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ORIGINAL REPORT

EIGHT MONTHS OF PHYSICAL TRAINING IN WARM WATER IMPROVES PHYSICAL AND MENTAL HEALTH IN WOMEN WITH FIBROMYALGIA: A RANDOMIZED CONTROLLED TRIAL

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Objective: **To evaluate the feasibility of 8 months of supervised exercise therapy in warm water and its effects on the impact of fibromyalgia on physical and mental health and physical fitness in affected women.**

Methods: **Thirty women with fibromyalgia were randomly assigned to an exercise therapy group ($n=15$) or a control group (inactive) ($n=15$). The impact of fibromyalgia on physical and mental health was assessed using the Fibromyalgia Impact Questionnaire and the anxiety state with State-Trait Anxiety Inventory. Physical fitness was measured using the following tests: Canadian Aerobic Fitness; hand-grip dynamometry; 10-metre walking; 10-step stair-climbing and blind 1-leg stance.**

Results: **After 8 months of training, the exercise therapy group improved compared with the control group in terms of physical function (20%), pain (8%), stiffness (53%), anxiety (41%), depression (27%), Fibromyalgia Impact Questionnaire total scores (18%), State-Trait Anxiety Inventory score (22%), aerobic capacity (22%), balance (30%), functional capacity for walking (6%), stair-climbing with no extra weight (14%) and stair-climbing 10 kg-weighted (25%).**

Conclusion: **Eight months of supervised exercise in warm water was feasible and led to long-term improvements in physical and mental health in patients with fibromyalgia at a similar magnitude to those of shorter therapy programmes.**

Keywords: **fibromyalgia, water, exercise, fitness, anxiety, depression.**

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INTRODUCTION

Fibromyalgia (FM) is a rheumatic disorder characterized by muscle pain, poor physical condition and fatigue (1, 2). The condition is frequently associated with psychological stress, high levels of anxiety and depressive status. Those symptoms have been treated effectively using physical exercise with low mechanical impact in water as well as on dry land (3–5).

Recent research into FM has focused on the effects of exercising exclusively in warm water, for a period of 12–24 weeks (6–8). The results have shown relevant improvements in the patients' physical condition and psychological status. In a previous study we showed that most of the gains in physical fitness and psychological stress achieved in 12 weeks of exercise tended to be lost after a subsequent similar period of physical inactivity (7). However, although water therapies may prove successful and result in improvements after a few weeks, the duration of the improvement remains very limited, and consequently, continued training is highly recommended.

Nevertheless, considering that previous experimental therapies in patients with FM lasted for a maximum of 24 weeks, knowledge of the effects and feasibility of extended water therapy in these patients is limited. This knowledge may be crucial for making decisions about the duration of aquatic therapy.

The aim of this study was therefore to evaluate the feasibility and effectiveness of 8 months of exercise training in warm water, 3 days per week, at a low, steady physical load.

SUBJECTS AND METHODS

Study sample

Participants were recruited by advertisements placed in the newsletters of a local FM association in Spain and the flow chart is described in Fig. 1. A total of 40 potentially eligible subjects responded and sought further information. The study protocol was explained, and 38 persons gave their written informed consent. Subjects were included if they met the diagnosis of FM according to the American College of Rheumatology (ACR) criteria (1). The following exclusion criteria were also applied: history of severe trauma; frequent migraines; peripheral nerve entrapment; inflammatory rheumatic diseases; severe psychiatric illness; other diseases that prevent physical loading and pregnancy; attendance at another psychological or physical therapy or regular physical exercise with more than one exercise session of 30 min per week during a 2-week period in the last 5 years. Five candidates were excluded due to attendance at other therapies. A final sample of 33 female patients, aged 37–71 years of age, intended to participate.

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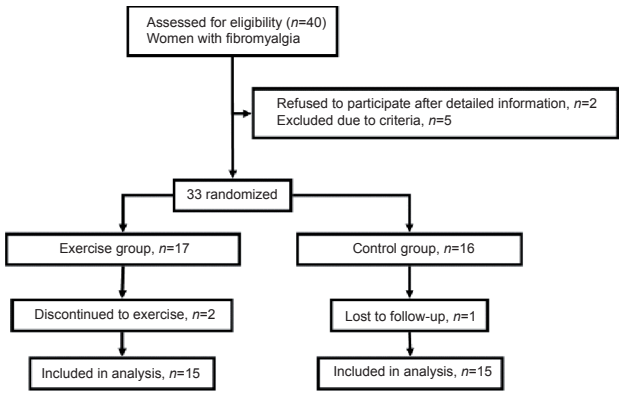

Fig. 1. Flow of participants through the trial.

All patients were randomized pair-wise into 2 groups, an exercise group (EG; $n = 17$) or a control group (CG; $n = 16$), by a staff member who was not otherwise involved in the study. Every 2 patients were randomized immediately after the physician had clinically examined them and checked they did not meet any of the aforementioned exclusion criteria (e.g. ACR criteria for FM, other diseases or that patients were sedentary with no attendance to other therapies of any kind in the last few years). This was done to ensure that neither researchers nor participant were able to choose the group influenced by their preferences, resulting in misleading conclusions to the trial. Two patients in the EG failed to attend for at least 95% of the treatment sessions due to personal reasons, while one of the patients in the CG also failed to attend for measurements due to personal reasons. These patients were consequently excluded from the statistical analyses. Finally, 15 patients in the EG (88%) and 15 in the CG (94%) fully completed the study protocol and their results were included in the analysis.

Assessments were performed at baseline and immediately after 8 months of physical training. All of them were performed by a laboratory assistant (i.e. an exercise physiologist specialized in the evaluation of the physical condition) different from the therapy instructor and the assistant involved in the randomization procedure, who was blinded to the patient's condition, group assignment in the trial and results in other tests and evaluations. This same laboratory assistant performed the pre- and post-therapy evaluations in order to reduce variability and improve consistency in the assessment process.

The trial was exclusively developed and performed at the University of Extremadura, Spain, with the approval of the Committee on Biomedical Ethics of the University of Extremadura and following the updates of the Declaration of Helsinki.

Fibromyalgia impact and anxiety status assessment

The Spanish version of the Fibromyalgia Impact Questionnaire (FIQ) (9) was used to evaluate the impact of FM on patients' physical and mental health. The FIQ has 8 sub-scales ranging from 0 = "no impact of the disease" to 10 = "very affected by the disease". Anxiety state was assessed using the Spanish version of the State-Trait Anxiety Inventory (STAI) (10) normalized to the international edition. The STAI is a 20-item questionnaire, offering a STAI score as outcome. A higher score on the scale of 20–80 indicated greater anxiety.

Physical fitness assessment

The Canadian Aerobic Fitness Test (11) was used to estimate maximal oxygen uptake ($VO_{2\,max}$). This test is a progressive, submaximal aerobic protocol, in which subjects step up and down a double step (40.6 cm), at a rhythm determined according to their age and sex. Stepping is performed with a 6-pace cycle: one foot on the middle step, both on the top step, one on the middle step, and both feet on the ground. The subject starts with a 3-min, specific warm-up. After that, there are 3 stages of 3 min, each at a different stepping rate. The subject's heart rate is monitored using a pulse meter (Polar Accurex Plus, Kempele Finland), to ensure that it remains within a specific "safety" zone. If the heart rate is appropriate after the first stage, the person may continue to the second period. After another 3 min of stepping, the heart rate is taken again. If the heart rate "safety" limit still has not been reached, the subject continues for a third stage, at an increased stepping rate. $VO_{2\,max}$ was later estimated based on performance level in the test, heart rate, age and gender, and considered as the outcome.

Hand-grip strength was assessed in both hands with a hand-dynamometer (TKK, Tokyo, Japan) and the mean measurement for both hands was considered to be the outcome (12). To evaluate functional capacity, 3 physical tests were performed: a maximal walking speed test over 10 m; 10-stairs climbing test; and a 10-stairs climbing test carrying a bag weighing 5 kg in each hand (13). Outcomes in these tests were recorded in sec using photocell devices. Flexibility was assessed using the sit-and-reach test (14). The distance (cm) from the extreme of the fingers in the starting to its final position during this trunk flexion was recorded. The best result out of 3 trials was considered as the outcome. Additionally, postural balance was assessed with a blind 1-leg stance test (15). The patient balanced on one leg with the other knee bent so that they could hold the foot on that side in the hand on the same side, with their eyes closed. This posture was assumed just prior to closing the eyes. Each time the patient lost balance, let go of their lifted leg and stepped on the floor, or used the security devices to maintain their posture, the stopwatch was paused. After each pause, the same procedure started again until completion of 30 sec of 1-leg stance position. The number of trials to complete 30 sec was recorded and considered as the outcome.

Exercise therapy

The EG participated in supervised training in a waist-high pool of warm water (33ºC) 3 times per week during the 8-month period. Each session lasted for 1 h and included 10 min of warming up with slow walks and easy movements of progressive intensity, 10 min of aerobic exercises at 60–65% of maximal heart rate (Hr_{max}), 20 min of overall mobility and lower limb strength exercises using water resistance (4 sets of 10 repetitions of unilateral flexion and extension of the knee at a slow pace with the body in a vertical position) and upper limb strength exercises without water resistance using light loads and elastic bands (4 sets of 10 repetitions of raising the arms over the head), another set of 10 minutes of aerobics at 60–65% Hr_{max}, and 10 minutes of cooling down with low intensity exercises. Heart rate was monitored using a pulse meter (Polar Accurex Plus, Kempele, Finland). During this 8-month period, participants in the CG continued their daily activities, which did not include any form of physical exercise similar to those in the therapy.

Data analysis

Normality of data was initially tested using the Kolgomorov-Smirnov test using the correction of Lillifors. Differences between the baseline characteristics of the EG and CG were tested using analyses of variance (ANOVA) for continuous variables, and the χ^2 test for categorical variables. The effects of the intervention programme were evaluated by age-adjusted analyses of covariance for repeated measures. For all tests the significance level was set at $p < 0.05$. The analyses were performed using SPSS 14.0 (SPSS Inc. Chicago, USA).

RESULTS

Table I presents the main characteristics of the participants in the EG and the CG. The baseline data did not show any significant differences in socio-demographic characteristics (Table I), disease impact anxiety status or physical fitness (Table II) between the EG and the CG. The rate of compliance with therapy sessions in the EG was 93 (standard deviation 2) times out of a maximum of 96 sessions.

Table I. *Socio-demographic characteristics of females with fibromyalgia at baseline*

	Exercise group $n=15$	Control group $n=15$	p-value
Age (years), mean (SD)	50.7 (10.6)	50.9 (6.7)	0.935*
Body mass index (kg/m^2), mean (SD)	28.8 (4.5)	26.6 (3.5)	0.147*
Duration of symptoms (years), mean (SD)	20.1 (8.0)	19.4 (6.9)	0.791*
Number of tender points (1–18 points), mean (SD)	16.9 (1.8)	17.2 (1.3)	0.563*
Number of specific drugs (antidepressives, muscular relaxants, analgesics), mean (SD)	1.3 (0.8)	1.5 (0.8)	0.379*
Employment status, *n* (%)			0.750†
Blue-collar	8 (53.3)	6 (40.0)	
White-collar	2 (13.3)	3 (20.0)	
Unemployed	5 (33.3)	6 (40.0)	
Education level, *n* (%)			0.184†
Unfinished studies	1 (6.7)	1 (6.7)	
Primary school	9 (60.0)	6 (40.0)	
Secondary school	1 (6.7)	6 (40.0)	
University degree	4 (26.7)	2 (13.3)	

*p-values of analysis of variance (ANOVA).
†p-values of analysis of χ^2.
SD: standard deviation.

Fibromyalgia impact and anxiety state

After 8 months of water exercise, significant improvements in the mean values of the treatment effects were found in the STAI score (22%), FIQ total scores (18%), physical function (20%), pain (8%), stiffness (53%), anxiety (41%) and depression (27%) in favour of the EG (Table II).

Physical fitness

The EG showed significant improvements in the mean values of the treatment effects in $VO_{2\,max}$ (22%), balance (30%), walking speed (6%) and stair-climbing with no extra weight (14%) and with the 10 kg weight (25%). The treatment did not produce significant improvements in hand grip and flexibility (Table II).

DISCUSSION

Hitherto, short exercise therapies have proven secure and feasible to reduce many of the symptoms of FM. However, it was not known whether patients with FM could engage in physical therapies of much longer duration, which might have a longer lasting effect. The main finding in the present investigation was that 8 months of water exercise resulted in a high retention of patients and gains, similar to those of shorter programmes (7, 16). In this time the patients' psychological wellbeing (e.g. anxiety and depression), physical fitness (e.g. physical functioning, aerobic capacity, balance, and muscle stiffness) and pain could improve.

Psychological benefits in anxiety, depression and other somatic symptoms of FM have been reported previously as a result of water exercise therapy (17). In this study the levels of anxiety and depression in the EG decreased moderately, as measured with the FIQ, as did the anxiety status measured with

Table II. *Impact of fibromyalgia on physical and mental health, anxiety state and physical fitness at baseline, and changes after 8 months of physical training in warm water*

		Baseline		After 8 months' training			
		Exercise $n=15$	Control $n=15$	Exercise $n=15$	Control $n=15$	Treatment effect	
Assessment	Dimension	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (95% CI)	p†
FIQ	Total score	6.1 (1.2)	6.3 (1.3)	5.2 (1.6)	6.5 (1.0)	–1.1 (–1.8 to –0.5)	0.017
	Physical function	3.0 (1.5)	3.7 (1.5)	2.4 (1.7)	3.7 (2.0)	–0.6 (–1.5 to 0.4)	0.047
	Feel bad	6.8 (2.7)	8.0 (1.6)	6.9 (2.8)	8.0 (1.9)	0.1 (–1.9 to 2.2)	0.212
	Pain	5.6 (1.9)	6.4 (2.3)	5.3 (1.4)	6.6 (1.8)	–0.5 (–1.8 to 0.7)	0.040
	Fatigue	7.2 (2.1)	8.3 (1.9)	6.6 (2.2)	7.1 (2.2)	0.6 (–0.5 to 1.7)	0.465
	Morning tiredness	7.7 (2.1)	6.8 (2.1)	7.1 (2.1)	6.9 (1.7)	–0.7 (–1.5 to 0.1)	0.804
	Stiffness	6.4 (1.5)	4.9 (2.9)	4.4 (2.4)	6.3 (1.6)	–3.4 (–5.4 to –1.4)	0.015
	Anxiety	6.5 (2.7)	5.7 (2.5)	4.7 (2.7)	6.6 (2.1)	–2.7 (–4.2 to –1.2)	0.037
	Depression	5.4 (2.6)	6.0 (2.1)	4.0 (3.3)	6.1 (1.7)	–1.5 (–3.5 to 0.5)	0.030
STAI	State anxiety	45.1 (9.9)	41.9 (8.0)	37.5 (8.0)	44.4 (8.9)	–10.1 (–19.5 to –0.6)	0.035
Physical fitness	Maximal oxygen uptake (ml/kg/min)	23.9 (3.6)	23.1 (2.9)	26.8 (2.6)	24.2 (2.9)	1.8 (–0.1 to 3.6)	0.015
	Hand grip strength (kg)	36.7 (11.6)	38.1 (15.9)	39.1 (11.0)	34.2 (11.7)	6.3 (–0.7 to 13.5)	0.249
	10-step stair-climbing weightless (sec)	4.3 (0.7)	4.7 (0.8)	4.1 (0.4)	5.1 (1.1)	–0.6 (–1.2 to –0.1)	0.003
	10-step stair-climbing with 10 kg weight (sec)	5.1 (1.0)	5.8 (2.2)	4.5 (0.5)	6.5 (2.3)	–1.3 (–2.1 to –0.5)	0.002
	10-m maximal walking speed (m/sec)	1.8 (0.3)	1.6 (0.3)	1.9 (0.2)	1.6 (0.3)	0.1 (–0.1 to 0.3)	0.006
	Flexibility – "Sit & Reach" (cm)	20.9 (8.6)	16.6 (7.1)	21.0 (8.9)	15.9 (6.0)	0.8 (–3.6 to 5.2)	0.072
	Balance (trial to 30 sec)	23.1 (7.2)	23.2 (6.4)	15 (10.0)	22.1 (8.7)	–7.0 (–16.0 to 1.8)	0.031

†p-values of analysis of variance to compare differences between groups at 8 months.
FIQ: Fibromyalgia Impact Questionnaire (scale 0–10); STAI: State-Trait Anxiety Inventory Questionnaire (scale 20–80); SD: standard deviation; CI: confidence interval.

the STAI. These results are consistent with previous findings showing improvements of a similar range (6, 17–20). Somatic symptoms, pain and muscle stiffness also improved, similar to the results observed in previous studies of shorter duration (up to 24 weeks) (6, 8, 18, 19).

In the present trial, patients also showed improvements in walking speed and stair climbing, and the results were slightly better than those obtained in previous shorter studies. Additionally, our therapy of 8 months of low intensity exercise (60–65% of Hr_{max}) resulted effectively in a moderate improvement in the patient's $VO_{2\,max}$. The patients had relatively low aerobic capacity at the beginning of the study compared with the healthy population (21), and this was somewhat improved by the therapy. Although not all previous studies demonstrated improvements in patients' $VO_{2\,max}$, our results are in accordance with those that also showed improvements (18, 22). In healthy adults, the intensity, frequency and total duration of the training period appear to interact to produce improvements in $VO_{2\,max}$ (23). Therefore, considering the long duration of our study, greater improvements could have been expected. However, improvements in our patients' $VO_{2\,max}$ may have been limited by the steady low-to-moderate exercise intensity. Unfortunately, due to limitations imposed by the study design, we cannot ensure the progression and sequence of further improvements induced by the training.

Another major finding in the present trial was the improvement in patient balance. Previous studies have shown reduced balance capacity among patients with FM compared with healthy adults (24). The participants in the present study also showed reduced balance capacity compared with normative values for healthy adults of the same age (25). In the present trial we found a 30% enhancement, similar in magnitude to our previous study of shorter duration (3-months and follow-up) (16), although the final values after completion of the trial remained below the normative levels for the Spanish healthy adult population.

Overall, despite the long duration of training in this study, the final results from most of the tests showed improvements within the range of those achieved in shorter therapies. A possible explanation for the limited results may be related to the low and steady intensity of the training, and it is likely that most of the improvements were achieved at the beginning of the therapy. As our study design did not include a mid-term follow-up, we cannot provide further information regarding patients' progression in the different variables. Further explanations may be possible, such as the possibility of a limited recuperation in the patients' condition. Evidence-based analysis from future randomized controlled trials may elucidate the most favourable rhythm of progression, optimal physical loads, weekly frequency and session duration that patients with FM can assume.

The present study also included several limitations, which require further discussion. The limited size of the sample may have contributed to decreased statistical power to detect changes in some variables. However, our trial showed positive effects in most variables measured and changes due to the treatment effect were easily detected. Our results are consistent with the literature, although the conclusions herein must be drawn with caution because of the somewhat small sample size. Furthermore participants were characterized by their gender (female), age (mean 51 years old), long duration of symptoms (mean 20 years) and high number of tender points (mean 17 tender points). Therefore, the present study presented the feasibility of this long-lasting exercise programme in adult women with long duration of symptoms and higher number of tender points. However, we must be very cautious about applying our conclusions to other populations with different backgrounds.

In conclusion, the present study showed that regular and long-lasting exercise at a moderate training intensity of 60–65% Hr_{max} in warm water was feasible and effective to improve physical and mental functioning in women with FM. The patients who exercised improved their aerobic capacity, mobility and balance capacity. In addition they experienced benefits in anxiety status, physical functioning, pain management, stiffness and depressive symptoms. These results provide evidence that FM patients can safely undergo long-term water therapies of low intensity.

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