

The Fibromyalgia Treatment With Physical Exercise in Warm Water Reduces the Impact of the Disease on Female Patients' Physical and Mental Health

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Introduction: Fibromyalgia (FM) patients present pain, muscle stiffness, reduced physical condition and fatigue that limit their daily life activities. The purpose of this study was to evaluate the effects of the addition of 12 weeks of physical exercise in warm water to usual medical care on the impact of FM on physical and mental health in female patients.

Patients, materials, and methods: Thirty-four physically untrained females with FM were randomly assigned into two groups: an experimental group (n=17), to perform 3 weekly sessions for 60 minutes of physical exercise in warm water; and control group (n=17), who did not receive the additional treatment. The impact of the FM on patients' physical and mental health was assessed using the Fibromyalgia Impact Questionnaire (FIQ).

Results: After 12 weeks of physical exercise, the experimental group showed improvements compared to the control group in physical function (35%; $P=.016$), feel good (34%; $P=.003$), job ability (14%; $P=.046$), pain (26%; $P=.030$), stiffness (33%; $P=.038$), anxiety (36%; $P=.044$), depression (26%; $P=.046$), and FIQ total scores (27%; $P=.004$).

Conclusions: The addition of the aquatic physical exercise programme to usual care was effective to decrease the impact of the disease on physical and mental health. However, the placebo effect could have contributed to this effectiveness.

Key words: Fibromyalgia. Warm-water exercise. Physical and mental health.

El tratamiento para la fibromialgia con ejercicio físico en agua caliente reduce el impacto de la enfermedad en la salud física y mental de mujeres afectadas

Introducción: Los pacientes con fibromialgia (FM) muestran dolor, rigidez muscular, condición física reducida y fatiga que limitan sus actividades de la vida diaria. El propósito de este estudio fue evaluar los efectos de la adición al tratamiento médico clásico de 12 semanas de ejercicio físico en agua caliente en el impacto de la FM en la salud física y mental de mujeres afectadas.

Pacientes, material y métodos: Treinta y cuatro pacientes no entrenadas físicamente se distribuyeron aleatoriamente en 2 grupos: un grupo experimental (n = 17), que realizó 3 sesiones semanales de 60 min de ejercicio físico en agua caliente, y un grupo de control (n = 17), que no recibió dicho tratamiento adicional. El impacto de la FM en la salud física y mental de las pacientes fue evaluado mediante el Cuestionario del Impacto de la Fibromialgia (Fibromyalgia Impact Questionnaire [FIQ]).

Resultados: A las 12 semanas de ejercicio físico se observaron mejoras significativas en el grupo experimental respecto al grupo de control, en la función física (35%; $p = 0,016$), sentirse bien (34%; $p = 0,003$), la capacidad de trabajo (14%; $p = 0,046$), el dolor (26%; $p = 0,030$), la rigidez (33%; $p = 0,038$), la ansiedad (36%; $p = 0,044$), la depresión (26%; $p = 0,046$) y en la escala total del FIQ (27%; $p = 0,004$).

Conclusiones: La adición del programa de ejercicio físico acuático al tratamiento médico usual redujo el impacto de la FM en la salud física y mental de las pacientes. Sin embargo, el efecto placebo podría haber contribuido parcialmente en estas mejoras.

Palabras clave: Fibromialgia. Ejercicio en agua caliente. Salud física y mental.

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Introduction

Fibromyalgia (FM) is a chronic disease characterized by generalized pain, muscle stiffness, a reduced physical capacity and fatigue.^{1,2} These symptoms are limiting factors in the everyday life of patients and interfere with such basic acts as walking and some others that imply, for example, lifting and transporting objects or working with the arms and hands in elevated, mid-body or lowered positions.³ All of this contributes to a specially reduced quality of life in personas with FM.⁴

Both low impact physical exercise as well as warm-water baths has shown to be useful tools in the treatment of a great part of the symptoms of FM and improve the quality of life of patients.⁵⁻⁸ Most studies that show the effects of exercise in patients with FM relate to activities on the floor⁹⁻¹¹ and only a few have examined the effect of mixed exercise programs, that is, with dry-floor exercises and in a warm-water pool.¹²⁻¹⁴ The most recent studies have investigated the effects of physical exercise and have been done entirely in warm-water pools, offering results that are especially positive on the general physical condition, neuromuscular function, pain and behavior of the patient.^{8,15,16} Nonetheless, the knowledge of the effects of physical exercise done exclusively in warm water and their impact over FM on the physical and mental health of the patients, beyond the symptoms, is very limited. In this sense, the purpose of the present study is to valuate the effects after 12 weeks of physical exercise in warm water and its impact on the physical and mental health of women affected with FM.

Patients, Material, and Methods

Using local communication media (written press and radio) and the regional FM association, a call was made to women from Extremadura affected by the illness to participate in the study. Once informed of the protocol and its possible risks and benefits, 59 persons gave their written consent to voluntarily participate in the investigation.

The selection procedure consisted in 2 exams for each women, one a personal medical history and the other a confirmation of the diagnosis by the physician responsible for the research group according to the criteria of the American College of Rheumatology.¹⁷

At the moment of inclusion, all patients were receiving conventional and similar drug therapy, based on antidepressants, muscle relaxants, analgesics, and anti-inflammatory drugs. This treatment was stable and suffered no changes during the month that preceded the start of the study and during the whole program. Persons previously diagnosed with alterations or serious lesions of the vertebral column, inflammatory rheumatic disease,

severe psychiatric illness, or other diseases that, at the time of the examination made a clear medical diagnosis of the illness difficult were excluded. We also excluded persons who, at the moment of the study, were receiving some sort of physical or psychological therapy. During this selection process, 25 persons were excluded for not filling the inclusion criteria. Finally, 34 women with FM, with ages that ranged between 35 and 73 years, were randomized into an experimental group (EG; n=17) or a control group (CG; n=17).

Physical Program Exercise

Patients assigned to the EG followed a training program of strength and muscle resistance exercises in a 33°C warm-water pool, 3 times a week for 12 weeks. Each session lasted 60 minutes and included a 10 minute warm-up in which the patients did motility exercises and walked slowly while in the water, 10 minutes of aerobic exercise at 60%-65% of the maximum heart rate (HR_{max}), 20 min of range of motion exercises and strength workout of the lower extremities (4 series with 10 repetitions with unilateral flexion and extension of the leg, using the body as a weight) and of the upper extremities (4 series with 10 repetitions, lifting the arm over the head, using lightweight material of up to 1 kg as a load and elastic bands), 10 min of aerobic exercise at 60%-65% of the HR_{max} and 10 min of returning to a reposing state with low intensity range-of-motion exercises and warm-water relaxation. During the protocols 12 week research, the CG did not carry out any kind of physical or psychological therapy and continued with its quotidian activities.

Impact of Fibromyalgia on Physical and Mental Health

To evaluate the impact that the symptoms of FM have on physical and mental health of patients the Spanish version of the Fibromyalgia Impact Questionnaire (FIQ)¹⁸ was employed. The FIQ is a questionnaire that contains multiple physical, psychological, social and global wellbeing components. The FIQ evaluated the physical function, well-being, work days lost and working capacity. It also includes 6 visual analog scales (VAS) to evaluate pain, fatigue, morning fatigue, stiffness and depression. Apart from this, a total FIQ scale can be obtained when adding the normalized subscales. The FIQ consists of 10 items with scales that range from 0 ("the best possible state or no disease impact") to 10 ("the worst possible state or very affected by the illness"). The impact of FM on the physical and mental health was evaluated at baseline and after 12 weeks of starting the research protocol.

Data Evaluation

Normality of data was examined initially using histograms and the Kolmogorov-Smirnov test, applying the Lilliefors signification. Changes in the measured variables were examined using variance analysis for repeated measurements, adjusted for age. The level of statistical significance was established at $P < .05$. Taking as a reference the study by Redondo et al,¹² it was estimated that to achieve a statistical power of 80% in the detection of possible changes of the total FIQ variable, due to the intervention program, with a 5% error margin, a minimum of 17 persons in each group were needed. All of the analysis was done using the SPSS 13.0 software (SPSS Inc., Chicago, United States).

Results

The exploratory analysis at baseline did not detect any statistically significant differences in the socio-demographic variables or in any of the subscales of the FIQ in both groups (Tables 1 and 2).

At 12 weeks into the program, significant statistical differences between the EG and the CG were noted in the total FIQ scale ($P = .004$) and in the physical function subscale ($P = .016$), well-being ($P = .003$), work capacity ($P = .046$), pain ($P = .030$), stiffness ($P = .038$), anxiety ($P = .044$), and depression ($P = .046$) (Table 2).

TABLE 1. Baseline Characteristics of Women With Fibromyalgia*

	Experimental Group (n=17)	Control Group (n=17)	P
Age, y	51±10	51±9	.986
Body mass index, kg/m ²	27±5	27±4	.597
Duration of symptoms, y	24±9	19±8	.155
Number of medically detectable trigger points (1-18)	17.3±1.2	17.1±1.4	.517
Number of specific medications (antidepressants, muscle relaxants, analgesics, and anti-inflammatory drugs)	2.8±1.1	2.8±1.2	.882

*Values expressed as means ± standard deviation.

Discussion

The results of this study showed that 12 weeks of warm-water exercise lead to improvement in different clinical manifestations of FM such as pain or muscle stiffness. In patients that made exercise the physical function, work capacity and general well-being were increased. The results from previous studies ave shown that exercise in a warm-water pool can be more effective than exercise done on the floor for the improvement of symptoms associated to

TABLE 2. Impact of Fibromyalgia on the Physical and Mental Health at Baseline and After 12 Weeks of Physical Exercise in a Warm-Water Pool (Experimental Group, n=17; Control Group, n=17)*

FIQ Subscale	Baseline		12 Weeks		P†
	Experimental	Control	Experimental	Control	
Physical function (0-10)	3.4±2.2	4.1±1.8	2.2±2	3±1.4	.016
Well-being (0-10)	8.7±2.8	9.2±1.1	5.7±4.1	9.1±1.4	.003
Work-loss (0-10)	6.6±4.9	4.6±4.8	4.7±5.1	5.2±4.8	.775
Work capacity (0-10)	5.6±3	5.7±2.4	4.8±3.3	6.7±2.1	.046
Pain (0-10)	6.1±2.6	6.4±2.5	4.5±2.5	6.5±2.5	.030
Fatigue (0-10)	8.3±2.2	7.7±2.2	6.8±2.1	8±2	.118
Morning fatigue (0-10)	8.1±2.5	7.8±2.4	6.7±3	7.4±1.7	.439
Stiffness (0-10)	7.8±2.4	6.2±2.7	5.2±1.5	6.5±2	.038
Anxiety (0-10)	6.9±2.9	7.4±2.6	4.4±2.7	6.3±2.6	.044
Depression (0-10)	5.8±3.6	6.6±2.9	4.3±3.5	6.5±2.6	.046
FIQ total scale (0-100)	67±18	66±15	49±21	65±15	.004

*FIQ indicates Fibromyalgia Impact Questionnaire. Values expressed as means ± standard deviations. †P, changes between groups at 12 weeks.

illness.¹⁶ This notwithstanding, until today, no exclusively warm-water exercise study for patients with FM had compared their results using an inactive control group. The present clinical trial contributes relevant and new insight because it is the first to include an inactive control group with the aim of evaluating the effects of physical exercise on the impact of disease with relation to the patients that were doing their activities of daily living. We found that, after 12 weeks of warm-water exercise, patients with FM improved 26% with respect to pain, 33% in the case of muscle stiffness, 26% with respect to anxiety, 26% in the case of depression, 35% in physical function, 34% regarding well-being and 14% with regards to the capacity to work, measured using the FIQ subscales, reflected finally in a 27% improvement in the total FIQ scale. Though the physiologic mechanisms implied in these improvements need to be investigated in a more profound manner, there is an ever growing field of evidence on the strengthening and relaxing of muscles and joints properties of warm-water exercise: pain relief, reduction in muscle stiffness, anxiety, depression, and a clear effect on everyday living.

On the other hand, though the level of fatigue in general and the morning fatigue showed a discrete reduction after the exercise program, these differences were not statistically different between both groups. In the same manner, no changes in the work-loss subscale were observed, suggesting that 12 weeks of exercise in the pool with a low intensity work load were enough to reduce the impact of the illness on the activities of daily living that require a minimum level of muscle strength, but at the same time were not enough to diminish in an ample way the degrees of general fatigue and allow an easier incorporation to the work force.

Physical treatments for patients with FM include until the present exercises in warm-water and can be divided in mixed (the experimental group exercises exclusively in warm-water, without any other educational or psychological intervention). Mixed studies that have developed one or two sessions per week (low weekly frequency) for a short period of time (6 weeks) have reported positive improvements on the total FIQ scale of 11%,¹⁴ though they are inferior to the ones shown in our study. Nonetheless, mixed physical treatments with a weekly frequency of 3 or more sessions and a duration of 8 to 20 weeks showed similar improvements to the ones in the present study on the total FIQ (21%-28%).^{12,19}

On the other hand, physical treatments done exclusively in a water environment with a low weekly frequency (one or 2 sessions) and a 3 month period or longer achieved improvement levels on the FIQ that were inferior to the ones reported here.¹⁶ Exclusive treatments in a water environment with a weekly frequency similar or larger than the present study and done for a mean period showed similar improvement to the ones in our study.⁸ Nonetheless,

one must take into account that none of these exclusive studies had an inactive control group. All of this suggests that carrying out exercise in a warm-water pool (combined with other activities or exclusively) is a safe way to reduce the impact of FM on the physical and mental health of patients.

In spite of the numerous positive results of experimental physical treatments as adjuvant in drug therapy, currently there is no precise knowledge of the dose-response relationship for these procedures, especially those that have resulted more positive as are warm-water pool exercises, making more research into the matter necessary. Additionally, a cost-effectiveness comparative study between programs based exclusively on floor exercises, exclusively on warm-water exercises or both, with an aim to facilitate decision making in the distribution of institutional resources and purveying instances of physical therapy treatments for patients with FM, is badly needed. One possible limitation of this study was the lack of a placebo control group. In practice, it is common to lack such a control group when studying the effects of physical exercise, because it is difficult to design an exercise program that is apparently equivalent (2-3 weekly sessions) but is not effective or compliant. In any way, once we have shown the effectiveness of incorporating the planned program of the present study to the classic treatment, it would be advisable that future research compared the efficacy of these findings to other physical exercise programs to reduce the possible influence of placebo effect on group comparisons.

Though the sample size was calculated from the global FIQ calculated variance, and statistical improvements in such a variable were observed in 7 of 10 variables, the size of our sample could have made the finding of statistically significant effects more difficult in 2 of the 10 dimensions analyzed using the FIQ (fatigue and sleep quality), which showed larger variation than the global calculation with regard to the baseline, both in our study as in previous ones.¹² Improvements larger than 10% in these dimensions were seen but the power of the statistical test could not verify it making it impossible to us to rule out that the program is also effective for these variables.

On the other hand, one must take into account that the sample analyzed is representative of a group of patients that had an elevated impact at baseline (total FIQ=67) with respect to other studies (total FIQ=52-63).^{8,12} Therefore, though the present study provides new information on the applicability and strength of physical therapy in women importantly affected by symptoms of FM, generalization of these findings to less affected samples must be approached cautiously.

In conclusion, the addition of a warm-water exercise program to classical medical treatment reduced the impact of fibromyalgia on the physical and mental health of affected women, something that can be partially interpreted as a placebo effect.

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