ORIGINAL ARTICLE

Assessment of the Effects of Aquatic Therapy on Global Symptomatology in Patients With Fibromyalgia Syndrome: A Randomized Controlled Trial

Diego Munguía-Izquierdo, PhD, Alejandro Legaz-Arrese, PhD

ABSTRACT. Munguía-Izquierdo D, Legaz-Arrese A. Assessment of the effects of aquatic therapy on global symptomatology in patients with fibromyalgia syndrome: a randomized controlled trial. Arch Phys Med Rehabil 2008;89:2250-7.

Objectives: To evaluate the effects of a 16-week exercise therapy in a chest-high pool of warm water through applicable tests in the clinical practice on the global symptomatology of women with fibromyalgia (FM) and to determine exercise adherence levels.

Design: A randomized controlled trial.

Setting: Testing and training were completed at the university.

Participants: Middle-aged women with FM (n=60) and healthy women (n=25).

Intervention: A 16-week aquatic training program, including strength training, aerobic training, and relaxation exercises.

Main Outcome Measures: Tender point count (syringe calibrated), health status (Fibromyalgia Impact Questionnaire); sleep quality (Pittsburgh Sleep Quality Index); physical (endurance strength to low loads tests), psychologic (State Anxiety Inventory), and cognitive function (Paced Auditory Serial Addition Task); and adherence 12 months after the completion of the study.

Results: For all the measurements, the patients showed significant deficiencies compared with the healthy subjects. Efficacy analysis (n=29) and intent-to-treat analysis (n=34) of the exercise therapy was effective in decreasing the tender point count and improving sleep quality, cognitive function, and physical function. Anxiety remained unchanged during the follow-up. The exercise group had a significant improvement of health status, not associated exclusively with the exercise intervention. There were no changes in the control group. Twenty-three patients in the exercise group were exercising regularly 12 months after completing the program.

Conclusions: An exercise therapy 3 times a week for 16 weeks in a warm pool could improve most of the symptoms of FM and cause a high adherence to exercise in unfit women with heightened FM symptomatology. The therapeutic intervention's effects can be assessed through applicable tests in the clinical practice.

Key Words: Exercise therapy; Fibromyalgia; Health status; Pain; Rehabilitation; Sleep.

FIBROMYALGIA IS A CHRONIC musculoskeletal pain syndrome that is associated with a wide variety of symptoms, such as sleep disturbances,[1] fatigue,[2] low muscular performance,[3] cognitive disturbances,[4] anxiety, and depressed moods.[5]

Several controlled studies have shown that different kinds of exercise programs may modulate pain,[6,7] health-related quality of life,[8] sleep quality,[6,7] cognitive function,[9] and anxiety[10] in patients with FM. However, no study has yet addressed the effects on sleep quality through a specific test or the effects of exercise alone on global FM symptomatology; a growing body of evidence has suggested that exercise is beneficial for patients with FM.[11]

One of the main effects of the therapeutic programs is the incorporation of physical activity in the patients' daily lives. Various studies[12] have shown that detraining affects the main cardiovascular, metabolic, and muscular parameters, even among elite athletes, within 4 weeks.

This state of disadaptation has also been shown in FM patients.[8] However, exercise adherence after several months of postintervention has been assessed in very few exercise programs in FM patients. With regards to the aquatic programs performed in water only, very few determined adherence after the intervening period.[13]

One of the major objectives of increasing scientific knowledge is its applicability to daily clinical practice. Researchers have assessed the symptomatology in FM patients and the effects of therapeutic interventions by using technology and/or tests of difficult accessibility for most health care professionals. For example, several studies have assessed pain threshold, sleep quality, cognitive dysfunction, strength, and cardiorespiratory fitness through dolorimetry,[14] polysomnography,[15,16] single photon-emission computed tomography or auditory P300 event-related brain potentials,[4] isokinetic dynamometers,[8] and the 6MWT.[10,17] At the same time, other studies continued

List of Abbreviations

ACR	American College of Rheumatology
FIQ	Fibromyalgia Impact Questionnaire
FM	fibromyalgia
ICC	intraclass correlation coefficient
ITT	intent to treat
PASAT	Paced Auditory Serial Addition Task
PSQI	Pittsburgh Sleep Quality Index
SAI	State Anxiety Inventory
6MWT	six-minute walk test
VAS	visual analog scale

From the Section of Physical Education and Sports, University Pablo de Olavide, Seville (Munguía-Izquierdo); Section of Physical Education and Sports, University of Zaragoza, Zaragoza (Legaz-Arrese), Spain.

Supported by the European Social Funds and Regional Government of Aragon (Spain: grant no. B187/2004).

No commercial party having a direct financial interest in the results of the research supporting this article has or will confer a benefit on the authors or on any organization with which the authors are associated.

Reprint requests to Diego Munguía-Izquierdo, PhD, Departamento de Deporte e Informática, Universidad Pablo de Olavide, Carretera Utrera, Km 1, s/n, 41013, Sevilla, Spain, e-mail: *dmunizq@upo.es*.

0003-9993/08/8912-00944$34.00/0
doi:10.1016/j.apmr.2008.03.026

to use less valid and precise methodologies, such as digital palpation in the assessment of pain,[17,18] VASs to assess pain[17,19,20] or sleep quality,[6,20,21] and the chair-stand test[22] to assess the strength.[7,10,23]

Therefore, the purpose of the present study was to evaluate the effects of a 16-week exercise therapy in a chest-high pool of warm water through applicable tests in the clinical practice on the global symptomatology of women with FM and to determine adherence to an exercise regimen. In addition, this study determined the differences in global symptomatology between FM patients and healthy subjects.

METHODS

Design and Participants

An invitation to participate in the study was sent to women (n=250) ages 18 to 60 years old from a local FM association in Spain. Sixty-eight potentially eligible subjects responded and sought more information. Those 68 eligible patients gave written consent after the study protocol was explained to them. Patients' personal medical records were examined by a physician, and a diagnosis of FM was confirmed according to the ACR classification criteria.[2] To determine the differences among patients with FM and healthy controls, a group of 25 healthy women volunteers matched according to age, weight, body mass index, educational, and physical activity level were recruited. All healthy subjects gave written consent. The study flow of participants is presented in figure 1.

The exclusion criteria included the presence of subjects with a history of morbid obesity, known cardiopulmonary diseases, endocrine or allergic disturbances uncontrolled, severe trauma, frequent migraines, inflammatory rheumatic diseases, and severe psychiatric illness. In addition, subjects with other diseases that prevent physical loading and those who were pregnant were also omitted. Finally, those FM women who attended another type of physical or psychologic therapy were excluded to avoid possible interactions with the present trial. Patients with a history of regular physical activity more strenuous than slow-paced walking a maximum of 2 times a week over 4 months before study entry were excluded from the final analysis according to the criteria of Schachter et al.[18] The Spanish version[24] of the revised Physical Activity Readiness Questionnaire[25] was also administered to identify persons at risk for adverse events while exercising. On the whole, 8 patients were excluded from the study because they were attending a psychologic therapy program (n=2), exercised regularly (n=2), or had a history of severe trauma (n=1), arrhythmia (n=1), inflammatory rheumatic disease (n=1), or psychiatric illness (n=1).

According to the aforementioned criteria, a final sample of 60 FM women was randomly assigned to either an exercise group or a control group according to a computer-generated randomization list. Different numbers of patients were allocated to each group to ensure that both groups completed the intervening period with a comparable quantity of patients, despite the elevated exercise therapy attrition rate[26,27] (randomization ratio, 1.4:1). The results of the randomization were unknown until the participant accepted or declined to participate in the project. Six patients in the exercise group and 1 in the control group were not included in the analysis for diverse

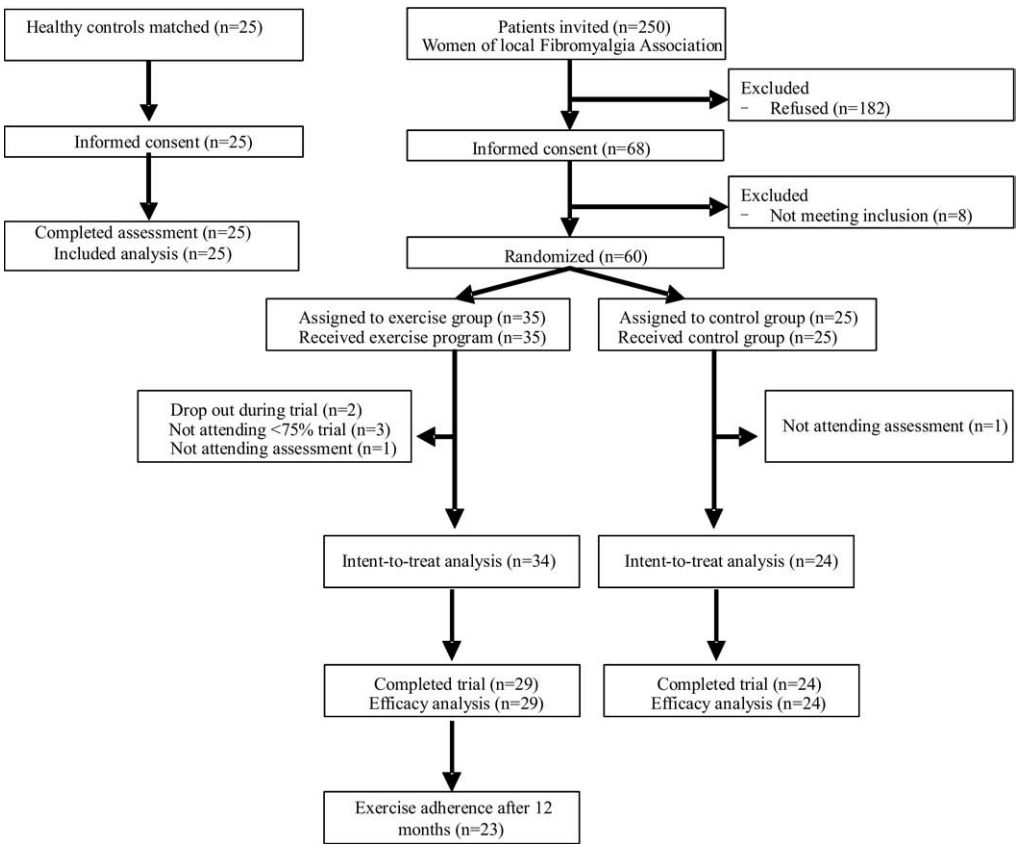

Fig 1. The flow of participants throughout the trial.

Table 1: Training Progression During the Program

Period (wk)	Strength Training Progression						Aerobic Training Progression		
	Repetitions	Weekly Routines	Sets	Exercises	Duration (min)	Weekly Frequency	Intensity (%) HR_{max}	Duration (min)	Weekly Frequency
1–2	10–15	A	1	8	8–10	3	50–60	20–25	3
3–4	10–15	A	1–2	8–10	10–15	3	55–65	20–25	3
5–8	10–12	B1, B2	1–2	8–10	10–15	3	60–70	20–25	3
9–12	10–12	B1, B2	2–3	8–10	15–20	3	65–75	25–30	3
13–16	8–10	C1, C2, C3	2–3	8–10	15–20	3	70–80	25–30	3

Abbreviations: A, all major muscular groups; B1, trapezius, latissimus-dorsi, biceps brachii, abductors, adductors and torso muscles (ie, abdominals, oblique and lumbar); B2, pectoralis, triceps brachii, deltoids, gluteus, quadriceps, knee flexors (ie, biceps femoris, semimembranosus, and semitendinosus) and gastrocnemius muscles; C1, trapezius, latissimus-dorsi, biceps brachii and torso muscles; C2, gluteus, quadriceps, knee flexors, gastrocnemius, abductors and adductors muscles; C3, pectoralis, triceps brachii, deltoids and torso muscles; HR_{max}, age-predicted maximal heart rate equation (220–age).

reasons. Finally, 29 women from the exercise group and 24 women from the control group fully completed the study and were included in the efficacy analysis (see fig 1). The control group was instructed not to change their habits regarding physical activities during the period. The exercise group followed an aquatic training program 3 times a week for 16 weeks. All patients were allowed to continue their usual daily activities as earlier, to use their regular medication, and to visit medical professionals if needed.

The evaluation of the outcome measures was performed immediately after the training period at 16 weeks. The initial measurements before the training period started were designated as baseline values. All measurements were taken by examiners blinded to group assignment. The Committee on Biomedical Ethics of the Aragon Government approved this study.

Exercise Therapy

The exercise group trained in a chest-high warm pool (32° C) 3 times a week for 16 weeks. Each session included 10 minutes of warming up with slow walks and mobility exercises, 10 to 20 minutes of strength exercises developed at a slow pace using water and aquatic materials as a means of resistance including a stepped progression during the program (table 1), 20 to 30 minutes of aerobic exercises developed progressively at intensity sufficient to achieve 50% to 80% of the age predicted maximum heart rate equation (220 – age) (see table 1), and 10 minutes of cooling down with low-intensity and relaxation exercises. Heart rate was monitored with a pulse meter.[a] The intervention program met the minimum training standards of the American College of Sports Medicine.[28]

Pain Measures

Pressure pain thresholds in all tender points, according to ACR-1990 classification criteria,[2] were measured by using a syringe calibrated like a pressure dolorimeter.[9] The syringe was calibrated to obtain the equivalency of cm^3 in kg of pressure to determine the amount of tender points positive to the exploration according to the guidelines the ACR recommends for FM diagnosis. The equivalencies of cm^3 in kg of pressure were $10cm^3$=2.5kg, $11cm^3$=3kg, $12cm^3$=3.5kg, $13cm^3$=4kg, and $14cm^3$=5kg. A tender point is considered positive to the exploration when the patient manifests pain with a pressure of $13cm^3$ or less.

For each patient, the number of examined points that were found to be positive during the exploration or sore to a pressure of 4kg or less ($13cm^3$) was recorded.

Health Status Measures

The influence of FM on functional impairment and health status was assessed with the validated Spanish version[29] of the FIQ. The original version of the FIQ was designed by Burckhardt et al[30] to evaluate the severity of FM on daily activities. Previous researches[31,32] have shown adequate reliability and validity of this measure. The questionnaire is scored from 0 to 100, in which a higher score indicates a greater impact of the syndrome on the person.

Psychologic Measures

The level of current anxiety was measured with the Spanish version[33] of the 20-item self-administered SAI.[34] Higher scores on the SAI indicate a greater state of anxiety (range, 20–80) and have been widely used to measure anxiety in psychiatric and medical samples and have proven to be sensitive to exercise-induced changes in anxiety.[35]

Sleep Quality Measures

The influence of FM on sleep quality was assessed with the Spanish version[36] of the PSQI,[37] an instrument previously administered in FM patients[38,39] with established reliability and validity. This method consists of 19 self-rating questions combined into 7 components: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, use of sleeping medications, and daytime dysfunction. These component scores are then summed to yield a global PSQI score, which has a range of 0 to 21, with higher scores indicating worse sleep quality.

Cognitive Function Measures

All participants were asked to complete the PASAT. This standardized neuropsychologic test measures sustained and divided attention, auditory information processing speed, and stimulus competition filtering skill.[40] In this study, the PASAT was administered only at the slowest presentation rate of 2.4 seconds. The score is the number of correct responses over 60 trials.

Physical Function Measures

The endurance strength of each subject's upper- and lower-extremities was evaluated by recording the number of repetitions from 2 properly designed tests: the endurance strength to low loads tests.

The lower-extremities endurance strength to low loads test was administered by using a folding chair without arms, with a seat height of 43.2cm. The chair, with rubber tips on the legs,

was placed against a wall to prevent it from moving during the test. The test began with the participant seated in the middle of the chair, back straight, feet approximately shoulder width apart and placed on the floor at an angle slightly back from the knees, with 1 foot slightly in front of the other to help maintain balance when standing. Arms were extended longitudinally to the trunk, and each hand held a dumbbell of 2.5kg. At the signal of the metronome, the participant rose to a full stand (body erect and straight), and at the next signal of the metronome, the participant returned back to the initial seated position maintaining the arms extended. The pace of the metronome was 90°/s. The score was the total number of stands executed correctly until the participant could not keep up with the pace. The test-retest reliability was satisfactory ($ICC_{2.1}$=.94, P<.001).

The upper-extremities endurance strength to low loads test was administered by using the same chair as the one used for the lower extremities. The test began with the participant seated in the middle of the chair, leaning back completely, with the arm being tested extended longitudinally to the trunk and holding a dumbbell of 2.5kg in weight. At the signal of the metronome, the participant curled the weight through a full range of motion. At the next signal of the metronome, the participant returned back to the initial position keeping the back straight. The pace of the metronome was 120°/s. The score was the total number of stands executed correctly until the participant could not keep up with the pace. This test was repeated for the other arm. The reliability was satisfactory ($ICC_{2.1}$=.88, P<.001 for the right arm; $ICC_{2.1}$=.91, P<.001 for the left arm).

Adherence to Training

For each patient, we recorded the number of training sessions attended during the study. After a 16-week intervention, the researchers did not have contact with the patients. Twelve months from the completion of the study, we contacted patients by telephone to determine whether they continued on an exercise program.

Statistical Analysis

We analyzed data on an efficacy (29 exercise and 24 control patients) and ITT (34 exercise and 24 control patients) basis. Subjects who attended the exercise sessions and participated in testing at all points (before and after sessions) were included in the ITT analysis. To be included in the efficacy analysis, participants had to attend 75% or more of the exercise sessions. We evaluated the normality of the variables through the Kolmogorov-Smirnov and Shapiro-Wilk tests, with Lilliefors significance. The results are expressed as the mean ± SD or 95% confidence interval. We compared the differences in baseline variables among the healthy, exercise, and control groups through the analysis of variance of a particular factor. We applied the Kruskall-Wallis and chi-square tests in samples with no homogeneous distribution and in qualitative variables, respectively. We used the Student t test and the Mann-Whitney U test to compare baseline measures between the healthy subjects and the FM patients. The statistical analysis of the data focused on the interactions between group (exercise/control) and time (times 1-2, with the first assessment occurring before the therapeutic intervention and time 2 occurring immediately after the 16-week intervention). This analysis also controlled for selected covariates. When data were not normally distributed, we applied the Wilcoxon analysis to observe differences for repeated measures. For these variables, we used the Mann-Whitney U test to observe if the changes in the variables were different between the experimental and control groups. We applied the Spearman analysis to examine the relation between the changes in the variables and selected baseline measures. We used the ICCs model 2.1 to establish test-retest reliability for the physical function measures. The α level was set at .05.

RESULTS

As far as program compliance is concerned, only 2 subjects had to be eliminated because of exercise recidivism rate. These women (6%) dropped out during the program because of transportation problems and employment commitments. The remaining 33 patients attended a mean of 42 (range, 30–48) exercise sessions out of a possible 48. This represents an 88% attendance rate. All subjects attended at least half (n=24) of the exercise sessions, with the majority (86%) attending at least 75% (n=6). Three women (9%) from the exercise group were excluded from the efficacy analysis for not attending at least 75% of the exercise sessions. Another woman (3%) was excluded from the efficacy analysis because she did not attend assessments. During the 12 months after completing the exercise program, 23 patients in the exercise group (79% efficacy analysis vs 68% ITT analysis) participated regularly in exercise programs: 20 patients in pool-based programs and 3 patients in other types of programs (see fig 1).

Efficacy and ITT analyses showed similar baseline characteristics for the exercise, control, and healthy groups (table 2). The healthy group showed significantly better efficacy and ITT analyses results. Specifically, the health status; sleep quality; and psychologic, physical, and cognitive function measures were improved as compared with the FM group in all parameters assessed. FM patients were severely affected (ie, SAI, PSQI, endurance strength to low loads tests scores >2 SD below and above healthy group, respectively) (table 3).

Efficacy and ITT analyses showed significant improvements of exercise therapy on the clinical variables (table 4). The number of tender points decreased significantly in the exercise group (29% efficacy analysis vs 26% ITT analysis). Exercise therapy also significantly improved the score on the PSQI (16% efficacy analysis vs 13% ITT analysis) and on the pace auditory serial addition task (26% efficacy analysis vs 23% ITT analysis). The repetitions performed in the endurance strength test increased significantly with therapeutic intervention: left arm (314% efficacy analysis vs 271% ITT analysis), right arm (265% efficacy analysis vs 231% ITT analysis), and lower extremities (116% efficacy analysis vs 102% ITT analysis). The score in the SAI remained unchanged during the follow-up. The exercise group showed a statistically significant improvement in the FIQ (8%, P=.020 efficacy analysis vs 7%, P=.005 ITT analysis), which was not associated exclusively with the exercise intervention (P=.122 efficacy analysis vs P=.116 ITT analysis). In the control group, none of the clinical variables showed significant changes with respect to the initial assessment. The effects of exercise therapy were independent of the baseline characteristics of the patients.

DISCUSSION

This study shows that exercise therapy 3 times a week over 16 weeks in a chest-high pool of warm water improves the majority of the symptoms of FM, including tender point count, sleep quality, cognitive function, and physical fitness. These improvements were shown in both the efficacy and ITT analysis, but the improvements were larger and more significant in the efficacy analysis. Health status, measured by means of the FIQ, also improved significantly in the exercise group. However, this change was not caused by the exercise therapy only. Probably the variation of the season between the pre- and postmeasures (January–May) partially explains the differ-

Table 2: Characteristics of Women Who Followed the Exercise Program, Control, and Healthy Groups From the Efficacy and ITT Analysis

	Efficacy Analysis				ITT Analysis			
Group	Exercise (n=29)	Control (n=24)	Healthy (n=25)	*P*	Exercise (n=34)	Control (n=24)	Healthy (n=25)	*P*
Ethnicity (%)								
White	100	100	100	NA	100	100	100	NA
Age (y)	50±7	46±8	47±10	0.175	50±7	46±8	47±10	0.182
Body mass index (kg/m^2)	27±5	27±4	26±4	0.985	27±4	27±4	26±4	0.965
Duration of symptoms (y)	14±10	14±9	ND	0.922	14±9	14±9	ND	0.883
Tender point count (1–18)	15.1±3.9	16.1±2.9	ND	0.355	15.2±3.6	16.1±2.9	ND	0.411
Occupation (%)				0.901				0.841
Domestic labor	52	67	60		50	67	60	
Operatives	21	17	12		21	17	12	
Office or store worker	17	13	20		17	13	20	
Manager	10	4	8		12	4	8	
Highest education (%)				0.916				0.901
Elementary school	59	63	60		56	63	60	
High school	31	29	24		32	29	24	
College/university	10	8	16		12	8	16	

NOTE. Values are the mean ± SD unless otherwise indicated; values listed as NA are NA because this variable is constant.
Abbreviations: NA, not applicable; ND, no data.

ences found in the health status. Some authors suggest that season influences the functional impairment and health status of the FM patients, improving significantly in the warm months.[23,41,42]

We did not find differences in anxiety levels after treatment. This was probably because of the duration of program intervention and because we did not include educational treatment. The majority of studies related to FM and exercise that achieved significant psychologic improvements developed programs greater than 20 weeks[17,20] and/or included educational programs.[10,43-45]

We emphasize the elevated adherence to the exercise program in the exercise group. This strong adherence has been observed in few studies.[13,46] It has been justified with the scarce dropout rate (6%, n=2), high attendance rate (88%) during the intervention period, and the high percentage of patients (79% efficacy analysis vs 68% ITT analysis, n=23) who continued the exercise program on their own cost and without our encouragement 12 months after the completion of the study. This indicates that our program has broken the vicious cycle of insufficient exercise and deteriorating fitness. An important finding is that most of the patients incorporated the exercise program into their daily lives and, consequently, minimized the detraining effects. These results suggest that the aquatic program is an adequate type of exercise to cause elevated exercise adherence. However, we are not aware of a study that determines the influence of different programs of physical activity on adherence.

This is the first study that assesses the effects of an exercise program on sleep quality by means of the PSQI. Other studies have assessed sleep by means of brief and nonspecific tests or simple VASs.[6,7,21,43,47,48] We consider that the PSQI is a more consistent and specific instrument, is broadly used, and is validated to establish and examine the quality and sleep disorders.[36,49,50] Furthermore, it is considered to be a useful and sensitive instrument for characterizing and quantifying sleep disturbances in FM patients.[38]

Another important finding is the sensitivity of the PASAT to determine changes in cognitive function. This test is used frequently in the scientific literature and has increased reliability and internal consistence.[51] However, it has currently been used only in very few studies to appraise the cognitive function in FM patients,[9,52,53] and only our research group has used it to determine exercise-induced changes.[9] In addition, the PASAT has larger applicability in the clinical daily practice than the single photon-emission computed tomography or auditory P300 event-related brain potentials.[4]

Table 3: Scores on Outcome Measures of Patients With Fibromyalgia Syndrome and Healthy Persons From the Efficacy and ITT Analysis

	Efficacy Analysis			ITT Analysis		
	FM Group (n=53)	Healthy Group (n=25)	*P*	FM Group (n=58)	Healthy Group (n=25)	*P*
FIQ (0–100)	66.1±15.0	10.6±9.2	0.000	66.3±14.4	10.6±9.2	0.000
Endurance-strength tests (reps)						
Left arm	14.8±21.9	55.0±41.9	0.000	14.7±20.9	55.0±41.9	0.000
Right arm	16.0±21.7	59.6±36.8	0.000	15.6±20.8	59.6±36.8	0.000
Lower extremities	22.3±26.7	82.0±46.3	0.000	22.4±25.5	82.0±46.3	0.000
SAI (20–80)	50.1±11.5	33.2±5.3	0.000	50.3±11.1	33.2±5.3	0.000
PSQI (0–21)	11.9±5.0	4.2±2.9	0.000	12.2±4.9	4.2±2.9	0.000
PASAT test, 2.4s (0–60)	26.8±14.2	40.5±12.6	0.000	26.7±13.6	40.5±12.6	0.000

NOTE. Values are the mean ± SD unless otherwise noted.

Table 4: Effects of a 16-Week Warm Water Exercise Program on Outcome Measures in Women With Fibromyalgia Syndrome Assigned to the Exercise or Control Group From the Efficacy and ITT Analysis*

	Efficacy Analysis (Exercise [n=29] vs Control [n=24])			Intent-To-Treat Analysis (Exercise [n=34] vs Control [n=24])		
	Baseline	Change From Baseline to 16 Weeks		Baseline	Change From Baseline to 16 Weeks	
	Mean ± SD	Mean (95% CI)	*P**	Mean ± SD	Mean (95% CI)	*P**
Tender point count (1–18)						
Exercise	15.1±3.9	−4.4 (−5.8 to −3.0)	0.000	15.2±3.6	−3.9 (−5.1 to −2.6)	0.001
Control	16.1±2.9	−0.3 (−1.7 to 1.1)		16.1±2.9	−0.3 (−1.7 to 1.1)	
FIQ (0–100)						
Exercise	68.2±13.4	−5.1 (−8.9 to −1.3)	0.122	68.1±12.4	−4.8 (−8.1 to −1.6)	0.116
Control	63.6±16.7	−0.9 (−4.8 to 2.9)		63.6±16.7	−0.9 (−4.8 to 2.9)	
Endurance strength tests (reps)						
Left arm						
Exercise	10.9±10.7	34.2 (25.2 to 43.4)	0.000	11.3±9.9	30.6 (22.3 to 38.9)	0.000
Control	19.5±30.1	4.4 (−2.2 to 11.0)		19.5±30.1	4.4 (−2.2 to 11.0)	
Right arm						
Exercise	12.1±12.2	32.1 (21.8 to 42.3)	0.000	12.2±11.3	28.2 (18.9 to 37.5)	0.001
Control	20.6±29.1	8.2 (−0.1 to 16.5)		20.6±29.1	8.2 (−0.1 to 16.5)	
Lower extremities						
Exercise	23.2±23.7	26.9 (14.3 to 39.6)	0.001	23.3±21.8	23.8 (12.7 to 34.8)	0.001
Control	21.2±30.4	9.8 (−1.7 to 21.3)		21.2±30.4	9.8 (−1.7 to 21.3)	
SAI (20–80)						
Exercise	52.2±11.7	−0.3 (−4.0 to 3.3)	0.979	52.2±10.8	−0.3 (−3.4 to 2.8)	0.961
Control	47.6±11.0	−0.4 (−4.6 to 3.8)		47.6±11.0	−0.4 (−4.6 to 3.8)	
PSQI (0–21)						
Exercise	13.3±4.7	−2.0 (−3.0 to −1.1)	0.000	13.4±4.4	−1.7 (−2.6 to −0.9)	0.000
Control	10.4±5.0	0.5 (−0.4 to 1.3)		10.4±5.0	0.5 (−0.4 to 1.3)	
PASAT Test, 2.4s (0–60)						
Exercise	25.7±15.5	6.7 (3.1 to 10.3)	0.004	25.7±14.3	5.9 (2.7 to 9.0)	0.006
Control	28.2±12.7	1.2 (−2.1 to 4.4)		28.2±12.7	1.2 (−2.1 to 4.4)	

NOTE. Values are mean ± SD unless otherwise noted.
Abbreviation: CI, confidence interval.
*Difference between the groups.

The introduction of a new method to appraise pain in FM patients is scientifically valuable.[9] Up until now, pain has been largely assessed through the use of a dolorimeter, digital palpation, or self-reported VASs. Digital palpation does not permit quantifying the pain threshold, and, therefore, it is not sensitive enough to the therapeutic changes. VASs do not permit quantifying the tender point count and have been shown to be insufficiently sensitive to the therapeutic changes.[11] In fact, we have observed that most studies that have assessed pain through quantitative instruments (myalgic scoring, readings from a calibrated syringe, dolorimeter, or pressure algometer) have obtained significant changes in pain after therapeutic exercise programs.[6,9,43,47,54] In contrast, exercise programs that used a dichotomous variable (present/absent) generally did not observe changes after the intervention period.[17,23]

Even though physical dysfunction is a major limitation among FM patients, its assessment in daily clinical practice is limited by the availability of scientific instruments and amenities, notably isokinetic dynamometers,[8,17,47] fitness machines,[26] ergospirometers,[13,55] and a 6MWT.[10,17] One of the few tests measuring physical fitness that is applicable in the daily clinical practice and used with FM patients[7,10,23] is the chair-stand test.[22] This test aims to have the patient complete as many full stands as possible within 30 seconds. The temporal limitation obligates the patient to perform the exercise at the maximum velocity possible. Therefore, the functional and metabolic perspective cannot adequately assess the healthy physical fitness in a clinical population. In this study, we have modified the chair-stand test by controlling the pace of movement through means of a metronome to induce heightened aerobic metabolism. Similarly, we have modified the arm curl test[56] in the assessment of the upper extremities because it presented the same temporary limitation as the chair-stand test. Both tests designed in our study have shown good reliability and sensitivity to therapeutic effects. These tests can be used in daily clinical practice to appraise fitness in FM patients.

We have observed an important increase in repetitions of lower and upper extremities endurance strength tests after completing the program. This increase in the strength could be symptomatic of a decrease of pain, even though the exercise program could have ameliorated central regulation of pain. This decrease of pain could be caused by the lower percentage of strength needed to perform the same physical activity (ie, climbing stairs). Furthermore, the values for the control and exercise group are similar. For this reason, we reject a neuromuscular and metabolic deficiency in FM patients. Given the short duration of the program, we consider that the increase in repetitions may not be exclusively attributed to neuromuscular and metabolic adaptations. The other factors that should be considered are the increase of the pain threshold and a decrease in fear of the physical effort induced by the therapeutic intervention.

Study Limitations

Because the results of our study could have been affected by the small sample size, we recommend determining the validity and reliability of the 2 tests we proposed with a more extensive sample.

CONCLUSIONS

The results of the efficacy and ITT analysis of this study show that an exercise therapy program with moderate intensity performed 3 times a week for 16 weeks in a chest-high pool of warm water (32°C) has no apparent negative effects and improves pain, sleep quality, and physical and cognitive function, causing a great adherence to exercise in previously unfit women with heightened and long FM symptomatology. Further research could determine what programs of physical activity induce a larger adherence in FM patients.

References

1. Yunus MB, Aldag JC. Restless legs syndrome and legs cramps in fibromyalgia: a controlled study. BMJ 1996;312:1339.
2. Wolfe F, Smythe HA, Yunus MB, et al. The American College of Rheumatology 1990 Criteria for the Classification of Fibromyalgia. Report of the Multicenter Criteria Committee. Arthritis Rheum 1990;33:160-72.
3. Mannerkorpi K, Burckhardt CS, Bjelle A. Physical performance characteristics of women with fibromyalgia. Arthritis Care Res 1994;7:123-9.
4. Alanoglu E, Ulas UH, Ozdăg F, Odabasi Z, Cakci A, Vural O. Auditory event-related brain potentials in fibromyalgia syndrome. Rheumatol Int 2005;25:345-9.
5. White KP, Nielson WR, Harth M, Ostbye T, Speechley M. Chronic widespread musculoskeletal pain with or without fibromyalgia: psychological distress in a representative community adult sample. J Rheumatol 2002;29:588-94.
6. Geel SE, Robergs RA. The effect of graded resistance exercise on fibromyalgia symptoms and muscle bioenergetics: a pilot study. Arthritis Rheum 2002;47:82-6.
7. Altan L, Bingol U, Aykac M, Koc Z, Yurtkuran M. Investigation of the effects of pool-based exercise on fibromyalgia syndrome. Rheumatol Int 2004;24:272-7.
8. Gusi N, Tomas-Carus P, Häkkinen A, Häkkinen K, Ortega-Alonso A. Exercise in waist-high warm water decreases pain and improves health-related quality of life and strength in the lower extremities in women with fibromyalgia. Arthritis Rheum 2006; 55:66-73.
9. Munguia-Izquierdo D, Legaz-Arrese A. Exercise in warm water decreases pain and improves cognitive function in middle-aged women with fibromyalgia. Clin Exp Rheumatol 2007;25:823-30.
10. Mannerkorpi K, Nyberg B, Ahlmén M, Ekdahl C. Pool exercise combined with an education program for patients with fibromyalgia syndrome. A prospective, randomized study. J Rheumatol 2000;27:2473-81.
11. Busch A, Schachter CL, Peloso PM, Bombardier C. Exercise for treating fibromyalgia syndrome. Cochrane Database Syst Rev 2002;(3):CD003786.
12. Mujika I, Padilla S. Detraining: loss of training-induced physiological and performance adaptations. Part I: short term insufficient training stimulus. Sports Med 2000;30:79-87.
13. Jentoft ES, Kvalvik AG, Mengshoel AM. Effects of pool-based and land-based aerobic exercise on women with fibromyalgia/chronic widespread muscle pain. Arthritis Rheum 2001;45:42-7.
14. Maquet D, Croisier JL, Demoulin C, Crielaard JM. Pressure pain thresholds of tender point sites in patients with fibromyalgia and in healthy controls. Eur J Pain 2004;8:111-7.
15. Landis CA, Lentz MJ, Rothermel J, Buchwald D, Shaver JL. Decreased sleep spindles and spindle activity in midlife women with fibromyalgia and pain. Sleep 2004;27:741-50.
16. Hindmarch I, Dawson J, Stanley N. A double-blind study in healthy volunteers to assess the effects on sleep of pregabalin compared with alprazolam and placebo. Sleep 2005;28;187-93.
17. Gowans SE, deHueck A, Voss S, Silaj A, Abbey SE, Reynolds WJ. Effect of a randomized, controlled trial of exercise on mood and physical function in individuals with fibromyalgia. Arthritis Rheum 2001;45:519-29.
18. Schachter CL, Busch AJ, Peloso PM, Sheppard MS. Effects of short versus long bouts of aerobic exercise in sedentary women with fibromyalgia: a randomized controlled trial. Phys Ther 2003; 83:340-58.
19. Mengshoel AM, Komnaes HB, Førre O. The effects of 20 weeks of physical fitness training in female patients with fibromyalgia. Clin Exp Rheumatol 1992;10:345-9.
20. Häkkinen A, Häkkinen K, Hannonen P, Alen M. Strength training induced adaptations in neuromuscular function of premenopausal women with fibromyalgia: comparison with healthy women. Ann Rheum Dis 2001;60:21-6.
21. Valkeinen H, Alen M, Hannonen P, Häkkinen A, Airaksinen O, Hakkinen K. Changes in knee extension and flexion force, EMG and functional capacity during strength training in older females with fibromyalgia and healthy controls. Rheumatology (Oxford) 2004;43:225-8.
22. Jones CJ, Rikli RE, Beam W. A 30-s chair-stand test as a measure of lower body strength in community-residing older adults. Res Q Exerc Sport 1999;70:113-9.
23. Burckhardt CS, Mannerkorpi K, Hedenberg L, Bjelle A. A randomized, controlled clinical trial of education and physical training for women with fibromyalgia. J Rheumatol 1994;21:714-20.
24. Rodríguez FA. Versión española del cuestionario de aptitud para la actividad física (C-AAF/rPAR-Q). Arch Med Deporte 1996;51: 63-8.
25. Thomas S, Reading J, Shepard RJ. Revision of the Physical Activity Readiness Questionnaire (PAR-Q). Can J Sport Sci 1992; 17:338-45.
26. Rooks DS, Silverman CB, Kantrowitz FG. The effects of progressive strength training and aerobic exercise on muscle strength and cardiovascular fitness in women with fibromyalgia: a pilot study. Arthritis Rheum 2002;47:22-8.
27. Meyer BB, Lemley KJ. Utilizing exercise to affect the symptomology of fibromyalgia: a pilot study. Med Sci Sports Exerc 2000; 32:1691-7.
28. American College of Sports Medicine Position Stand. The recommended quantity and quality of exercise for developing and maintaining cardiorespiratory and muscular fitness, and flexibility in healthy adults. Med Sci Sports Exerc 1998;30:975-91.
29. Rivera J, Gonzalez T. The Fibromyalgia Impact Questionnaire: a validated Spanish version to assess the health status in women with fibromyalgia. Clin Exp Rheumatol 2004;22:554-60.
30. Burckhardt CS, Clark SR, Bennett RM. The fibromyalgia impact questionnaire: development and validation. J Rheumatol 1991;18: 728-33.
31. Mannerkorpi K, Ekdahl C. Assessment of functional limitation and disability in patients with fibromyalgia. Scand J Rheumatol 1997;26:4-13.
32. Bennett R. The Fibromyalgia Impact Questionnaire (FIQ): a review of its development, current version, operating characteristics and uses. Clin Exp Rheumatol 2005;23(Suppl 39):154-62.
33. Spielberger CD, Gorsuch RL, Lushene RE. STAI: Manual del Cuestionario de Ansiedad Estado-Rasgo. Madrid: TEA Ediciones; 2002.

34. Spielberger CD, Gorsuch RL, Lushene RE. STAI: Manual for the State-Trait Anxiety Inventory (self evaluation questionnaire). Palo Alto: Consulting Psychologists Pr; 1970.
35. Altchiler L, Motta R. Effects of aerobic and nonaerobic exercise on anxiety, absenteeism, and job satisfaction. J Clin Psychol 1994;50:829-40.
36. Macias Fernandez JA, Royuela Rico A. La versión española del índice de calidad de sueño de Pittsburg. Informaciones Psiquiátricas 1996;146:465-72.
37. Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. Psychiatry Res 1989;28:193-213.
38. Agargun MY, Tekeoglu I, Gunes A, Adak B, Kara H, Ercan M. Sleep quality and pain threshold in patients with fibromyalgia. Compr Psychiatry 1999;40:226-8.
39. Osorio CD, Gallinaro AL, Lorenzi-Filho G, Lage LV. Sleep quality in patients with fibromyalgia using the Pittsburgh Sleep Quality Index. J Rheumatol 2006;33:1863-5.
40. Brittain JL, La Marche JA, Reeder KP, Roth DL, Boll TJ. Effects of age and IQ on Paced Auditory Serial Addition Task (PASAT) performance. Clin Neuropsychol 1991;5:163-75.
41. Moldofsky H, Lue FA, Natarajan MN, Reynolds WJ. Seasonality of pain, mood, energy and sleep in fibromyalgia vs. rheumatoid arthritis. Scand J Rheumatol 1992;94(Suppl):4.
42. Pollmann L. Fibromyalgia: chronobiological aspects. Chronobiol Int 1994;11:393-6.
43. Buckelew SP, Conway R, Parker J, et al. Biofeedback/relaxation training and exercise interventions for fibromyalgia: a prospective trial. Arthritis Care Res 1998;11:196-209.
44. Singh BB, Berman BM, Hadhazy VA, Creamer P. A pilot study of cognitive behavioural therapy in fibromyalgia. Altern Ther Health Med 1998;4:67-70.
45. King SJ, Wessel J, Bhambhani Y, Sholter D, Maksymowych W. The effects of exercise and education, individually or combined, in women with fibromyalgia. J Rheumatol 2002;29:2620-7.
46. Verstappen FT, van Santen-Hoeuftt HM, Bolwijn PH, van der Linden S, Kuipers H. Effects of a group activity program for fibromyalgia patients on physical fitness and well being. J Musculoskeletal Pain 1997;5:17-28.
47. Jones KD, Burckhardt CS, Clark SR, Bennett RM, Potempa KM. A randomized controlled trial of muscle strengthening versus flexibility training in fibromyalgia. J Rheumatol 2002;29:1041-8.
48. De Melo Vitorino DF, de Carvalho LB, do Prado GF. Hydrotherapy and conventional physiotherapy improve total sleep time and quality of life of fibromyalgia patients: randomized clinical trial. Sleep Medicine 2006;7:293-6.
49. Backhaus J, Junghanns K, Broocks A, Riemann D, Hohagen F. Test-retest reliability and validity of the Pittsburgh Sleep Quality Index in primary insomnia. J Psychosom Res 2002;53:737-40.
50. Hidalgo J, Rico-Villademoros F, Calandre EP. An open-label study of quetiapine in the treatment of fibromyalgia. Prog Neuropsychopharmacol Biol Psychiatry 2007;31:71-7.
51. McCaffrey RJ, Cousins JP, Westeervelt HJ, et al. Practice effects with the NIMH AIDS abbreviated neuropsychological battery. Arch Clin Neuropsychol 1995;10:241-50.
52. Grace GM, Nielson WR, Hopkins M, Berg MA. Concentration and memory deficits in patients with fibromyalgia syndrome. J Clin Exp Neuropsychol 1999;21:477-87.
53. Leavitt F, Katz RS. Distraction as a key determinant of impaired memory in patients with fibromyalgia. J Rheumatol 2006;33: 127-32.
54. Wigers SH, Stiles TC, Vogel PA. Effects of aerobic exercise versus stress management treatment in fibromyalgia. A 4.5 year prospective study. Scand J Rheumatol 1996;25:77-86.
55. Valim V, Oliveira L, Suda A, et al. Aerobic fitness effects in fibromyalgia. J Rheumatol 2003;30:1060-9.
56. Rikli RE, Jones CJ. Development and validation of a functional fitness test for community-residing older adults. J Aging Phys Act 1999;7:129-61.

Supplier

a. Polar Accurex Plus; Polar Electro Oy, Kempele, 90440, Finland.