

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

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Objective. To evaluate the short- and long-term efficacy of exercise therapy in a warm, waist-high pool in women with fibromyalgia.

Methods. Thirty-four women (mean \pm SD tender points 17 ± 1) were randomly assigned to either an exercise group (n = 17) to perform 3 weekly sessions of training including aerobic, proprioceptive, and strengthening exercises during 12 weeks, or to a control group (n = 17). Maximal unilateral isokinetic strength was measured in the knee extensors and flexors in concentric and eccentric actions at 60°/second and 210°/second, and in the shoulder abductors and adductors in concentric contractions. Health-related quality of life (HRQOL) was assessed using the EQ-5D questionnaire; pain was assessed on a visual analog scale. All were measured at baseline, posttreatment, and after 6 months.

Results. The strength of the knee extensors in concentric actions increased by 20% in both limbs after the training period, and these improvements were maintained after the de-training period in the exercise group. The strength of other muscle actions measured did not change. HRQOL improved by 93% ($P = 0.007$) and pain was reduced by 29% ($P = 0.012$) in the exercise group during the training, but pain returned close to the pretraining level during the subsequent de-training. However, there were no changes in the control group during the entire period.

Conclusion. The therapy relieved pain and improved HRQOL and muscle strength in the lower limbs at low velocity in patients with initial low muscle strength and high number of tender points. Most of these improvements were maintained long term.

KEYWORDS. Fibromyalgia; Muscle strength; Pain; Quality of life; Exercise.

INTRODUCTION

Patients with fibromyalgia (FM) have muscle weakness (1), widespread muscle pain, and lower pressure pain thresholds of tender sites in the upper and lower limbs (2,3). In addition to pain, the most prominent symptoms in FM are

localized to peripheral soft tissues, and there have been numerous studies of abnormalities in muscle structure and function in individuals with FM. The muscle tissues of these individuals are reportedly characterized by ultrastructural abnormalities and DNA fragmentation not related to apoptosis, aging, or deconditioning (4).

Muscle strength depends on both the cross-sectional area of the muscle and the neural activity. The cross-sectional area of the quadriceps femoris muscle has been reported to be within normal ranges in persons with FM (5,6). However, some studies have shown that maximal isometric and dynamic muscle strength in short tests (1–5 repetitions) is lower in persons with FM than in healthy individuals (1,5,7,8); however, these reports have been contradicted in the longer tests that are more related to resistance (9,10). The reduced maximal muscle strength of knee extensors has been associated with lower outcomes in functional tests related to daily living (sit up and sit down on a chair, walking) in persons with FM (11) and with the increase of disability, especially in females with

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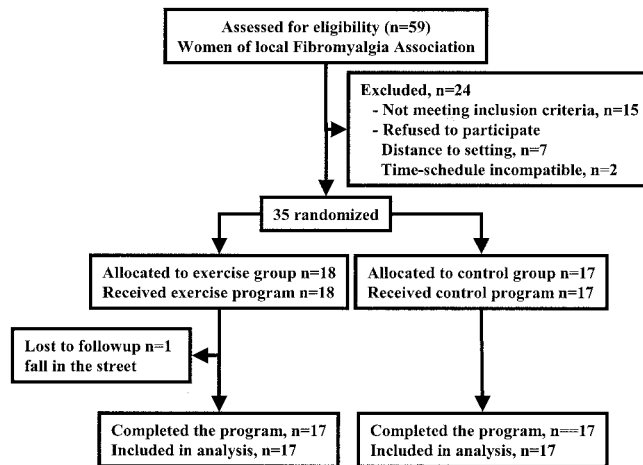


Figure 1. Flow of participants throughout trial.

rheumatoid arthritis (12). In fact, the decline of knee extensors strength has been associated with gait disorders, falls, and loss of independence (13).

Physical exercise with low mechanical impact such as Tai Chi, yoga, low-impact aerobics, walking, or water aerobics has been frequently recommended in the treatment of FM (14–17). Balneotherapy, or warm-water baths, has also been shown to be effective in managing muscle pain, usually assessed by subjective methods such as rating pain with the visual analog scale (VAS) and the index of the Fibromyalgia Impact Questionnaire (18). Despite the additional effects of warm water, the facilities required for warm-water programs are more expensive and scarce than those usually used for land programs; therefore, several authors have proposed mixed water- and land-based programs (18) or rotating the patients who exercised in water. In this sense, there is a lack of knowledge about the remaining effects or long-term effects of water-based exercise protocols.

In earlier studies, warm-water pools and land-based exercises have shown a similar capacity to reduce pain and fatigue. They have also been shown to improve cardiovascular capacity, walking time, and mental health (19). However, the impact of pool exercise on strength remains mainly unknown (20) and needs to be studied in more detail (21). The purpose of the present study was 1) to evaluate the short-term effect of 12 weeks of exercise therapy in a waist-high pool of warm water on muscle strength, pain, and health-related quality of life (HRQOL) in women with FM, and 2) to evaluate the long-term or remaining effects after a subsequent 12-week de-training period.

SUBJECTS AND METHODS

Participants. An invitation to participate in the study was sent to all female members ($n = 63$) of a local FM association in Spain. Fifty-nine potentially eligible subjects responded and sought more information. Those 59 eligible persons gave their written informed consent after

the study protocol was explained to them. The study flow of participants is presented in Figure 1. Participants' personal medical records were examined and updated by a physician, and their diagnosis of FM was also confirmed according to the American College of Rheumatology criteria (22).

The exclusion criteria included the presence of any severe disorders of the spine, such as a prolapsed disk and spinal stenosis. Subjects with a history of severe trauma, frequent migraines, peripheral nerve entrapment, inflammatory rheumatic diseases, and severe psychiatric illness were also excluded. In addition, subjects with other diseases that prevent physical loading and those who were pregnant were also omitted. Finally, those women with FM who attended another psychological or physical therapy were excluded to avoid possible interactions with the present trial, which included a de-training period. Patients with a history of more than one 30-minutes exercise session per week during 2 weeks in the last 5 years would have been excluded from the final analysis, but none of the eligible women exercised regularly, except for easy walking and work, in the last 8 years. On the whole, 15 persons were excluded from the study because they were attending a psychological therapy program ($n = 9$) or had inflammatory rheumatic disease ($n = 4$), severe disorder of the spine ($n = 1$), or psychiatric illness ($n = 1$). According to the exposed criteria, a final sample of 35 women with FM between ages 35 and 73 years were randomly assigned to either an exercise training group or a control group.

The evaluation of the primary outcome measures was carried out immediately after the training period at 12 weeks, and again at 24 weeks after 12 weeks of de-training for the exercise group. The initial measurements before the training period started were designated as baseline values.

The Committee on Biomedical Ethics of the University of Extremadura (Spain) gave approval for the study. The intervention program and the measurements were performed in the Faculty of Sport Sciences of the University of Extremadura.

Isokinetic muscle strength measurement. Maximal torque of the knee extensors and flexors, and of the shoulder abductors and adductors was recorded using the Biodex System-3 Isokinetic Dynamometer (Biodex, Shirley, NY). Each subject was attached to the seat of the dynamometer so that the axis of the knee or shoulder coincided with the axis of the dynamometer, following standardized protocols (23). At the start of each test, the subject was asked to relax his or her leg or shoulder, so that passive determinations of the effects of gravity on the limb were determined and corrected for the outcome. Testing was performed using hard deceleration cushion. Maximal flexion and extension of the knee was first measured in concentric action at slow ($60^\circ/\text{second}$) and fast ($210^\circ/\text{second}$) velocities, and then in eccentric action at a slow velocity only ($60^\circ/\text{second}$) (24). The motion ranged from 80° of knee flexion to full extension. Maximal abductions and adductions of the shoulder were measured at a speed of $60^\circ/\text{second}$ from 45° to 135° , with the elbow in 90° flexion.

Table 1. Characteristics of women with fibromyalgia who followed the pool-based exercise program and controls*

Group	Exercise (n = 17)	Control (n = 17)	P
Age, years	51 ± 10	51 ± 9	0.986
Body mass index, kg/m ²	27 ± 5	27 ± 4	0.597
Duration of symptoms, years	24 ± 9	19 ± 8	0.155
Number of tender points (1–18)	17.3 ± 1.2	17.1 ± 1.4	0.517
Number of specific drugs (antidepressives and muscular relaxants)	2.8 ± 1.1	2.8 ± 1.2	0.882
Type of work, %			0.931
Unemployed	35.2	41.2	
White collar	17.8	17.8	
Blue collar	47.0	41.0	

* Values are the mean ± SD unless otherwise indicated.

Each subject performed 3 trials at moderate intensity before each test to become familiar with movement and velocity. During the actual test, subjects were asked to repeat 3 maximal complete movements, first with the dominant limb. They were verbally encouraged during the performance. Participants rested 2 minutes between each trial (25). The highest gravity-corrected peak moment value (peak torque) at a predetermined velocity and filtered output was rounded to the nearest 0.1 value and recorded for further analysis.

Health related-quality of life and pain. The Spanish version of the EQ-5D (26) was used to assess 5 dimensions of HRQOL: mobility, self care, daily activities, pain and discomfort, and anxiety or depression. The scale for the dimensions ranges from 1 to 3 (no problems, some problems, or extreme problems/unable to do). Using combinations of these dimensions, there is a total of 243 possible health states. Each health state has been previously defined using the time tradeoff method of utility analysis based on the responses of a sample of the Spanish population (27). This EQ-5D_{utility} was scaled from 1 (full functional quality of life) to 0 (death). This nonspecific disease score is useful for comparing the cost utility of different interventions in health care, so the report of this utility could help make decisions in health care management. Participants also completed a VAS reflecting pain (0 = no pain; 100 = worst possible pain).

Spare time and work activities questionnaire. To detect possible interaction with other forms of physical activity, all participants were asked to complete a questionnaire concerning their spare time and work activities. This questionnaire included items about physical activity habits (habitual walking, running, jogging, aerobics, or others), activities of daily living (shopping, ironing, doing the laundry, visiting friends and relatives, or others), work activities (unemployed, blue-collar worker, or white-collar worker), and whether subjects were receiving other physical or psychological treatment. As outlined above, presence of regular physical exercise (more than once per

week) or another physical or psychological therapy were exclusion criteria at any time during the study.

Exercise therapy. The exercise group trained in a waist-high warm pool (33°C) 3 times per week for 12 weeks. Each 1-hour session included 10 minutes of warming up with slow walks and mobility exercises, 10 minutes of aerobic exercises at 65–75% of maximal heart rate (HR_{max}), 20 minutes of overall mobility and lower-limb strength exercises (4 sets of 10 repetitions of unilateral flexion and extension of the knee at slow pace with the body in a vertical position using water as resistance), another set of 10 minutes of aerobics at 65–75% HR_{max}, and 10 minutes of cooling down with low-intensity exercises. Heart rate was monitored with a pulse meter (Polar Accurex Plus; Polar Electro Oy, Kempele, Finland). At the end of the 12-week therapy, all patients were instructed to avoid physical exercise training until the next evaluation. During the entire 24-week period, the control group continued to follow normal daily activities, which did not include any form of exercise related to those in the therapy.

Statistical analysis. The normality of the variables was evaluated by the Kolmogorov-Smirnov test, with Lilliefors significance. The results are expressed as the mean ± SD or 95% confidence interval. The effects of the intervention program were evaluated by age- and weight-adjusted analysis of covariance for repeated measures. The significance level was determined at $P < 0.05$. Statistical analysis was carried out using SPSS for Windows 12 (SPSS, Chicago, IL).

RESULTS

Seventeen (94%) of 18 exercisers who attended >34 of the 36 sessions completed the followup at 24 weeks (Figure 1). One woman from the exercise group dropped out following an accident in the street. Seventeen women from each group fully completed the study and were included in the analysis. The cost of the supervised exercise program was €112 per person for 3 months.

Tables 1 and 2 show similar baseline characteristics for

Table 2. Effects of a 12-week warm-water exercise program in a therapeutic pool and 12 weeks of de-training on functional health-related quality of life measured with the EQ-5D in women with fibromyalgia syndrome assigned to the exercise group (n = 17) or control group (n = 17)*

Measured	Baseline	Change from baseline to 12 weeks		Change from baseline to 24 weeks	
	Mean \pm SD	Mean (95% CI)	P†	Mean (95% CI)	P†
Pain (0–100)					
Exercise	63.1 \pm 26.0	–18.4 (–31.5, –5.3)	0.012	–1.6 (–12.7, 0.9)	0.693
Control	63.9 \pm 25.0	1.0 (–7.2, 9.3)		0.9 (–7.3, 9.2)	
EQ-5D (scale 0–1)					
Exercise	0.29 \pm 0.28	0.27 (0.12, 0.42)	0.007	0.14 (–0.03, 0.32)	0.138
Control	0.32 \pm 0.32	–0.02 (–0.18, 0.13)		–0.02 (–0.17, 0.13)	
EQ-5D dimensions (scale 1–3)					
Mobility					
Exercise	1.9 \pm 0.3	–0.3 (–0.5, –0.1)	0.029	–0.2 (–0.5, –0.1)	0.056
Control	1.8 \pm 0.4	0.1 (–0.2, 0.3)		0.1 (–0.2, 0.3)	
Self care					
Exercise	1.8 \pm 0.4	–0.5 (–0.7, –0.2)	0.001	–0.4 (–0.6, –0.1)	0.004
Control	1.7 \pm 0.5	0.1 (–0.1, 0.2)		0.1 (–0.1, 0.2)	
Daily living					
Exercise	2.1 \pm 0.3	–0.4 (–0.6, –0.1)	0.112	–0.2 (–0.4, 0)	0.155
Control	2.0 \pm 0.3	–0.1 (–0.3, 0.1)		–0.1 (–0.2, 0.1)	
Pain/discomfort					
Exercise	2.5 \pm 0.5	–0.4 (–0.7, –0.1)	0.047	–0.1 (–0.4, 0.3)	0.789
Control	2.5 \pm 0.5	0 (–0.3, 0.3)		0 (–0.3, 0.3)	
Anxiety/depression					
Exercise	2.2 \pm 0.6	–0.4 (–0.7, –0.1)	0.023	–0.5 (–0.8, –0.1)	0.011
Control	2.2 \pm 0.6	0 (–0.2, 0.2)		0 (–0.2, 0.2)	

* 95% CI = 95% confidence interval.
† Difference between the groups.

the intervention and control groups. The number of tender points remained unchanged in both groups during the followup. Excluding the intervention program, participants did not change their physical activity level during the entire period of research.

There were statistically significant improvements in the EQ-5D_{utility} and in all of its dimensions in the exercise group after the training period. All dimensions, except daily living, were favorable in the exercise group after the training period. The gain in the pain dimension was lost after the subsequent 12 weeks of de-training. No changes occurred in the HRQOL of the control group. Consistently, the decrease in pain measured by VAS was significant during the training period (29%), but the improvement disappeared during the de-training in the exercise group. In the control group, pain levels remained unchanged during the entire 24-week period (Table 2).

After the 12-week exercise period, maximal strength of the knee extensors at 60°/second significantly improved by 20% on the right and left side in the exercise group, and that of knee flexors improved by 33% on each limb (Table 3). These changes remained after the subsequent 12 weeks of de-training in the exercise group. No changes were found in eccentric knee flexion at 60°/second or in concentric knee flexion or extension at 210°/second in either group. The minor changes in concentric strength of the shoulder abductors and adductors were statistically non-significant in both groups (Table 4).

DISCUSSION

The present 12-week pool exercise program led to significant and clinically relevant gains in muscle strength of the knee extensors at low velocities, which is a major predictor of activities of daily living dependency in tasks such as stair climbing or sitting up from a chair (11,13,28). However, the program did not improve the muscle strength at medium-high velocities, which are more linked to gait speed (29). This finding reflects the nature of water training, in which reduced-gravity conditions decrease body-weight resistance but increase resistance throughout the range of movement. This is because water is ~800 times denser than air (30). Furthermore, the resistance to movement increases with speed in water, quadrupling the drag produced by water when the velocity doubles (31). The muscular action as measured by the isokinetic dynamometer in the current study is similar to movement in an aquatic environment. Speed is a crucial factor in continuous water resistance, and external gravity loads applied to the lower extremities are reduced in comparison with those produced in more ballistic movements in land-based exercise.

The comparison between the effects of resistance training on land and in water is largely unknown. The few studies that compared the effects of land- and water-based exercise programs did not find significant differences in quadriceps strength after 8 weeks of training in healthy

Table 3. Effects of a 12-week warm-water training program and 12 weeks of de-training on the isokinetic strength of knee flexion/extension in women with fibromyalgia syndrome assigned to an exercise group (n = 17) or control group (n = 17)*

Muscles	°/second	Baseline	Change from baseline to 12 weeks		Change from baseline to 24 weeks	
		Mean ± SD	Mean (95% CI)	P†	Mean (95% CI)	P†
Right knee						
Extensors (ec)	60					
Exercise		1.6 ± 0.5	0.1 (0.0, 0.3)	0.061	0.0 (-0.2, 0.2)	0.049
Control		1.9 ± 0.5	-0.1 (-0.4, 0.1)		-0.3 (-0.5, -0.1)	
Extensors (cc)	60					
Exercise		1.0 ± 0.4	0.2 (0.1, 0.3)	0.041	0.3 (0.1, 0.4)	0.115
Control		1.1 ± 0.4	0.0 (-0.1, 0.2)		0.1 (0.0, 0.2)	
Flexors (cc)	60					
Exercise		0.3 ± 0.2	0.1 (0.0, 0.2)	0.080	0.1 (0.0, 0.2)	0.631
Control		0.4 ± 0.2	0.0 (-0.3, 0.1)		0.1 (0.0, 0.1)	
Extensors (cc)	210					
Exercise		0.5 ± 0.2	0.1 (0.0, 0.1)	0.802	0.2 (0.1, 0.3)	0.864
Control		0.6 ± 0.2	0.1 (-0.2, 0.2)		0.2 (0.1, 0.3)	
Flexors (cc)	210					
Exercise		0.2 ± 0.1	0.1 (0.0, 0.1)	0.420	0.1 (0.0, 0.2)	0.925
Control		0.3 ± 0.2	0.0 (0.0, 0.1)		0.1 (0.0, 0.2)	
Left knee						
Extensors (ec)	60					
Exercise		1.6 ± 0.4	0.2 (0.0, 0.4)	0.105	0.2 (0.0, 0.4)	0.151
Control		1.9 ± 0.6	0.0 (-0.2, 0.2)		0.0 (-0.2, 0.2)	
Extensors (cc)	60					
Exercise		1.0 ± 0.4	0.2 (0.1, 0.3)	0.009	0.2 (0.0, 0.3)	0.061
Control		1.2 ± 0.4	0.0 (-0.2, 0.1)		0.0 (-0.1, 0.1)	
Flexors (cc)	60					
Exercise		0.3 ± 0.2	0.1 (0.0, 0.1)	0.004	0.1 (0.0, 0.1)	0.007
Control		0.5 ± 0.2	0.0 (-0.1, 0.0)		0.0 (-0.1, 0.0)	
Extensors (cc)	210					
Exercise		0.5 ± 0.2	0.1 (0.0, 0.2)	0.945	0.1 (0.0, 0.2)	0.441
Control		0.7 ± 0.2	0.1 (0.0, 0.2)		0.1 (0.0, 0.2)	
Flexors (cc)	210					
Exercise		0.2 ± 0.1	0.1 (0.0, 0.1)	0.227	0.0 (0.0, 0.1)	0.750
Control		0.3 ± 0.2	0.0 (0.0, 0.1)		0.1 (0.0, 0.2)	

* Values expressed in N·m·kg⁻¹. 95% CI = 95% confidence interval; ec = eccentric; cc = concentric.

† P values of analysis of variance to compare the differences of change between groups.

young women (32), nor did they find significant differences in trunk or grip strength after 12 weeks of training in healthy older women (33). Earlier studies using land-based resistance training in persons with FM consistently reported strength improvements and, for example, a 24% increase in isometric strength and 39–51% improvements in 1 maximal repetition strength (34,35). An 8-week water exercise program increased knee extension strength by 16% in patients with rheumatoid arthritis whose initial values were 70% of that found in healthy controls (36). In contrast, a 10-week course of progressive resistance-type aquatic training led to a 7% increase in isokinetic torque of the knee flexors and extensors at 60°/second in healthy women (31). These increases in strength were accompanied by 28% and 20% increases in quadriceps and hamstring electromyography activity, respectively. The same study also showed a 5% increase in the cross-sectional area of the thigh muscles, demonstrating that the improvements were due to both neural and structural neuromuscular changes.

The high improvements of the current study in strength

of the extensors (20%) and flexors (33%) of both knees in isokinetic concentric actions at slow speed (60°/second) may reflect the specific neuromuscular nature of the present training program, which included aerobics and as many as 4 sets of 10 repetitions of unilateral knee flexion/extension. Also, the rather low initial isokinetic knee-extension strength of the present participants at baseline, corresponding to 50% of the reference of healthy women depicted from literature (1), may in part explain the large training-induced strength gains. In addition, the high enhancement of knee flexors strength could be explained by hydrodynamic principles. In the lower extremities, the resistance of the water reduced the velocity of the exercises, and thus no improvement occurred in the knees at higher velocities (210°/second), reflecting again the specificity of water training. The constant water resistance to movement during knee flexion and extension differs from the ballistic and free movements on land with only air opposition (weight lifting, aerobics, etc.), and the loading modality is closer to isokinetic muscular actions. In contrast, the improvements of isokinetic knee strength at low

Table 4. Effects of a 12-week warm-water training program and 12 weeks de-training on isokinetic concentric abduction/adduction strength of the shoulder at 60°/second in women with fibromyalgia syndrome assigned to an exercise group (n = 17) or control group (n = 17)*

Muscles	Baseline	Change from baseline to 12 weeks		Change from baseline to 24 weeks	
	Mean \pm SD	Mean (95% CI)	P†	Mean (95% CI)	P†
Right shoulder					
Abductors					
Exercise	21 \pm 7	4 (-1, 8)	0.102	2 (-2, 5)	0.076
Control	23 \pm 6	-1 (-4, 2)		-3 (-5, 0)	
Adductors					
Exercise	22 \pm 10	-1 (-4, 3)	0.806	-1 (-4, 3)	0.344
Control	22 \pm 7	-1 (-1, 4)		0 (-2, 2)	
Left shoulder					
Abductors					
Exercise	20 \pm 6	1 (-3, 5)	0.577	-3 (-8, -2)	0.079
Control	22 \pm 6	-2 (-4, 1)		2 (-4, 1)	
Adductors					
Exercise	22 \pm 8	-1 (-4, 2)	0.312	-1 (-4, 1)	0.353
Control	24 \pm 12	1 (-3, 6)		1 (-3, 5)	

* Values expressed in N·m. 95% CI = 95% confidence interval.
† P values of analysis of variance to compare the differences of change between groups.

velocities in concentric actions were above the onset of clinical relevance set at 20% (37), whereas those in eccentric actions were below the clinical relevance.

In contrast, the current training program failed to have any significant effect on upper-limb strength because the lack of water resistance above the waist limited the effects on upper-limb muscles. This result is in accordance with another study of 20 weeks of pool-based training in subjects with FM (19) and a study of deep-water running exercise in athletes (38).

Both balneotherapy and dry-land training have previously been shown to be effective in reducing FM symptoms such as the number of tender points and pain (39–42). Geel and Robergs (34) reported a 50% improvement in pain measured by VAS after resistance training. Redondo et al (43) found an improvement of 40% in bodily pain measured by Short Form 36, but they did not detect a significant gain in pain on VAS after 8 weeks of training with 5 different sessions per week (one of them in water). Jentoft et al (19) also detected higher reductions in pain after 2 sessions per week during 20 weeks of training in a heated pool (19%; $P < 0.01$) than in the land-based program (10%; $P =$ not significant). Mannerkorpi et al (44) demonstrated significant pain reduction (15%) after 1 pool-based session per week during 6 months; this reduction was maintained during the 2 years of followup with exercise. In the current study, the training of 3 sessions per week in warm water decreased pain measured on VAS by 29% and the pain/discomfort item of the EQ-5D by 16%. However, the pain values returned to baseline values after the cessation of training. Combining the results of earlier investigations and those of the present study, we may infer that pain relief is related to a higher length and frequency of warm-water exercise sessions per week. In contrast, although subjects with FM usually report pain in muscles,

intensive strength training in water did not aggravate the symptoms.

Although the EQ-5D has been used in cross-sectional studies in patients with FM (45–47), the current study is, to our knowledge, the first longitudinal research using the EQ-5D. The EQ-5D_{utility} is a useful tool for calculating the number of quality adjusted life years gained and for making decisions for health managers and economists by comparing the cost utility of different treatments in several diseases (48). The current training program obtained relevant improvements in all 5 HRQOL dimensions. The improvements in the self-care and depression dimensions were even maintained after the subsequent de-training. In earlier studies, Redondo et al (43) did not detect changes in depression measured by Beck's Depression Inventory after 8 weeks of mixed training. However, longer trials conducted by Mannerkorpi and Iversen (17) and Jentoft et al (19) that also used physical exercise found 16–23% decreases in anxiety and 18–35% decreases in depression. Furthermore, Gowans et al (41) detected a significant correlation between amount of physical training and the Beck Depression Inventory after 12 months of exercising. Therefore, it seems that sufficient intensity, length, and frequency of training is needed to create positive effects of exercise on mood. As far as the current exercise program was performed in a group, the improvements in the anxiety/depression dimension and in overall HRQOL could be partially explained by the biologic effects of training, the interaction with the trainer, and sharing experiences of living with FM with other participants (49).

Previous studies have analyzed the changes at 6–12 months after the end of the exercise trial, and participants were encouraged or instructed to continue exercising regularly. However, the results of these studies have been controversial. Mannerkorpi et al (44) and Gowans et al (41)

reported that participants retained most of the gains in mood and pain that they achieved in the exercise period; however, Redondo et al (43) and Jentoft et al (19) reported that participants lost most of their gains. In the current study, the participants neither continued the intervention nor received instructions to continue exercising by themselves. In fact, they were instructed to remain physically untrained. After a 12-week break, most of the improvements in muscle strength and HRQOL were maintained, but the pain reduction gained during training was lost during the de-training.

The main limitations of the current study had to do with the characteristics of the sample and sample size related to the primary outcomes: 1) the HRQOL expressed as the time-tradeoff utility of the EQ-5D and the perceived pain using the VAS scale, and 2) the maximal torque of the knee extensors at 60°/second during concentric actions. At baseline, the participants' score of the EQ-5D_{utility} (mean \pm SD 0.31 \pm 0.30) matched the scores previously reported to depict patients with fibromyalgia (0.31 \pm 0.31) (47). The perceived pain of FM participants (mean \pm SD 63 \pm 26 mm) was not different from that previously reported for the exercisers with FM at baseline (19,34,43,44). However, Mannerkorpi et al (44) depicted slightly higher levels of pain at baseline (mean \pm SD 78 \pm 19). The maximal torque of participants (mean \pm SD 1.1 \pm 0.4 N·m/kg) was not significantly different from that previously reported in patients with FM (1.3 \pm 0.4) (1); however, they reflected an especially unfit sample of patients with FM who presented with a high number of tender points (mean \pm SD 17.2 \pm 1.3). Therefore, some of the great strength improvements obtained in the current study could be partially attributed to a relatively low fitness level at baseline. However, this fact indicated that the pool exercise program was useful and feasible in persons with severe FM symptoms, contributing to the scarce literature about these types of patients.

The sample size could limit the statistical power to detect changes in some variables. The program was statistically and clinically effective to improve torque in concentric actions at 60°/second after the period of exercise. Nevertheless, the statistical significance of the changes between baseline and the end of the subsequent de-training was >5%, although the magnitude of effect was mainly maintained in EQ-5D_{utility} (50%) and torque (20%). More clinical trials, and the subsequent meta-analyses, are encouraged to improve the evidence of maintenance and long-term effects after the subsequent de-training period, although the immediate positive effects of training were well indicated.

In contrast, some secondary outcomes were close to reaching statistical significance, such as the strength of knee extensors in eccentric actions at 60°/second ($P = 0.061$ in the right knee and $P = 0.105$ in left side). However, the absolute magnitude of effects was below the threshold of 20% to be considered a real improvement because the small and statistically not significant increases may not be solely the result of effective treatment, but rather may be due to biologic variation, measurement error, and learning effect due to repeated testing (37). The effects on the torque measured at 210°/second were also

<20%. Therefore, a wider sample could reach statistical significance in the previously mentioned secondary variables, but the low absolute magnitude of effects observed in these secondary variables would limit their practical relevance.

To conclude, exercise therapy in a waist-high pool of warm water resulted in effective and safe improvements in HRQOL and muscle strength in the lower limbs, and reduced pain in previously unfit women with FM and high numbers of tender points. The waist-high water improved strength of the lower limbs but not in the upper limbs, which had less resistance to water. Because movements in water are normally at low velocities, the improvements in leg strength were shown only in concentric actions at low velocities, reflecting the specificity of water training. Most of the improvements in muscle strength and HRQOL were maintained in the subsequent de-training period; however, these gains in pain reduction were lost, indicating the need for long-term training as part of the nonpharmacologic treatment of persons with FM.

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