessions were not significantly different between the 2 groups when compared (F[1,660] = 0.12, P = 0.73).

Cardiorespiratory fitness and peak power. Results of tests of cardiorespiratory fitness are shown in Table 3. A significant improvement in maximum workload obtained during the VO2peak test was demonstrated in the aerobics group at study completion when compared with the qigong group (F[1,14] = 11.5, P = 0.009). There were no significant differences in VO2submax or VO2peak in either training group. In addition, no significant differences were demonstrated in anaerobic peak power between training groups at the completion of the study program. However, there was an overall improvement in peak power at 30 seconds in both training groups at posttesting (F[1,22] = 7.84, P = 0.01). A significant decrease in end power after the 30-second Wingate Anaerobic Test was demonstrated in the qigong group but not in the aerobics group when training groups were compared over time (F[1, 22] = 5.33, P = 0.03). There were no significant differences in scores between training groups for end power at 10 seconds, but there was an overall improvement in both groups at the completion of the program (F[1,22] = 8.24, P = 0.009).

Questionnaire outcomes. Results of questionnaires evaluating physical function, FM symptoms, QOL, and the results of tender point examinations are shown in Table 4.

Physical function and activity. The aerobics group improved significantly more than the qigong group on physical function scores as determined by the C-HAQ (F[1,22] = 4.4, P = 0.05). C-HAQ VAS scores measuring the severity of illness and pain also improved significantly more in the aerobics group as compared with the qigong group at the completion of the study program (F[1,21] = 5.32, P = 0.03 versus F[1,21] = 9.75, P = 0.005). Overall VAS ratings of the impact of illness on the patient’s life did not differ significantly between the 2 training groups, but an overall improvement in both groups was demonstrated at study completion (F[1,22] = 5.82, P = 0.02). Participation in physical activity as measured by the HAES did not improve significantly in either training group.

FM symptoms. The aerobics group demonstrated a significantly greater improvement in fatigue as determined by the PedsQL fatigue score in comparison with the qigong group at study completion (F[1,22] = 7.96, P = 0.01). There were no significant differences between the groups for worst or present pain as determined by the PedsQL pain scores. However, significant improvements in worst pain were demonstrated by both groups at study completion (F[1,22] = 7.35, P = 0.01). No significant differences between groups were demonstrated in symptom severity or task difficulty as mea-

<table>
<thead>
<tr>
<th>Table 2. Adherence in both groups*</th>
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</thead>
<tbody>
<tr>
<td><strong>Adherence measure</strong></td>
</tr>
<tr>
<td>Training sessions completed</td>
</tr>
<tr>
<td>Supervised class, 12 possible sessions</td>
</tr>
<tr>
<td>Home-based sessions, 24 possible sessions</td>
</tr>
<tr>
<td>Total sessions completed of 36 possible sessions, no. (%)</td>
</tr>
<tr>
<td>HR during sessions, beats/minute</td>
</tr>
<tr>
<td>Sessions in which HR was 70% of HRM, %</td>
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<tr>
<td>Total minutes of training per session</td>
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</tbody>
</table>

* Values are the mean ± SD unless otherwise indicated. HR = heart rate; HRM = heart rate maximum.
sured by the FSSQ; however, an equal improvement was seen in both groups at study completion \( (F[1,22] = 13.35, P = 0.001 \text{ versus } F[1,22] = 8.22, P = 0.009) \). Tender point counts did not change differently between the 2 training groups, but a significant improvement was demonstrated by both groups at the completion of the study \( (F[1,22] = 7.74, P = 0.01) \). There were no differences in depression as measured by the CDI in either training group. Changes in FM symptoms as measured by the FIQ could not be determined for this study due to low response rates.

**QOL.** Significant differences were demonstrated between groups in overall QOL determined from the QOML scale, with a greater improvement in the aerobics group compared with the qigong group \( (F[1,22] = 6.50, P = 0.01) \). HRQOL determined by the QOML scale was not significantly different between groups, but a significant improvement was demonstrated in both groups at the study completion \( (F[1,22] = 4.77, P = 0.04) \).

**DISCUSSION**

To our knowledge, this is the first randomized controlled trial (RCT) of an exercise intervention in children with FM. Our results suggest that it is feasible to recruit and

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**Table 3. Fitness results at enrollment and completion for patients that completed the trial**

<table>
<thead>
<tr>
<th>Outcome variable</th>
<th>Qigong group (n = 16)</th>
<th>Aerobics group (n = 14)</th>
<th>F(df)†</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>V\textsubscript{O2}\textsubscript{submax}, 3.0 km/hour</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relative, ml/kg/minute</td>
<td>10.0 ± 0.93</td>
<td>9.5 ± 1.3</td>
<td>11.1 ± 1.8</td>
<td>10.2 ± 1.3</td>
</tr>
<tr>
<td>Absolute, liters/minute</td>
<td>0.63 ± 0.11</td>
<td>0.61 ± 0.14</td>
<td>0.53 ± 0.18</td>
<td>0.52 ± 0.20</td>
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<tr>
<td>V\textsubscript{O2}\textsubscript{submax}, CWS</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>Relative, ml/kg/minute</td>
<td>12.6 ± 1.2</td>
<td>11.9 ± 1.8</td>
<td>14.32 ± 2.3</td>
<td>14.0 ± 2.5</td>
</tr>
<tr>
<td>Absolute, liters/minute</td>
<td>0.79 ± 0.16</td>
<td>0.77 ± 0.21</td>
<td>0.71 ± 0.22</td>
<td>0.70 ± 0.26</td>
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<tr>
<td>V\textsubscript{O2}\text{peak}</td>
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<tr>
<td>Relative, ml/kg/minute</td>
<td>25.0 ± 6.0</td>
<td>24.7 ± 7.8</td>
<td>29.3 ± 7.8</td>
<td>32.0 ± 8.5</td>
</tr>
<tr>
<td>Absolute, liters/minute</td>
<td>1.54 ± 0.31</td>
<td>1.55 ± 0.44</td>
<td>1.41 ± 0.5</td>
<td>1.58 ± 0.58</td>
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<tr>
<td>Maximum workload, watts</td>
<td>92 ± 16</td>
<td>90 ± 24</td>
<td>81 ± 35</td>
<td>94 ± 42</td>
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<tr>
<td>Peak power, watts</td>
<td></td>
<td></td>
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<tr>
<td>10 seconds</td>
<td>331 ± 125</td>
<td>340 ± 129</td>
<td>320 ± 125</td>
<td>365 ± 188</td>
</tr>
<tr>
<td>30 seconds</td>
<td>322 ± 94</td>
<td>362 ± 127</td>
<td>324 ± 148</td>
<td>374 ± 170</td>
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<tr>
<td>End power, watts</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 seconds</td>
<td>279 ± 106</td>
<td>307 ± 115</td>
<td>279 ± 112</td>
<td>324 ± 154</td>
</tr>
<tr>
<td>30 seconds</td>
<td>195 ± 50.0</td>
<td>158 ± 69.0</td>
<td>157 ± 70</td>
<td>169 ± 73.0</td>
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</table>

* Values are the mean ± SD. V\textsubscript{O2}\textsubscript{submax} = submaximal oxygen consumption; CWS = comfortable walking speed; V\textsubscript{O2}\text{peak} = peak aerobic capacity. † F and P values shown are for a repeated-measures analysis of variance test and describe the interaction term test × group.

**Table 4. Questionnaire results at enrollment and completion for patients that completed the trial**

<table>
<thead>
<tr>
<th>Outcome variable</th>
<th>Qigong group (n = 16)</th>
<th>Aerobics group (n = 14)</th>
<th>F(df)†</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tender points</td>
<td>11.3 ± 4.3</td>
<td>11.0 ± 6.0</td>
<td>10 ± 4.8</td>
<td>5.9 ± 5.9</td>
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<tr>
<td>C-HAQ score</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Total</td>
<td>0.85 ± 0.54</td>
<td>1.0 ± 0.50</td>
<td>0.66 ± 0.57</td>
<td>0.42 ± 0.63</td>
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<tr>
<td>Pain VAS</td>
<td>6.3 ± 2.44</td>
<td>6.1 ± 2.34</td>
<td>6.5 ± 1.8</td>
<td>3.7 ± 2.5</td>
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<tr>
<td>Illness VAS</td>
<td>6.1 ± 2.41</td>
<td>5.90 ± 2.1</td>
<td>5.8 ± 1.9</td>
<td>3.5 ± 2.5</td>
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<td>QOL</td>
<td>7.71 ± 1.71</td>
<td>7.3 ± 1.8</td>
<td>6.7 ± 2.8</td>
<td>8.6 ± 2.2</td>
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<tr>
<td>HRQOL</td>
<td>5.99 ± 2.03</td>
<td>6.5 ± 1.3</td>
<td>4.6 ± 2.4</td>
<td>6.8 ± 2.5</td>
</tr>
<tr>
<td>PedsQL fatigue</td>
<td>858 ± 156</td>
<td>811 ± 247</td>
<td>757 ± 351</td>
<td>1,025 ± 432</td>
</tr>
<tr>
<td>PedsQL pain 1</td>
<td>5.1 ± 2.5</td>
<td>5.3 ± 2.4</td>
<td>4.2 ± 3.2</td>
<td>3.2 ± 2.9</td>
</tr>
<tr>
<td>PedsQL pain 2</td>
<td>7.8 ± 1.7</td>
<td>7.0 ± 2.2</td>
<td>7.6 ± 3.5</td>
<td>5.2 ± 3.1</td>
</tr>
<tr>
<td>FSSQ</td>
<td></td>
<td></td>
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<tr>
<td>Symptom score</td>
<td>5.1 ± 1.4</td>
<td>4.7 ± 0.8</td>
<td>5.8 ± 2.1</td>
<td>3.6 ± 2.5</td>
</tr>
<tr>
<td>Mean score</td>
<td>3.6 ± 1.4</td>
<td>3.2 ± 0.9</td>
<td>3.6 ± 2.0</td>
<td>1.6 ± 1.5</td>
</tr>
<tr>
<td>CDI</td>
<td>9.0 ± 5.3</td>
<td>8.0 ± 6.3</td>
<td>14.0 ± 12.0</td>
<td>7.7 ± 8.2</td>
</tr>
<tr>
<td>HAES total</td>
<td>5.1 ± 4.4</td>
<td>5.1 ± 3.0</td>
<td>5.2 ± 5.5</td>
<td>5.9 ± 2.9</td>
</tr>
<tr>
<td>weekday hours</td>
<td></td>
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</tbody>
</table>

* Values are the mean ± SD. C-HAQ = Childhood Health Assessment Questionnaire; VAS = visual analog scale; QOL = quality of life; HRQOL = health-related quality of life; PedsQL = Pediatric Quality of Life Inventory; pain 1 = present pain; pain 2 = worst pain; FSSQ = Functional Status and Symptom Questionnaire; CDI = Children’s Depression Index; HAES = Habitual Activity Estimation Scale. † F and P values shown are for a repeated-measures analysis of variance test and describe the interaction term test × group.
retain children with FM in an exercise intervention study. The results also suggest that children with FM can adhere to a 12-week aerobic training program without exacerbation of their disease. In an exploratory analysis, we found that aerobic training results in improvements in physical function, functional capacity, FM symptoms of fatigue, pain, and QOL in children with FM. Both programs resulted in improvements in end anaerobic power, FM symptom severity, tender point counts, and pain measures. No improvements in cardiorespiratory fitness as measured by VO2peak, peak anaerobic power, and VO2peakmax were made during the program.

Adherence rates in our study are similar to or better than those found in other similar intervention trials (18). We previously reported a program compliance of 57% in children with juvenile idiopathic arthritis (JIA) randomized to aerobic training in a similar 12-week exercise training program (18). A 67% adherence rate was reported in 37 women with FM participating in a randomized trial of 20-week training programs (39). These findings suggest that children with FM are as capable and compliant with participating in a 12-week aerobic exercise training program as adults with FM or children with other rheumatic diseases.

Findings of significant improvements in physical function, FM symptoms (fatigue), pain, and QOL in our study are consistent with results from other intervention trials of exercise in adults with FM and children with other rheumatic diseases (12.40–43). For example, a significant clinically important difference (0.125 points) in physical function measured by the C-HAQ was reported in 80 patients with JIA participating in a similar RCT (18). Valim et al reported significant improvements in depression and pain in 60 women with FM participating in a 20-week aerobic program as compared with controls (12). In an RCT of a 23-week aerobic exercise program, significant improvements were reported for measures of physical function (6-minute walk test), depression, anxiety, and self-efficacy in 50 women with FM compared with controls (42). These findings in adults with FM support our results and suggest that children with FM are capable of improving their physical function, FM symptoms, pain, and QOL after participating in a 12-week aerobic exercise program.

In our trial, we found that measures of cardiorespiratory fitness (aerobic capacity, anaerobic power, or submaximal walking economy) did not change after a 12-week exercise program. However, we demonstrated that patients were able to work at a higher workload after completing the aerobic exercise program. Exercise interventions in adults with FM have reported significant improvements in cardiorespiratory fitness by as much as 15–25% over baseline values, which do not agree with our findings (12.40–43). However, our findings are consistent with those of exercise interventions in children with JIA (18,44). For example, in our trial of 80 children with JIA participating in a similar 12-week exercise intervention, cardiorespiratory fitness also did not significantly change (18). It is certainly possible that a small treatment effect was missed due to Type II error because of our small sample size, or adherence to the prescribed training intensity and frequency may have also precluded a training effect. Although the findings from this study suggest that children with FM do not improve cardiorespiratory fitness after a 12-week exercise intervention, an improvement in maximal workload on the cycle ergometer task achieved by the aerobics group seems to suggest an improvement in functional capacity.

Participants in the qigong program also had improvements in QOL, pain, and FM symptom measures. Although the participants in the qigong program did not improve more than the aerobics group in some measures, it is possible that the full benefits of qigong training were not realized because the program was taught by trained instructors rather than a Master in qigong. The small sample size in this study may have also limited the generalizability of our results to other children with FM. We must consider the impact of patients joining the study who are somehow different than their peers. Patients who were interested in exercise or who were more physically active may have been more likely to join the study than those who were less likely to engage in active behaviors. Although it is difficult to determine if this truly impacted the recruitment in this study, our recruitment rate of 28% is similar to the recruitment rate of 30% reported in our RCT of children with JIA (18). This suggests that patients with FM are as willing to participate in exercise as those with other rheumatic diseases.

Adherence with the exercise program may have been overestimated by self-report data (45). Combining self-report data with electronic data collection techniques may have resulted in a better estimate of adherence (45). Data from our study suggests a minimum adherence rate of 50% (calculated from supervised sessions), and it is likely that the true adherence rate falls between 50% and 72%, calculated from supervised and unsupervised sessions in this study.

The results of this randomized controlled pilot trial of a 12-week aerobic exercise intervention suggest that it is feasible and safe for children with FM to participate in a moderate-intensity aerobic exercise program. Exploratory analyses suggest that aerobic exercise may be beneficial in reducing pain, improving QOL, decreasing FM symptoms of fatigue, and increasing physical function in children with FM. Further work is needed to determine the effect of exercise training on children with FM.

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AUTHOR CONTRIBUTIONS
Dr. Tse had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

**Study design.** Stephens, Feldman, Schneideman, Wright, Singh-Grewal, Lefebvre, Benseler, Cameron, O’Brien, Whitney, Stinson, Tse.

**Acquisition of data.** Stephens, Feldman, Bradley, Cameron, Laxer, Silverman, Whitney, Spiegel, Tyrrell, Tse.

**Analysis and interpretation of data.** Stephens, Feldman, Bradley, Schneideman, Benseler, Laxer, O’Brien, Schneider, Tse.


**Statistical analysis.** Stephens, Feldman, Tyrrell, Tse.
REFERENCES


