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Improvements of muscle strength predicted benefits in HRQOL and postural balance in women with fibromyalgia: an 8-month randomized controlled trial

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Objective. To evaluate whether changes in muscle strength due to 32 weeks of supervised aquatic training predicted improvements on health-related quality of life (HRQOL).

Methods. Thirty women with FM aged 50.8 ± 8.7 years were randomly assigned to an experimental group ($n = 15$), performing 3 weekly sessions of 60 min of warm-water exercise; or to a control group ($n = 15$). HRQOL was evaluated using the Short Form 36 Health Survey (SF-36). Maximal unilateral isokinetic strength was measured at 60°/s and 210°/s in the knee extensors and flexors in concentric action and at 60°/s in knee extensors eccentric action. Postural balance was evaluated using the one-leg stance, eyes closed.

Results. After 32 weeks of water exercise therapy, statistically significant improvements occurred in concentric knee flexors and extensors strength at 60°/s, in eccentric knee extensors and in postural balance. The treatment led to additional improvements in physical function, role physical problems, body pain, general health, vitality, role emotional problems and mental health dimensions of SF-36. Gains in the concentric knee flexors strength predicted improvements in role of physical problems, whereas those in concentric knee extensors did the same for mental health and role emotional problems. Gains in eccentric knee extensors strength predicted improvements in postural balance.

Conclusions. A long-lasting exercise therapy in warm water produced relevant gains in muscle strength at low velocities of movements, some of which predicted improvements in physical problems, emotional problems, mental health and balance.

Trial registration. International Standard Randomized Controlled Trial Number ISRCTN53367487, information available in http://www.controlled-trials.com/ISRCTN53367487.

KEY WORDS: Fibromyalgia, Pool exercise, Muscle strength, Quality of life.

Introduction

FM is a rheumatological syndrome of unknown aetiology in which patients are characterized by a variety of symptoms, such as pain, muscle weakness, fatigue or balance problems [1–3] leading them to reduced health-related quality of life (HRQOL) [4]. FM symptoms can be successfully treated by aquatic training. Most of the earlier studies have shown that short periods (5–24 weeks) of water exercise may induce benefits, especially in neuromuscular condition [5], physical fitness [6, 7] and QOL [5, 6, 8–10]. For example, in our earlier randomized controlled trial (RCT) of 12 weeks of duration, we observed that warm-water exercises at low intensity, combining strength and aerobic activities induced important benefits in strength, pain, physical fitness and HRQOL [5, 6]. A critical observation in this earlier study was that these ameliorations in the FM symptoms were reversed to initial levels after an equal period of physical inactivity following the exercise therapy. This indicated that FM patients may require regular, long-lasting exercise therapy to possibly achieve unremitting benefits.

The neuromuscular condition of the FM patients can be improved with several weeks of water exercise. For example, in our earlier RCT of 12 weeks of water exercise [5], we found positive effects of this exercise on concentric and eccentric leg muscle strength. However, these preliminary results from our 12-week RCT also suggested that a better recuperation of optimal levels of eccentric strength in particular could require longer periods of training, as the improvements were small. An adequate recuperation and tuning of both concentric and eccentric muscle strength in knee flexors and extensors is important for these patients because it may for instance attenuate balancing problems, which is one of the most common disturbances in FM [3, 11].

With this idea, our group developed a new RCT of 8 months of water exercise. In initial reports from this 32-week trial, we concluded that long-lasting exercising in warm water was feasible, cost effective and led to long-term improvements in physical fitness, disease impact and anxiety status relatively similar in magnitude to those of shorter therapy programmes [12, 13]. To broaden this knowledge, the present report aims to provide further understanding of the effects of long-lasting water exercise in two possible ways: first, by analysing whether combined strength and endurance type water exercise may induce additional benefits in neuromuscular condition (isokinetic muscle strength and postural balance) and HRQOL of the FM patient; and secondly, whether the changes in the neuromuscular condition are associated with improvements in postural balance and HRQOL of the patients. This latter knowledge will allow researchers and clinicians to better characterize changes induced by a given long-lasting therapy, and to hypothesize about the mechanistic relation of possibly clustered benefits.

Subjects and methods

Study sample

Forty potentially eligible subjects responded to advertisements placed in the local newsletters. Once the study protocol was explained to them, 38 persons gave their written informed consent

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according to the Declaration of Helsinki. They were included if they met the diagnosis of FM according to the ACR criteria [1]. Exclusion criteria were history of severe trauma, frequent migraines, peripheral nerve entrapment, inflammatory rheumatic diseases, severe psychiatric illness and other diseases that prevent physical loading and pregnancy. Those who attended to another psychological or physical therapy or who may have partaken in more than one exercise session of 30 min/week during a 2-week period in the last 5 years were excluded to avoid possible interactions with the present trial ($n = 5$). A resulting sample of 33 female patients aged 37–71 years intended to participate.

All patients were randomized pairwise into two 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 and immediately after the physician had clinically examined them and checked that they did not meet any of the aforementioned exclusion criteria. This was done to ensure that neither researchers nor participants 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 to 95% of the exercise sessions, and one CG patient failed to attend to the measurements for personal reasons. They were consequently excluded from the statistical analyses. Finally, 15 (88%) patients in the EG and 15 (94%) patients in the CG fully completed the study protocol and their results were included in the analysis.

Isokinetic muscle strength in lower extremities, postural balance and HRQOL were assessed at baseline and immediately after 32 weeks of physical training. All tests were performed by the same exercise physiologist specialized in the evaluation of the physical condition in order to reduce variability and improve consistency in the assessment process. He was blinded to the patient's condition and group assignment. Randomization was carried out by a staff member who was not otherwise involved in the study. The study was approved by the Committee on Biomedical Ethics of the University of Extremadura (Spain) (ISRCTN53367487).

Isokinetic muscle strength measurement

Maximal torque of the knee extensors and flexors was recorded by using the Biodex System-3 Isokinetic Dynamometer (Biodex, Shirley, NY, USA). Each subject was attached to the seat of the dynamometer so that the axis of their knee coincided with the axis of the dynamometer, following standardized protocols [14]. At the start of each single test, the subject was asked to relax his leg to determine the effect of gravity on the limb. Testing was performed using hard deceleration cushion. First, maximal flexion and extension of the knee at 60°/s and 210°/s in concentric action was measured, and after that, in eccentric action at 60°/s, but only in extensors of the knee [15]. The motion ranged from 80° of knee flexion to full extension. Each subject performed three previous trials at moderate intensity before each testing to become familiar with movement and velocity. During actual testing, subjects were asked to repeat three maximal complete movements, first with the dominant limb. They were verbally encouraged during the performance. Participants rested 2 min between each trial [16]. The highest gravity-corrected peak moment value (peak torque) at a pre-determined velocity and filtered output was rounded to the nearest 0.1 value and recorded for further analysis.

Balance assessment

Postural balance was assessed with one-leg stance test [17]. Each patient stood on one leg, whereas the knee of the other leg was folded towards the back and its foot also held by the hand of the same body side, keeping eyes closed. Posture was assumed just prior to eyes closure. Each time the patient lost the balance, released her lifted leg and stepped on the floor or used the security devices to maintain the posture, the stopwatch was paused. After each pause, the same procedure started all over again till completing 30 s of one-leg stance position. The number of trials to complete 30 s was recorded and considered as the outcome.

HRQOL

The Spanish version of the Short Form 36 Health Survey (SF-36) [18] was used to evaluate HRQOL. The SF-36 assesses eight dimensions: physical function, role physical problems, body pain, general health perception, vitality, social function, role emotional problems and mental health. The scale of each dimension runs from 0, 'very poor', to 100, 'very good'.

Exercise therapy

The experimental group trained in a waist-high pool of warm water (33°C) three times per week during 32 weeks. Each session was 1 h long 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 strength exercises (four sets of 10 repetitions of unilateral flexion and extension of knee at slow pace with the body in a vertical position using water as resistance), another set of 10 min of aerobics at 60–65% Hr_{max} and 10 min of cooling down with low-intensity exercises. Heart rate was monitored using a pulse meter (Polar Accurex Plus, Kempele, Finland). During this 32-week period, participants in the control group continued their daily activities, which did not include any psychological therapy or physical exercise similar to those in the programme.

Data analysis

Normality of data was initially tested using the Kolmogorov–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 chi-square test for categorical variables. The treatment effect states the differences between changes in the exercise and the control group [change in the EG minus change in the CG (treatment effect $= \Delta EG - \Delta CG$)]. The relationships between the selected variables were assessed by the Pearson product moment correlation coefficient. First, all isokinetic tests showing improvements entered into univariated regression models predicting HRQOL variables (adjusted by age if necessary). When gains in muscle strength (treatment effects) in a particular action were significantly related to gains in a HRQOL variable (treatment effects), they were entered into a multivariate model (i.e. gains in both legs predicting simultaneously gains in a single HRQOL variable). The assumptions of linear regression analysis (e.g. linearity, normal distribution and scattering of residuals and multicollinearity) were tested and they were found to be reasonably valid. For all tests the significance level was set at $P < 0.05$. The analyses were performed using SPSS 16.0 (SPSS, Chicago, IL, USA).

Results

Baseline data did not show any significant differences in sociodemographical characteristics (Table 1), HRQOL, isokinetic muscle strength or postural balance (Table 2) between the EG and the CG.

Isokinetic muscle strength and postural balance

After 32 weeks, the treatment led to significant improvements in concentric knee extensors strength at 60°/s of the right and left legs (30 and 18%, respectively) and in concentric knee flexors strength of right and left legs (67 and 50%, respectively) in the experimental group compared with control group. In addition, the treatment led to gains in eccentric knee extensors strength at 60°/s of the right and left legs (31 and 23%, respectively). The changes in concentric knee flexors and extensors strength with high speed were not significant in either group. Finally, postural balance was improved by 30% due to the treatment effect (Table 2).

HRQOL

After 32 weeks of warm-water therapy, we observed changes in HRQOL in favour with experimental group in all other dimensions of SF-36 except social function: in physical function (16%), role physical problems (25%), body pain (58%), general health perception (33%), vitality (40%), role emotional problems (100%) and mental health (52%) (Table 2).

Predictive capacity of changes in strength for improvements HRQOL and postural balance

Multivariate regression analyses indicated that gains in concentric knee flexors strength predicted improvements in the role of physical problems [$F(2, 12) = 11.228$; $R^2 = 0.652$; $P = 0.002$]. Gains in concentric knee extensors strength predicted improvements in role emotional problems [$F(2,12) = 6.358$; $R^2 = 0.514$; $P = 0.013$] as well as in mental health [$F(2,13) = 5.969$; $R^2 = 0.480$; $P = 0.014$). In addition, the observed gains in eccentric knee extensors strength at 60°/s predicted improvements in postural balance [$F(2,13) = 12.590$; $R^2 = 0.660$; $P < 0.001$] (Fig. 1).

Table 1. Socio-demographic characteristics of females with FM at the baseline

	EG, $n = 15$	CG, $n = 15$	*P*-value
Age, years[a]	50.7 ± 10.6	50.9 ± 6.7	0.935
BMI, kg/m[2a]	28.8 ± 4.5	26.6 ± 3.5	0.147
Duration of symptoms, years[a]	20.1 ± 8	19.4 ± 6.9	0.791
Number of tender points (scale 1–18)[a]	16.9 ± 1.8	17.2 ± 1.3	0.563
Number of specific drugs (anti-depressives, muscular relaxants, and analgesics)[a]	1.3 ± 0.8	1.5 ± 0.8	0.379
Employment status			0.750
Blue collar[b]	8 (53.3)	6 (40)	
White collar[b]	2 (13.3)	3 (20)	
Unemployed[b]	5 (33.3)	6 (40)	
Education level			0.184
Unfinished studies[b]	1 (6.7)	1 (6.7)	
Primary school[b]	9 (60)	6 (40)	
Secondary school[b]	1 (6.7)	6 (40)	
University degree[b]	4 (26.7)	2 (13.3)	

[a]Values expressed as mean ± s.d., *P*-values of ANOVA. [b]Values expressed as *n* (%), *P*-values of analysis of chi-square test.

Discussion

The present study shows valuable data on improvements in isokinetic muscle strength, balance and HRQOL applying long-term water exercise in FM women. However, the main finding in the present study was that these gains in muscle strength induced by 32 weeks of warm-water exercises predicted moderate to high improvements in mental health and the reductions in physical and emotional problems of the FM patients. Although other studies offered similar conclusions for osteoporosis [19], cancer [20] or COPD [21] patients, to our knowledge, there are no previous data on the extent of such relations in FM syndrome.

Previous trials have reported that in persons with FM, reduced leg muscle strength was associated with lower outcomes in physical functioning tests [22]. Sufficient leg strength is essential in FM patients to permit activities of daily living, such as walking, climbing upstairs or carrying small weights [12]. The present study showed that 32 weeks of water exercise led to relevant improvements (23–67%) in both concentric and eccentric strength at low velocity of movement (60°/s). These changes were higher than those reported from our shorter (12 weeks) water exercise trial [5]. Considering that the patients in both trials were different persons but had similar characteristics and followed a comparable training in intensity and load, the results suggest that the duration of the programme may partially account for the differences in magnitude of the final gains in leg muscle strength. However, either shorter or longer water training period did not improve leg muscle strength at higher velocity of movements (210°/s). This may be to some extent explained by the specificity of the aquatic environment that offers resistance to movement constantly while reducing the action velocity [5].

Previous studies have shown FM patients with reduced postural balance compared with healthy adults [3, 11, 23]. In the present study, the participants showed as well reduced postural balance compared with normative values for healthy adult population of

Table 2. Isokinetic strength, postural balance and HRQOL outcomes in women with FM syndrome at baseline and after the 8 months of physical training in warm water (EG, $n = 15$; CG, $n = 15$)

	Baseline, mean ± s.d.		8 months, mean ± s.d.		Treatment effect, mean (95% CI)	*P*-value*
	Exercise	Control	Exercise	Control		
Right leg strength, N m/kg						
Extensors (cc) 60°/s	1 ± 0.4	1.1 ± 0.2	1.3 ± 0.2	1.1 ± 0.3	0.3 (0, 0.5)	0.017
Flexors (cc) 60°/s	0.3 ± 0.2	0.4 ± 0.2	0.5 ± 0.2	0.4 ± 0.1	0.2 (0, 0.3)	0.021
Extensors (cc) 210 °/s	0.6 ± 0.2	0.6 ± 0.2	0.8 ± 0.2	0.8 ± 0.3	0 (−0.2, 0.2)	0.956
Flexors (cc) 210°/s	0.3 ± 0.1	0.3 ± 0.1	0.4 ± 0.1	0.4 ± 0.1	0 (−0.1, 0.1)	0.804
Extensors (ec) 60°/s	1.6 ± 0.3	1.9 ± 0.4	1.8 ± 0.6	1.6 ± 0.3	0.5 (0.2, 0.9)	0.001
Left leg strength, N m/kg						
Extensors (cc) 60°/s	1.1 ± 0.3	1.1 ± 0.4	1.3 ± 0.2	1.1 ± 0.2	0.2 (0, 0.4)	0.042
Flexors (cc) 60°/s	0.4 ± 0.1	0.5 ± 0.2	0.5 ± 0.2	0.4 ± 0.1	0.2 (0.1, 0.3)	0.007
Extensors (cc) 210°/s	0.5 ± 0.2	0.7 ± 0.2	0.7 ± 0.2	0.9 ± 0.2	0 (−0.2, 0.1)	0.694
Flexors (cc) 210°/s	0.2 ± 0.1	0.3 ± 0.3	0.3 ± 0.1	0.4 ± 0.1	0 (−0.1, 0.2)	0.642
Extensors (ec) 60°/s	1.7 ± 0.4	1.9 ± 0.7	1.9 ± 0.5	1.7 ± 0.4	0.4 (0.1, 0.7)	0.049
Postural balance						
Number of trials in 30 s	23.1 ± 7.2	23.2 ± 6.4	15 ± 10	22.1 ± 8.7	−7 (−16, to 1.8)	0.031
SF-36 dimensions (scale 0–100)						
Physical function	43.4 ± 14.2	32.8 ± 19.8	54.1 ± 19.8	36.6 ± 17.8	6.8 (−8.3, 21.8)	0.017
Role physical problems	41 ± 21.7	26.7 ± 25.8	48.1 ± 36.5	23.3 ± 27.5	10.4 (−9.7, 30.5)	0.045
Body pain	28.7 ± 13.4	20.8 ± 19.2	51.7 ± 13.1	27.1 ± 20.9	16.8 (6, 27.4)	0.001
General health	36.8 ± 19.1	29.1 ± 16	46.2 ± 23.9	26.1 ± 16	12.3 (2.8, 21.8)	0.012
Vitality	31.6 ± 15.4	23.3 ± 14.1	50 ± 18.3	29 ± 11.8	12.7 (2.4, 22.9)	0.001
Social function	60.1 ± 31.4	51.6 ± 26.6	65.1 ± 22.9	58.3 ± 25.3	−1.7 (−21.2, 17.9)	0.445
Role emotional problems	38.3 ± 36.8	37.7 ± 35.4	70.3 ± 30.6	31.1 ± 30.1	38.5 (13.8, 63.2)	0.003
Mental health	45.5 ± 18.5	51.2 ± 26.2	67.3 ± 21.4	49 ± 20.8	23.9 (9.3, 38.6)	0.025

**P*-values of ANOVA to compare differences between groups at 8 months. cc: concentric; ec: eccentric.

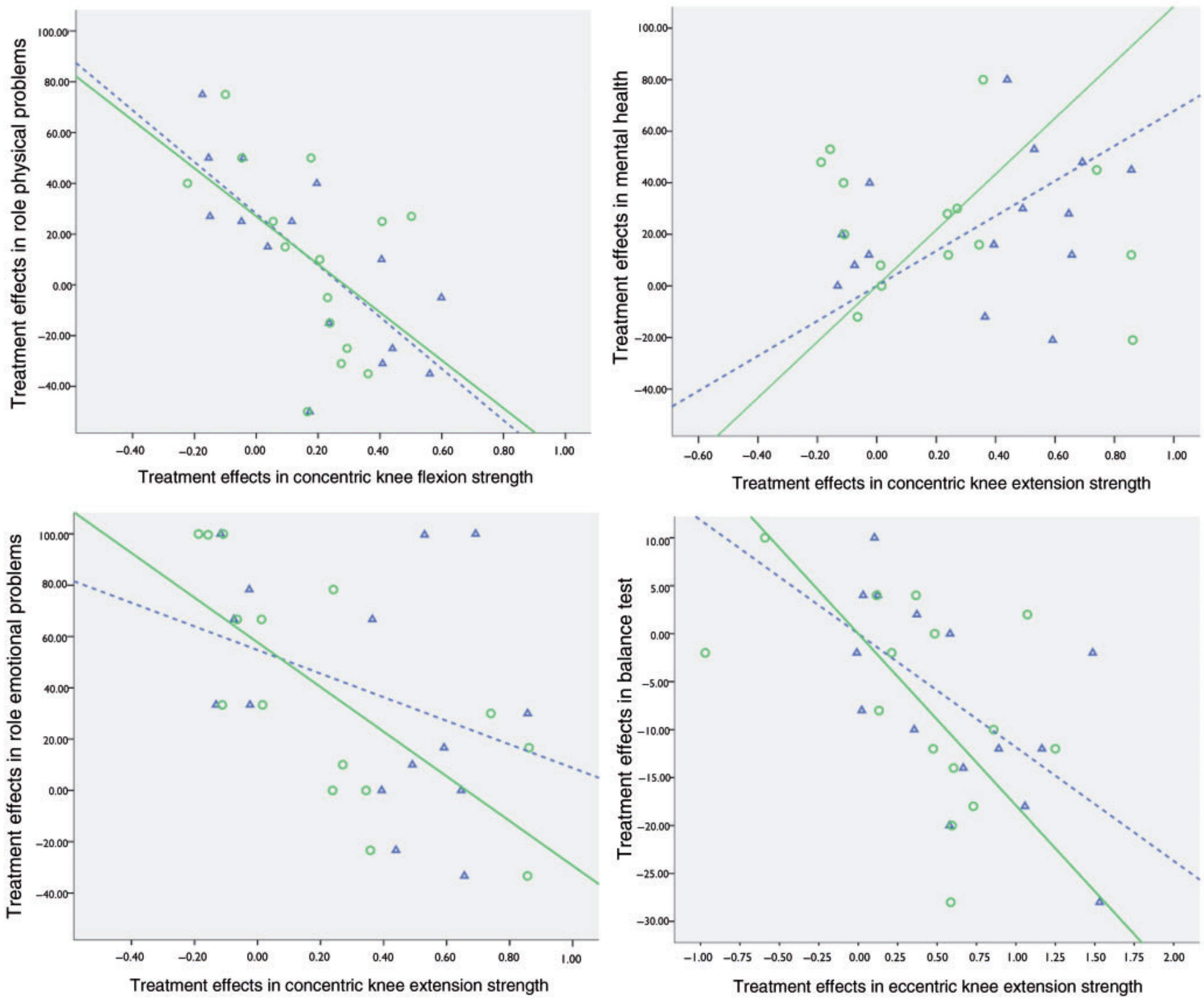

FIG. 1. Relation among changes in strength, changes in HRQOL and balance of the FM due to the treatment effects. Regression lines for every leg are shown as dotted lines for right legs, and as regular lines for left legs. Individuals' values are represented as triangles for right legs and as circles for left legs. Treatment effects in muscle strength are in isokinetic strength units (newton metres per kilogram), whereas treatment effects in HRQOL variables are expressed in SF-36 units. Treatment effects in balance test are expressed as number of trials to complete 30 s in the 'blind flamingo stance'.

the same age [24]. After the training period, FM patients who exercise improved postural balance by 30%, which is in a similar level to those reported earlier from shorter water exercise trials [6]. Nevertheless, those values were still under the normative levels for healthy population. Initially a poor balance capacity may be attributed to declines in sensory acuity and in the CNS integration function, in addition to muscle weakness. Although their relative contribution is unknown, our results suggested that in our sample of FM patients, muscle weakness could be an important factor, as gains in eccentric knee extensors strength predicted by 66% improvements in balance. This relation between strength and balance is well documented in literature through the study of different indicators. For example, it is known that postural balance requires enough strength and fine-tuning of agonist and antagonist muscles controlling the knee [25]. In healthy women with good balance, the torque ratio of agonist/antagonist muscles for the knee extension at 60°/s is documented to be 55% [26]. In our sample of women with FM, the torque ratios at baseline were 30%, improving to 38% at the end of the intervention. Another good indicator is the ratio of eccentric/concentric strength of the knee extensors. In healthy women, the normative value for this ratio is 1.3 for a speed of movement of 60°/s [27]. In our sample of FM patients, the value for this ratio at baseline was 2, whereas value at follow-up improved to 1.4. A last indicator to understand the relation between strength and balance is the muscle strength bi-lateral asymmetry between legs [28]. In this study, the initial values of bi-lateral asymmetry in leg muscle strength in concentric knee extensors (9.1%) and flexors (25%) were nearer to null asymmetry values after the 32-week exercise. Thus, although not optimal yet, these ratios were improved and approached to normative levels.

Our study of 32-week duration showed also that FM patients who exercise improved in most of the dimensions of HRQOL, measured by SF-36. These improvements were higher in magnitude than those from our earlier study of shorter duration (12 weeks) in most of the dimensions, for example, in role physical problems (25% here *vs* non-significant earlier), vitality (40 *vs* 33%), role emotional problems (100 *vs* 79%) and mental health (52 *vs* 39%) [6]. In other study, in which patients exercised in water during 24 weeks, results also showed lower benefits in most of the dimensions, e.g. in role physical problems (25% here *vs* non-significant earlier), body pain (58 *vs* 33%), general health (33 *vs* 19%), role emotional problems (100 *vs* non-significant) and mental health (52 *vs* non-significant) [29]. Therefore, it seems that a longer exercise therapy may carry additional benefits mainly in the mental and emotional status of the patients.

On the other hand, previous water exercise trials have shown relief in pain status in overall by 33–85% measured by the SF-36 scale [6, 29, 30]. The present trial also showed a relief in pain of 58% in the SF-36 dimension. However, despite this important relief in pain, our analyses confirmed that it was not linked to the overall improvements in muscle strength. This initially suggests that this pain relief due to exercise could be better connected, for instance, to improvements in central factors [31] such as cardio-respiratory or aerobic condition [32]. In addition, psychosomatic benefits derived from the peculiarities of the warm-water environment and supervised group training cannot be excluded, as most of the patients regard it as 'very pleasant'.

The present study also included limitations, which require further discussion. As our study design did not include a mid-term follow-up, we cannot provide further information regarding the patients' progression in the different variables. Therefore, we cannot overthrow the possibility that most of the improvements were achieved at the beginning of the therapy, nor the likelihood of a limited recuperation in the patients' condition. More frequent follow-up measurements are needed to study the timing of progression. The limited size of the sample may have contributed to decreased statistical power to detect changes in some variables. Nevertheless, our trial still showed positive effects in most variables measured and changes due to the treatment effect were easily detected. Besides, 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 conclusions here must be drawn with caution.

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 highly effective to produce changes in leg muscle strength, balance and HRQOL. The patients who showed higher changes in muscle strength also got the higher benefits in postural balance and in the dimensions of the HRQOL related to the role of physical and psychological/emotional problems. These results provide further support to idea that FM patients with long duration of symptom benefit from long-term, low-intensity water therapies.

Rheumatology key messages

- A long-lasting exercise therapy for FM improved patients' muscle strength, HRQOL and postural balance.
- Muscle strength predicted postural balance and physical and mental dimensions of the HRQOL.

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