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ORIGINAL ARTICLE

A Randomized Controlled Trial of Deep Water Running: Clinical Effectiveness of Aquatic Exercise to Treat Fibromyalgia

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Objective. **To compare the clinical effectiveness of aerobic exercise in the water with walking/jogging for women with fibromyalgia (FM).**

Methods. **Sixty sedentary women with FM, ages 18–60 years, were randomly assigned to either deep water running (DWR) or land-based exercises (LBE). Patients were trained for 15 weeks at their anaerobic threshold. Visual analog scale of pain, Fibromyalgia Impact Questionnaire (FIQ), Beck Depression Inventory, Short Form 36 Health Survey (SF-36), and a patient's global assessment of response to therapy (PGART) were measured at baseline, week 8, and week 15. Statistical analysis included all patients.**

Results. **Four patients dropped out from each group. Both groups improved significantly at week 15 compared with baseline, with an average 36% reduction in pain intensity. For PGART, 40% of the DWR group and 30% of the LBE group answered "much better" at posttreatment. FIQ total score and FIQ depression improvements in the DWR group were faster (week 8) than the LBE group and kept improving (week 15; $P < 0.05$). Only the DWR group showed improvements in SF-36 role emotional ($P = 0.006$). No significant between-group differences were observed for peak oxygen uptake and other outcomes.**

Conclusion. **DWR is a safe exercise that has been shown to be as effective as LBE regarding pain. However, it has been shown to bring more advantages related to emotional aspects. Aerobic gain was similar for both groups, regardless of symptom improvement. Therefore, DWR could be studied as an exercise option for patients with FM who have problems adapting to LBE or lower limbs limitations.**

KEY WORDS. Fibromyalgia; Treatment; Hydrotherapy; Physical fitness; Aerobic exercise; Randomized clinical trial.

INTRODUCTION

Fibromyalgia (FM) is a widespread musculoskeletal pain syndrome with diminished pain threshold. Many studies have now demonstrated abnormal sensory processing in individuals with FM, further supporting the organic nature of the abnormal central pain processing in FM (1). Sedentary lifestyle and unfitness are factors that can trigger this illness in which reduced tolerance and sympathetic response to exercise are found (2–8).

Regular physical exercise has been proven to be useful in treating patients with FM (9–11). Several studies have demonstrated a reduction in pain and fatigue and improvements in sleep and mood quality. Many mechanisms of exercise benefits can be attributed to tissue oxygenation improvements, increased muscle endurance, and high energy phosphate levels (11–13). Most studies provide the scientific evidence of the therapeutic effects of exercise using aerobic training by walking or running. These studies do not clarify the exact duration and intensity needed, nor do they clarify the relationship between aerobic gain and symptom improvement (9–11,14,15).

Individualized prescription based on fitness assessment

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and monitoring with frequency meters may favor exercise performance with enough intensity for aerobic gain. The anaerobic threshold seems to be a physiologic limit and may be the best outcome measure of an ergometric evaluation because it is less influenced by pain (8).

Several modalities of aerobic training can benefit patients with FM; however, pool exercises can bring some advantages due to the effects of the biophysical properties of immersion: buoyancy, hydrostatic pressure gradient, water viscosity, specific heat of water, and controlled temperature (16,17). Weight-bearing, tactile, and thermal stimulation as well as the inertial effect of the movement can lead to relaxation, joint overload and eccentric effort reduction, vasodilatation by warming, and analgesia. When the immersed limbs move faster, reaching a critical level of speed, water turbulence occurs. This situation creates a hydrodynamic force that offers resistance to body movement (16–18). Also, a wide repertoire of movement is possible, allowing proprioception, body balance, strength, and aerobic exercises (17).

Although hydrotherapy is widely used in general practice, there are few studies related to FM. Aquatic exercise seems to be useful for improvement in FM symptoms, but none of the water-based studies used standardized evaluation, prescription, and training. Improvement due to galvanic baths has been demonstrated in 2 studies (19,20). Mixed exercises (aerobic, endurance, and flexibility), on land and in water, were effective in 2 studies, one of which demonstrated an association between relaxation and education (21,22). Patients who underwent pool exercises associated with education showed better results, which were maintained after 2 years, than controls (23,24). Only Jentoft et al (25) compared pool-based and land-based exercises (LBE) in a randomized clinical trial. Thirty-four patients completed a 20-week training program consisting of exercise sessions 2 times a week with mixed exercises. For 20 minutes they maintained 60–80% of the maximum heart rate. Within-group improvements in symptoms and cardiovascular capacity were noted for both groups. The warm-water pool group achieved greater reduction in pain, anxiety, and depression; however, a small sample of patients was studied and 22.7% dropped out (25).

Regarding the scientific evidence favoring aerobic training and the possible advantages of water-based exercises, a safe modality of aerobic conditioning in water has been proposed: deep water running (DWR). In DWR, the patient performs a running movement in the pool while wearing a floating belt, with no contact with the bottom of the pool, which eliminates impact (18,26). Therefore, the aim of this study was to compare the effects of 2 different aerobic exercise programs in women with FM: water- and land-based exercises. Adverse events, aerobic conditioning, and relationship between improvements in symptoms and aerobic gain were also studied.

PATIENTS AND METHODS

A total of 60 sedentary women who fulfilled the American College of Rheumatology classification criteria for FM (1) were recruited from the rheumatology outpatient clinic of the Federal University of São Paulo (UNIFESP), a tertiary level of care, from September 2000 to December 2001 (Figure 1). Patients were screened for entry into the study by just one investigator (DF) who was blind to forthcoming patients' allocation. All patients who were included were required to be literate, age 18–60 years old, and kept in an unchanged drug regimen for at least 4 weeks before starting the study. Patients with symptomatic cardiac failure, uncontrolled thyroid disturbances, body mass index ≥40, infectious contagious skin diseases, coronary disease, pulmonary disease, neurologic disease, and rheumatic disease limiting or hindering their ability to exercise, and those who had performed regular physical activity in the 6 weeks before the trial were not included. The inability to swim was not an exclusion criterion.

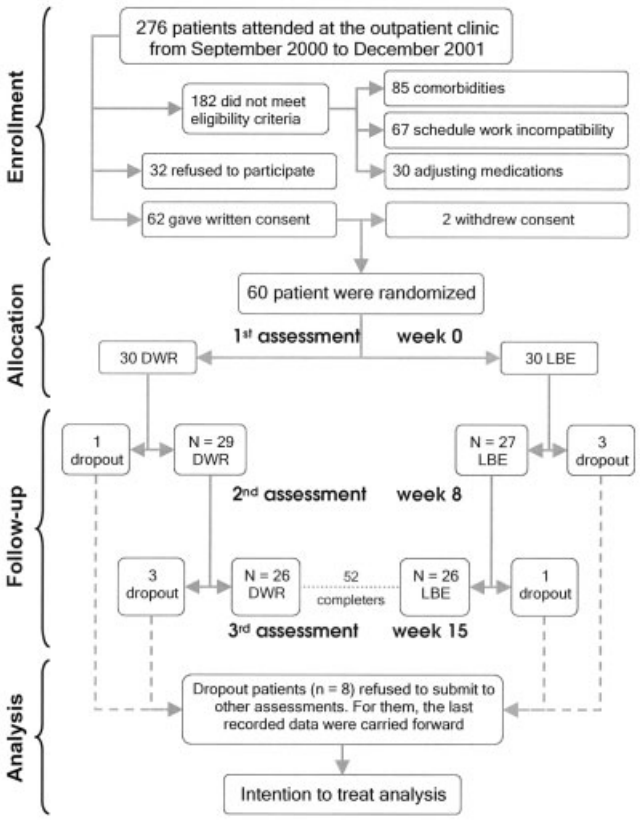

Figure 1. Diagram showing the flow of participants through each stage of the trial. DWR = deep water running; LBE = land-based exercises.

The 60 patients were randomly assigned to either DWR in a warmed swimming pool (28–31°C) or LBE (walking or jogging). Patients were allocated to treatment groups by simple randomization according to drawing lots. Folded pieces of paper in which the interventions' label were written (LBE and DWR) were contained in a set of sealed envelopes. One of the investigators (JN) took the envelopes out of a container to see who would go to which group. He remained unaware of screening and assessments of the patients during the randomization process.

Patients performed supervised training at their anaerobic threshold determined by a graded treadmill exercise test with spirometric analyses. All the assessments of both

groups and the pool-based exercises were performed in the Sports and Physical Medical Center (CEMAFE) of UNIFESP. LBEs took place in a local city park. The Ethics Committee of UNIFESP approved the study. Patients were required to sign a written consent form to be able to participate.

Procedures. Patients were interviewed to complete a set of questionnaires, and afterwards they underwent a spiroergometric test prior to intervention at weeks 8 and 15 (week 0, 8, 15). Patients were randomized after the initial assessment. All the assessments were performed by the same investigator (AMBA) who remained unaware of the allocation throughout the trial.

Both groups exercised for 60 minutes, 3 times a week for 15 weeks, following the 1998 American College of Sports Medicine guidelines (27). For both groups, each session was composed of a 10-minute stretching warmup, followed by aerobic training according to the desired intensity for 40 minutes and after that a 10-minute relaxation period. The exercise prescription was based on the heart rate at the anaerobic threshold (HR_{AT}) determined at the initial assessment. Heart rate (HR) was readjusted after week 8 based on the second test.

The HR variation in immersion is influenced by water temperature and exercise intensity; therefore, the DWR group trained at 9 beats/minute lower than the LBE group. This was based on previous studies of submaximum underwater exercise in temperatures from 28°C to 31°C (18,28).

All sessions were supervised by 2 physical therapists (LES and APP) who alternated groups weekly; neither of them was involved in the clinical and fitness assessments. The HR of the patients was registered in 10-minute intervals with a pulse watch recorder model A1 Polar (Polar, Helsinki, Finland). An adaptation interval with low-intensity exercises lasted 2 weeks, emphasizing the learning of the new movements. Afterwards, the patients were asked to exercise at the HR_{AT}. In case of pain while exercising, the patients were instructed to reduce the intensity for a short time for pain relief. After that they were expected to reach the target HR again. The patients' drug regimen was unaltered throughout the study. Acetaminophen, up to 3 gm/day, was allowed as rescue medication.

Patients from the LBE group were instructed to begin walking and maintain their paces to achieve the target HR. Each patient should set a controlled regular speed based on individualized prescription rather than keeping pace with another patient. If the exercise intensity was not found to be within the desired limits, the patient could jog or run in the training area near the supervisor, without talking to other patients.

Patients in the DWR group were submitted to adaptation to the underwater medium because some of them had never entered a swimming pool before or were not able to swim. DWR consisted of simulated running in the deep end of a pool aided by a flotation device that maintained the head above the water. Patients were instructed in the following DWR technique: 1) an upright posture with spine maintained in a neutral position; 2) running in place, held in one location by a tether cord; 3) water line kept at shoulder level; 4) upper limbs alternating shoulder flexion-extension movements, with elbows in right angle, moving hands from the waist level to 5 cm below the water surface; 5) hands held tightly clenched; 6) lower limbs in a bicycling action; 7) end of hip flexion at ~70° with lower leg being perpendicular to the horizontal; and 8) throughout the cycle, ankle dorsal flexion and eversion occurring during the lower leg flexion and plantar flexion and inversion during the extension. Patients from the DWR group were also instructed to keep a regular speed to achieve the prescribed HR.

Clinical outcomes. The primary outcome was a visual analog scale of pain (VAS) graded from 0 to 10, with 0 being no pain and 10 being the worst imaginable pain. Secondary outcomes included patient global assessment of response to therapy (PGART) on a 5-point scale (1 = much better, 2 = better, 3 = slightly better, 4 = no change, and 5 = worse); Short Form 36 Health Survey (SF-36) (29), a generic health status questionnaire that is widely used and has been validated into Portuguese (30), with calculation of the physical and mental components summary; Beck Depression Inventory (BDI) (31), a 21-item inventory measuring depression that has been validated into Portuguese (32), recommended for the assessment of changes induced by exercise (33); and Fibromyalgia Impact Questionnaire (FIQ), a brief 10-item instrument that measures physical functioning and symptom severity, developed and validated for an FM population (34).

Physical fitness outcomes. Patients performed an increasing load protocol on a treadmill model 9100HR Life Fitness (Life Fitness, Franklin Park, IL). HR was recorded at the end of each stage. The expired gas was collected by a transparent silicone mask, which covered the nose and mouth. A computerized metabolic system, Mini Vista CPX Turbofit Vacumed (Vacumed, Ventura, CA), was used to analyze the data obtained in 30-second intervals.

The following outcomes of physical fitness were obtained: peak oxygen uptake (peak Vo_2), expressed in $ml \cdot kg^{-1} \cdot minute^{-1}$; anaerobic threshold, determined using the slope point on the curve of the oxygen ventilatory equivalent, which corresponds to lactic acidosis increase (35); peak HR; and HR_{AT}. Anaerobic threshold was considered the mean value of 2 blinded investigators' independent readings.

Sample size. To achieve an improvement in VAS pain of 2.0, with a SD (11) of 2.1, an alpha (2-tailed) of 0.05, and a beta of 0.10, a minimum of 23 patients per group was necessary. However, 30 patients were randomized as a previous compensation for the possible 20% loss at followup.

Statistics. An intent-to-treat analysis was performed, using the last-observation-carried-forward method. A level of significance of $P < 0.05$ (2-tailed tests) was accepted for the trial. For normally distributed data, the dependent variables were analyzed using a 2 per 3 repeated-measures

Table 1. Demographic and physical fitness data at study entry for the DWR and the LBE groups in the intent-to-treat analysis and per protocol*

	Intent-to-treat analysis		Per protocol		
	LBE group n = 30	DWR group n = 30	LBE group n = 26	DWR group n = 26	Dropout n = 8
Age, mean ± SD years	42.17 ± 10.05	43.43 ± 10.76	44.04 ± 8.87	43.96 ± 10.28	35.00 ± 12.76
Marital status, no.					
Single	8	7	6	6	3
Married	21	22	19	19	5
Separated	1	1	1	1	—
Education level, no. (%)					
<4 years	11 (36.7)	14 (46.7)	10 (38.5)	13 (50)	2 (25)
4–11 years	9 (30)	5 (16.7)	8 (30.7)	3 (11.5)	3 (37.5)
>11 years	10 (33.3)	11 (36.7)	8 (30.7)	10 (38.5)	3 (37.5)
Complaint duration, mean ± SD months	83.13 ± 54.84	61.93 ± 47.17	88.81 ± 54.42	63.15 ± 47.82	50.12 ± 44.83
Psychotropic drugs, no. (%)					
Neuroleptic	2 (6.7)	3 (10)	2 (7.7)	2 (7.7)	1 (12.5)
Tricyclic compounds	8 (26.7)	9 (30)	8 (30.8)	9 (34.6)	—
SRI	1 (3.3)	1 (3.3)	1 (3.8)	1 (3.8)	—
HRT	3 (10)	2 (6.7)	2 (7.7)	1 (3.8)	2 (25)
Fitness characteristics, mean ± SD					
BMI	26.89 ± 4.63	27.31 ± 5.43	27.72 ± 4.36	27.19 ± 5.40	24.79 ± 5.63
AT, ml · kg^{-1} · minute^{-1}	17.86 ± 3.91	19.41 ± 4.25	17.61 ± 4.04	19.41 ± 4.41	19.45 ± 2.98
Peak Vo_2, ml · kg^{-1} · minute^{-1}	27.67 ± 5.19	28.77 ± 5.17	26.86 ± 4.71	28.79 ± 5.18	30.82 ± 5.91
Questionnaires, mean ± SD					
FIQ total	60.69 ± 12.85	67.59 ± 13.86	60.76 ± 13.17	66.09 ± 14.06	68.80 ± 13.21
BDI	16.40 ± 7.97	21.83 ± 8.94	15.50 ± 7.60	21.46 ± 9.54	23.25 ± 6.20
SF-36 physical component	64.12 ± 7.26	65.57 ± 6.38	64.34 ± 7.05	65.38 ± 6.80	64.75 ± 6.85
SF-36 mental component	56.73 ± 5.91	57.66 ± 5.00	56.89 ± 6.18	57.38 ± 5.32	57.57 ± 3.45

* Studied population comprised women only. DWR = deep water running; LBE = land-based exercise; SRI = serotonin reuptake inhibitor; HRT = hormonal replacement therapy; BMI = body mass index; AT = anaerobic threshold; peak Vo_2 = peak oxygen uptake; FIQ = Fibromyalgia Impact Questionnaire; BDI = Beck Depression Inventory; SF-36 = Short Form 36 Health Survey.

analysis of variance (ANOVA). The independent variables in all analyses were group (DWR versus LBE; between subjects factors) and time (baseline, 8 weeks, and 15 weeks; within subjects factors). Independent sample *t*-tests were used in the between-groups comparison of the change scores at midline and treatment completion, when interaction time × group was significant. A 95% confidence interval (95% CI) was used. Friedman's test was used for non-normally distributed variables, as an equivalent of ANOVA. Wilcoxon's signed rank test was used to analyze the difference between times separated by group when the change score was non-normally distributed. The *P* values and the confidence intervals from the comparisons of the means are shown with Bonferroni correction.

In addition to the analyses of continuous numeric data of VAS pain and BDI, an analysis of data was also conducted in categories to detect changes of clinical significance. BDI scores were reanalyzed using the following cutoff scores (22): <12 (not depressed), 12–16 (mildly depressed), 17–23 (moderately depressed), and ≥24 (severely depressed). VAS pain was also reanalyzed according to the percentage of improvement shown by patients over time as proposed by Wigers et al (36). The following categories were determined: worse or unchanged (deterioration or improvement <10%), 11–20% reduction, 21–30% reduction, and >30% reduction on initial VAS score.

To analyze PGART, a score of 1 or 2 was considered clinically important; missing values from dropout patients and the other scores were computed as nonresponse to treatment. For each physical fitness outcome, a 15% improvement between week 0 and week 15 was considered clinically significant (11). Fisher's exact test and chi-square test were used to determine differences in rates of improvement between the 2 groups. Pearson's and Spearman's correlation coefficients were used. All tests were performed using SPSS version 10.0.1 (SPSS, Chicago, IL).

RESULTS

A total of 276 patients were screened, of whom 60 were included in the study after initial assessment. Four participants in each group dropped out during the intervention, leaving 56 participants at midline and 52 participants at the final assessment (Figure 1). The alleged reasons for leaving the study were related to personal problems and incompatibility with patients' work schedules; thus, adverse events were not indicated as a cause of interruption. Patients who left treatment refused to undergo other evaluations; for these patients, any missing data were replaced with the last known value, even if this was the baseline value.

There were no statistically significant differences between study groups at baseline (Table 1). There were no

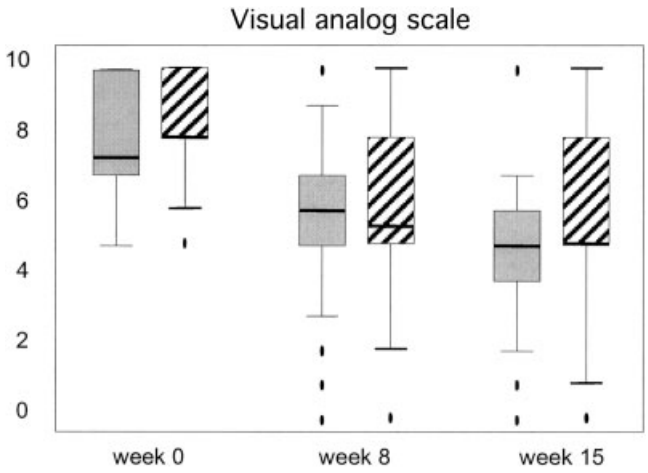

Figure 2. Comparisons of scores from the visual analog scale by treatment group. Gray boxes denote land-based exercise group; striped boxes denote deep water running group. Box plots show the median, quartiles, extreme values, and outliers for the variable.

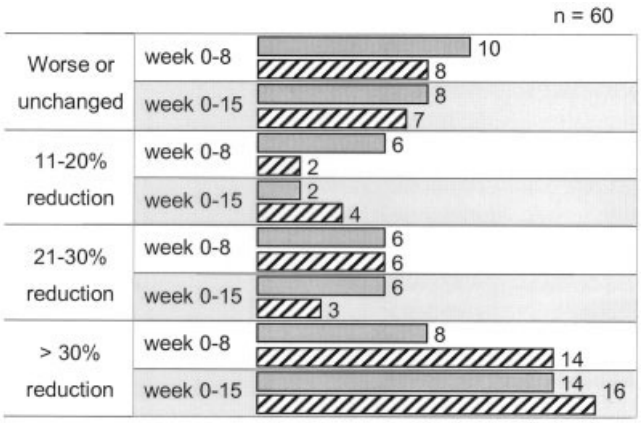

Figure 3. Number of patients from the land-based exercise and deep water running groups reporting <11%, 11–20%, 21–30%, and >30% reduction in visual analog scale pain score. No difference was found by chi-square-test. Gray boxes denote land-based exercise group; striped boxes denote deep water running group.

statistically significant differences in demographic and physical fitness data between patients who dropped out and those who remained in the program, except for age (mean age 35 years versus 43 years). The completers performed at least two-thirds of the sessions, and no one missed more than 3 consecutive sessions.

Among the patients who completed the program, there were 10 adverse events in the DWR group and 16 in the LBE group, with no significant difference (Fisher's exact test, $P = 0.19$). In case of pain, training intensity was reduced, but the duration of the session was maintained. Four patients in the DWR group reported muscle pain and 1 reported tinea pedis. There were 12 patients in the LBE group who reported muscle pain. One of them presented an impingement syndrome (on the right side); another presented bilateral ankle arthritis; and a third presented a Baker cyst.

VAS. The VAS scores improved progressively, and both groups experienced a mean decrease of 36% from baseline to week 15 ($P < 0.001$). Median (interquartile range [IQR]) VAS scores at the 3 assessments were 7.5 (6.75–10.0), 6.0 (5.0–7.25), and 5.0 (3.75–6.0) for the LBE group and 8.0 (8.0–10.0), 5.50 (5.0–8.0), and 5.00 (4.75–8.0) for the DWR group (Figure 2). There was no difference between groups in continuous or categorical analysis of VAS score changes (Figure 3).

PGART. Fifty percent of the patients from the LBE group rated themselves as clinically improved at week 8; this group continued improving up to 73% at week 15. Seventy percent from the DWR group were considered responders at week 8, and showed no further improvement at the end.

The proportions of patients rating themselves as clinically improved or as not improved were compared, although no statistical difference was observed between the groups at the middle (chi-square test, $P = 0.28$) or at the end (chi-square test, $P = 0.77$). One patient in the LBE group reported worsening in the PGART.

FIQ. Both groups had improved FIQ total scores at the 3 assessments, with mean ± SD scores of 60.69 ± 12.85, 47.24 ± 19.66, and 43.09 ± 19.99 for the LBE group and 67.59 ± 13.86, 44.24 ± 19.26, and 38.63 ± 19.57 for the DWR group, respectively ($F = 60.121$, $P < 0.001$). The interaction time × group was significant ($F = 3.810$, $P < 0.025$), and greater improvements were achieved by the DWR group at week 15 ($P = 0.033$, 95% CI 0.764–21.955) (Figure 4).

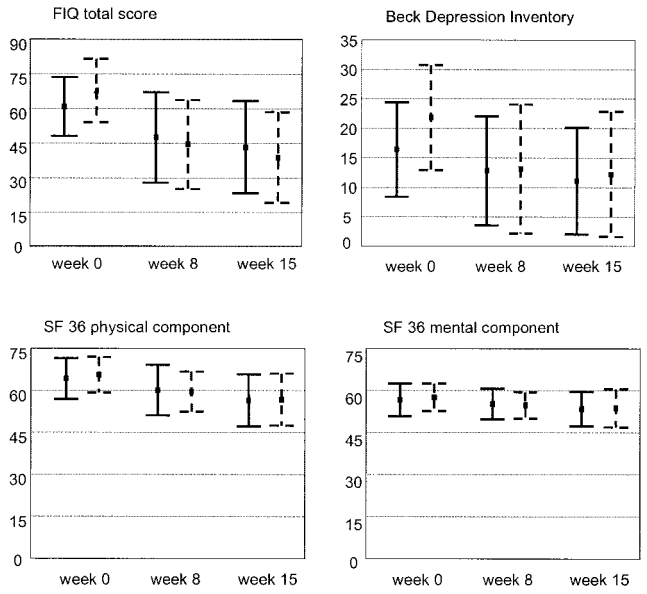

Figure 4. Comparisons of the scores from functional, depression, and quality of life questionnaires by treatment group. Solid line denotes land-based exercise group; dotted line denotes deep water running group. Error bars are mean ± 1 SD. FIQ = Fibromyalgia Impact Questionnaire; SF 36 = Short Form 36 Health Survey.

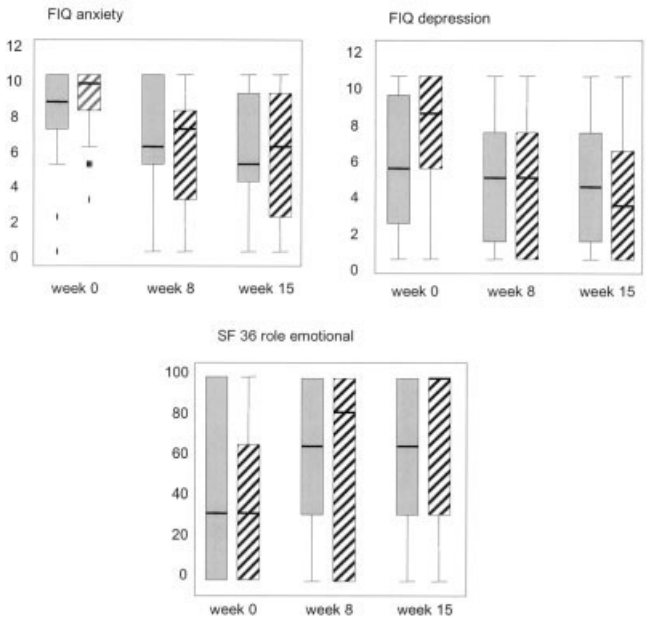

Figure 5. Comparisons of the scores from questionnaire items related to emotional aspects by treatment group. Gray boxes denote land-based exercise group; striped boxes denote deep water running group. Box plots show the median, quartiles, extreme values, and outliers for the variable. FIQ = Fibromyalgia Impact Questionnaire; SF 36 = Short Form 36 Health Survey.

The median (IQR) FIQ anxiety scores at the 3 assessments were 8.5 (7.0–10.0), 6.0 (5.0–10.0), and 5.0 (4.0–9.0) for the LBE group and 9.5 (7.75–10.0), 7.0 (2.75–8.25), and 6.0 (2.0–9.0) for the DWR group, respectively. Both groups improved (Friedman's test, LBE and DWR, $P < 0.001$ for both), although no difference between groups was noticed (Wilcoxon, LBE and DWR, $P = 0.063$ and $P = 0.092$, respectively) (Figure 5).

The median (IQR) FIQ depression scores at the 3 assessments were 5.0 (2.0–9.25), 4.5 (0.75–7.75), and 4.0 (0.75–7.0) for the LBE group and 8.0 (5.0–10.0), 4.5 (0.0–7.25), and 3.0 (0.0–6.0) for the DWR group. Both groups improved in the FIQ depression (Friedman's test, $P = 0.040$ for LBE; $P < 0.001$ for DWR), and *t*-tests showed better results for the DWR group after 8 weeks ($P = 0.028$, 95% CI 0.179–3.621) and 15 weeks ($P = 0.025$, 95% CI 0.214–3.719) (Figure 5).

BDI. Both groups improved in BDI ($F = 24.293$, $P < 0.0001$); the mean ± SD outcomes at the 3 assessments were 16.40 ± 7.97, 12.80 ± 9.26, and 11.07 ± 9.07 for the LBE group and 21.83 ± 8.94, 13.10 ± 10.96, and 12.23 ± 10.60 for the DWR group, with no difference between groups ($F = 2.882$, $P = 0.066$). BDI categorical data did not show a difference between groups (Figure 4).

SF-36. The mean ± SD SF-36 physical component scores at the 3 assessments were 64.12 ± 7.26, 60.01 ± 9.05, and 56.42 ± 9.32 for the LBE group and 65.57 ± 6.38, 59.51 ± 7.16, and 56.74 ± 9.29 for the DWR group. The mean ± SD SF-36 mental component was 56.73 ± 5.91, 55.29 ± 5.48, and 53.51 ± 6.20 for the LBE group and 57.66 ± 5.00, 54.84 ± 4.75, and 53.83 ± 6.81 for the DWR group. Both groups improved in the physical ($F = 31.349$, $P < 0.0001$) and mental ($F = 9.166$, $P = 0.0003$) component summaries, although there was no difference between groups ($F = 0.433$, $P = 0.650$ versus $F = 0.347$, $P = 0.687$) (Figure 4).

The mean (IQR) SF-36 role emotional outcomes were 33.33 (0.0–10.0), 66.67 (25.0–100.0), and 66.67 (25.0–100.0) for the LBE group. The scores improved in weeks 0 and 15 ($P = 0.012$) for the DWR group, whereas the LBE group remained unchanged during the 3 assessments (Figure 5).

Fitness. For analysis of physical fitness, outcomes showed no difference between groups, except for a greater improvement in anaerobic threshold in the LBE group ($F = 3.991$, $P = 0.021$). Mean ± SD values at the 3 assessments were 17.86 ± 3.91, 18.83 ± 4.65, and 19.32 ± 4.18 for the LBE group and 19.41 ± 4.25, 20.20 ± 5.06, and 17.96 ± 3.39 for the DWR group. A significant difference was observed between week 0 and week 15 ($P = 0.021$, 95% CI 0.370–5.439).

Considering an improvement of at least 15% in any outcome as clinically meaningful, an analysis of categorical variables was performed. Anaerobic threshold enhancement was observed in 31% of patients in both groups. An increase in peak V_{O_2} was observed in 38% and 42% of the patients in the DWR and LBE groups, respectively. Fitness categorical variables also did not show between-group differences. No important correlation was found between aerobic gain and clinical outcomes (VAS, BDI, SF-36, or FIQ scores).

DISCUSSION

Nonpharmacologic interventions in FM have been used with success in different trials, either in combination with other therapies or as isolated treatment (9). In 1976, Moldofsky and Scarisbrick showed that induction of diffuse muscle pain by sleep deprivation was delayed and intensity was reduced in fit subjects, which led exercise to be proposed as a treatment (37). Physical exercise is relatively easy to do and offers a lower risk of adverse effects when correctly performed (14).

Studies have shown that aerobic exercises have beneficial effects in terms of quality of life and pain reduction in patients with FM. Therefore, it is routinely indicated in clinical practice (9–11,14). Walking is a cheap, easily accessible and safe exercise that has been used as the standard aerobic exercise to treat FM, whereas aquatic exercise has not been extensively studied (9,14). Therefore, we proposed an aquatic exercise modality that is the most similar to walking, i.e., the deep water running.

The use of 2 therapists allowed both groups to be trained simultaneously. The interchange of the 2 therapists was thought to avoid a confounding effect, a better outcome attributable to one of the therapists.

Our results showed that clinical endpoints, including pain, mood, function, and quality of life, improved to a similar degree after both land- and water-based exercises. There were no serious side effects in the groups, confirm-

ing that patients with FM can undergo physical training without damage (38).

This study with aquatic exercise differs from previous studies because of its larger sample size, excellent compliance, and individualized, strictly controlled and supervised exercise program with higher training frequency and intensity (21–23). According to a recent meta-analysis, only the study by Wigers et al with aerobic exercise on land demonstrated an 11.4% pain decrease against 1.6% in the control group (9,36). Our patients had the highest VAS pain score at baseline among the studies reviewed, and showed an expressive mean ± SD VAS reduction of 2.8 ± 36% in the LBE group and 3.1 ± 36% in the DWR group, which are clinically relevant for approximately two-thirds of the patients in both groups. This effect was comparable only with Valim et al's work, in which the VAS pain decreased 45% in the aerobic exercise group against 26% in the stretching exercise group (11).

Previous studies that have shown modest or nonsignificant improvements in pain and/or functional outcomes prescribed very low-intensity exercise with short training and assessment periods (9,15,39,40). In both works by Van Santen et al (15,41), no important benefit in VAS was reported, even in the high-intensity physical conditioning group, which was not superior to the low-intensity group. On the contrary, exceeding a certain training intensity could increase adverse effects; patients in the high-intensity group claimed to have pain and difficulty during their training (15,39,40). In another study, the high-intensity group, reaching 85% of peak HR, worsened in the 20th week (42). Many patients reported worsening and abandoned a program that used aerobic dance (40). In the study by Mannerkorpi et al, the planned intensity of exercise was reduced because many patients reported increased pain after the training sessions (23). In another study, 17% of the patients reported symptom worsening and intolerance to the level of exercise prescribed (39). This confirms the concept that excessive effort leads to a worsening of symptoms (3,9).

In our study, we used an intensity lower than that used in the study by Meyer and Lemley (42), but higher than that used in the study by Van Santen et al (41). In spite of this, there were no frequent complaints, and the final results were better in our study. Three important differences between these previous studies and our study justify the results: we set a 2–3-week adaptation period to prevent pain due to exercise in sedentary individuals, we tolerated a temporary reduction of training intensity in patients who reported pain, and we trained the patients for a longer period. These adjustments in training intensity in the adaptation phase and during the worsening appear to be a fundamental strategy to carry out the exercise program successfully. No adverse events were cause for discontinuation.

Higher intensity exercise might lead to better results as long as it remains below the pain and fatigue threshold (11,14). We believe the best results are obtained when the exercise program follows some exercise prescription principles: minimize muscular trauma and central sensitization, avoiding important increase in pain; increase autoefficacy, allowing a sense of body control; and individualize prescription (14).

Our patients had improved PGART in the first and second halves of the study, showing that the benefit continues with time. If we consider only the best response of the PGART in the last assessment of our study, at least 70% of the groups showed high or moderate improvement, results that are more expressive than those found in the study by Richards and Scott (10).

Most outcomes showing improvement did so as early as week 8 and kept improving up to week 15. Valim et al's study (11) has also shown that several outcomes continue to improve after 10 weeks, implying that trials should be held for longer periods as others have stated (38). Several randomized trials with exercise have demonstrated improvement in FIQ total score related to control groups (21–23,43). However, a significant difference between 2 types of intervention was seen only in the study by Valim et al, which compared 20 weeks of aerobic exercise with stretching (11). In our study, we demonstrated not only an FIQ total score improvement for both groups, but also superiority of the DWR group over the LBE group at the middle and the last assessments.

In 2001, Gowans et al reported improvements in depression according to the Mental Health Inventory and the BDI after the first 6 weeks of exclusively underwater exercise (22). FIQ depression improved in the study of aquatic exercise by Jentoft et al, but not in the land-based exercises group (25).

In our study, ANOVA showed that groups equally improved in BDI. However, a significant difference favoring the DWR group was seen in FIQ depression after 8 and 15 weeks. Also, the SF-36 role emotional showed within-group improvements only for aquatic exercise. We must be careful to conclude an advantage of aquatic exercise in improving emotional aspects because this study was not designed to test this hypothesis, and the 2 analyses of BDI did not show between-group differences. Nonetheless, we can not ignore that 2 other outcomes of our study and Jentoft et al's study (25) are pointed toward the same direction.

We made use of pulse watch recorders, similar to other studies (11,15,22,25,38,43). This ensured that patients maintained an HR equal to or higher than that prescribed, from week 3 on. An intensity reduction for adverse painful events was necessary for no more than 3 consecutive sessions. Wigers et al allowed resting breaks during sessions when necessary and also obtained symptom improvements and physical fitness (36). Some studies used the same prescription for all patients (36,38,44), whereas others considered maximum HR (21,22,25,39,43,45–47). In our study, the intensity of the exercise program was individualized based on spiroergometric tests such as that in Valim et al's study (11). It was prescribed at the HR_{AT}, and the accomplishment of the intensity ensured the minimum suggested to obtain physical fitness (27).

Our program improved patients' aerobic performance. Anaerobic threshold from the LBE group was statistically higher than that from the DWR group, but the difference was not clinically relevant. A better performance by the LBE group can be explained by the exercise principle of

specificity, because the treadmill test is practically identical to the LBE but differs from the DWR. Analysis of categorical outcome data showed no significant difference in the other physical fitness outcomes between the groups. There was not a significant association between clinical improvement and aerobic gain, suggesting the benefits are not necessarily a consequence of better physical fitness as noted in a previous study (11).

Every program must consider strategies to maintain patient compliance, which is fundamental to the success of the treatment, as observed by many authors (9,10,14). Underwater adaptation was fairly easy, even for patients who were not able to swim. Furthermore, some individuals would rather exercise in water, and this modality was shown to be an effective option to walking or running. In spite of this randomized trial comparing aerobic training in water with a largely supported modality of aerobic exercise on land, definitive affirmation of DWR effectiveness may be debatable, because there is not a placebo control.

Although our study followed the patients for 3 months, it is also very important to study long-term benefits of physical training, considering the chronic nature of FM; the exercise effects usually disappear when exercise is discontinued. Walking is a practical type of exercise for most individuals; however, some individuals are limited even for simple physical tasks due to comorbidities, such as knee or hip arthritis, hindering their own weight-bearing ability. For these individuals, land-based physical activity can be difficult and painful, worsening their symptoms. Several aerobic exercise modalities in warm water could be as beneficial as walking, especially for persons with lower limb limitations. However, further studies are necessary to confirm this hypothesis.

We conclude that aerobic exercise in a warmed swimming pool was as effective as a land-based program in treating patients with FM regarding pain. It may bring advantages regarding emotional aspects because it is a pleasant stimulus for exercise compliance. Aerobic gain was similar in the 2 groups and did not correlate with clinical improvement. When properly performed, DWR is a safe and viable form of low-impact aerobic exercise for patients with FM.

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