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Efficacy of aquatic vs land-based therapy for pain management in women with fibromyalgia: a randomised controlled trial

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Abstract

Objective To determine the efficacy of two physiotherapeutic interventions – aquatic therapy (AT) and land-based therapy (LBT) – for reducing pain in women with fibromyalgia.
Design Single-blind, randomised controlled, equivalence trial.
Setting Fibromyalgia, Chronic Fatigue Syndrome and Multiple Chemical Sensitivity Association in A Coruña, Spain.
Participants Forty women with fibromyalgia were assigned at random in a 1:1 manner to two groups: AT ($n = 20$) and LBT ($n = 20$).
Interventions Two therapeutic exercise programmes, with 60-min sessions, were undertaken three times per week for 12 weeks. Sessions were carried out in groups by a trained physiotherapist.
Outcome The primary outcome was pain intensity (visual analogue scale). The secondary outcomes were pressure pain threshold (algometer), quality of life (Revised Fibromyalgia Impact Questionnaire), sleep quality (Pittsburgh Sleep Quality Index), fatigue (Multidimensional Fatigue Inventory) and physical ability (6-Minute Walk Test). Patients were evaluated at baseline, 12 weeks (post-treatment) and 18 weeks (follow-up). The statistical analysis was per-protocol. $P < 0.05$ was considered to indicate significance. Effect size was calculated.
Results The mean age was 50 [standard deviation (SD) 9] years, with median body mass index of 27 [interquartile range (IQR) 25–30] kg/m^2 and median symptom duration of 11 (IQR 6–15) years. No differences were observed between the groups post-treatment, but differences in favour of AT were found in pain intensity [2.7 (IQR 1.5-4.9) vs 5.5 (IQR 3.3-7.6); p= 0.023; large effect, Cohen's d= 0.8; 95% confidence interval (CI) 0.1-1.5] and sleep quality [12.0 (IQR 7.3-15.3) vs 15.0 (IQR 13.0-17.0); p= 0.030; large effect, Cohen's d= 0.8; 95% CI 0.1-1.5] at follow-up.
Conclusions The results suggest that AT is better than LBT for reducing pain intensity and improving sleep quality after 6 weeks of follow-up. AT may be a good treatment option for women with fibromyalgia.
Clinical Trials Registration Number ClinicalTrials.gov NCT02695875

Contribution of the paper

- This paper provides evidence that aquatic therapy is an effective intervention for reducing pain and improving sleep quality of women with fibromyalgia.
- The matched protocols designed for this study highlighted the influence of the environment on symptom management in women with fibromyalgia.

Keywords: Fibromyalgia; Physiotherapy; Aquatic therapy; Exercise therapy; Pain; Sleep quality

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Introduction

Fibromyalgia (FM) is a chronic musculoskeletal pain condition associated with sleep disturbance and fatigue [1]. The syndrome is defined by widespread pain and mechanical hyperalgesia, which are reported to be linked to central pain sensitisation [2]. The prevalence of FM in Spain is 2.5%, being more common in women, similar to that observed in Europe as a whole (2.6%) [3].

According to the EULAR guidelines [4], exercise has the strongest recommendation among non-pharmacological interventions. Therapeutic exercise reduces pain, depression and symptom severity, improving the health-related quality of life (QOL) of patients with FM [5]. This modality of exercise may include aerobic exercise (AE) [6], strengthening exercises [7], coordination and balance training [8], posture stabilisation [9], body mechanics [10], flexibility exercises [7], gait training [11] and relaxation techniques [12], and can be developed on land or water.

A 2014 Cochrane review on aquatic exercise for FM [13] showed that aquatic therapy (AT) is effective for the improvement of pain, physical well-being, muscular strength, and functional and cardiovascular capacity, and is a better option compared with not exercising.

AT is an exercise programme designed by a qualified physiotherapist using the properties of water to improve function, ideally in a suitably heated pool [14]. The literature reports the positive effects of AT and land-based therapy (LBT) in FM; however, few high-quality studies have been undertaken to compare them [9,16]. Systematic reviews [13,17] have suggested that AT and LBT are equally effective, but the evidence is rated low to very low.

As such, this study with a rigorous methodology was developed to compare the efficacy of two physiotherapeutic protocols – AT and LBT – in women with FM for pain reduction. The therapeutic effect in each intervention group was analysed, along with maintenance at follow-up. It was hypothesised that AT would be equivalent to LBT, and both AT and LBT would improve pain intensity in people with FM.

Materials and methods

Study design

This study was a single-blind, randomised controlled, equivalence trial. There were no changes from the original protocol [18].

Sample size

The sample size was calculated to find a difference of ± 2.5 points [19] between the intervention groups using a visual analogue scale (VAS) for pain intensity, with a standard deviation (SD) of 2.5 [20]. The analysis was defined for a two-tailed hypothesis and was undertaken using Epidat. The following parameters were used: $\alpha = 0.05$, power= 0.80 and dropout rate = 20%. It was estimated that a minimum of 20 subjects was needed in each group.

Procedure

The lead investigator (JV) was responsible for subject enrolment. From February to March 2016, 70 members of the Association of Fibromyalgia, Chronic Fatigue Syndrome and Multiple Chemical Sensitivity of A Coruña (Spain) were recruited by telephone. Of these, 40 women met the eligibility criteria and signed an informed consent form. These women were assigned at random to the AT group ($n = 20$) or the LBT group ($n = 20$).

Concealed allocation was performed, with a 1:1 ratio, using a computer-generated list of random numbers created by an investigator with no clinical involvement in the trial. Individual and consecutively numbered cards with the intervention assignment were placed in sealed opaque envelopes. A second external researcher opened the envelopes and proceeded with patient allocation.

Participants were evaluated at baseline, 12 weeks (post-treatment) and 18 weeks (follow-up). The assessments were performed by a trained physiotherapist blinded to group assignment.

Participants

Eligibility criteria

The inclusion criteria were: female, age 35 to 64 years [21], and FM diagnosed in accordance with both the 1990 [22] and 2010 [1] American College of Rheumatology (ACR) criteria.

The exclusion criteria were: medical history of severe trauma, neurological disease, frequent migraines, diabetes, severe psychiatric disease, peripheral nerve entrapment, inflammatory rheumatic disease, chlorine allergy, anxiety conditions related to water, severe cardiovascular disease, heat intolerance, traumatic injuries in preceding 6 months, exercised at moderate intensity at least three times per week for 30 to 60 min/day [23] 3 months before study commencement or during the study, pregnant, active infectious disease, and significant changes in pharmacological treatment (e.g. substituting one medication for another, changes in dosage, self-medication).

Primary outcome measures

Pain intensity

Pain intensity was measured using a VAS [24] based on average pain intensity in the preceding week.

Secondary outcome measures

Given the clinical use of pressure pain threshold (PPT) for the diagnosis of FM, as well as other variables that influence the degree of activity and participation of this population, the selected secondary outcome measures are shown below. The definitions are developed further in the study protocol [18].

Pressure pain threshold

PPT is defined as the minimum pressure that triggers a painful response. An electronic algometer (Commander Algometer de JTECH Medical) was used to measure PPT on the 18 tender points [22].

Quality of life

QOL was assessed with the Revised Fibromyalgia Impact Questionnaire (FIQR) [25], a 21-item self-administered questionnaire, based on symptoms reported within the preceding 7 days. The total FIQR score can reach a maximum of 100 points. Higher values indicate worse QOL.

Sleep quality

Sleep quality was evaluated with the Pittsburgh Sleep Quality Index (PSQI) [26], a retrospective tool for measuring sleep quality and sleep disorders. Higher values indicate worse sleep quality.

Fatigue

Fatigue was evaluated using the Multidimensional Fatigue Inventory (MFI) [27], a 20-item assessment tool with five domains. Higher scores indicate a higher degree of fatigue.

Functional capacity

Functional capacity was measured with the 6-Minute Walk Test (6MWT) [28], which determines the maximum distance walked by the participant in 6 min along a 20-m corridor.

Interventions

Two similar interventions were designed based on studies published between 2000 and 2015: AT and LBT. Both included 60-minute sessions that were carried out three times per week for 12 weeks by a physiotherapist with 5 years of clinical experience and training in AT. The same physiotherapist led both treatments in groups of 10 people. The physiotherapist observed exercise performance, made corrections as required, and praised participants for their effort. The protocols were matched in terms of exercise features, structured in four blocks: 15 minutes of warm-up, 25 minutes of proprioceptive exercises, 8 minutes of stretching and 12 minutes of relaxation. There were clear objectives and progression in difficulty. Therapy started with exercise intensity of 3 to 4 points on the modified Borg scale [29]. At the end of the fifth week of treatment, exercise intensity was increased in blocks 1 and 2, with higher numbers of repetitions and less pause time. Supports and visual inputs were decreased for the proprioceptive exercises. The physiotherapist modified exercise progression based on the patient's perceived exertion, such that it did not exceed 5 on the modified Borg scale. Exercise adherence data were recorded manually at every supervised session, and 93% of participants attended all the sessions. Due to the relationship between weather and the severity of FM symptoms [30], the intervention period was planned during the spring (April to July), with more neutral climatology. No adverse events were registered during the treatment.

Tables 1 and 2 report the specific details of the AT and LBT protocols, describing exercises and including repetitions, sets and rest intervals.

Intervention settings

AT was performed in the pool of a sports complex. The water temperature was 30 ºC, with < 1 ºC variation, and the depth was 120 cm. LBT was performed in one of the laboratories at the Faculty of Physiotherapy at the Universidade da Coruña.

Statistics

Demographic data are presented using descriptive statistics. A per-protocol analysis was conducted, with the intention of obtaining an accurate measure of the treatment effect at all relevant time points. The study design assumed high adherence; ultimately, this was 90%, with only three patients lost post-treatment and a further two patients lost at follow-up..

The normality of the distribution was assessed using the Kolmogorov−Smirnov test. In cases where the assumptions of normality and homogeneity of variances were not met, non-parametric tests were used. The Mann−Whitney *U*-test was used to compare therapeutic groups. The Friedman test was used for the analysis of repeated measures data. To identify significant differences between groups, the Wilcoxon signed-rank test was used as a post-hoc comparison method, with Bonferroni's correction applied. The effect size was calculated using Cohen's d. $P < 0.05$ was considered to indicate significance. Analyses were performed using SPSS Version 26.0 (IBM Corp., Armonk, NY, USA)..

Results

The demographic characteristics of participants are presented in Table 3. The study included 40 patients with a mean age of 50 (SD 9) years, body mass index of 27 [interquartile range (IQR) 25 to 30] kg/m^2, and symptom duration of 11 (IQR 6 to 15) years. The recruitment rate was 100%, with a 13% attrition rate (Fig. 1).

The results for primary and secondary outcomes are summarised in Table 4.

Table 1
Description of aquatic therapy protocol.

Exercise blocks	Exercise descriptions	Repetitions/action/pause
Warm-up (15 minutes)	1. Running in water: with water at waist level, patients will run along the bottom of the pool, changing trajectory. 2. Can-can kicks: submerged to chest depth, patients will kick the water with alternating legs. 3. Hydro-jumps: with feet on the pool's floor, patients will jump, bending their knees at the highest point in their jump. 4. Pedalling: with a pool noodle under the neck, patients will move their legs in the motion of pedalling a bicycle while moving along the pool. 5. Rocking horse: with one foot before the other, patients will alternate jumps with the front and back leg. 6. Relay race: two groups. The winner will be the group that returns the ball to the first participant in the shortest time.	1. 3 minutes uninterrupted activity 2. 3/30 seconds/15 seconds 3. 3/30 seconds/15 seconds 4. 3 minutes uninterrupted activity 5. 3/30 seconds/15 seconds 6. 2/1 minutes/20 seconds
Proprioceptive exercises (25 minutes)	1. Playing catch: in a group, patients will be sitting on a pool noodle and will have to maintain balance while throwing and catching the ball.	1. 3 minutes uninterrupted activity
	2. Balance over pool noodles: patients will be sitting on a pool noodle with hips and knees bent 90º and will have to keep balance in three different positions: (a) arms submerged and 90º abduction; (b) one arm out of the water and the other under the water; (c) from the initial position, patients perform a trunk extension with shoulder extension, hip extension, knees pointing to the pool's floor and neck extension.	2. 2 (for each position)/1 minutes/20 seconds
	3. Turbulence standing: Standing, with water at the level of the chest and arms along the body; patients do quick and short flexion/extension movements with the ULs generating significant turbulence. Good activation of local musculature will be essential for avoiding imbalance.	3. 4/1 seconds/15 seconds
	4. Exercises with kickboard: (a) patients will be sitting on a kickboard, with water at neck height. They will have to keep afloat with only the aid of pedalling and without moving along the pool; (b) with one foot on the kickboard and the other on the pool's floor, patients will have to lower the kickboard and place it 10 cm above the pool's floor. They will have to maintain this position and move the kickboard forward, backward and sideways without allowing it to go to the water's surface. The exercise will be done with both LLs, first placing the kickboard vertically and then horizontally.	4. a. 2/1 minutes/20 seconds b. 2/40 seconds/15 seconds
	5. Double pool noodle: patients will be standing with a pool noodle in each hand. They will have to submerge them in the water while raising knees to chest.	5. 3/50 seconds/20 seconds
	6. The boat: two groups. Patients will have to submerge a mat (3′ width x 5′ length) while maintaining a standing position with different supports: double-leg, single-leg and tandem.	6. 3 minutes uninterrupted activity
Stretching (8 minutes)	Gastrocnemius, quadriceps, ischiotibial, adductors, quadratus lumborum, deltoid, triceps brachii, superior trapezius	2 (right and left side)/30 seconds/5 seconds
Relaxation (12 minutes)	An Ai-Chi sequence with music. Six movements of the 19 that comprise Ai-Chi, performed in the following order: 'folding', 'soothing', 'gathering', 'freeing', 'shifting' and 'accepting'	12 minutes uninterrupted activity

ULs, upper limbs; LLs, lower limbs.

Primary outcome

Pain intensity

When comparing post-treatment pain intensity, no significant differences were found between groups. However, in the LBT group, the VAS score increased by almost 2 points in comparison with the AT group [large effect, Cohen's d= 0.8; 95% confidence interval (CI) 0.1 to 1.5] at follow-up. On post-hoc analysis, significant differences were observed for both groups when comparing baseline with post-treatment scores. However, when comparing baseline and follow-up scores, a significant difference was found for the AT group alone ($P = 0.016$).

Secondary outcomes

Pressure pain threshold

PPT refers to a single variable which is the result of the quotient of the sum of each of the values from each tender point divided by the total number of values (i.e. 18). The aim is to provide a measure of overall central sensitisation.

When comparing baseline and post-treatment scores, there was a significant increase in PPT for both groups. However, when comparing baseline and follow-up scores, the therapeutic effect was maintained in the AT group alone ($P = 0.002$).

Quality of life

In post-hoc comparisons, a significant reduction in the total FIQR score post-treatment was seen in the AT group alone ($P = 0.001$).

Sleep quality

A significant difference was found between the groups at follow-up (large effect size, Cohen's d=0.8; 95% CI 0.1 to 1.5). However, the Friedman test did not find significant differences for either of the groups.

Table 2
Description of land-based therapy protocol.

Exercise blocks	Exercise descriptions	Repetitions/action/pause
Warm-up (15 minutes)	1. Vigorous walking: patients will have to walk forwards, backwards, snaking and changing direction energetically. 2. Standing exercises: (a) on one leg, with an UL and its contralateral LL, patients will do a simultaneous abduction followed by adduction; (b) the shoulder flexion movement is combined with contralateral knee elevation; (c) patients will perform jumping jacks. 3. Ball jumps: patients will be sitting on a Bobath ball and will have to jump. 4. Pedalling: patients will be positioned face up, with the hips and knees bent 90º and will have to do a pedalling motion with their legs, keeping the pelvis in a neutral position. 5. Relay race: two groups. The winner will be the group that return the ball to the first participant in the shortest time.	1. 3 minutes uninterrupted activity 2. a and b. 6 (3 for each diagonal)/15 seconds/5 seconds; c. 3/20 seconds/10 seconds 3. 3/45 seconds/20 seconds 4. 3/45 seconds/20 seconds 5. 3/1 minutes /20 seconds
Proprioceptive exercises (25 minutes)	1. Playing catch: patients will be placed in a circle and sitting on a Bobath ball. With single-foot support, they will have to maintain a good position while throwing and catching the ball.	1. 3 minutes uninterrupted activity
	2. The bridge: (a) patients will be positioned face up on a mat, with arms along the body and feet on a Bobath ball. They will have to raise their buttocks off the floor and hold this position (the bridge); (b) starting from the previous position, patients will do the bridge raising one of the LL supported on the ball together with the contralateral UL at the same time.	2. a. 2/1 minutes /20 seconds b. 4 (2 for each diagonal)/40 seconds/5 seconds
	3. The knight: with one knee on a Dynair and the contralateral foot on a hedgehog (Erizo Senso Balance), patients will have to maintain the position without losing balance.	3. 6 (3 for each side)/30 seconds/10 seconds
	4. Standing balance: standing on a Dynair, patients will have to maintain their balance while moving their centre of gravity forward, backward and sideways. There cannot be any contact with the floor through the Dynair. The exercise will also be performed on one leg.	4. 3/1 minutes /15 seconds
	5. Superman: on all fours, with hands holding a roll (SISSEL Pilates Roller), patients will have to perform and hold the superman position (simultaneous extension of an UL and contralateral LL). The exercise will also be performed dynamically: hand touching the knee and then moving away, while keeping the pelvis in a neutral position.	5. 8 (4 for each diagonal: 2 dynamic and 2 keeping the position)/30 seconds/10 seconds
	6. Exercises with the Pilates roll: (a) patients will be sitting on one end of the roll (SISSEL Pilates Roller) and must move their trunk backward (reaching the stability limit), while keeping both feet fully supported on the floor; (b) with the spine resting on the roll and hands and feet on the floor, patients will place their hips and knees in flexion of 90º, without losing balance. This exercise will also be performed dynamically (raising and lowering the legs) and removing one of the hand supports.	6. a. 3/15 seconds/10 seconds b. 4 (2 dynamic and 2 keeping the position)/50 seconds/10 seconds
Stretching (8 minutes)	Gastrocnemius, quadriceps, ischiotibial, adductors, quadratus lumborum, deltoid, triceps brachii, superior trapezius	2 (right and left side)/30 seconds/5 seconds
Relaxation (12 minutes)	Jacobson progressive muscle relaxation, with classical music	12 minutes uninterrupted activity

UL, upper limb; LL, lower limb; Dynair, balance disc.

Table 3
Descriptive anthropometric and demographic analysis.

	Study population ($n = 40$)	AT ($n = 20$)	LBT ($n = 20$)
	Mean (SD)	Mean (SD)	Mean (SD)
Age (years)	50 (9)	48 (9)	52 (9)
	Median (IQR)	Median (IQR)	Median (IQR)
Height (m)	1.6 (1.5 to 1.6)	1.6 (1.5 to 1.6)	1.6 (1.5 to 1.6)
Weight (kg)	67 (62 to 72)	67 (61 to 76)	65 (63 to 79)
Body mass index (kg/m^2)	27 (25 to 30)	26 (25 to 30)	27 (25 to 32)
Symptom duration (years)	11 (6 to 15)	11 (7 to 14)	11 (5 to 17)

SD, standard deviation; IQR, interquartile range; AT, aquatic therapy; LBT, land-based therapy.

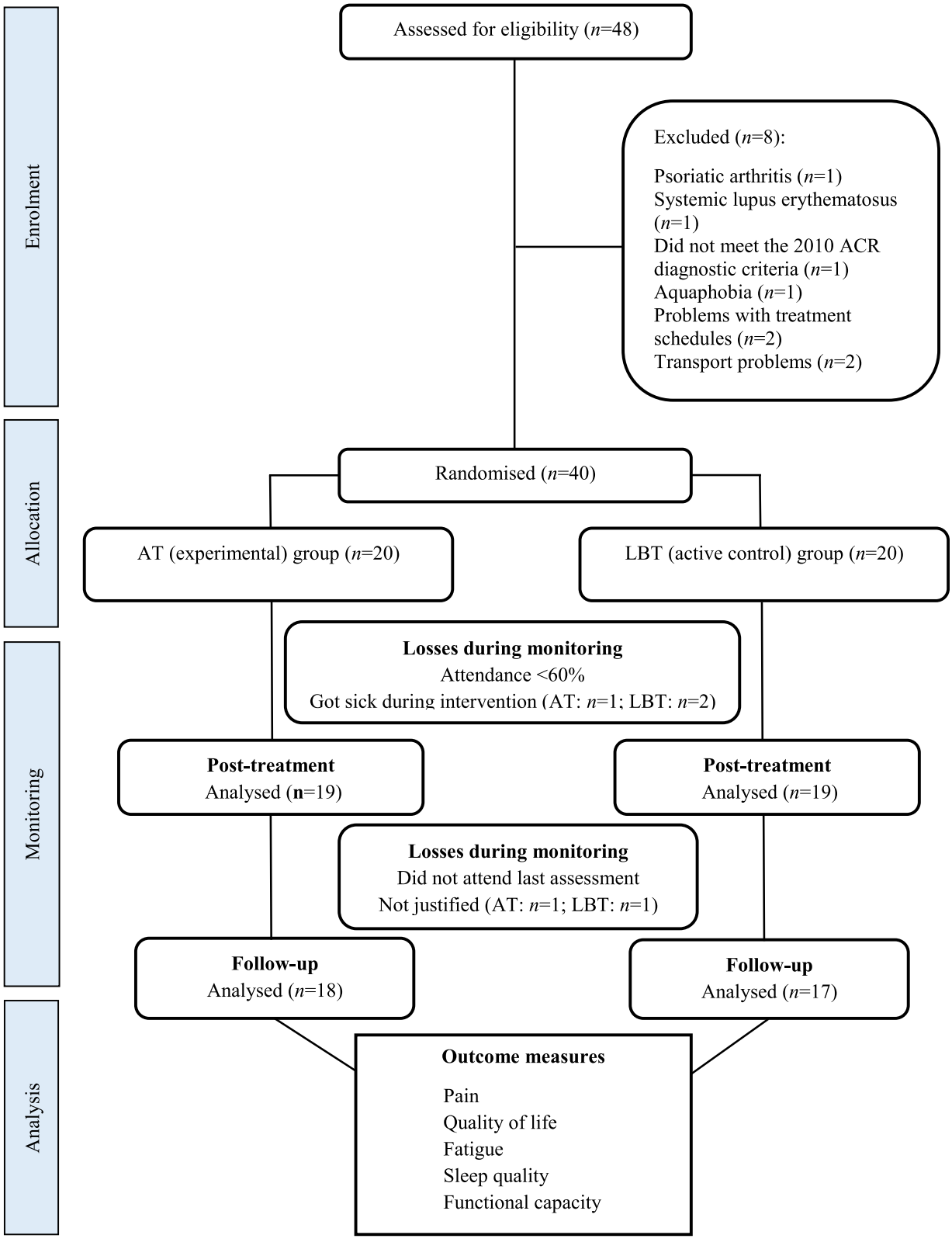

Fig. 1. Study flowchart. AT, aquatic therapy; LBT, land-based therapy.

Table 4
Post-hoc comparisons: baseline vs post-treatment, post-treatment vs follow-up, and follow-up vs baseline scores. Intergroup comparisons: post-treatment and follow-up time points of the assessed outcomes in women with fibromyalgia.

	Baseline (Week 0) $n = 40$	Post-treatment (Week 12) $n = 37$	Follow-up (Week 18) n = 35	B vs P	P vs F	B vs F	AT vs LBT in P	Cohen's d[a] (95% CI)	AT vs LBT in F	Cohen's d[b] (95% CI)
Primary outcome	Median (IQR)	Median (IQR)	Median (IQR)	*P*-value	*P*-value	*P*-value	*P*-value[c]		*P*-value[c]	
VAS							0.80	0.1 (−0.6 to 0.7)	**0.023**	0.8 (0.1 to 1.5)
AT	4.6 (3.6 to 6.0)	3.8 (1.2 to 5.6)	2.7 (1.5 to 4.9)	**0.020**[d]	0.93[d]	**0.016**[d]				
LBT	5.8 (4.3 to 7.1)	3.7 (2.7 to 5.5)	5.5 (3.3 to 7.6)	**0.002**[d]	**0.026**[d]	0.35[d]				
Secondary outcomes										
PPT (kg/cm^2)							0.49	0.5 (−0.2 to 1.1)	0.58	0.3 (−0.4 to 1.0)
AT	0.7 (0.5 to 0.9)	0.9 (0.7 to 1.2)	0.9 (0.7 to 1.3)	**0.005**[d]	0.74[d]	**0.002**[d]				
LBT	0.7 (0.4 to 1.1)	0.9 (0.7 to 1.6)	1.2 (0.7 to 1.3)	**0.001**[d]	0.17[d]	0.06[d]				
FIQR total							0.29	0.4 (−0.2 to 1.1)	0.48	0.2 (−0.4 to 0.9)
AT	62.3 (47.5 to 77.6)	48.3 (25.8 to 56.8)	45.4 (36.2 to 67.1)	**0.001**[d]	0.51[d]	**0.008**[d]				
LBT	61.3 (57.9 to 73.0)	52.1 (38.4 to 69.1)	48.2 (39.3 to 66.8)	NS	NS	NS				
PSQI total	14.5 (10.8 to 16.8)	11.0 (10.0 to 14.0)	12.0 (7.3 to 15.3)	NS	NS	NS	0.12	0.5 (−0.2 to 1.1)	**0.030**	0.8 (0.1 to 1.5)
AT	15.0 (11.3 to 18.0)	14.0 (11.5 to 16.3)	15.0 (13.0 to 17.0)	NS	NS	NS				
LBT										
General fatigue (MFI)	11.0 (10.0 to 14.5)	10.0 (8.0 to 11.0)	10.5 (9.0 to 12.3)	NS	NS	NS	0.15	0.4 (−0.3 to 1.0)	0.18	0.5 (−0.2 to 1.2)
AT	13.5 (12.0 to 16.0)	10.0 (10.0 to 12.0)	12.0 (10.5 to 13.0)	**0.003**[d]	0.27[d]	0.06[d]				
LBT										
Physical fatigue (MFI)	10.0 (7.0 to 11.8)	8.0 (7.0 to 11.0)	9.0 (7.8 to 10.3)	NS	NS	NS	0.43	0.3 (−0.4 to 0.9)	0.34	0.5 (−0.2 to 1.2)
AT	12.0 (8.3 to 12.8)	9.0 (8.0 to 11.3)	9.0 (8.0 to 12.0)	NS	NS	NS				
LBT										
Mental fatigue (MFI)	14.0 (12.0 to 16.8)	15.0 (12.0 to 16.0)	15.5 (12.8 to 16.3)	NS	NS	NS	0.71	-0.1 (−0.7 to 0.6)	0.29	-0.3 (−1.0 to 0.4)
AT	12.5 (12.0 to 16.0)	14.0 (12.5 to 16.3)	15.0 (12.5 to 16.0)	NS	NS	NS				
LBT										
Reduced activity (MFI)	7.0 (5.3 to 10.8)	9.0 (7.0 to 11.0)	9.0 (5.8 to 12.0)	**0.012**[d]	0.13[d]	0.32[d]	0.49	0.2 (−0.5 to 0.8)	0.93	0.03 (−0.6 to 0.7)
AT	7.5 (5.0 to 9.0)	10.0 (7.3 to 13.0)	8.0 (8.0 to 11.0)	**0.013**[d]	0.27[d]	0.17[d]				
LBT										
Reduced motivation (MFI)							0.77	-0.1 (−0.7 to 0.6)	0.23	-0.4 (−1.1 to 0.3)
AT	13.5 (10.5 to 14.8)	14.0 (12.0 to 16.0)	14.0 (11.5 to 16.0)	NS	NS	NS				
LBT	12.0 (10.0 to 13.0)	13.5 (12.0 to 16.0)	13.0 (10.5 to 15.5)	NS	NS	NS				
6MWT (m)							0.58	0.4 (−0.3 to 1.0)	0.25	0.2 (−0.5 to 0.9)
AT	475 (436 to 528)	528 (507 to 554)	527 (475 to 567)	**0.001**[d]	0.74	**< 0.001**[d]				
LBT	492 (402 to 532)	535 (502 to 597)	562 (508 to 580)	**< 0.001**[d]	0.61	**< 0.001**[d]				

B, baseline; P, post-treatment; F, follow-up; AT, aquatic therapy; LBT, land-based therapy; IQR, interquartile range; VAS, visual analogue scale; PPT, pressure pain threshold; FIQR, Revised Fibromyalgia Impact Questionnaire; PSQI, Pittsburgh Sleep Quality Index; MFI, Multidimensional Fatigue Inventory; 6MWT, 6-Minute Walk Test; CI, confidence interval; NS, non-significant comparisons in the Friedman test.
[a]Effect size: AT vs LBT post-treatment.
[b]Effect size: AT vs LBT follow-up.
[c]Mann–Whitney *U*-test.
[d]Bonferroni correction post-hoc test comparisons.
Bold type indicates significance.

Fatigue

When comparing the baseline and post-treatment scores, significant differences were observed in the 'reduced activity' domain for both groups. Differences in the 'general fatigue' domain were found in the LBT group alone ($P = 0.003$).

Functional capacity

A significant change in functional capacity was observed for both groups post-treatment (AT: $P = 0.001$; LBT: $P < 0.001$), with the therapeutic effects maintained at follow-up.

Discussion

This study found that women with FM who had undertaken AT experienced significantly greater improvements in pain and sleep quality compared with women who had undertaken LBT at follow-up. Additionally, the women in the AT group achieved significant increases in QOL and functional capacity post-treatment, which were maintained at follow-up.

Regarding pain intensity, significant differences were not found between the groups post-treatment, but a significant difference was observed at follow-up, in favour of AT. These differences could be due to the results of post-hoc comparisons. After the 3-month intervention, the VAS score was reduced significantly in both groups. However, pain progression differed between the groups at follow-up; the therapeutic effect was maintained in the AT group, but returned to the baseline value in the LBT group.

The results of a recent study [16], with a similar intervention design, coincides with the post-treatment observations in the present study after 8 weeks of treatment, no significant differences were found between the groups. However, these results do not align with those of Evcik *et al*. [15], who demonstrated that AT was more effective in reducing pain than LBT after 5 weeks of intervention. This discrepancy could be due to methodological differences. Unlike the present study, where the interventions were very similar to each other, Evcik *et al.* compared a supervised AT programme with an unsupervised home exercise programme [15]. This could explain the differences between the groups observed after treatment.

While it is true that both AT and LBT can reduce pain intensity significantly in FM, it seems that AT could have a greater effect in terms of magnitude and duration, possibly due to the physiological effects of immersion in warm water. Sensorimotor hyperstimulation exerted by hydrostatic pressure, viscosity and water temperature increases the triggering of thermal receptors and mechanoreceptors while blocking nociceptors, which would lead to less pain [31]. Also, immersion helps to increase blood flow, improving nutrition and the removal of cytokines involved in the inflammatory process of FM [32]. The present results showed a longer-lasting therapeutic effect for the AT group, although the follow-up period cannot be considered medium term [17]. The duration and frequency of the study interventions may have allowed the unique thermal and mechanical properties of the aquatic environment to act for a long time, increasing activation of the descending pain inhibitory system [15] and ultimately promoting changes in pain processing.

Regarding PPT, no differences were found between the groups. Nevertheless, López-Rodríguez *et al.* [33] observed that, when comparing aquatic biodance with stretching, PPT was significantly higher at most tender points in the aquatic biodance group. The fact that the protocols consisted of exercises of different activity levels [i.e. active (aquatic biodance) and passive (stretching) exercises] could have influenced the results. A more recent study [16] with a water and land-based intervention design more similar to the present study did not find significant differences between groups after treatment in terms of reducing the number of tender points.

Both groups experienced improvements in QOL after treatment; the difference was significant for the AT group, and very close to significance for the LBT group. These results suggest that an intervention, in or out of water, could be an effective resource for the management of FM. The global impact of FM includes personal, professional, family and social aspects. Sieczkowska *et al.* [34] observed that patients with FM who practised active exercise showed improvement in several aspects related to QOL, such as general well-being, lower rates of depression and fewer work absences. In the same way, the therapies in the present study involved active exercise, including different body functions (aerobic, resistance, balance, strength and flexibility), and significant improvements were observed in pain intensity and functional capacity in both groups; these symptoms are strongly correlated with QOL [35].

For sleep quality, significant differences between groups were observed in favour of AT at follow-up. Differences may not have been observed post-treatment due to the evaluation tool used. The PSQI assesses sleep quality for the preceding month, so the follow-up results would refer to a date closer to the end of therapy. During immersion in warm water, there is activation of the parasympathetic nervous system, analgesia in nerve endings and an increase in the pain threshold, leading to a reduction in pain and induction of relaxation. This could create favourable conditions for improving sleep [36]. Additionally, the PSQI did

not show differences between the evaluations for either of the groups, but the reduction in score was clinically relevant for the AT group post-treatment, with a decrease of >3 points [26]. These results coincide with a recent study [37] which supported the influence of an aquatic environment in sleep induction.

The results of this study did not reflect a significant effect on fatigue. There was a significant decrease in general fatigue in the LBT group, but a significant increase in the degree of reduced activity in both groups post-treatment. Observing intergroup comparisons, the groups were not homogeneous at baseline for general fatigue: the score for the LBT group was almost 2 points higher compared with the score for the AT group. In FM, patients with more severe initial symptoms experience a greater degree of improvement [38]. Perhaps for this reason, significant differences were seen in the LBT group but not in the AT group. The results for the activity reduction dimension could be because, for these patients, the commitment to attend intervention sessions three times per week for 12 weeks could influence their perception of time available for other activities.

The protocols for this study included AE, which seems to have a moderate effect on FM compared with no intervention [39]. The interventions were undertaken at moderate intensity, monitored with the modified Borg scale, and as the therapies were performed in groups, this fostered a supportive environment where participants encouraged each other, maintaining motivation throughout the therapy. A larger sample with more time dedicated to AE may have shown more conclusive differences in general or physical fatigue.

With regards to functional capacity, both groups improved post-treatment, maintaining the therapeutic effect at follow-up. These results coincide with those of Sevimli *et al*. [40], who observed that the AE and aquatic AE groups experienced significant improvements in functional capacity compared with the isometric strength and stretching exercise groups. However, they did not find differences between the AE groups, concluding that both programmes were effective. Both of these interventions involved AE, which was also included in the treatment protocols in the present study, and had a positive impact on the functional capacity of patients with FM [39] when performed in water.

The present study has some limitations. Although the study demonstrated beneficial effects in most outcomes, the results should be interpreted with caution due to the small sample size. Regarding the relaxation techniques of the interventions, although it is true that they differed in terms of activity level, their objective was the same: to induce relaxation. In water, due to the instability of the environment, it is more difficult to perform passive relaxation in a group, which is why Ai Chi was chosen.

Future clinical trials with a rigorous methodology and longer follow-up are needed to confirm if AT maintains the decrease in pain intensity for longer than LBT.

Conclusion

The results suggest that AT is better than LBT for reducing pain and improving sleep quality in women with FM at 6 weeks of follow-up. Although both therapies improved pain at the end of treatment, the therapeutic effect was maintained for longer in the AT group. Thus, regular AT can be adopted as a complementary approach to FM treatment, as it may promote pain reduction and enhance sleep quality, and could be beneficial for restoring physical capacity while improving QOL.

Ethical approval: The Autonomic Committee of Research Ethics of Galicia (Spain) approved this study on 18 February 2015 (Registration Code 2015/021).

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.physio.2024.02.005.

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