Tesis Doctoral Europea

Ejercicio Físico en Personas con Fibromialgia: Efectos Sobre el Grado de Dolor, Capacidad Funcional y Aspectos Psicosociales

PHYSICAL EXERCISE IN FIBROMYALGIA PATIENTS: EFFECTS ON PAIN, FUNCTIONAL CAPACITY AND PSYCHOLOGICAL OUTCOMES

ANA CARBONELL BAEZA

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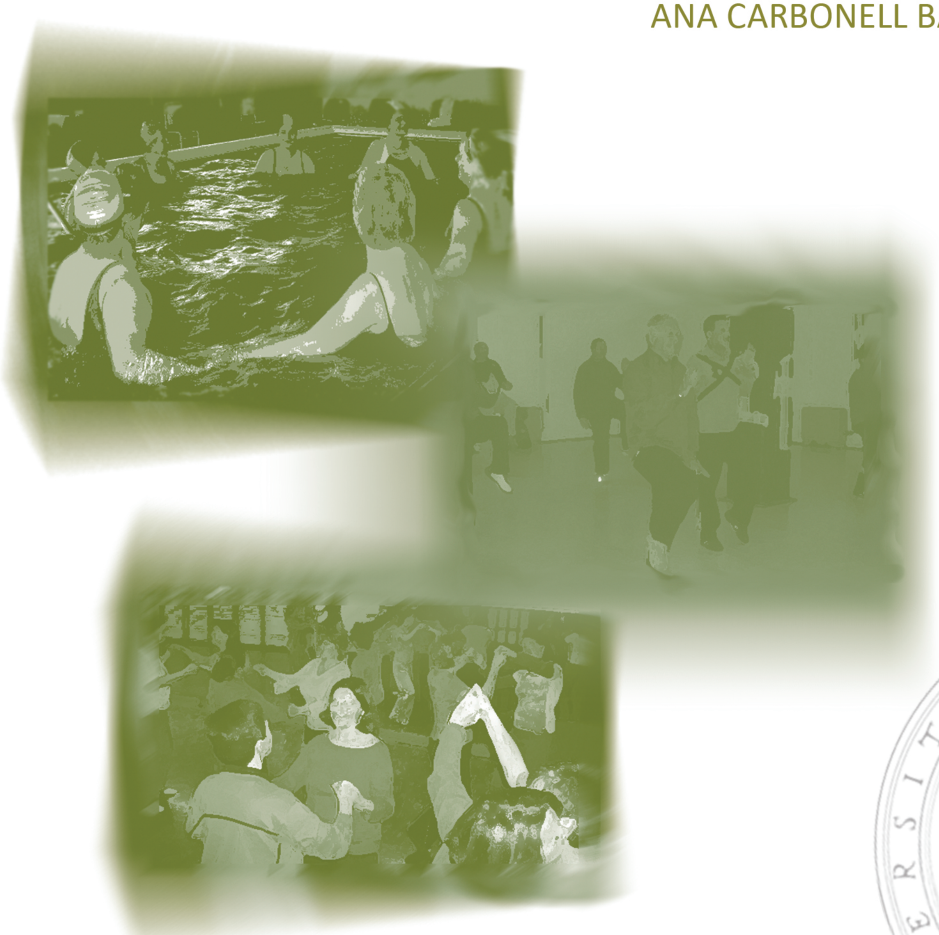

Tesis Doctoral Europea / European Doctoral Thesis

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DEPARTAMENTO DE EDUCACIÓN FÍSICA Y DEPORTIVA

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ANA CARBONELL BAEZA

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A mis padres y hermanos

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CERTIFICA:

Que la Tesis Doctoral titulada "Ejercicio físico en personas con fibromialgia: efectos sobre el grado de dolor, capacidad funcional y aspectos psicosociales" que presenta Dña. ANA CARBONELL BAEZA al superior juicio del Tribunal que designe la Universidad de Granada, ha sido realizada bajo mi dirección durante los años 2006-2010, siendo expresión de la capacidad técnica e interpretativa de su autor en condiciones tan aventajadas que le hacen merecedor del Título de Doctor, siempre y cuando así lo considere el citado Tribunal.

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Fdo. Jonatan Ruiz Ruiz

En Granada, 17 de Mayo de 2010

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PROYECTOS DE INVESTIGACIÓN [RESEARCH PROJECTS]

El trabajo desarrollado y los artículos que componen la presente memoria de Tesis Doctoral están basados en los siguientes proyectos de investigación:

- Evaluación y promoción de calidad de vida relacionada con la salud para enfermos de fibromialgia. Financiación recibida por el Instituto Andaluz del Deporte. Fecha: 04/01/2008 a 04/01/2009.

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I. **Carbonell-Baeza A**, Aparicio VA, Sjöström M, Ruiz JR, Delgado-Fernández M. Functional capacity in female and male fibromyalgia patients. *Submitted.*

II. **Carbonell-Baeza A**, Aparicio VA, Ortega FB, Cuevas AM, Álvarez I, Ruiz JR, Delgado-Fernández M. Does a 3-month multidisciplinary intervention improve pain, body composition and physical fitness in women with fibromyalgia? Br J Sport Med, *in press*.

III. **Carbonell-Baeza A**, Cuevas AM, Aparicio VA, Chillón P, Delgado-Fernández M, Ruiz JR. Effectiveness of multidisciplinary therapy in women with fibromyalgia. *Submitted.*

IV. **Carbonell-Baeza A**, Aparicio VA, Martins-Pereira CM, Gatto-Cardia MC, Ortega FB, Huertas FJ, Tercedor P, Delgado-Fernández M, Ruiz JR. Efficacy of Biodanza in the treatment of women with fibromyalgia. J Altern Complement Med, *in press*.

V. **Carbonell-Baeza A**, Romero A, Aparicio VA, Tercedor P, Delgado-Fernández M, Ruiz JR. Preliminary findings of a 4-month Tai Chi intervention in men with fibromyalgia. *Submitted.*

VI. **Carbonell-Baeza A**, Ruiz JR, Aparicio VA, Martins-Pereira CM, Gatto-Cardia MC, Martínez JM, Ortega FB, Delgado-Fernández M. Multidisciplinary and Biodanza intervention for the management of fibromyalgia. *Submitted*.

RESUMEN

La fibromialgia es un síndrome de etiología aún desconocida, caracterizada por un estado de dolor crónico y generalizado, que presenta una elevada comorbilidad y afecta a la calidad de vida de la persona.

El objetivo general de la presente memoria de Tesis es describir el perfil de capacidad funcional de pacientes con fibromialgia, así como analizar el efecto de diferentes programas de ejercicio físico sobre el grado de dolor, la capacidad funcional y aspectos psicosociales.

La muestra que ha participado en los estudios incluidos en la presente memoria de Tesis esta compuesta por 131 adultos con fibromialgia, 123 mujeres y 8 hombres, que cumplen con el criterio de diagnóstico del Colegio Americano de Reumatología (1990).

Los principales resultados de la memoria de Tesis sugieren que: a) En general, los pacientes con fibromialgia presentan una capacidad funcional reducida. b) La fuerza del tren inferior y la capacidad aeróbica están inversamente relacionadas con el dolor en pacientes con fibromialgia. c) Tres meses de intervención multidisciplinar induce beneficios sobre el umbral de varios puntos de dolor, la fuerza de tren inferior, la calidad de vida y reduce el impacto de la enfermedad. d) Una intervención de Biodanza de tres meses reduce el dolor y el impacto de la enfermedad en mujeres con fibromialgia. e) Cuatro meses de Tai Chi en hombres con fibromialgia no produce mejoras significativas en el grado de dolor, la condición física y variables psicosociales. f) Cuatro meses de intervención multidisciplinar induce mayores beneficios que una intervención de Biodanza en la función social y en el uso de estrategias de afrontamiento de dolor en mujeres con fibromialgia.

Los resultados de la presente memoria de Tesis ponen de manifiesto la utilidad del ejercicio físico en el tratamiento de los síntomas de la fibromialgia.

SUMMARY

Fibromyalgia is a disorder of unknown etiology, characterized by widespread and chronic pain, and elevated comorbidity. Fibromyalgia has an impact on the health related quality of life of patients.

The overall objective of this Thesis was to describe the functional capacity profile in patients with fibromialgia, as well as to study the effectiveness of physical interventions on pain, functional capacity and psychological outcomes.

A total of 131 adults with fibromyalgia, 123 women and 8 men, who fulfill with the American College of Rheumatology (1990) criteria, were involved in the studies of this Thesis.

The main findings and conclusions were: a) Overall, patients with fibromyalgia had a reduced functional capacity. b) Lower limb muscular strength and aerobic capacity were inversely associated with pain in female with fibromialgia. c) A 3-month of multidisciplinary intervention program had a positive effect on pain threshold in several tender points, lower body flexibility, improved quality of life and reduced fibromyalgia impact in women with fibromyalgia. d) A 3-month Biodanza intervention reduced pain and fibromyalgia impact in female patients. e) A 4-month Tai Chi intervention program did not have any significant effect on pain, functional capacity and psychological outcomes in men with fibromyalgia. f) A 4-month multidisciplinary intervention induced greater benefits than a Biodanza intervention for social functioning and coping strategies in women with fibromyalgia.

These findings highlight the usefulness of physical interventions in the management of fibromyalgia symptoms.

ABREVIATURAS [ABBREVIATIONS]

ACR	American College of Rheumatology
ANCOVA	Analysis of Covariance
BF	Body Fat
BIA	Bioelectrical Impedance Analysis
BMI	Body Mass Index
CAM	Complementary and Alternative Medicine
EULAR	European League Against Rheumatism
FIQ	Fibromyalgia Impact Questionnaire
FM	Fibromyalgia
GSES	General Self Efficacy Scale
HADS	Hospital Anxiety and Depression Scale
RSES	Rosenberg Self-Esteem Scale
SEM	Standard Error of the Mean
SF-36	Short-Form Health Survey 36
TP	Tender Point
VPMI	Vanderbilt Pain Management Inventory

INTRODUCCIÓN [INTRODUCTION]

Characteristics of the disorder

Fibromyalgia is a condition characterised by the concurrent existence of chronic, widespread, musculoskeletal pain and multiple sites of tenderness[1]. The definition is based on the American College of Rheumatology (ACR) classification scheme. To fulfill these criteria, the patient is required to have a history of chronic widespread pain and the finding of at least 11 of 18 possible tender points on examination[1] .

Fibromyalgia is considered a disorder of pain regulation[2], indicated by an increased sensitivity to painful stimuli (hyperalgesia) and lowered pain threshold (allodynia)[3]. The increased pain sensitivity in fibromyalgia is not limited to mechanical stimuli, but also includes electrical, heat, and cold stimuli[4, 5]. The cause for the heightened sensitivity of fibromyalgia patients is unknown, but is likely to involve abnormalities in central nervous system sensory processing[6]. Indeed, accumulating evidence suggests that fibromyalgia probably results from abnormal central pain processing rather than a dysfunction in the peripheral tissues where such pain is perceived[7]. Although a hallmark of fibromyalgia is pain, fibromyalgia patients are usually poly-symptomatic with symptoms and syndromes affecting several organ systems[8]. Prominent symptoms include fatigue, stiffness, nonrestorative sleep patterns, and memory and cognitive difficulties[1, 8, 9]. Other common symptom are low back pain, recurrent headaches, arthritis, muscle-spasm, and balance problems[8].

Despite substantial research in the past decade, the pathophysiology and etiology of the disease remain unclear[10], yet recent studies indicate that gene polymorphisms in the serotoninergic, dopaminergic and catecholaminergic systems, play key role in the etiology of the disease[11, 12].

People with fibromyalgia often associate a specific event to the onset of their symptoms[8]. Bennett *et al.*[8] explored the perceived triggering events in fibromyalgia patients and showed that approximately 21% of patients indicated that they could not identify any association between an event and the onset of their symptoms, 73% indicated some emotional trauma or chronic stress, 26.7 % acute illness and 17.1% by physical stressors (e.g. surgery, motor vehicle collisions, and other injuries)[8]. Patients with fibromyalgia also reported that various events exacerbate their symptoms. The most common exacerbating events acknowledged were mental stressors, weather changes, sleeping problems and strenuous activity[8].

In Spain, the prevalence of fibromyalgia is ~2.4%, being more frequent in rural (~4.1%) than in urban settings (~1.7%)[13]. The clinical manifestation of fibromyalgia appears between the 40s and 50s, and is more common in women (~4.2%) than in men (~0.2%)[13]. The prevalence of comorbidities among patients diagnosed with fibromyalgia is very high, which increases fibromyalgia patients' needs for appropriate medical management and results in higher healthcare resource utilization compared with patients without fibromyalgia[10]. Fibromyalgia comorbidity is dominated by depression, mental illness, and symptom-type comorbidity (e.g., gastrointestinal and genitourinary disorders)[14]. The fibromyalgia patients incur in significant direct medical care costs[15, 16]. In Spain, two studies[16, 17] analyzed the mean total cost per patient per year, and indicated that this was up to €8,654 and €9,982, respectively. Of note is that in comparison with a reference group, patients incur in an extra annual average cost of €5,010[16]. Rivera *et al.*[17] observed that 32.5% corresponded to health care costs (direct cost), and 67.5% to indirect costs (sick leave and early retirement). Both, direct and indirect costs are significantly correlated to disease severity, the degree of functional disability, the presence of depressive symptoms, the existence of comorbidities, and a younger patient age [17]. A delay in the diagnosis of the disease therefore appears to be another factor contributing to the high health care costs of fibromyalgia[17] .

The central problem in fibromyalgia criteria is the absence of a gold standard or case definition[18]. The diagnosis of fibromyalgia is mostly based on the identification of tender points. The 1990 ACR criteria for the diagnosis of fibromyalgia considers: widespread pain for more than 3 months and pain with 4 kg/cm of pressure for 11 or more of 18 tender points[1]. Application of these criteria has resulted in a diverse group of people being diagnosed with fibromyalgia[9].

Twenty years later, Wolfe *et al.*[18] presented the ACR new preliminary diagnostic criteria for fibromyalgia. The objective of this new criteria is to develop a simple, practical criteria for clinical diagnosis of fibromyalgia in primary and specialty care and that do not require a tender point examination and to provide a severity scale for characteristic fibromyalgia symptoms[18]. This preliminary diagnostic criteria establishes 3 conditions[18]: i) Widespread Pain Index $\geq$ 7 and Symptom Severity Score $\geq$ 5 or Widespread Pain Index between 3-6 and Symptom severity score $\geq$ 9. ii) Symptoms have been present at a similar level for at least 3 months. iii) The patients do not have a disorder that would otherwise explain the pain.

The Widespread Pain Index is a measure of the number of painful body regions. The patients are asked to indicate in which of 19 body areas they had pain during the last week[18]. The Symptom severity score is the result of the symptom severity scale, a composite variable composed of physician rated cognitive problems, unrefreshed sleep, fatigue and somatic symptom count to measure fibromyalgia symptom severity[18].

Fibromyalgia and Functional Capacity

In the present Thesis, functional capacity and physical fitness refer to the same concept and are used interchangeably. S*ensu stricto,* functional capacity is considered as the ability to engage in activities needed for daily living; whereas physical fitness refers to the ability to carry out daily tasks with vigor and alertness, without undue fatigue, and with ample energy to enjoy leisure-time pursuits and respond to emergencies.

Fibromyalgia has an enormous impact on the health-related quality of life of patients[19, 20], since symptomatology of fibromyalgia limits activities of daily life as walk, raise and transport objects[19-21].

In general, functional capacity is decreased in people with fibromyalgia[22-26] and is similar to older adults[25, 27]. Panton *et al.* [25] showed that lower-body strength and functionality was similar in women with fibromyalgia compared with older healthy women, which suggest that fibromyalgia potentially enhances the risk for premature age-associated disability. Jones *et al.*[27] found that women with fibromyalgia reported difficulty on doing tasks associated with staying physically independent. In fact, several symptoms/conditions (e.g. fatigue, pain, spasticity, depression, restless legs, balance problems, dizziness/fear of falling, bladder problems) were found to be associated with physical impairment[27].

During the past decade, several studies analyzed the physical fitness level of fibromyalgia patients compared with healthy people, especially in relation with aerobic capacity and strength. Women with fibromyalgia had significantly lower isometric force in bilateral leg extensors, unilateral knee extensors and flexors than healthy women[28]. Furthermore, several studies observed lower upper muscular strength, as measured by handgrip strength, in fibromyalgia patients[29-31]. The aerobic capacity is also lower in fibromyalgia patients than in healthy adults[22, 32]. Fibromyalgia is also associated with balance problems and increased risk of falling[24, 33]. Indeed, gait parameters of women with fibromyalgia are severely impaired compared to those of healthy women[26]. Flexibility level in female patients is below the average age-specific norms for healthy women[30]. Flexibility plays a key role in the capacity to carry out the activities of daily living.

The majority of fibromyalgia patients are overweight, partially due to physical inactivity[34-36]. There is an association between obesity and increased tenderness[35]. Obese fibromyalgia patients display higher pain sensitivity and lower levels of quality of life than patients with normal weight[35]. A high body mass index (BMI) (i.e., overweight or obesity) is a strong and independent risk factor for future development of fibromyalgia[3]. A recent study showed that overweight and obesity is associated with an increased risk of fibromyalgia, especially among women who also reported low levels of physical exercise[3]. Cherry *et al.*[37] found that physical ability is strongly associated with cognitive ability in people with fibromyalgia; that is, better physical performance on tests that measured body strength and flexibility, dynamic balance, and overall functional mobility was associated with better performance on objective measures of complex attention, cognitive flexibility/executive function, and psychomotor speed[37].

A better characterization of previous physical activity levels of participants in exercise trials and a complete description of functional capacity will improve the prescription of individualised exercise doses[38].

The Management of Fibromyalgia

Treatment of fibromyalgia is a complicated and controversial process, but successful management of the disorder is possible[39]. Both pharmacologic and non-pharmacologic approaches are used to relieve pain and improve patients' quality of life[10]. A multidisciplinary approach using a combination of the best evidenced efficacy therapy modalities may conduct to a best cost effective treatment of these patients saving direct costs for the health care system as well as for the patient[17].

The European League Against Rheumatism (EULAR) recommend[40]: "*Optimal treatment requires a multidisciplinary approach with a combination of non-pharmacological and pharmacological treatment modalities tailored according to pain intensity, function, associated features, such as depression, fatigue and sleep disturbance in discussion with the patient*"

A single medication, given alone, is unlikely to be totally effective[41]. Several authors consider that medications are most effective when combined with non-medicinal therapy, including exercise and behavior treatment[42]. Disease education, exercise and cognitive behavioural therapy enable a patient to develop their own personal disease management strategy into which the new drugs can be incorporated for maximum effect[41].

The most common non-pharmacological treatments include regular physical activity and educational-psychological programs[43]. There is strong evidence that multidisciplinary treatment (at least 1 educational or other psychological therapy with at least 1 exercise therapy) has beneficial short-term effects on the key symptoms of fibromyalgia[44]. The education combined with physical exercise has been shown to produce improvements in terms of self-efficacy, physical function and general well-being[43]. The combination of education and exercise appears to produce synergies[43].

There is no conclusive evidence that one type of multidisciplinary program is better than other, and the effectiveness of a multidisciplinary intervention program based on exercise (pool and land-based) and psychological therapy (based on Acceptance and Commitment Therapy) on pain, physical fitness and psychological outcomes in women with fibromyalgia remains to be known.

Exercise therapies

Low- to moderate-intensity exercise, such as walking and pool exercise, appears to improve symptoms and distress, and may improve physical capacity in sedentary patients[43]. Even accumulating 30 minutes of lifestyle physical activity throughout the day produces clinically relevant changes in perceived physical function and pain in previously minimally active adults with fibromyalgia[45].

Several reviews concerning the effect of exercise in fibromyalgia patients concluded that: i) There is moderate evidence that aerobic exercise produces important benefits in fibromyalgia patients in global outcome measures, physical function, and possibly pain and tender points[38, 46]. ii) There is limited evidence that strength training improves a number of outcomes including pain, global wellbeing, physical function, tender points and depression[38]. iii) There is not enough evidence regarding the effects of flexibility exercise[38].

A recent meta-analysis[47] concluded that exercise (aerobic, strength training or both) improves global well being, assessed by fibromyalgia impact questionnaire, in women with fibromyalgia. The Ottawa Panel supports the use of aerobic exercise programs and strengthening exercises for the overall management of fibromyalgia[48, 49]. After a revision, they obtained the most improvements after aerobic exercise for quality of life and pain relief. Aerobic fitness exercises also were found to greatly increase endurance, which, in turn, greatly improved the everyday functional mobility of patients[48]. For strengthening exercises most improvements were shown for muscle strength, quality of life, and decreases in depression[49]. Jones *et al.*[50] concluded that patients attained symptom relief, particularly decreased pain and fatigue as well as improved sleep and mood, with low to moderate intensity exercise of any type.

Exercise therapy in fibromyalgia patients has been usually focused on either pool or land-based exercises. Hydrotherapy (with or without exercise) has been recommended for the management of fibromyalgia because of the water's buoyancy and warm temperature[51-53]. Pool exercise interventions appear to improve physical function and overall health in terms of symptom severity and distress in sedentary fibromyalgia patients[43, 54-57]. Improvements in cognitive function and sleep quality have been also reported after pool exercise interventions[52, 57]. Jentoff *et al.*[58] compared the effect of 20-week pool-based exercise and land-based exercise (twice a week) in symptoms, self-efficacy, self reported physical impairment, and physical capacity in a group of fibromyalgia patients. Except for the difference in grip strength at the end of the exercise period in favour of the land-based exercise group, no significant differences between groups were found. In both exercise groups significant improvements in aerobic capacity and walking time were observed. The pool-exercise group also improved with regard to self-reported physical impairment, number of days of feeling good, pain, anxiety, and depression[58].

Complementary and Alternative Therapies

During the last decade, physical interventions such as water-based exercise, aerobic, strength or multidisciplinary approach have been extensively used for the treatment of fibromyalgia. Less is known however about the efficacy of complementary and alternative therapies (CAM). Complementary and alternative therapies is a group of diverse medical and health care systems, practices, and products that are not generally considered to be part of conventional medicine[59]. Complementary and alternative therapies compromised mind-body therapies, biologically based practices as dietary supplements or herbs, manipulative and body-based practices as massage or manipulation and energy medicine as Reiki or Therapeutic touch[59]. Some techniques that were considered CAM in the past have become a standard conventional care, (for example, patient support groups and cognitive-behavioral therapy)[59].

Patients with fibromyalgia are prone to use CAM despite there are currently no conclusive evidence about the effects of these therapies in fibromyalgia[43, 60, 61].

Mind body therapies are commonly used in a wide range of medical conditions, but future research is needed for better understanding of the potential efficacy of this type of treatments[62]. Mind-body medicine uses a variety of techniques designed to enhance the mind's capacity to affect bodily function and symptoms[59].

"Rolando Toro's Biodanza" is a therapeutical strategy of human development and growth that uses music, movement and emotions to induce integrative living experiences or "vivencias" to group participants[63]. Biodanza is an integrative dance therapy that combines motor, sensory and affective exercises performed at low intensity/speed. Moreover, Jones *et al.*[50] recommended for future research the study of movement therapies for a broader array of physical and mental health outcomes, beyond symptoms and physical fitness.

Tai chi, which originated in China as a martial art, is a mind-body practice in CAM[59]. Overall, Tai Chi seems to have physiologic and psychosocial benefits and appears to be safe and effective in promoting balance control, flexibility, and aerobic fitness in patients with chronic conditions[64, 65]. Tai chi exercises combined aspect of mind-body therapy and physical exercise it is potentially beneficial to fibromyalgia patients but further research is needed to support the evidence-based practice[66]. Only one uncontrolled pilot study evaluated the effect of 6 week of biweekly Tai Chi sessions in women with fibromyalgia[66]. Although there was a high dropout rate, the group had significantly reduced symptoms and increased quality of life. Whether Tai Chi intervention influences pain, functional capacity and quality of life in men with fibromyalgia is unknown.

Several reviews highlighted the needed of future research on the effects of exercise in men with fibromyalgia, given the lack of studies[43, 47, 50]. Even, a recent meta-analysis about exercise considers that it is not possible to generalize the positive findings to men with fibromyalgia[47].

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OBJETIVOS

General:

El objetivo general de esta Tesis Doctoral es describir el perfil de capacidad funcional de pacientes con fibromialgia, así como analizar el efecto de diferentes programas de ejercicio físico sobre el grado de dolor, la capacidad funcional y aspectos psicosociales.

Específicos:

- Describir el perfil de capacidad funcional de mujeres y hombres con fibromialgia del sur de España **(Artículo I).**
- Examinar la asociación entre capacidad funcional y dolor evaluado mediante puntos de dolor en mujeres con fibromialgia **(Artículo I).**
- Determinar el efecto de tres meses de intervención multidisciplinar (ejercicio y terapia psicológica) sobre el grado de dolor, la condición física y aspectos psicosociales en mujeres con fibromialgia **(Artículo II y III).**
- Determinar el efecto de tres meses de intervención de Biodanza sobre el grado de dolor, la condición física y aspectos psicosociales en mujeres con fibromialgia **(Artículo IV).**
- Estudiar el efecto de un programa de Tai Chi de cuatro meses sobre el grado de dolor, la condición física y aspectos psicosociales en hombres con fibromialgia **(Artículo V).**
- Comparar la efectividad de cuatro meses de una intervención multidisciplinar (ejercicio y terapia psicológica) y una intervención alternativa (Biodanza) sobre el grado dolor, la condición física y aspectos psicosociales en mujeres con fibromialgia **(Artículo VI).**

AIMS

Overall:

The overall objective of this Thesis was to describe the functional capacity profile in patients with fibromyalgia, as well as to study the effect of physical interventions on pain, functional capacity and psychological outcomes.

Specific:

- To describe functional capacity of female and male fibromyalgia patients from southern Spain **(Paper I)**.
- To examine the association between functional capacity and pain, assessed by tender point count in female patients **(Paper I)**.
- To determine the effects of a 3-month multidisciplinary intervention on pain, physical fitness and psychological outcomes in women with fibromyalgia **(Paper II and III)**.
- To determine the effects of a 3-month Biodanza intervention on pain, physical fitness and psychological outcomes in women with fibromyalgia **(Paper IV)**.
- To study the effects of 4-month Tai Chi training program on pain, physical fitness and psychological outcomes in men with fibromyalgia **(Paper V)**.
- To compare the effectiveness of 4-month multidisciplinary (exercise plus psychological therapy) and an alternative intervention (Biodanza) on pain, physical fitness and psychological outcomes in women with fibromyalgia **(Paper VI)**.

MATERIAL Y MÉTODOS [MATERIAL AND METHODS]

La sección de material y métodos de la presente memoria de Tesis se resume en la siguiente tabla que incluye la información metodológica más relevante de los artículos que componen la memoria de Tesis.

Table 1. Summary table of the methodology used in the current Thesis.

Paper	Study desing	Participants	Intervention	Main variables studied	Methods
I. Functional capacity in female and male fibromyalgia patients	Cross-sectional	131 FM patients 123 women 8 men	Not applicable	Weight, height, BMI, BF, skeletal muscle mass, pain threshold, TP, algometer score, resting blood pressure, heart rate and functional capacity	BIA, standard pressure algometer, 30-s chair stand, handgrip strength, chair sit and reach, back scratch, blind flamingo, 8 ft up and go and 6-min walk tests
II. Does a 3-month multidisciplinary intervention improve pain, body composition and physical fitness in women with fibromyalgia?	Control trial	65 female patients - INT, n=33 - CONT, n=32	3-month multidisciplinary (pool, land-based and psychological sessions based on the Acceptance and Commitment Therapy) program) program (3-times/ week)	Pain threshold, TP, algometer score, weight, height, BMI, BF, skeletal muscle mass and physical fitness	BIA, standard pressure algometer, 30-s chair stand, handgrip strength, chair sit and reach, back scratch, blind flamingo, 8 ft up and go and 6-min walk test
III. Effectiveness of multidisciplinary therapy in women with fibromyalgia	Control trial	65 female patients - INT, n=33 - CONT, n=32	3-month multidisciplinary program (3-times/ week)	FM Impact, quality of life, anxiety, depression, coping strategies, self-esteem	FIQ, SF-36, HADS, VPMI and RSES
IV. Efficacy of Biodanza in the treatment of women with fibromyalgia	Control trial	59 female patients - INT, n=27 - CONT, n=32	3-month Biodanza intervention (once a week, 2 hours)	Pain threshold, TP, algometer score, body composition (BMI and BF), physical fitness and psychological outcomes	BIA, standard pressure algometer, 30-s chair stand, handgrip strength, chair sit and reach, back scratch, blind flamingo, 8 ft up and go and 6-min walk test; FIQ, SF-36, VPMI, HADS, GSES and RSES

Table 1. (cont.) Summary table of the methodology used in the current Thesis.

Paper	Study Desing	Participants	Intervention	Main variables studied	Methods
V. Preliminary findings of a 4-month Tai Chi intervention in men with fibromyalgia	Control trial	6 male patients	4-month Tai Chi intervention (3 sessions per week)	Pain threshold, TP, algometer score, physical fitness and psychological outcomes	30-s chair stand, handgrip strength, chair sit and reach, back scratch, blind flamingo, 8 ft up and go and 6-min walk test; FIQ, SF-36, VPMI, HADS, GSES and RSES
VI. Multidisciplinary and Biodanza intervention for the management of fibromyalgia	Control trial	38 female patients - INT-M, n= 21 - INT-B, n= 17	4-month multidisciplinary intervention and Biodanza intervention	Pain threshold, TP, algometer score, physical fitness and psychological outcomes	BIA, standard pressure algometer, 30-s chair stand, handgrip strength, chair sit and reach, back scratch, blind flamingo, 8 ft up and go and 6-min walk test; FIQ, SF-36, VPMI, HADS, GSES and RSES

BIA: Bioelectrical Impedance Analysis, BF: Body Fat, BMI: Body Mass Index, CONT: Control Group, FIQ: Fibromyalgia Impact Questionnaire, FM: Fibromyalgia, GSES: General Self Efficacy Scale, HADS: Hospital Anxiety and Depression Scale, INT: Intervention Group, INT-M: Multidisciplinary Intervention Group, INT-B: Biodanza Intervention Group RSES: Rosenberg Self-Esteem Scale. SF-36: Short-Form Health Survey 36, VPMI: Vanderbilt Pain Management Inventory,

RESULTADOS Y DISCUSIÓN [RESULTS AND DISCUSSION]

Los resultados y discusión se presentan en la forma en que han sido previamente publicados/sometidos en revistas científicas.

1. PERFIL DE CAPACIDAD FUNCIONAL EN PACIENTES CON FIBROMIALGIA

(Artículo I)

I

FUNCTIONAL CAPACITY IN FEMALE AND MALE FIBROMYALGIA PATIENTS

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Submitted

Functional capacity in female and male fibromyalgia patients

Running head: Functional capacity and fibromyalgia

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SUMMARY

Objective: To describe functional capacity levels of female and male fibromyalgia (FM) patients from southern Spain. We also examined the association between functional fitness and pain, assessed by tender point count in female patients.

Methods: One hundred twenty three women (51.7 ± 7.2 years) and eight men (52.3 ± 9.3 years) with FM were included in the study. We measured weight and height, and body mass index (BMI) was calculated. Weight status was defined according to the BMI international cut-off values. We assessed tender points and functional capacity by means of the 30-s chair stand, handgrip strength, chair sit and reach, back scratch, blind flamingo, 8 ft up and go and 6-min walk tests.

Results: The prevalence of overweight and obese women was 39.2% and 33.3%, respectively, whereas in men was 62.5% and 25.0%, respectively. There were no significant differences in functional capacity level and tenderness between male and female. There was a weak association between the chair stand test and pain (r = -0.273, P=0.004), and between the distance walked in 6-min walk test and pain (r=-0.183, P=0.046).

Conclusions: The prevalence of overweight and obesity among FM patients is high, and the functional capacity is similar to that observed in elderly populations. Both, lower body muscular strength and aerobic capacity are inversely associated with pain.

Key words: Fibromyalgia, pain, functional capacity.

INTRODUCTION

Fibromyalgia (FM) is a condition characterized by the concurrent existence of chronic, widespread musculoskeletal pain and multiple sites of tenderness (1). Prominent symptoms include fatigue, stiffness, nonrestorative sleep patterns, and memory and cognitive difficulties (1, 2). In Spain, the prevalence of FM is ~2.4% (3). The clinical manifestation of FM appears between the 40s and 50s, and is more common in women (~4.2%) than in men (~0.2%) (3). Fibromyalgia patients are heavy users of the healthcare system, which experiences high levels of comorbidity and incur in significant direct medical care costs (4, 5). In Spain, FM patients incurred €614 more in average annual health care costs and €4,397 more in indirect costs (sick leave and early retirement) in comparison with the reference group, totaling an extra annual average cost per patient of €5,010 (5).

Fibromyalgia patients report a high impact on their quality of life (6). Physical performance and functionality are decreased in people with FM (7-11) and is similar to older adults (10, 12). Bush *et al.* (13) highlighted the importance of a better characterization of FM patients' physical fitness/functional capacity levels. Furthermore, it is important to know their functional capacity levels in order to adequately prescribe an individualized exercise dose. There is strong evidence that multidisciplinary treatment including exercise and behavioral therapy has beneficial short-term effects on the key symptoms of FM (14). The Ottawa Panel supports the use of aerobic exercise programs and strengthening exercises for the overall management of FM which included the enhancement of functional capacity (15, 16). Despite of this, many studies do not assess functional capacity.

The main purpose of this study was to describe functional capacity levels in female and male FM patients. We also examined the association between functional capacity and pain assessed by tender point count in female patients.

METHOD

Participants

We contacted a total of 255 Spanish female members of a FM patients association (Granada, Spain). A total of 141 (n=130 women) potentially eligible patients responded, and gave their written informed consent after receiving detailed information about the aims and study procedures. The inclusion criteria were: (i) meeting the American College of Rheumatology criteria: widespread pain for more than 3 months, and pain with 4 kg/cm of pressure reported for 11 or more of 18 tender points (1), (ii) not to have other severe somatic or psychiatric disorders, or other diseases that prevent physical loading. A total of 7 women and 3 men did not meet this criteria and were then not included in the study.

A final sample of 123 women (aged 51.8 ± 7.2 years) and 8 men (aged 52.3 ± 8.5 years) with FM participated in the study. Patients were not engaged in regular physical activity >20 minutes on >3 days/week. The study was approved by the Ethics' Committee of the *Hospital Virgen de las Nieves* (Granada, Spain).

Procedures

Each participant performed all the tests, which were carried out on two separate days with at least 48 hours between each session. This was done in order to prevent fatigue and flare-ups (acute exacerbation of symptoms) in the patients.

The assessment of the tender-points, blind flamingo test and chair stand test were completed on the first visit. Body composition, resting blood pressure and heart rate, chair sit and reach, back scratch, 8 feet up & go, handgrip strength and 6 minute walk was assessed on the second day.

Pain

Patients were requested to rate their present pain intensity on a visual analog scale of pain graded from 0 to 10, with 0 being no pain and 10 being the worst imaginable pain. Pain was recorded immediately before the fitness assessment sessions.

Tender points

A standard pressure algometer (EFFEGI, FPK 20, Italy) was used to measure tender point count. We assessed the 18 tender points according to the American College of Rheumatology criteria for classification of FM(1). The pain threshold at each tender point was determined by applying increasing pressure with the algometer perpendicular to the tissue, at a rate of ~1 kg/s. Patients were asked to say 'stop' at the moment pressure became painful. The mean of two successive measurements at each tender point was used for the analysis. Tender point scored as positive when the patient noted pain at pressure of 4 kg/cm^2 or less. The total of such positive tender points was recorded as the individual's tender point count. This examination was conducted by a trained physiotherapist.

Body composition

We performed a bioelectrical impedance analysis with an eight-polar tactile-electrode impedanciometer (InBody 720, Biospace). We measured weight (kg) and body fat (%) and skeletal muscle mass (kg) was estimated. The validity of this instrument was reported elsewhere (17, 18). Waist circumference (cm) was measured with the participant standing at the middle point between the ribs and ileac crest (Harpenden anthropometric tape Holtain Ltd). Height (cm) was measured using a stadiometer (Seca 22, Hamburg, Germany). Body mass index (BMI) was calculated as weight (in kilograms) divided by height (in meters) squared and categorized using the international criteria: underweight (<18.5 kg/m^2), normal weight (18.5-24.9 kg/m^2), overweight (25.0-29.9 kg/m^2) and obese (≥30.0 kg/m^2). The examination was conducted by a trained physical therapist.

Resting blood pressure and heart rate

Systolic (SBP) and diastolic blood pressure (DBP), as well as heart rate (HR) was measured after 5 minutes of rest, two times 2 minutes apart (M6 upper arm blood pressure monitor Omron. Omron Health Care Europe B.V. Hoolddorp, The Netherlands). The lowest value of two trials was selected for analysis. This examination was conducted by a trained physical therapist.

Functional capacity

The Functional Fitness Test battery (19) was used because it is relatively easy to administer and score, requires minimal equipment and space, the exercises are safe, it has almost no ceiling and floor effects (this aspect is relevance because of the heterogeneity of FM patients (20), and there are “normative scores” for healthy population (21), which makes comparisons among groups possible. Therefore, fitness testing might be feasible to be performed in clinical and community settings. Additionally, we also measured the handgrip strength and blind flamingo test, which have been used in FM patients (22). We assessed the rate of perceived exertion (RPE) after each test using the Borg’s scale (6-20).

Lower body muscular strength: The 30-s chair stand test involves counting the number of times within 30 s that an individual can rise to a full stand from a seated position with back straight and feet flat on the floor, without pushing off the arms. Patients realized 1 trial, after familiarization with the test (19).

Upper body muscular strength: Handgrip strength was measured using a digital dynamometer (TKK 5101 Grip-D;Takey, Tokyo, Japan). The participants maintained the standard bipedal position during the entire test with the arm in complete extension. Each patient performed (alternately with both hands) the test twice allowing a 1-minute rest period between measures. The best value of 2 trials for each hand was chosen for analysis and an average score was computed. The grip position of the TKK dynamometer was adjusted to the individual’s hand size (23).

Lower body flexibility: In the “chair sit and reach test”, the patient seated with one leg extended, slowly bends forward sliding the hands down the extended leg in an attempt to touch (or pass) the toes. The number of centimeters short of reaching the toe (minus score) or reaching beyond it (plus score) are recorded (19). Two trials with each leg were measured and the best value of each leg was registered, being the average of both legs used in the analysis.

Upper body flexibility: The “back scratch test”, a measure of overall shoulder range of motion, involves measuring the distance between (or overlap of) the middle fingers behind the back (19). This test was measured alternately with both hands twice and the best value was registered. The average of both hands was used in the analysis.

Static balance: It was assessed with the "blind flamingo test" (24). The number of trials needed to complete 30 s of the static position is recorded, and the chronometer is stopped whenever the patient does not comply with the protocol conditions. One trial was accomplished for each leg and the average of both values was selected for the analysis.

Motor agility/dynamic balance: the 8 feet up and go test involves standing up from a chair, walking 8 feet to and around a cone, and returning to the chair in the shortest possible time (19). The best time of two trials was recorded.

Aerobic endurance: We assessed the 6-min walk test. The maximum distance (meters) walked by the patients in 6 min along a 45.7 meters rectangular course was measured (19). Heart rate was measured during the test with a heart rate monitor (4 SW. Kempele, Finland), and the HR at the end of the test was selected for analysis. The 6-minute walk test is a reliable measure in people with FM (25-27).

Statistical analysis

All statistical analyses were performed using the Statistical Package for Social Sciences (SPSS, v. 15.0 for WINDOWS; SPSS Inc, Chicago). Data are presented as means ± standard deviation, unless otherwise stated. Centiles 10^{th}, 25^{th}, 50^{th}, 75^{th} and 90^{th} were calculated for each physical fitness test in the female sample, whereas this was not possible in men due to the small sample of male participants. Sex comparisons were analyzed by the Mann–Whitney tests. Pain differences between day 1 and 2 were analyzed by Wilcoxon signed-rank test. We analyzed the associations between functional capacity and tender points count by Spearman's correlation coefficients. Due to the small number of male patients, this was done only in women. The analyses were adjusted for multiple comparisons (28).

RESULTS

The background of the patients is presented in Table 1.

Individual tender point scores are detailed in Table 2. The highest and lowest mean values of pain threshold found in women were 2.73 and 1.72 kg/cm^2 respectively and 3.32 and 1.98 kg/cm^2 respectively in men. There are no differences between men and women in pain threshold of any tender points, algometer score and tender point count. The group reported similar pain during the two days assessed ($P>0.1$ for women and men).

Table 3 shows the characteristics of the study participants by sex. In women, one patient was underweight (0.8%) and 32 (26.7%) were normal weight. We observed that 47 (39.2%) patients were overweight and 40 (33.3%) were obese. In men, one patient (12.5%) was normal weight, 5 (62.5%) patients were overweight and 2 (25.0%) patient were obese.

Men were significantly taller, heavier, had higher levels of skeletal muscle mass and handgrip strength and had lower levels of body fat percentage than women. After adjusting for multiple comparisons, these differences remained significant for height and skeletal muscle mass.

Women reported the highest value on Borg's RPE scale after the 30-s blind flamingo test (15 ± 3) and men after the chair sit and reach test (15 ± 2) and least RPE on 8 feet up & go test in both groups (10 ± 2 and 12 ± 3 in women and men respectively).

Table 4 shows the functional capacity percentiles for women.

The correlations between tender point count and functional capacity in women are shown in Table 5. Chair stand test and distance walked in 6-min walk tests were inversely correlated with tender points count, so that the higher the chair stand and the 6-min walk test performance the lower the tender point count in women ($r = -0.273$, $P=0.004$ and $r=-0.183$, $P=0.046$, respectively).

DISCUSSION

The present study describes the functional capacity of female FM patients from southern Spain. Furthermore, we present the functional capacity profile for a relatively small sample of male FM patients. This is one of the few studies that examines a large range of functional capacity parameters in FM patients, and to the author`s knowledge it may be the first one of this kind which also included men. We did not find a correlation between functional capacity and pain measured by tender point count, except a weak association between chair stand test and distance walked in the 6-min walk test.

The algometer scores obtained in this study were lower than those reported in Harden *et al.* (29) (50.28) and Altan *et al.* (30) (48.9), but higher than the study of Mcveight *et al.* (31) (40.4). Each tender point presented a different mean, which indicates that some points have higher sensitivity than others. The most sensitive spots were the anterior cervical and second rib points, which concur with other studies (29, 31, 32).

The prevalence of overweight women in our study (39%) is slightly higher than that reported in U.S. female population (21-28%)(33, 34) and in women with FM from Israel (~28%) (35). However, these studies reported a similar or higher prevalence of obesity, 32-50% in US (33, 34) and 45% in Israel (35), than those observed in our study (33%). Our results support the those reported by Yunus *et al.* (33), that also indicated that FM patients are overweight. The level of body fat percentage observed in the present study was higher than that reported by Lowe *et al.* (36) but lower than Kingsley *et al.* (37) Female patients in our study showed higher values of waist circumference than Loevinger *et al.* (38).

We did not observe an association between body composition (weight, height, waist circumference, BMI, muscle mass and percentage body fat) and tender points count. Yunus *et al.* (33) observed a relationship with a trend towards significant between BMI and tender point counts (n= 211) and Neumann *et al.* (33, 35) reported a positive correlation between these variables (r=0.261, P=0.011; n=100) in female FM patients. Data on the relationship between body composition and chronic pain are limited and further studies are needed to clarify this uncertain association.

Levels of both SBP and DBP seem to be higher in FM patients compared with healthy people (38, 39). The values of blood pressure observed in our patients were slightly higher than the values reported by others studies in FM patients (38, 39). The resting HR obtained was similar to that reported by Thieme *et al.*(40) They found that HR during baseline was higher in women with FM than aged and sex matched healthy control (40).

The levels of handgrip strength observed in the present study were lower than those reported in others studies in FM patients (10, 22). The levels of handgrip strength observed in our study are clearly lower than those normative values from a healthy female age-matched population (41, 42). Jones *et al.* (43) reported better values in lower body strength, upper and lower flexibility in FM patients than our results.

Fibromyalgia is associated with balance problems and increased fall frequency (9). Heredia *et al.* (11) reported that gait parameters of women affected by FM were severely impaired when compared to those of healthy women. The blind flamingo scores observed in this study were better than the values reported by others studies in FM patients (22, 44).

The average distance walked in the 6-min walk test by our female patients was 447.02 $\pm$ 83.54 m, which is higher than that obtained by Ayan *et al.* (45) in FM patients, but lower than that reported in other studies conducted in FM patients (37, 46-50). The values of HR at the end of the 6-min walk test were higher in our study compared with the study by Ayan *et al.* (45) (105.88$\pm$14.1 bpm vs. 102.6$\pm$12.1 bpm respectively). The distance walked obtained in our study is lower than that reported in healthy adults women (42).

Mannerkorpi *et al.* (49) compared measures of functional capacity between FM patients and healthy adults and the FM group had significantly lower physical functioning scores on all variables. Panton *et al.* (10) showed that lower-body strength and functionality was similar in women with FM and older healthy women, which suggest that FM potentially enhance the risk for premature age-associated disability. Comparing data from this survey with the functional capacity levels of community-residing older women aged 60–94 (*n*=5,048) (21), our median values (percentile 50) on chair sit and reach, back scratch and chair stand test are below the 50th percentile in women aged 90-94 years. Likewise, 8 feet up and go and 6 minute walk test are approximately in the 50th percentile in women aged 85-89 years. This suggests that FM patients have an aged functional capacity. Those data are worrisome and support the findings of Panton *et al.* (10) with regard to the high risk of disability in women with FM.

Among the variables of functional capacity studied, only chair stand test and distance walked in the 6-min test were weak and inversely correlated with tenderness in women. To our knowledge, only one study (51) analyzed the association between lower extremity strength (isokinetic knee muscle strength) and tender point count and it did not find significant correlations. Other studies (7, 45, 47) analyzed the relationship between physical performance and pain (measured with the Fibromyalgia Impact Questionnaire, FIQ). They found no correlation between anaerobic threshold (7) and FIQ. The 6-min walk test, chair rising test and handgrip strength showed a fair relationship with physical function scale (45, 47) and a moderate relationship with pain scale on the FIQ (47). There is a need of future studies to confirm the influences of functional capacity on pain in this disease.

Fibromyalgia is uncommon in men (~0.2%) (3) and data on functional capacity in male FM patients are very limited. To our knowledge only one study examined several functional capacity parameters in two male patients (52). We founded similar mean lower body muscular strength values when compared with this study (52). The pain threshold values obtained from the present study sample of male FM patients are below those found by Harden *et al.* (29).

We only observed significant differences between women and men in height and muscle mass. Buskila *et al.* (53) found that men reported more severe symptoms than women with FM, pain thresholds in women were significantly lower than in men, but the mean tender point counts were similar in both groups. Yunus *et al.* (54) reported that male FM patients had fewer TP, and less fatigue and irritable bowel syndrome, compared with female patients, and that there were no difference between their psychological status (55). In Spain, Ruiz-Perez *et al.* (56) examined the differences between women and men with FM in sociodemographic, clinical, psychosocial and health care characteristics and the results obtained confirm the sex differences in clinical and psychosocial features. This highlights that studies in male patients are urgently needed to deep in the clinical manifestation of this disease in men. The current study analyses functional capacity profile in men with FM improving the current knowledge in this field. Nevertheless, larger samples are needed.

Several limitations should be acknowledged. First, our participants were volunteers and may have been in a better physical condition than average FM patients. Second, individually tailored medication used for FM symptoms may have had some limiting effects on physical performance in the patients. Third, the study population of men was small, but despite of this, is the higher published up-to-date with a whole description of functional capacity. Finally, the lack of a group of healthy individuals limits further comparisons.

In summary, the present study describes the functional capacity in female FM patients. Further functional capacity mean values for men were also provided. The results showed a reduced functional capacity in FM patients. There are no differences between male and female patients in functional capacity or tenderness. We only found a weak association between lower body strength and aerobic capacity with pain in female with FM, but not for other parameters of functional capacity.

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Table 1. Demographic and clinical variables of the patients.

Variable	**Women** (n=123)	**Men** (n=8)
Years since clinical diagnosis, n (%) ^		
≤ 5 years	62 (51.7)	5 (62.5)
> 5 years	58 (49.3)	3 (37.5)
Marital status, n (%)		
Married	91 (74.0)	7 (87.5)
Unmarried	11 (8.9)	1 (12.5)
Separated /Divorced/ Widowed	21 (17.1)	0 (0.0)
Educational status, n (%) ^		
Unfinished studies	10 (8.3)	1 (14.3)
Primary school	54 (44.6)	3 (42.9)
Secondary school	24 (19.8)	3 (42.9)
University degree	33 (27.3)	0 (0.0)
Occupational status, n (%) ^		
Housewife	70 (60.3)	1 (14.3)
Student	2 (1.7)	0 (0.00
Working	29 (25.0)	1 (14.3)
Unemployed	7 (6.0)	0 (0.0)
Retired	8 (6.9)	5 (71.4)
Income*, n (%) ^		
< 1200,00 €	50 (43.1)	4 (50.0)
1201,00 – 1800,00 €	21 (18.1)	1 (12.5)
> 1800,00 €	45 (38.8)	3 (37.5)

NOTE. Values are the mean (standard deviation) unless otherwise indicated.

*1676.70 € is the average salary in Spain in 2007 (57).

^ Lost values: in women, diagnosis 3, educational status 2, occupational status 7, income, 7; in men, educational status and occupational status 1.

Table 2. Mean (standard deviation) tender point (TP) scores.

Tender points	**Women** (n=123)	**Men** (n=8)	**P**
Occiput R	2.31 (0.85)	2.61 (0.60)	0.261
Occiput L	2.29 (0.84)	2.56 (0.87)	0.468
Anterior cervical R	1.78 (0.76)	2.08 (0.70)	0.193
Anterior cervical L	1.72 (0.72)	1.98 (0.62)	0.154
Trapezius R	2.46 (0.94)	2.98 (1.08)	0.224
Trapezius L	2.55 (0.99)	2.98 (1.00)	0.292
Supraspinatus R	2.70 (1.10)	3.32 (1.13)	0.163
Supraspinatus L	2.73 (1.07)	3.31 (1.12)	0.168
Second rib R	1.87 (0.68)	2.31 (0.75)	0.103
Second rib L	1.89 (0.72)	2.36 (0.67)	0.059
Lateral epicondyle R	2.26 (0.81)	2.38 (0.69)	0.690
Lateral epicondyle L	2.31 (0.89)	2.32 (0.68)	0.889
Gluteal R	2.59 (1.02)	3.06 (0.94)	0.188
Gluteal L	2.71 (1.06)	3.17 (1.06)	0.218
Great trochanter R	2.51 (0.94)	2.56 (0.87)	0.791
Great trochanter L	2.53 (0.94)	2.62 (1.00)	0.766
Knee R	2.15 (0.85)	2.67 (0.96)	0.125
Knee L	2.23 (0.90)	2.63 (0.89)	0.194
Algometer score	46.48 (11.45)	48.43 (12.28)	0.737
Number of TP	17.06 (1.85)	16.63 (2.33)	0.556

NOTE. R = right; L= left. P values before adjustment for multiple comparisons.

Table 3. Characteristics of the study participants by sex.

Variable	n	Women	n	Men	P
Pain. First day evaluation	123	6.73 (2.13)	8	7.21 (1.38)	0.751
Pain. Second day evaluation	119	6.83 (1.82)	8	7.56 (1.92)	0.447
Weight (kg)	120	70.75 (13.66)	8	79.94 (9.00)	0.022
Height (cm)	120	157.26 (4.97)	8	169.86 (7.12)	<0.001
Body mass index (kg/m^2)	120	28.54 (5.60)	8	27.75 (3.44)	0.902
Waist circumference (cm)	120	89.47 (13.78)	8	94.46 (10.24)	0.094
Body fat percentage	118	37.50 (9.11)	8	28.84 (8.39)	0.006
Skeletal muscle mass (kg)	118	23.86 (3.53)	8	31.39 (2.43)	<0.001
Systolic Blood pressure (mmHg)	120	126.04 (18.82)	8	126.25 (10.00)	0.658
Diastolic blood pressure (mmHg)	120	79.56 (11.27)	8	85.25 (8.83)	0.096
Heart rate (beats per minute)	120	77.36 (12.91)	8	77.25 (4.86)	0.976
Chair sit and reach (cm)	119	-10.09 (14.37)	8	-14.38 (9.69)	0.326
Back scratch test (cm)	119	-9.52 (13.43)	8	-7.66 (9.10)	0.804
Hand grip strength (kg)	119	17.13 (6.38)	8	29.14 (11.81)	0.005
Chair stand test (no. stands)	110	7.20 (2.77)	8	8.43 (2.70)	0.222
8 feet up & go test (s)	119	8.35 (2.32)	8	7.89 (2.26)	0.372
30-s blind flamingo test (failures)	95	10.65 (5.35)	8	8.20 (2.17)	0.410
6 minute walk (metres)	119	447.02 (83.54)	8	484.42 (84.58)	0.295
Heart rate after 6 minute walk	74	105.88 (14.06)	8	99.00 (12.92)	0.203

NOTE. Values are the mean (standard deviation) unless otherwise indicated. P values before adjustment for multiple comparisons.

Table 4. Percentiles for functional capacity in women with fibromyalgia.

Tests	10th	25th	50th	75th	90th
Chair sit and reach (cm)	-28.00	-21.00	-9.50	-0.75	10.25
Back scratch test (cm)	-22.00	-17.00	-10.00	-1.00	7.50
Hand grip strength (kg)	8.80	12.50	16.70	21.85	25.45
Chair stand test (no. stands)	4.00	5.00	7.00	9.00	11.00
8 feet up & go test (s)	5.94	6.76	7.88	9.1	11.09
30-s blind flamingo test (failures)	3.80	7.00	10.00	13.50	19.20
6-minutes walk (metres)	342.75	397.59	438.72	506.7	562.11

Table 5. Spearman's correlation coefficients between tender points count and functional capacity.

Variable	Women
Weight (kg)	0.043
Body mass index (kg/m^2)	0.054
Waist circumference (cm)	0.089
Body fat percentage	0.021
Skeletal muscle mass (kg)	0.068
Chair sit and reach (cm)	-0.032
Back scratch test (cm)	-0.128
Hand grip strength (kg)	0.024
Chair stand test (no. stands)	-0.273**
8 feet up & go test (s)	0.069
30-s blind flamingo test (failures)	-0.047
6 minute walk (metres)	-0.183*

NOTE. ** $P < 0.01$, * $P < 0.05$

2. EFECTO DE DIFERENTES PROGRAMAS DE EJERCICIO FÍSICO SOBRE EL GRADO DE DOLOR, CONDICIÓN FÍSICA Y ASPECTOS PSICOSOCIALES

(Artículos II, III, IV, V, VI)

II

DOES A 3-MONTH MULTIDISCIPLINARY INTERVENTION IMPROVE PAIN, BODY COMPOSITION AND PHYSICAL FITNESS IN WOMEN WITH FIBROMYALGIA?

Carbonell-Baeza A, Aparicio VA, Ortega FB, Cuevas AM, Álvarez I, Ruiz JR, Delgado-Fernández M

Br J Sport Med

In press

Does a 3-month multidisciplinary intervention improve pain, body composition and physical fitness in women with fibromyalgia?

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ABSTRACT

Objective To determine the effects of a 3-month multidisciplinary intervention on pain (primary outcome), body composition and physical fitness (secondary outcomes) in women with fibromyalgia (FM).

Methods 75 women with FM were allocated to a low-moderate intensity 3-month (three times/week) multidisciplinary (pool, land-based and psychological sessions) programme (n=33) or to a usual care group (n=32). The outcome variables were pain threshold, body composition (body mass index and estimated body fat percentage) and physical fitness (30 s chair stand, handgrip strength, chair sit and reach, back scratch, blind flamingo, 8 feet up and go and 6 min walk test).

Results The authors observed a significant interaction effect (group*time) for the left (L) and right (R) side of the anterior cervical ($p<0.001$) and the lateral epicondyle R ($p=0.001$) tender point. Post hoc analysis revealed that pain threshold increased in the intervention group (positive) in the anterior cervical R ($p<0.001$) and L ($p=0.012$), and in the lateral epicondyle R ($p=0.010$), whereas it decreased (negative) in the anterior cervical R ($p<0.001$) and L ($p=0.002$) in the usual care group. There was also a significant interaction effect for chair sit and reach. Post hoc analysis revealed improvement in the intervention group ($p=0.002$). No significant improvement attributed to the training was observed in the rest of physical fitness or body composition variables.

Conclusions A 3-month multidisciplinary intervention three times/week had a positive effect on pain threshold in several tender points in women with FM. Though no overall improvements were observed in physical fitness or body composition, the intervention had positive effects on lower-body flexibility.

INTRODUCTION

Fibromyalgia (FM) is considered a disorder of pain regulation, but its aetiology is not fully understood.[1] FM is characterised by concurrent existence of chronic, widespread musculoskeletal pain and multiple sites of tenderness.[2] Prominent symptoms include fatigue, stiffness, non-restorative sleep patterns, and memory and cognitive difficulties.[2 3]

Treatment of FM is a complicated and controversial process, but successful management of the disorder is possible.[4] The most common non-pharmacological treatments include physical activity and educational–psychological programmes.[5] Since FM affects the physical and psychological aspects of the patient,[6] a multidisciplinary approach such as exercise combined with psychological therapy could be more effective than pharmacological treatment alone.[1 5] There is evidence about the efficacy of multicomponent therapy to reduce the pain, fatigue and mood depression, and improve the self-efficacy and physical fitness in FM.[4 7]

Developments in behavioural therapy such as acceptance and commitment therapy promotes engaging the person in goal life and the acceptance, in contrast to control, the negative experiences like chronic pain or fatigue.[8 9] This therapy seems effective for reducing fear of pain and movement, and for improving pain severity, physical and psychosocial disability, and life satisfaction in patients with chronic musculoskeletal pain.[10–13]

Exercise therapy in FM patients has usually focused on either pool or land-based exercises. The combination of warm water-based exercise with psychological therapy is likely to be effective in the management of FM[14 15] as well as land-based exercise in combination with psychological therapy.[16 17] There is no conclusive evidence that one type of multidisciplinary programme is better than another, and studies using multidisciplinary programmes including pool, land-based and psychological sessions in the same week are scarce.

The purpose of the present controlled trial was to study the effects of a 3-month multidisciplinary training programme based on exercise (pool- and land-based) and psychological therapy, pain (primary outcome), body composition and physical fitness (secondary outcomes) in women with FM.

METHODS

Study participants

We contacted a total of 255 Spanish female members of an FM patients association (Granada, Spain). Eighty-seven potentially eligible patients responded, and gave their written informed consent after receiving detailed information about the aims and study procedures. The inclusion criteria were: (1) meeting the American College of Rheumatology criteria: widespread pain for more than 3 months and pain with 4 kg/cm of pressure for 11 or more of 18 tender points;[2] (2) not to have any other severe somatic or psychiatric disorders, such as stroke or schizophrenia, allergy to chlorine or other diseases that prevent physical loading; and (3) not to be attending another type of physical or psychological therapy at the same time.

A total of nine patients were not included in the study (eight did not have 11 of the 18 tender points, and one presented locomotion problems). After the first day of the baseline measurements, three patients refused to participate. Therefore, a final sample of 75 women with FM participated in the study. Patients were not engaged in regular physical activity >20 min on >3 days/week. The study flow of patients is presented in figure 1. The sociodemographic characteristics of women with FM in the intervention and usual care groups are shown in table 1.

Study design

The present study was a controlled trial with allocation of participants into the intervention (n=41) or usual care (control) group (n=34). For practical and ethical reasons, it was not possible to randomise the patients. We had an ethical obligation with the Association of Fibromyalgia Patients (Granada, Spain) to provide treatment to all patients willing to participate in the study, but due to limitation of resources, we created a waiting list. Patients from the waiting list agreed to be part of the usual care group (control group) and were offered the intervention programme at the end of the follow-up period. Data collected only during the control period were included in the current analysis.

The research protocol was reviewed and approved by the Ethics Committee of the Virgen de las Nieves Hospital (Granada, Spain). The study was developed between January 2008 and June 2009, following the ethical guidelines of the Declaration of Helsinki, last modified in 2000.

Interventions

The multidisciplinary programme comprised three sessions/week for 12 weeks. The first two sessions of each week (Monday and Wednesday) were performed in a chest-high warm pool for 45 min, and the third session (Friday) included 45 min of activity in the exercise room and 90 min of psychological–educational therapy. The exercise sessions were carefully supervised by a fitness specialist and by a physical therapist who worked with groups of 10–12 women. The psychological–educational sessions were conducted by a psychologist with experience treating FM patients.

Participants in the control group were asked not to change their activity levels and medication during the 12-week intervention period.

Exercise sessions

Each exercise session included a 10 min warm-up period with slow walk, mobility and stretching exercises, followed by 25 min of exercise, and finishing with a 10 min cool-down period of stretching and relaxation exercises. Monday sessions involved strength exercises developed at a slow pace using water and aquatic materials as a means of resistance including a stepped progression during the programme. Wednesday sessions included balance-oriented activities: changes of position, monopodal and bipodal stance, backwards walks, coordination by means of exercises with aquatic materials, and dancing aerobic exercises. Fridays included aerobic-type exercises and coordination using a circuit of different exercises.

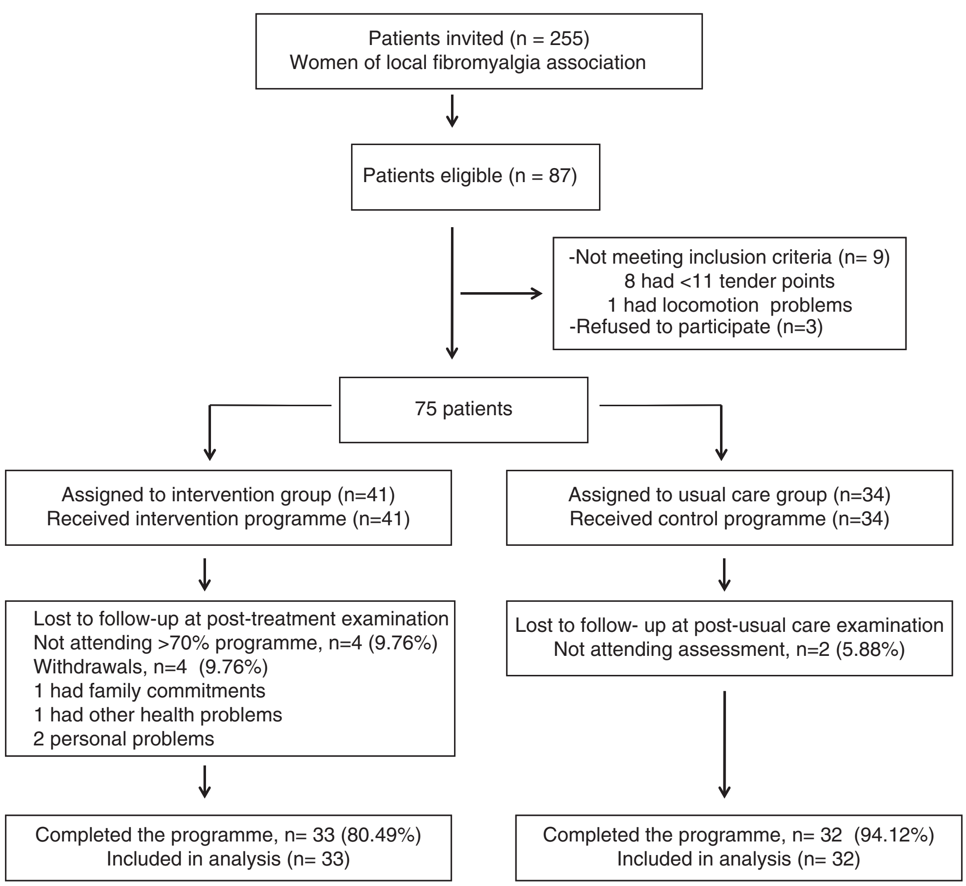

Figure 1 Flow of patients throughout the trial.

Training intensity was controlled by the rate of perceived exertion (RPE) based on Borg's conventional (6–20 point) scale. The medium values of RPE were 12±2 on Monday, 12±2 on Wednesday and 13±3 on Friday. These RPE values correspond to a subjective perceived exertion of 'fairly light exertion and somewhat hard exertion,' that is, low–moderate intensity.

Psychological–educational therapy

Psychological therapy was based on the acceptance and commitment therapy developed by Hayes *et al*.[8] The sessions consisted in: (1) sessions 1, 2 and 3: general information of the disease from a bio-psycho-social perspective, enhancing the role of physical activity; (2) sessions 4–10: assessment of individual goal life and promotion of actions to develop these goals, while trying to cope with the thoughts and feelings related to pain that act as barriers to achieve this goals; (3) session 11: relaxation exercises aiming to improve body awareness; and (4) session 12: solving doubts, and general conclusions of the intervention. The pedagogical approach was based on the active participation of the patients through discussions, practical exercises and role-playing. Educational materials were provided to improve understanding of FM by the patients.

Outcome measures

Pre- and postintervention assessment was carried out on two separate days with at least 48 h between each session. This was done in order to prevent fatigue and flare-ups (acute exacerbation of symptoms) in the patients. The assessment of the tender-points, blind flamingo test and chair stand test were completed on the first visit, and body composition, chair sit and reach, back scratch, 8 feet up and go, hand grip strength and 6 min walk test on the second day. Both the intervention and usual care groups were assessed the week immediately before the intervention started and the week after the intervention was finished.

Tender points (primary outcome)

We assessed 18 tender points according to the American College of Rheumatology criteria for classification of FM using a standard pressure algometer (EFFEGI, FPK 20; Italy).[2] The mean of two successive measurements at each tender point was used for the analysis. Tender point scored as positive when the patient noted pain at pressure of 4 kg/cm^2 or less. The total count of such positive tender points was recorded for each participant. The algometer score was calculated as the sum of the minimum pain-pressure values obtained for each tender point.

Body composition (secondary outcome)

We performed a bioelectrical impedance analysis with an eight-polar tactile-electrode impedanciometer (InBody 720; Biospace, Gateshead, UK). We measured weight (kg), and body fat percentage and skeletal muscle mass (kg) were estimated. The validity of this instrument was reported elsewhere.[18 19] Height (cm) was measured using a stadiometer (Seca 22; Seca, Hamburg, Germany). Body mass index (BMI) was calculated (kg/m^2).

Physical fitness (secondary outcome)

Fitness tests were part of the Functional Fitness Test battery by Rikli and Jones.[20] Additionally, we also measured the handgrip strength and the blind flamingo test, which have been used in patients with FM.[21]

Lower-body muscular strength

The 30 s chair stand test involves counting the number of times within 30 s that an individual can rise to a full stand from a seated position with back straight and feet flat on the floor, without pushing off with the arms. The patients carried out one trial after familiarisation.[20]

Upper-body muscular strength

Handgrip strength was measured using a digital dynamometer (TKK 5101 Grip-D; Takey, Tokyo) as described elsewhere.[22] Patients performed (alternately with both hands) the test twice allowing a 1 min rest period between measures. The best value of two trials for each hand was chosen, and the average of both hands was registered.

Lower-body flexibility

In the 'chair sit and reach test,' the patient seated with one leg extended slowly bends forward, sliding the hands down the extended leg in an attempt to touch (or past) the toes. The number of centimetres short of reaching the toe (minus score) or reaching beyond it (plus score) are recorded.[20] We measured two trials with each leg, and the best value of each leg was registered. The average of both legs was used in the statistical analysis.

Upper-body flexibility

The back scratch test, a measure of overall shoulder range of motion, involves measuring the distance between (or overlap of) the middle fingers behind the back with a ruler.[20] This test was measured alternately with both hands twice, and the best value was registered. The average of both hands was used in the analysis.

Static balance

This was assessed with the blind flamingo test with eyes closed.[23] The number of trials needed to complete 30 s of the static position is recorded, and the chronometer is stopped whenever the patient does not comply with the protocol conditions. One trial was accomplished for each leg, and the average of both values was selected for the analysis.

Motor agility/dynamic balance

The 8 feet up and go test involves standing up from a chair, walking 8 feet to and around a cone, and returning to the chair in the shortest possible time.[20] The best time of two trials was recorded and used in the analysis.

Aerobic endurance

We assessed the 6 min walk test.[20] This test involves determining the maximum distance (metres) that can be walked in 6 min along a 45.7 m rectangular course.[24–26]

Data analysis

An independent t test and χ^2 test were used to compare demographic variables between groups. We used a two-factor (group and time) analysis of covariance with repeated measures to assess the training effects on the outcome variables (pain, body composition and physical fitness) after adjusting for age. For each variable, we reported the p value corresponding to the group (between-subjects), time (within-subjects) and interaction (group×time) effects. We calculated the p value for within-group differences by group when a significant interaction effect was present. Multiple comparisons were adjusted for mass significance.[27] We performed an intention-to-treat analysis.

Analyses were performed using the Statistical Package for Social Sciences (SPSS, v. 16.0 for Windows; SPSS, Chicago).

RESULTS

Four women from the intervention group discontinued the programme due to family commitments, personal and health problems, and another four were excluded for attending less than 70% of the programme (attendance: 32.4%, 53.1%, 55.9% and 59.4%). Adherence to the intervention was 84.4% (range 70–96.9%). A total of 33 (80.5%) women from the intervention group and 32 (94.1%) from the usual care group completed both pre- and postintervention assessments and were included in the final analysis. Compliers (n=33) and non-compliers (n=8) were similar in all the studied variables except on weight (71.6±12.7 kg vs 82.1±14.9 kg, respectively, $p<0.05$) and BMI (28.6±5.0 kg/m^2 vs 33.8±5.7 kg/m^2, respectively, $p<0.05$).

During the study period, no participant reported an exacerbation of FM symptoms beyond normal flares, and there were no serious adverse events. No women changed from the control group to the intervention group or vice versa, and there were no protocol deviations from the study as planned.

Sociodemographic characteristics of women with FM by group are shown in table 1. Tender points are presented in table 2. We observed no significant differences between or within-groups in all the variables analysed except for the occiput tender point. After adjusting for multiple comparisons,[27] we observed a significant interaction effect (group×time) for the left (L) and right (R) side of the anterior cervical and the lateral epicondyle R tender point. Post hoc analysis revealed that pain threshold in the control group significantly decreased (negative) in anterior cervical R ($p<0.001$) and L ($p=0.002$), whereas in the intervention group, the threshold pain significantly increased (positive) in the anterior cervical R ($p<0.001$) and L ($p=0.012$) and in the lateral epicondyle R ($p=0.010$). We did not observe a significant interaction effect (group×time) in the algometer score or tender points count, after adjusting for multiple comparisons.[27] Likewise, we observed no significant interaction effect in body composition (table 3).

There was a significant interaction effect for the chair sit at reach test (table 4), after adjusting for multiple comparisons.[27] Post hoc analysis revealed that there was an improvement on the chair sit at reach test ($p=0.002$) in the intervention group. No significant improvement attributed to the training was observed in the rest of physical fitness variables.

Table 1 Sociodemographic characteristics of women with fibromyalgia by group

Variable	Usual care group (n=32)	Training group (n=33)	p Value
Age, years	51.4 (7.4)	50.0 (7.3)	0.455
Years since clinical diagnosis, n (%)			0.903
≤5 years	16 (50.0)	17 (51.5)	
>5 years	16 (50.0)	16 (48.5)	
Marital status, n (%)			0.318
Married	24 (75.0)	25 (75.8)	
Unmarried	5 (15.6)	2 (6.1)	
Separated/divorced/widowed	3 (9.4)	6 (18.2)	
Educational status, n (%)			0.543
Unfinished studies	2 (6.2)	1 (3.0)	
Primary school	11 (34.4)	17 (51.5)	
Secondary school	8 (25.0)	7 (21.2)	
University degree	11 (34.4)	8 (24.2)	
Occupational status, n (%)*			0.669
Housewife	14 (46.7)	18 (54.5)	
Student	0 (0)	1 (3.0)	
Working	11 (36.7)	11 (33.3)	
Unemployed	2 (6.7)	2 (6.1)	
Retired	3 (10.0)	1 (3.0)	
Income, n (%)			0.601
€<120000	15 (46.9)	14 (42.4)	
€120100–180000	7 (21.9)	5 (15.2)	
€>180000	10 (31.2)	14 (42.4)	

Values are the mean (SD) unless otherwise indicated.
*Two missing data, one by group.

DISCUSSION

The present study shows that a low–moderate 3-month multidisciplinary intervention training programme was well tolerated and did not have any deleterious effects on patients' health. We observed that the pain threshold increased in several points in the intervention group, whereas there was a decreased pain threshold in several tender points in the usual care group. Although no overall improvements were observed in body composition or physical fitness, the intervention had positive effects on lower body flexibility. Further research is needed in order to determine whether programmes of longer duration (>3 months), higher frequency (>3 sessions/week) or higher intensity (>13 RPE) induce major improvements on pain, body composition and functional capacity in women with FM.

We did not observe any significant changes in tender points count, which concurs with the results observed by Mannerkorpi *et al*[15] (16.3±1.8 vs 15±3.3; n=28) after 6 months of pool exercise (once a week) combined with a six-session education programme. Similarly, Burckhardt *et al*[28] did not observe changes in the number of tender points (15.0 vs 15.3; n=28) after 6 weeks of education plus physical training. Gusi *et al*[29] did not report any improvement after 12 weeks of pool exercise (three times/week). King *et al*[16] did not report any improvements in tender points count (15.8±2.5 vs 14.6±4.0; n=26) with a 3-month intervention that combined exercise and educational programme (three sessions/week). In contrast, Altan *et al*[30] and de Andrade *et al*[31] carried out interventions solely based on pool exercise during 12 weeks (3 days/week) and showed a significant change (15.3±2.2 vs 8.5±3.7, n=24; 15.5±1.9 vs 11.4±2.6, n=19, respectively) in tender points count. Discrepancy among studies could be due to the fact that pain relief is related to a higher length and frequency of warm-water exercise sessions per week.[29] In fact, several studies with intensity balneotherapy programmes (2–3 weeks with bath all days) reported an improvement in tender points count.[32–34] Hydrotherapy (with or without exercise) has been recommended for the management of FM because of the water' buoyancy and warm temperature.[35–37] The buoyancy of the water limits the impact of exercise on weight-bearing joints because the external gravity load applied to the lower extremities is reduced in comparison with the load produced in land-based exercises.[36 37] In addition, the vasodilatory effect of heating may improve muscular ischaemia and help to clear analgesic mediators in FM.[37]

In the present study, we observed a significant improvement in the chair sit and reach test, whereas the improvement in upper-body flexibility was not statistically significant. Tomas-Carus *et al*[21] did not observe improvement in lower-body flexibility (sit and reach test) after a 12-week pool-based programme. Flexibility of upper and lower limbs in FM

Table 2 Effects of 12-week intervention on tender points in women with fibromyalgia

	Group	Pre	Post	p Value for group effect	p Value for time effect	p Value for interaction effect
Occiput R	Control	2.87 (0.11)	2.41 (0.12)	0.043	0.972	0.007
	Training	2.33 (0.11)	2.38 (0.12)			
Occiput L	Control	2.84 (0.12)	2.39 (0.11)	0.012	0.526	0.004
	Training	2.22 (0.12)	2.25 (0.11)			
Anterior cervical R	Control	2.36 (0.12)	1.83 (0.11)	0.130	0.852	<0.001
	Training	1.70 (0.12)	2.05 (0.11)			
Anterior cervical L	Control	2.19 (0.12)	1.84 (0.10)	0.231	0.343	<0.001
	Training	1.73 (0.12)	1.96 (0.10)			
Trapezius R	Control	2.96 (0.15)	2.62 (0.16)	0.143	0.817	0.047
	Training	2.48 (0.14)	2.51 (0.16)			
Trapezius L	Control	3.14 (0.14)	2.73 (0.15)	0.074	0.328	0.016
	Training	2.58 (0.14)	2.63 (0.15)			
Supraspinatus R	Control	3.34 (0.15)	3.05 (0.17)	0.225	0.038	0.012
	Training	2.81 (0.15)	3.10 (0.17)			
Supraspinatus L	Control	3.43 (0.15)	3.16 (0.17)	0.074	0.017	0.004
	Training	2.75 (0.15)	3.12 (0.17)			
Second rib R	Control	2.24 (0.11)	2.16 (0.13)	0.062	0.502	0.278
	Training	1.88 (0.10)	1.97 (0.12)			
Second rib L	Control	2.28 (0.10)	2.06 (0.13)	0.089	0.171	0.006
	Training	1.83 (0.10)	2.00 (0.13)			
Lateral epicondyle R	Control	2.64 (0.11)	2.43 (0.13)	0.154	0.551	0.001
	Training	2.10 (0.11)	2.56 (0.13)			
Lateral epicondyle L	Control	2.76 (0.14)	2.52 (0.15)	0.219	0.607	0.037
	Training	2.32 (0.14)	2.55 (0.14)			
Gluteal R	Control	2.87 (0.17)	3.14 (0.17)	0.944	0.680	0.496
	Training	2.94 (0.16)	3.04 (0.17)			
Gluteal L	Control	2.99 (0.18)	3.34 (0.17)	0.963	0.361	0.581
	Training	3.04 (0.17)	3.26 (0.17)			
Great trochanter R	Control	2.87 (0.15)	2.94 (0.15)	0.598	0.428	0.786
	Training	2.75 (0.15)	2.87 (0.15)			
Great trochanter L	Control	2.97 (0.16)	3.07 (0.17)	0.377	0.261	0.694
	Training	2.74 (0.16)	2.94 (0.17)			
Knee R	Control	2.63 (0.15)	2.78 (0.15)	0.056	0.048	0.478
	Training	2.36 (0.14)	2.35 (0.15)			
Knee L	Control	2.60 (0.15)	2.79 (0.16)	0.206	0.011	0.258
	Training	2.46 (0.15)	2.43 (0.16)			
Algometer score	Control	49.99 (1.88)	47.29 (2.06)	0.108	0.105	0.016
	Training	43.05 (1.86)	45.98 (2.02)			
Total number points	Control	16.26 (0.34)	16.34 (0.47)	0.288	0.081	0.288
	Training	17.11 (0.34)	16.55 (0.46)			

Data are means (SEM).
L, left; R, right.

Table 3 Effects of 12-week intervention on body composition in women with fibromyalgia

	Group	Pre	Post	p Value for group effect	p Value for time effect	p Value for interaction effect
Weight (kg)	Control	68.1 (2.2)	68.3 (2.3)	0.407	0.575	0.053
	Training	71.2 (2.1)	70.4 (2.2)			
BMI (kg/m^2)	Control	27.8 (0.9)	27.8 (0.9)	0.639	0.579	0.250
	Training	28.5 (0.9)	28.4 (0.9)			
Body fat percentage	Control	37.9 (1.3)	37.2 (1.5)	0.868	0.908	0.218
	Training	39.2 (1.2)	36.6 (1.3)			
Muscle mass (kg)	Control	22.8 (0.5)	22.9 (0.6)	0.295	0.781	0.134
	Training	23.0 (0.4)	24.0 (0.6)			

Data are means (SEM).
BMI, body mass index.

patients is markedly below that of healthy-matched people.[38] Flexibility plays a key role in the capacity to carry out the activities of daily living. Decreased flexibility in multiple anatomical sites is involved in the aetiology of physical impairments and related disabilities among older adults;[39] therefore, the improvement observed in our study could be considered as clinically relevant.

We did not observe any significant improvement on a 6 min walk, yet the patients were able to walk for ~22 m more after treatment. Burckhardt *et al*[28] did not observe any changes in this test (488.6 m vs 493.9 m) after a 6-week exercise plus education-based programme. In contrast, other studies reported improvements in the 6-min walk test after multidisciplinary interventions of 6 weeks (72 m; frequency: twice a week),[14] 16

Table 4 Effects of 12-week intervention on physical fitness in women with fibromyalgia

	Group	Pre	Post	p Value for group effect	p Value for time effect	p Value for interaction effect
Chair sit and reach (cm)	Control	–12.3 (2.8)	–15.1 (3.3)	0.193	0.967	0.006
	Training	–12.5 (2.6)	–4.9 (3.1)			
Back scratch test (cm)	Control	–6.5 (2.8)	–8.5 (3.0)	0.261	0.881	0.032
	Training	–13.3 (2.5)	–10.2 (2.8)			
Handgrip strength (kg)	Control	15.9 (1.3)	17.4 (1.3)	0.951	0.757	0.295
	Training	16.7 (1.2)	16.9 (1.3)			
Chair stand test (n)	Control	7 (0.5)	8 (0.5)	0.341	0.376	0.030
	Training	7 (0.5)	9 (0.5)			
8 feet up and go (s)	Control	8.2 (0.4)	7.7 (0.3)	0.813	0.301	0.166
	Training	8.5 (0.4)	7.3 (0.3)			
30 s blind flamingo (failures)	Control	9 (1)	10 (1)	0.996	0.784	0.012
	Training	11 (1)	8 (1)			
6 min walk (m)	Control	458.7 (15.0)	459.3 (14.0)	0.852	0.657	0.181
	Training	451.9 (14.0)	473.0 (13.2)			

Data are means (SEM).

weeks (28 m; frequency: twice a week),[40] 20 weeks (14.5 m; frequency: once a week)[41] and 24 weeks (39.6 m; frequency: once a week).[15] It is likely that the small size of the swimming pool (4×7 m), the frequency and the intensity used in our programme could hamper the possibility to induce greater changes in walked distance.

There was no significant improvement in the blind flamingo balance test after adjustment for multiple comparisons; however the intervention group reported three failures less (27% of improvement) in this test at post-treatment. Due to the fact that FM is associated with balance problems and increased fall frequency,[42] the improvement in this variable would be of clinical relevance. Tomas-Carus *et al*[21] obtained significant improvements (eight failures less) after 12 weeks of aquatic training.

We did not observe any improvements in strength in the upper or lower extremities. Similarly, Tomas-Carus *et al*[21] did not find improvement in handgrip strength after 12 weeks of pool exercise (three times/week), and Altan *et al*[30] did not report any improvement in chair test (1 min) after 12 and 24 weeks of pool exercise. In contrast, Mannerkorpi *et al*[15] obtained significant gains in chair test (1 min) and handgrip strength on the left but not on the right hand after 6 months of pool exercise and education intervention.

The fact that we were not able to randomise the participants into the intervention and usual care group is a limitation of our study. Despite this, there was no difference between groups in all the variables studied. Strengths include the assessment of body composition and physical fitness measures, which are limited in others studies. We applied a correction for multiple statistical tests[27] in order to avoid statistically significant effects by chance.

In summary, a low–moderate-intensity 3-month multidisciplinary training had a positive effect on pain threshold in several tender points. Although no overall improvements were observed on body composition or physical fitness, the intervention had positive effects on lower-body flexibility. Future research might determine whether longer and more intense programmes are necessary to induce significant improvements in body composition and physical fitness in these patients.

What is already known on this topic

The most used non-pharmacological strategies are physical exercise and psychological treatment. Multidisciplinary treatment seem to improve rating of pain, fatigue and depression; however, further studies are needed to determine whether this treatment has a positive effect on tender points, body composition and physical fitness.

What this study adds

A 3-month multidisciplinary intervention three times/week is enough to affect pain threshold positively in several tender points in women with fibromyalgia. Though no overall improvements were observed in physical fitness or body composition, this type of intervention seems to have positive effects on lower-body flexibility.

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Competing interests None.

Patient consent Obtained.

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EFFECTIVENESS OF MULTIDISCIPLINARY THERAPY IN WOMEN WITH FIBROMYALGIA

III

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Submitted

Effectiveness of multidisciplinary therapy in women with fibromyalgia

Running head: Multidisciplinary therapy and fibromyalgia

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ABSTRACT

Objective: To study the effects of a 3-month multidisciplinary intervention based on exercise (pool and land-based) and psychological therapy on psychological outcomes in women with fibromyalgia (FM).

Design: Control trial.

Setting: University research laboratory.

Participants: Sixty-five women with FM.

Interventions: Low-moderate intensity 3-month (3-times/week) multidisciplinary (pool, land-based and psychological sessions based on the Acceptance and Commitment Therapy) intervention (n=33) or to a usual care group (n=32).

Main Outcome Measures: Fibromyalgia Impact Questionnaire (FIQ), Short Form Health Survey 36 (SF-36), Hospital Anxiety and Depression Scale, Vanderbilt Pain Management Inventory and Rosenberg Self-Esteem Scale.

Results: We observed a significant interaction effect (group x time) for the total score of FIQ, the subscales fatigue, stiffness, anxiety and depression, and the subscales of SF-36 physical role, bodily pain, vitality and social functioning. Post-hoc analysis revealed significant improvements in total score of FIQ ($p<0.001$), fatigue ($p=0.001$), stiffness ($p<0.001$), anxiety ($p=0.011$), depression ($p=0.008$), physical role ($p=0.002$), bodily pain ($p<0.001$), vitality ($p<0.001$) and social functioning ($p<0.001$) in the intervention group, whereas in the control group, there was a significant worsening in the subscale depression ($p=0.006$) and a significant decrease in social functioning ($p=0.019$).

Conclusions: A 3-months of low-moderate intensity multidisciplinary intervention reduced FM impact and improved quality of life in women with FM.

Key words: fibromyalgia, quality of life, exercise, Acceptance and Commitment Therapy.

INTRODUCTION

Fibromyalgia (FM) is a chronic disease that affects the person in different vital areas, such as physical condition, emotional state, working status, daily functioning and social relationships [1, 2]. FM is a condition characterized for chronic and widespread musculoskeletal pain; and symptoms, such as fatigue, stiffness, sleep disturbance, anxiety, depression and cognitive difficulties are frequently associated[3].

To avoid pain, the patients usually decrease their activity level because of the fear of pain involved in each movement. When this inactivity pattern is prolonged, the consequences are more depression, functional incapacity and worse physical performance [4]. A possible alternative is the acceptance of pain, defined as a willingness to remain in contact with the chronic pain, without reaction, disapproval or attempts to reduce or avoid together with an engagement in positive everyday activities [5]. The acceptance of chronic pain has been associated with better quality of life and emotional, social and physical functioning [5-7], better positive affect [8], decrease of depression and anxiety [6] and adaptive coping [7].

The Acceptance and Commitment Therapy (ACT) developed by Hayes *et al.* [9], promotes engaging the person in goal life and the acceptance of the negative experiences like chronic pain, distress and fatigue in contrast to reduction or control them like proposes Cognitive and Behavioural Therapy [10, 11].

The goals of the FM treatment are the relief of pain, which is the main symptom, and increasing the level of functional capabilities [12]. There is strong evidence that the multidisciplinary treatment (educational or psychological therapy, and exercise therapy) has beneficial short-term effects on key symptoms of FM and health-related quality of life [13]. FM patients seem to attain symptom relief, particularly decreased pain and fatigue as well as improved sleep and mood, with low to moderate intensity exercise of any type [14]. On the other hand, ACT has shown to be an effective intervention in the management of chronic pain [15, 16]. Several studies investigated the effect of combining both exercise and ACT in chronic pain patients and reported significant improvements in emotional, social and physical functioning after treatment [17, 18]. The effectiveness of a multidisciplinary intervention based on exercise (pool and land-based) and psychological therapy (ACT based) on psychological outcomes in women with FM remains to be known.

The aim of the present controlled trial was to study the effects of a 3-month multidisciplinary intervention based on exercise (pool and land-based) and ACT on psychological outcomes in women with FM.

METHOD

Study participants

We contacted a total of 255 Spanish female members of a FM association (Granada, Spain). Eighty-seven potentially eligible patients responded and gave their written informed consent after receiving detailed information about the aims and study procedures. The inclusion criteria were: (i) meeting the American College of Rheumatology criteria: widespread pain for more than 3 months, and pain with 4 kg/cm of pressure reported for 11 or more of 18 tender points [3], (ii) not to have other severe somatic or psychiatric disorders, such as stroke or schizophrenia, allergy to chlorine, or other diseases that prevent physical loading, and (iii) no to be attending another type of physical or psychological therapy at the same time.

A total of 9 patients were not included in the study (8 did not have 11 of the 18 tender points, and 1 presented locomotion problems). After the first day of the baseline measurements, 3 patients refused to participate. Therefore, a final sample of 75 women with FM participated in the study. Patients were not engaged in regular physical activity >20 minutes on >3 days/week. The study flow of patients is presented in **Figure 1**.

Study design

The present study was a controlled trial with allocation of participants into the intervention (n=41) or usual care (control) group (n=34). For practical and ethical reasons, it was not possible to randomize the patients. We had an ethical obligation with the Association of FM Patients (Granada, Spain) to provide treatment to all patients willing to participate in the study, but due to limitation of resources, we created a waiting list. Patients from the waiting list agreed to be part of the usual care group (control group) and were offered the intervention at the end of the follow-up period. Data collected only during the control period were included in the current analysis.

The research protocol was reviewed and approved by the Ethics Committee of the *Virgen de las Nieves Hospital* (Granada, Spain). The study was developed between January 2008 and June 2009, following the ethical guidelines of the Declaration of Helsinki, last modified in 2000.

Intervention

The multidisciplinary intervention comprised 3 sessions per week for 12 weeks. The first two sessions of each week (Monday and Wednesday) were performed in a chest-high warm pool during 45 minutes, and the third session (Friday) included 45 minutes of activity in the exercise room and 90 minutes of psychological-educational therapy. The exercise sessions were carefully supervised by a fitness specialist and by a physical therapist that worked with groups of 10-12 women. The psychological-educational sessions were conducted by a psychologist with experience treating FM patients.

Participants in the control group were asked not to change their activity levels and medication during the 12-week intervention period.

Exercise sessions

Each exercise session included a 10 minute warm-up period with slow walk, mobility and stretching exercises, followed by 25 minute of exercise, and finished with a 10 minute cool-down period of stretching and relaxation exercises. Monday sessions involved strength exercises. Wednesday sessions included balance-oriented activities and dancing aerobic exercises. Fridays included aerobic-type exercises and coordination using a circuit with diverse exercises.

Training intensity was controlled by the rate of perceived exertion (RPE) based on Borg's conventional (6-20 point) scale. The medium values of RPE were 12 ± 2 on Monday, 12 ± 2 on Wednesday and 13 ± 3 on Friday. These RPE values correspond to a subjective perceived exertion of 'fairly light exertion and somewhat hard exertion', that is, low-moderate intensity.

Psychological therapy

Psychological therapy was based on the ACT developed by Hayes *et al.* [9] adapted for chronic pain [10] and group format [19]. This intervention included components of the Cognitive and Behavioural Therapy for chronic pain [20] like role of the complaint, regulations of activity levels and social abilities (assertivities). To note is that it was always based in patients' goals and not to cognitive restructuring or control and elimination of symptoms strategies.

The therapy consisted of: (i) Sessions 1, 2 and 3: General information of the disease from a bio-psycho-social perspective, enhancing the role of physical activity and expectative of intervention; (ii) Sessions 4-6: To clarify individual's life values and goals as well as to encourage commitment in actions which are directed towards the achievement of such goals. Encouragement of acceptance of those thoughts, feelings and emotions related to pain which act as a barriers to life goals achievement: (iii) Sessions 7-8: Being aware about to what extent the patient is focused on her symptoms and moved away from her values as well as the consequences of it on her life; (iv) Sessions 9-10: To distinguish different interpersonal communication styles (passive, aggressive and assertive) and to encourage the expression of needs in a direct way. On the other hand, analyzing the role of complaints in communication is highlighted; (v) Session 11-12: Exercises aiming to improve body awareness and solving doubts, problems, etc. and general conclusions of the intervention. The pedagogical approach was based on the active participation of the patients through discussions, practical exercises, self-registration, metaphors, exposition and role-playing. Educational materials were provided to improve understanding of FM by the patients.

Outcome measures

The Fibromyalgia Impact Questionnaire (FIQ) [21] was used to evaluate the severity and impact of FM on daily activities. The FIQ is a self-administered questionnaire, comprising 10 subscales (scored 0-10) of disabilities and symptoms, and has been validated in Spanish FM population [22]. FIQ assess the components of health status that are believed to be most affected by FM. The total score of FIQ, being the mean of the 10 subscales, and the subscales for physical function, days feel good, pain, fatigue, morning tiredness, stiffness, anxiety, and depression were applied in the study. The questionnaire is scored from 0 to 100, in which a higher score indicates a greater impact of the syndrome [22].

The Short-Form Health Survey 36 (SF-36) is a generic instrument assessing health related quality of life. In this study we used the Spanish version of SF-36 [23]. It contains 36 items grouped into 8 subscales: physical functioning, physical role, bodily pain, general health, vitality, social functioning, emotional role, and mental health. The range of scores is between 0 and 100 in every subscale, where higher scores indicate better health.

We used the Spanish version of the Hospital Anxiety and Depression Scale (HADS) [24] The HADS contains 14 statements, ranging from 0 to 3, in which a higher score indicates a higher degree of distress. The scores build 2 subscales: anxiety (0–21) and depression (0–21) [25]. Zigmond and Snaith [25] suggested subscale cut-offs equal or greater than 8 to indicate the likely presence of clinically significant levels of depression or anxiety at mild intensity and cut-offs equal or greater than 11 to indicate moderate to severe intensity.

The Vanderbilt Pain Management Inventory (VPMI) [26] adapted into Spanish [27] was used to assess coping strategies. The scale has 18 items divided into two subscales designed to assess how often chronic pain sufferers use active and passive coping. Active coping, where patients attempt to function in spite of their pain; and passive coping, where patients relinquish control of their pain to others, or allow other areas of their life to be adversely affected by pain.

The Spanish version of the Rosenberg Self-Esteem Scale (RSES) [28] was used to analyze the self-esteem of the FM patients . RSES is a self-report measure designed to assess the concept of global self-esteem [29] and comprises 10 items scored on a 4-point scale that are summed to produce a single index of self-esteem. A higher score indicates a greater self-steem.

Data Analysis

Independent t test and chi-square test were used to compare demographic variables between groups. We used a two-factor (group and time) analysis of covariance (ANCOVA) with repeated measures to assess the Intervention effects on the outcome variables after adjusting for age. For each variable we reported the P value corresponding to the group (between-subjects), time (within-subjects) and interaction (group*time) effects. We calculated the P value for within-group differences by group when a significant interaction effect was present. Multiple comparisons were adjusted for mass significance [30].

We performed a per-protocol analysis to study the participants who complied with the study protocol, which was defined as attendance at least 70% of the sessions. Moreover, we also performed an intention to treat analysis with all the participants (regardless of attendance) and when post-test data were missing, baseline scores were considered post-test scores.

Analyses were performed using the Statistical Package for Social Sciences (SPSS, v. 16.0 for WINDOWS; SPSS Inc, Chicago).

RESULTS

Four women from the intervention group discontinued the intervention due to family commitments, personal and health problems, and another four were excluded for attending less than 70% of the intervention (attendance: 32.4%, 53.1%, 55.9%, and 59.4%). Adherence to the intervention was 84.4% (range 70 – 96.9%). A total of 33 (80.5%) women from the intervention group and 32 (94.1%) from the usual care group completed both pre-and post-intervention assessments and were included in the final analysis. Compliers (n=33) and non-compliers (n=8) were similar in all the studied variables except the FIQ subscale of pain (7.4 ± 1.5 vs. 9.0 ± 0.8, respectively, $p<0.05$)

During the study period, no participant reported an exacerbation of FM symptoms beyond normal flares, and there were no serious adverse events. No women changed from the control group to the intervention group or *vice versa*, and there were no protocol deviations from the study, as planned.

Sociodemographic characteristics of women with FM by group are shown in **Table 1**. We observed no significant differences between or within-groups in all the variables analyzed except for the subscale FIQ fatigue. After adjusting for multiple comparisons [30], we observed a significant interaction effect (group*time) for the FIQ total score, and the subscales fatigue, stiffness, anxiety and depression **(Table 2)**. Post hoc analysis revealed significant improvement in FIQ total score ($p<0.001$), fatigue ($p=0.001$), stiffness ($p<0.001$), anxiety ($p=0.011$) and depression ($p=0.008$) in the intervention group, whereas, in the control group there was a significant worsening in the subscale depression ($p=0.006$). There was also a significant interaction effect in the subscales of SF36 physical role, bodily pain, vitality and social functioning, after adjustment for multiple comparisons [30] **(Table 3)**. Post hoc analysis revealed significant improvement in physical role ($p=0.002$), bodily pain ($p<0.001$), vitality ($p<0.001$) and social functioning ($p<0.001$) in the intervention group, whereas, in the control group, there was a significant decrease in social functioning ($p=0.019$).

After adjusting for multiple comparisons [30], no significant improvement attributed to the Intervention was observed in the rest of outcome measures (Table 4).

The intention to treat analysis showed similar results than those observe in the per protocol analysis, except for the subscales of SF-36 bodily pain and vitality, that did not remain significant after adjusting for multiple comparisons.

DISCUSSION

The main finding of the present study is that a low-moderate intensity 3-month multidisciplinary intervention improves quality of life and reduces FM impact, as measured by FIQ, in women with FM. The intervention was well tolerated and did not have any deleterious effects on patients' health.

Due to the lack of studies that applied a multidisciplinary intervention based on exercise and ACT in FM patients, it is difficult to directly compare our results, yet, there are several studies performed in chronic pain patients. McCracken *et al.* [17] conducted an intensive multidisciplinary study for 3-4 weeks (5 days/week) based on physical exercise in group sessions twice a day and an ACT-based psychological intervention once per day. They found a 41.2% reduction in depression, 25.0% reduction in physical disability and 39.3% reduction in psychosocial disability. Likewise, Vowles and McCracken [18] obtained significant improvements in pain, depression, pain-related anxiety, disability, medical visits, work status, and physical performance in chronic pain patients who followed a similar intervention.

Several studies have investigated the effects of the combination of exercise with other type of psychological intervention such as educational or self-management intervention in FM patients. Cedraski *et al.* [31] observed improvements in the total score of FIQ and in the subscales pain, fatigue and depression after 6 weeks (2 times per week) of combined pool exercise and educational intervention compared with a control group, but not in SF-36. Rooks *et al.* [32] compared 2 interventions of exercise with 1 intervention of educational intervention and 1 intervention combining exercise and education. The combined intervention reported greater improvement in total score of FIQ than the others interventions, and concluded that the benefits of exercise are enhanced when combined with targeted self-management education. Mannerkorpi *et al.* [33] carried out 20 sessions of pool exercise (once a week) and 6 educational sessions focused on the strategies to cope with FM symptoms and to encourage regular physical activity. They observed improvements in total score of FIQ and the pain subscale compared with only educational intervention [33], whereas they did not observed differences in HADS and some dimensions of SF-36. Hammond and Freeman [34] compared a 10 week of education-exercise (land-based, once a week 2 hours) intervention with a relaxation group (once a week, 1 hour) and found significant differences after treatment between groups in total score of FIQ and the subscales feel good, fatigue and morning tiredness. In contrast, King *et al.* [35] compared the effect of 12-week exercise intervention, education intervention and exercise with education intervention with a control group, and found no differences in FIQ score.

We also observed improvements in several FIQ subscales such as anxiety and depression symptoms, whereas no changes were observed in HADS, which concur with other studies [33]. Overall, these findings could indicate that FIQ is more specific to measure changes after a multidisciplinary intervention than other instruments are [36]. Moreover, we did not observed changes in self-esteem, which suggest that FM patients can improve their quality of life and reduce the impact of the illness without changes in HADS scores or self-esteem. Indeed, this is in accordance with the ACT theory [9].

Variability in educational-psychological content, type of exercise, intervention duration and statistical analysis differ among studies, which makes comparisons difficult. Nevertheless, our results concur with the findings of a recent meta-analysis of randomized controlled trials of multidisciplinary treatment (at least 1 educational or other psychological therapy, and at least 1 exercise therapy). It was concluded that there is a strong evidence that multidisciplinary treatment reduces pain, fatigue and depression [13].

Study limitations

A limitation of our study is that we were not able to randomize the participants into the intervention and usual care group. Despite this, there was no difference between groups in all the variables studied and we applied a correction for multiple statistical tests in order to avoid statistically significant effects by chance [30].

CONCLUSIONS

In summary, a low-moderate intensity 3-month multidisciplinary intervention (exercise plus ACT-based psychological therapy) improved quality of life and reduced FM impact in women. Future research might determine whether longer interventions are necessary to induce significant improvements in self-esteem and to increase the use of active coping.

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Table 1. Sociodemographic characteristics of women with fibromyalgia by group.

Variable	Usual care group (n=32)	Intervention group (n=33)	P
Age, years	51.4 (7.4)	50.0 (7.3)	0.423
Weight (kg)	67.2 (12.5)	71.1 (12.4)	0.211
Height (cm)	157.0 (6.2)	158.4 (5.1)	0.320
BMI (kg/m^2)	27.3 (5.9)	28.4 (4.7)	0.443
Total number points	16.3 (2.4)	17.1 (1.5)	0.077
Years since clinical diagnosis, n (%)			0.903
≤ 5 years	16 (50.0)	17 (51.5)	
> 5 years	16 (50.0)	16 (48.5)	
Marital status, n (%)			0.318
Married	24 (75.0)	25 (75.8)	
Unmarried	5 (15.6)	2 (6.1)	
Separated /Divorced/ Widowed	3 (9.4)	6 (18.2)	
Educational status, n (%)			0.543
Unfinished studies	2 (6.2)	1 (3.0)	
Primary school	11 (34.4)	17 (51.5)	
Secondary school	8 (25.0)	7 (21.2)	
University degree	11 (34.4)	8 (24.3)	
Occupational status, n (%)*			0.669
Housewife	14 (46.7)	18 (54.5)	
Student	0 (0)	1 (3.0)	
Working	11 (36.7)	11 (33.4)	
Unemployed	2 (6.6)	2 (6.1)	
Retired	3 (10.0)	1 (3.0)	
Income, n (%)			0.601
< 1200,00 €	15 (46.9)	14 (42.4)	
1201,00 – 1800,00 €	7 (21.9)	5 (15.2)	
> 1800,00 €	10 (31.2)	14 (42.4)	

Values are the mean (standard deviation) unless otherwise indicated.
*Two missing data by usual care group.

Table 2. Effects of 12-week intervention on FM impact in women with fibromyalgia.

	Group	Pre	Post	*P* for Group effect	*P* for Time effect	*P* for Interaction Effect
FIQ						
Total score	Control	70.5 (2.3)	74.7 (2.6)	0.122	0.435	<0.001
	Intervention***	72.5 (2.2)	63.3 (2.5)			
Physical function	Control	4.4 (0.3)	4.9 (0.4)	0.451	0.800	0.014
	Intervention	4.7 (0.3)	4.0 (0.3)			
Feel good	Control	8.5 (0.4)	8.8 (0.4)	0.133	0.035	0.072
	Intervention	8.3 (0.4)	7.4 (0.4)			
Pain	Control	7.3 (0.3)	8.0 (0.3)	0.179	0.514	0.015
	Intervention	7.4 (0.3)	7.0 (0.3)			
Fatigue	Control	8.3 (0.3)	8.7 (0.3)	0.032	0.892	0.001
	Intervention**	8.5 (0.3)	7.2 (0.3)			
Sleep	Control	8.1 (0.3)	8.2 (0.3)	0.989	0.763	0.010
	Intervention	8.7 (0.3)	7.6 (0.3)			
Stiffness	Control	7.7 (0.4)	8.0 (0.3)	0.463	0.317	0.001
	Intervention***	8.0 (0.3)	7.0 (0.3)			
Anxiety	Control	7.4 (0.4)	8.0 (0.4)	0.116	0.360	0.001
	Intervention*	7.4 (0.4)	6.3 (0.4)			
Depression	Control**	6.1 (0.5)	7.0 (0.5)	0.233	0.251	<0.001
	Intervention**	5.7 (0.6)	4.9 (0.6)			

FIQ = Fibromyalgia Impact Questionnaire. Data are means (standard error of the mean). P values before adjustment for multiple comparisons.

*p<0.05 **p<0.01 *** p<0.001, for post hoc analysis Pre vs. Post

Table 3. Effects of 12-week intervention on quality of life in women with fibromyalgia.

	Group	Pre	Post	*P* for Group effect	*P* for Time effect	*P* for Interaction Effect
SF-36						
Physical function	Control	38.4 (3.2)	37.5 (2.7)	0.756	0.153	0.068
	Intervention	36.0 (3.2)	42.3 (2.7)			
Physical role	Control	4.3 (2.0)	2.0 (3.9)	0.088	0.606	0.001
	Intervention**	1.9 (2.0)	17.0 (3.8)			
Bodily pain	Control	21.1 (2.2)	21.3 (3.0)	0.467	0.864	0.003
	Intervention***	17.5 (2.2)	29.6 (3.0)			
General health	Control	26.7 (2.7)	29.4 (3.0)	0.063	0.121	0.263
	Intervention	31.4 (2.7)	38.2 (3.0)			
Vitality	Control	17.7 (2.8)	18.0 (3.3)	0.133	0.740	0.003
	Intervention***	17.3 (2.7)	29.9 (3.2)			
Social functioning	Control**	42.9 (4.0)	35.0 (4.4)	0.487	0.925	<0.001
	Intervention***	33.5 (4.0)	52.1 (4.3)			
Emotional role	Control	33.3 (7.3)	37.5 (8.1)	0.792	0.726	0.108
	Intervention	26.3 (7.2)	49.5 (8.0)			
Mental health	Control	45.7 (3.6)	44.8 (4.1)	0.502	0.346	0.008
	Intervention	44.4 (3.5)	53.1 (4.1)			

SF-36 = Short Form Health Survey questionnaire. Data are means (standard error of the mean). P values before adjustment for multiple comparisons.

*p<0.05 **p<0.01 *** p<0.001, for post hoc analysis Pre vs. Post

Table 4. Effects of 12-week intervention on psychological outcomes in women with fibromyalgia.

	Group	Pre	Post	*P* for Group effect	*P* for Time effect	*P* for Interaction Effect
VPMI						
Passive coping	Control	24.9 (0.8)	24.3 (0.8)	0.079	0.259	0.005
	Intervention	24.8 (0.8)	21.3 (0.8)			
Active Coping	Control	15.9 (0.7)	15.9 (0.6)	0.556	0.827	0.044
	Intervention	15.2 (0.7)	17.4 (0.6)			
HADS						
Anxiety	Control	11.3 (0.7)	11.1 (0.7)	0.766	0.018	0.134
	Intervention	11.6 (0.7)	10.2 (0.7)			
Depression	Control	9.4 (0.8)	9.1 (0.8)	0.403	0.554	0.139
	Intervention	9.1 (0.8)	7.5 (0.8)			
RSES	Control	27.7 (1.1)	25.0 (1.2)	0.164	0.282	0.183
	Intervention	29.0 (1.0)	27.9 (1.2)			

VPMI = Vanderbilt Pain Management Inventory; HADS = Hospital Anxiety and Depression Scale; RSES = Rosenberg Self-Esteem Scale.

Data are means (standard error of the mean). P values before adjustment for multiple comparisons.

$^{*}p<0.05^{**}p<0.01^{***}$ $p<0.001$, for post hoc analysis Pre vs. Post

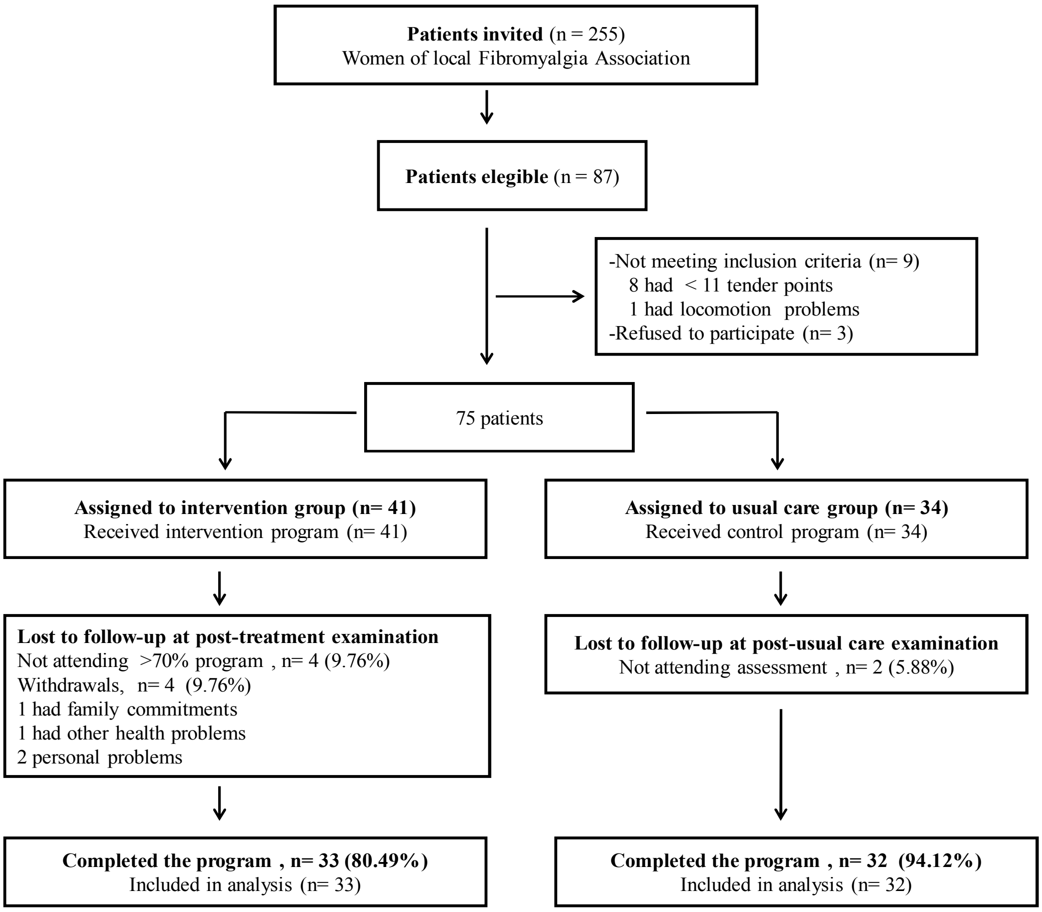

Figure 1. Flow of patients throughout the trial.

EFFICACY OF BIODANZA IN THE TREATMENT OF WOMEN WITH FIBROMYALGIA

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J Altern Complement Med

In press

Efficacy of Biodanza in the treatment of women with fibromyalgia

Short title: Biodanza intervention in fibromyalgia

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ABSTRACT

Objective: To determine the effects of a 3-month Biodanza intervention in women with fibromyalgia (FM).

Design: Controlled trial.

Setting/location: University research laboratory and social center.

Subject: The study comprised 59 women with FM recruited from a local association of FM patients. Participants were allocated to Biodanza intervention group (n=27) or usual care group (n=32).

Intervention: Biodanza intervention was carried out once a week for 3 months.

Outcome measure: Pain threshold, body composition (body mass index and estimated body fat percentage), physical fitness (30-s chair stand, handgrip strength, chair sit and reach, back scratch, blind flamingo, 8 ft up and go and 6-min walk test) and psychological outcomes (Fibromyalgia Impact Questionnaire (FIQ), Short-Form Health Survey 36, Vanderbilt Pain Management Inventory, Hospital Anxiety and Depression Scale, General Self Efficacy Scale and Rosenberg Self-Esteem Scale).

Results: We observed a significant interaction effect (group*time) for pain threshold of several tender points (Left (L) and right (R) side of the anterior cervical and supraespinatus, trapezius L and lateral epicondyle R, algometer score, tender points count), body fat percentage and FIQ total score. In the intervention group, post hoc analysis revealed a significant improvement in pain threshold of the anterior cervical R and L and supraespinatus R and L tender points (all $P<0.05$), algometer score ($P=0.008$), tender point count ($P=0.002$), body fat percentage ($P=0.001$) and FIQ total score ($P=0.003$).

Conclusions: A 3-month (one session per week) Biodanza intervention shows improvements on pain, body composition and FM impact in female patients.

Introduction

Fibromyalgia (FM) is a chronic diffuse pain condition that probably results from abnormal central pain processing [1-3]. The symptoms most frequently associated are pain, fatigue, stiffness, sleep disturbance, anxiety, depression and cognitive difficulties [2, 4]. The level of psychological distress is higher in FM patients compared to patients with other pain syndromes [5]. Likewise, women with FM reported poorer emotional and physical health and lower positive affect than other chronic pain patients [6]. Overall, FM patients report a high impact on their quality of life [5].

Diagnosis and treatment of FM is a complicated and controversial process, but successful management of the disorder is possible [7]. The two most common non-pharmacological FM treatments are physical exercise and educational-psychological programs, which are increasingly recommended for the treatment of FM patients [8, 9]. During the last decade, physical interventions such as water-based exercise, aerobic, strength or multidisciplinary approach have been extensively used for the treatment of FM. Less is known however about the efficacy of complementary and alternative therapies. FM patients are prone to use complementary and alternative therapies despite there are currently no conclusive evidence about the effects of these therapies in FM [8, 10, 11].

"Rolando Toro's Biodanza" is a therapeutical strategy of human development and growth that uses music, movement and emotions to induce integrative living experiences or "vivencias" to group participants [12]. "Vivencia" is a concept borrowed from the german "Erlebnis" meaning a vivid, intensely felt moment in the "here-and-now". Connections and interactions with self, partners and the group are also encouraged to improve participants' health, wellbeing, vitality and joy [13].

Since Biodanza is an integrative dance therapy that combines motor, sensory and affective exercises performed at low intensity/speed, it can be hypothesized that this complementary approach may have positive effects in persons with FM. The purpose of the present controlled trial was to determine the effects of a 3-month Biodanza intervention, carried out once a week, on pain, body composition, physical fitness and psychological outcomes in women with FM.

Materials and Methods

Study participants

We contacted a total of 255 Spanish female members from a Local Association of Fibromyalgia Patients (Granada, Spain). Seventy-nine potentially eligible patients responded, and gave their written informed consent after receiving detailed information about the aims and study procedures. The inclusion criteria were: (i) meeting the American College of Rheumatology criteria: widespread pain for more than 3 months, and pain with 4 kg/cm of pressure reported for 11 or more of 18 tender points [2], (ii) not to have other severe somatic or psychiatric disorders, or other diseases that prevent physical loading. A total of 7 patients were not included in the study because they did not have 11 of the 18 tender points. After the baseline measurements, 1 patient refused to participate due to incompatibility with job schedule. Therefore, a final sample of 71 women with FM participated in the study. The study flow of patients is presented in **Figure 1**. Patients were not engaged in regular physical activity >20 minutes on >3 days/week.

Study design

The present study was a controlled trial with participants assigned to either the intervention (n=37) or to the usual care (control) group (n=34). For practical and ethical reasons, it was not possible to randomize the patients. We had an ethical obligation with the association of FM patients (Granada, Spain) to provide treatment to all patients willing to participate in the study, but due to limitation of resources, we created a waiting list. Patients from the waiting list agreed to be part of the usual care group (control group) and were offered the intervention program at the end of the follow-up period. Data collected only during the control period were included in the current analysis.

The research protocol was reviewed and approved by the Ethics Committee of the *Hospital Virgen de las Nieves* (Granada, Spain). The study was developed between January 2008 and June 2009, following the ethical guidelines of the Declaration of Helsinki, last modified in 2000.

Intervention

The program consisted of 12 sessions (one per week). Each session lasted 120 minutes and was divided into two parts: 1) a verbal phase of 35-45 minutes. In the first sessions, theoretical information about the program was provided, and from the 3rd session on, participants (seated in circle) were encouraged to express their feelings and to share with the group their experiences from the previous sessions; 2) the "vivencia" (living experience) itself (75-80 minutes), which involves moving/dancing according both to the suggestion given by the facilitator and the music played. The movements should express the emotions elicited by the songs (~12) as well as be a response to other peers' presence, proximity and feedback. Dances were performed in three different ways: (i) individually, (ii) in pairs, (iii) and with the whole group. The exercises proposed in each living experience were chosen according to the objective of the session and belong to 5 main groups: Vitality, sexuality, creativity, affectivity and transcendence. Intervention intensity was controlled by the rate of perceived exertion (RPE) based on Borg's conventional (6-20 point) scale. The medium values of RPE were 11 ± 1. These RPE values correspond to a subjective perceived exertion of 'fairly light exertion', that is, low intensity.

The Biodanza intervention took place once a week due to the fact that participants may feel these living experiences ("vivencias") so intensely that they need at least one week to assimilate/integrate these experiences. Participants in the usual care group were asked not to change their activity levels and medications during the 12-week intervention period.

Outcomes

Pre and post-intervention assessment were carried out on two separate days with at least 48 hours between each session. This was done in order to prevent patients' fatigue and flare-ups (acute exacerbation of symptoms). The assessment of the tender-points, blind flamingo test, chair stand test and psychological outcomes were completed on the first visit. Body composition and the chair sit and reach, back scratch, 8 feet up & go, handgrip strength and 6-min walk tests on the second day.

Tender points

We assessed 18 tender points according to the American College of Rheumatology criteria for classification of FM using a standard pressure algometer (EFFEGI, FPK 20, Italy) [2]. The mean of two successive measurements at each tender point was used for the analysis. Tender point scored as positive when the patient noted pain at pressure of 4 kg/cm^2 or less. The total count of such positive tender points was recorded for each participant. The algometer score was calculated as the sum of the minimum pain-pressure values obtained for each tender point.

Body composition

We performed a bioelectrical impedance analysis with an eight-polar tactile-electrode impedanciometer (InBody 720, Biospace). Weight (kg) was measured, and body fat percentage and skeletal muscle mass (kg) were estimated. Validity of this instrument was reported elsewhere [14, 15]. Height (cm) was measured using a stadiometer (Seca 22, Hamburg, Germany). Body mass index (BMI) was calculated as weight (in kilograms) divided by height (in meters squared).

Physical fitness

Fitness tests were part of the Functional Senior Fitness Test Battery [16]. Additionally, we also measured the handgrip strength and the blind flamingo test, which have been used in FM patients [17].

Lower body muscular strength. The “30-s chair stand test” involves counting the number of times within 30 s that an individual can rise to a full stand from a seated position with back straight and feet flat on the floor, without pushing off with the arms. The patients carried out 1 trial after familiarization [16].

Upper body muscular strength. “Handgrip strength” was measured using a digital dynamometer (TKK 5101 Grip-D;Takey, Tokyo, Japan) as described elsewhere [18]. Patient performs (alternately with both hands) the test twice allowing a 1-minute rest period between measures. The best value of 2 trials for each hand was chosen and the average of both hands was used in the analysis.

Lower body flexibility. In the “chair sit and reach test”, the patient seated with one leg extended, slowly bends forward sliding the hands down the extended leg in an attempt to touch (or pass) the toes. The number of centimeters short of reaching the toe (minus score) or reaching beyond it (plus score) are recorded [16]. Two trials with each leg were measured and the best value of each leg was registered, being the average of both legs used in the analysis.

Upper body flexibility. The “back scratch test”, a measure of overall shoulder range of motion, involves measuring the distance between (or overlap of) the middle fingers behind the back with a ruler [16]. This test was measured alternately with both hands twice and the best value was registered. The average of both hands was used in the analysis.

Static balance. It was assessed with the “blind flamingo test” with eyes closed [19]. The number of trials needed to complete 30 s of the static position is recorded, and the chronometer is stopped whenever the patient does not comply with the protocol conditions. One trial was accomplished for each leg and the average of both values was selected for the analysis.

Motor agility/dynamic balance. The “8 ft up and go test” involves standing up from a chair, walking 8 ft to and around a cone, and returning to the chair in the shortest possible time [16]. The best time of two trials was recorded and used in the analysis.

Aerobic endurance. We assessed the “6-min walk test”. This test involves determining the maximum distance (meters) that can be walked in 6 min along a 45.7 meters rectangular course [16, 20-22].

Psychological outcomes

Fibromyalgia Impact Questionnaire (FIQ). The original version of the FIQ was designed by Burckhardt *et al.* [23] to evaluate the severity of FM on daily activities. This is a self-administered questionnaire, comprising 10 subscales of disabilities and symptoms, and has been validated for Spanish FM population [24]. The total score, being the mean of the 10 subscales, and the subscales for physical function, feel good, pain, fatigue, morning tiredness, stiffness, anxiety, and depression were applied in the study. The questionnaire is scored from 0 to 100, and a higher score indicates a greater impact of the syndrome [24].

The Short-Form Health Survey 36 (SF-36). It is a generic instrument assessing health related quality of life. It contains 36 items grouped into 8 subscales: physical functioning, physical role, bodily pain, general health, vitality, social functioning, emotional role, and mental health. The range of scores is between 0 and 100 in every subscale, where higher scores indicate better health. In this study we used the Spanish version of SF-36 [25].

Hospital Anxiety and Depression Scale (HADS). It contains 14 statements, ranging from 0 to 3, in which a higher score indicates a higher degree of distress. The scores build 2 subscales: anxiety (0–21) and depression (0–21) [26]. Zigmond and Snaith [26] suggested subscale cut-offs of scores higher than or equal to 8 to indicate the likely presence of clinically significant levels of depression or anxiety at mild intensity and cut-offs of scores higher than or equal to 11 to indicate moderate to severe intensity. The Spanish version of the scale was used in this study [27].

Vanderbilt Pain Management Inventory (VPMI). The Vanderbilt Pain Management Inventory [28] adapted to the Spanish version [29] was used to assess coping strategies. The scale has 18 items divided into two subscales designed to assess how often chronic pain sufferers use active and passive coping. Active coping, when patients attempt to function in spite of their pain; and passive coping, when patients relinquish control of their pain to others, or allow other areas of their life to be adversely affected by pain.

Rosenberg Self-Esteem Scale (RSES). It is a self-report measure designed to assess the concept of global self-esteem [30]. The RSES comprises just 10 items scored on a 4-point scale that are summed to produce a single index of self-esteem. In this study we used the Spanish version [31].

General Self-Efficacy Scale. It was evaluated with a Spanish version translated by Bäßler and Schwarzer [32, 33]. This instrument contains 10 items scored on a 4-point Likert scale from 1 (not at all true) to 4 (exactly true). The scale assesses the individual`s beliefs in her/his own capabilities to attain aims. In this case, higher scores indicate a higher level of perceived general self-efficacy.

Data Analysis

Analyses of data included: (i) Intention to treat (ITT). A patient was considered a study participant if she attended at least one treatment session. Participants who dropped out before completion of the study were asked to return for post-testing. When post-test data were missing, baseline scores were considered post-test scores; (ii) The analysis was repeated using only those participants with valid data at both baseline and post-test, and with an attendance rate of ≥70% of the sessions, namely per-protocol analysis. Independent t and chi-square tests were used to compare demographic variables between groups. We used a two-factor (group and time) analysis of covariance with repeated measures to assess the training effects on the outcome variables (pain, body composition, physical fitness and psychological outcomes) after adjusting for age. For each variable we reported the P value corresponding to the group (between-subjects), time (within-subjects) and interaction (group*time) effects. We calculated the P value for within-group differences by group when a significant interaction effect was present. Multiple comparisons (for a priori statistics) were adjusted for mass significance [34]. Analyses were performed using the Statistical Package for Social Sciences (SPSS, v. 16.0 for WINDOWS; SPSS Inc, Chicago).

Results

Nine women from the intervention group discontinued the program due to family commitments, personal and health problems, and another one was not included in the analysis for attending less than 70% of the program (attendance: 58.3%). Adherence to the intervention was 85.6 % (range 70 – 100%). A total of 27 (72.97%) women from the intervention group and 32 (94.12%) from the usual care group completed the 3 month follow up and were included in the final analysis. Compliers and non-compliers were similar in all the studied variables except on the subscales of FIQ feel good (8.0±2.1 vs. 9.6±0.7; respectively, P<0.05) and general self-efficacy (25.8±7.2 vs. 17.1±10.0, respectively, P<0.01).

During the study period, no participant reported an exacerbation of FM symptoms beyond normal flares, and there were no serious adverse events. No women changed from the control group to the intervention group or *viceversa*, and there were no protocol deviations from the study, as planned.

Sociodemographic characteristics of women with FM by group are shown in **Table 1**.

Intention to treat analysis

Seventy-one patients were included in the ITT analysis (intervention group, n=37 and usual care group, n=34). After adjusting for multiple comparisons [34], we observed interaction (group*time) effects in the following outcomes: (i) Left (L) and right (R) side of the anterior cervical, supraespinatus L, second rib L (all, P<0.001), supraespinatus R and trapezius L (all, P=0.001) and occiput L tender points (P=0.003). (ii) Algometer score (P=0.001) and tender point count (P=0.003). (iii) Total score of FIQ (P=0.001).

Per-protocol analysis

After adjusting for multiple comparisons [34], we observed interaction effects in the following measures:

(i) Tender points. Left (L) and right (R) side of the anterior cervical and supraespinatus tender point, left side of the trapezius and right side of the lateral epicondyle tender points. Post hoc analysis revealed that pain threshold in the control group significantly decreased (negative) on anterior cervical R (P<0.001) and L (P=0.002), trapezius L (P=0.002), supraespinatus R (P=0.045) and L (P=0.030). In the intervention group, post hoc analysis revealed that pain threshold significantly increased (positive) on the anterior cervical R (P=0.025) and L (P=0.005) and supraespinatus R (P=0. 045) and L (P<0.001) **(Table 2)**.

(ii) Algometer score and tender point count. Post hoc analysis revealed a significant increase in algometer score (P=0.008) and a decrease in tender point count (P=0.002) in the intervention group, whereas, in the control group there was a significant decrease in algometer score (P=0.05).

(iii) Body fat percentage **(Table 3)**. Post hoc analysis revealed a significant decrease in body fat percentage (P=0.001) in the intervention group. No significant improvement attributed to the intervention was observed in physical fitness **(Table 4)**.

(iv) FIQ. Post hoc analysis revealed that there was an improvement in total score of FIQ in the intervention group (P=0.003) **(Table 5)**. We observed no significant interaction effect and hence no intervention-attributable improvement for SF36, VPMI, HAD, RSES and general self-efficacy.

Discussion

The main finding of the present study is that a 3-month (one session per week) Biodanza intervention reduced pain and FM impact (measured by FIQ) in female patients. We also observed significant benefits in body fat percentage. We did not observe a significant improvement on physical fitness test, yet the patients were able to walk ~30 meters more in the 6-min walk test after treatment. The program was well tolerated and did not have any deleterious effects on patients' health.

FM has significant impact on a patient's quality of life and physical functioning [5, 35]. The goals of the treatment in FM patients are the relief of pain, which is the main symptom, and increasing the level of functional capabilities [36]. We observed that the pain threshold increased in several points in the intervention group, whereas pain threshold decreased in several tender points in the usual care group. In addition, there was an improvement in the algometer score and tender point count after treatment.

We also observed a significant improvement in FIQ, which concurs with the results obtained by other complementary and alternative therapies in female FM patients [37-42]. Da Silva *et al.* [38] observed significant decreases in FIQ scores but not in pain threshold after 8-week Relaxing Yoga and Relaxing Yoga plus Touch treatment in FM patients. Mezies *et al.* [39] investigated the effects of a 6-week guided imagery intervention on symptom management in FM patients. They observed a decrease in FIQ scores and an increase in self efficacy for managing pain in the intervention group compared to the usual care group [39]. Astin *et al.* [40] found improvements in FIQ, pain and depression, but not in the 6-min walk test after 8-week of multimodal mind-body intervention (mindfulness meditation plus Qigong). Septhon *et al.* [43] obtained improvements in depressive symptoms after 8-week of Mindfulness-Based Stress Reduction intervention. Hammon and Freeman [41] and Taggard *et al.* [42] reported improvement in FIQ after treatments based in Tai Chi exercises (2 times/week for 10 weeks and twice weekly classes for 6 weeks, respectively). Taggard *et al.* [42] observed significant improvement in the dimensions of SF-36 physical functioning, bodily pain, general health, vitality and emotional role as well. However, they did not report the total FIQ score or tender point count and they did not establish as inclusion criteria the American College of Rheumatology diagnosis criteria for FM. Therefore, it is not possible to know the level of severity in these patients.

In contrast with these positive results, other studies using similar therapies, did not find significant changes after treatments. Assefi *et al.* [44] did not observe any improvement in FM patients after 8-week of Reiki (a form of energy medicine) intervention on pain and SF-36. Mannerkorpi and Arndorw [45] did not show improvement in the FIQ score, chair test and handgrip strength after 3-months of body awareness therapy combined with Qigong. In fact, a recent review concluded that no positive evidence could be identified for Qigong and body awareness therapy in FM [11]. Although alternative and complementary therapies have been used in the management of FM, they are still in the ongoing process of being evaluated by scientific research and future research is needed for better understanding of the potential efficacy of these type of treatments [11, 46].

We observed no significant intervention-attributable improvement for SF36, VPMI, HAD, RSES and general self-efficacy. Whether increasing the number of sessions per week, or increasing the time of the intervention (i.e. 6 months) may have a significant impact on these psychological outcomes remains to be elucidated.

The fact that we were not able to randomize the participants into the intervention and usual care group is a limitation of our study. Strengths include the assessment of body composition and physical fitness measures, which are limited in others studies. We applied a correction for multiple statistical tests [34] in order to avoid statistically significant effects by chance.

Biodanza is an intervention carried out once a week with low intensity, therefore, a priori it is an appropriate option for those patients who are sedentary and want to initiate a more active lifestyle. In the light of the improvements observed in this study, we believe that Biodanza may be an effective complementary therapy in the management of FM.

Conclusion

A 3-month (one session per week) Biodanza intervention reduces pain and FM impact in female patients. The results also show that Biodanza intervention may be, in the short term, a very helpful resource for the management of FM. Further studies should replicate these results and deepen our understanding of this therapy.

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Disclosure Statement

No authors have competing financial interests.

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Table 1. Sociodemographic characteristics of women with fibromyalgia by group.

	Usual care group (n=32)	**Intervention group** (n=27)	**P**
Age, years	51.4 (7.4)	54.2 (6.2)	0.126
Years since clinical diagnosis, n (%)			0.670
≤ 5 years	16 (50.0)	12 (44.4)	
> 5 years	16 (50.0)	15 (45.6)	
Marital status, n (%)			0.527
Married	24 (75.0)	17 (63.0)	
Unmarried	5 (15.6)	5 (18.5)	
Separated /Divorced/ Widowed	3 (9.4)	5 (18.5)	
Educational status, n (%)*			0.692
Unfinished studies	2 (6.2)	2 (8.0)	
Primary school	11 (34.4)	5 (20.0)	
Secondary school	8 (25.0)	8 (32.0)	
University degree	11 (34.4)	10 (40.0)	
Occupational status, n (%)^			0.588
Housewife	14 (46.7)	15 (65.2)	
Working	11 (36.7)	5 (21.7)	
Unemployed	2 (6.7)	1 (4.3)	
Retired	3 (10.0)	2 (8.7)	
Income, n (%)			0.407
< 1200,00 €	15 (46.9)	10 (37.0)	
1201,00 – 1800,00 €	7 (21.9)	4 (14.8)	
> 1800,00 €	10 (31.2)	13 (48.1)	

*Two missing data in the intervention group. ^Four missing data in the intervention group and two missing data in the usual care group.

Table 2. Effects of a 12-week intervention on tender points in women with fibromyalgia.

	Group	Pre	Post	*P* for Group effect	*P* for Time effect	*P* for Interaction effect
Occiput R	Control Intervention	2.81 (0.12) 2.69 (0.13)	2.40 (0.10) 2.57 (0.11)	0.958	0.931	0.042
Occiput L	Control Intervention	2.84 (0.12) 2.70 (0.13)	2.39 (0.11) 2.72 (0.12)	0.521	0.475	0.010
Anterior cervical R	Control*** Intervention*	2.41 (0.13) 2.00 (0.15)	1.86 (0.11) 2.33 (0.12)	0.837	0.497	<0.001
Anterior cervical L	Control** Intervention**	2.25 (0.13) 2.01 (0.14)	1.89 (0.10) 2.41 (0.11)	0.331	0.291	<0.001
Trapezius R	Control Intervention	3.02 (0.15) 2.79 (0.16)	2.66 (0.16) 2.74 (0.17)	0.713	0.499	0.091
Trapezius L	Control*** Intervention	3.21 (0.14) 2.98 (0.15)	2.76 (0.15) 3.21 (0.17)	0.573	0.161	0.001
Supraspinatus R	Control* Intervention*	3.41 (0.14) 3.24 (0.16)	3.07 (0.16) 3.70 (0.18)	0.263	0.204	0.001
Supraspinatus L	Control* Intervention***	3.51 (0.14) 3.27 (0.15)	3.18 (0.16) 3.99 (0.17)	0.142	0.122	<0.001
Second rib R	Control Intervention	2.24 (0.11) 2.08 (0.12)	2.14 (0.13) 2.35 (0.14)	0.852	0.558	0.042
Second rib L	Control Intervention	2.28 (0.10) 1.83 (0.10)	2.06 (0.13) 2.00 (0.13)	0.089	0.171	0.006
Lateral epicondyle R	Control Intervention	2.28 (0.10) 2.10 (0.11)	2.05 (0.13) 2.53 (0.14)	0.335	0.401	<0.001
Lateral epicondyle L	Control Intervention	2.76 (0.13) 2.54 (0.14)	2.52 (0.14) 2.81 (0.15)	0.811	0.916	0.019
Gluteal R	Control Intervention	2.85 (0.16) 3.22 (0.17)	3.12 (0.18) 3.49 (0.20)	0.102	0.769	0.977

Gluteal L	Control Intervention	2.97 (0.17) 3.34 (0.18)	3.32 (0.17) 3.86 (0.19)	0.042	0.868	0.498
Great trochanter R	Control Intervention	2.86 (0.16) 2.96 (0.17)	2.93 (0.15) 3.24 (0.16)	0.313	0.680	0.359
Great trochanter L	Control Intervention	2.96 (0.14) 2.97 (0.16)	3.06 (0.17) 3.39 (0.18)	0.391	0.788	0.215
Knee R	Control Intervention	2.62 (0.16) 2.43 (0.17)	2.73 (0.16) 2.61 (0.17)	0.465	0.418	0.738
Knee L	Control Intervention	2.62 (0.16) 2.52 (0.18)	2.77 (0.17) 2.78 (0.18)	0.839	0.292	0.643
Algometer score	Control* Intervention**	50.30 (1.77) 48.38 (1.94)	47.29 (1.91) 53.39 (2.08)	0.410	0.500	0.001
Total number of points	Control Intervention**	16.16 (0.38) 16.77 (0.42)	16.38 (0.46) 15.32 (0.50)	0.695	0.025	0.002

Data are means (standard error of the mean). P values before adjustment for multiple comparisons.

*P<0.05, **P<0.01, ***P<0.001 for post hoc analysis Pre vs. Post. R, right; L, left.

Table 3. Effects of a 12-week intervention on body composition in women with fibromyalgia.

	Group	Pre	Post	*P* for Group effect	*P* for Time effect	*P* for Interaction effect
Weight (kg)	Control	68.5 (2.1)	68.8 (2.0)	0.778	0.876	0.209
	Intervention	68.1 (2.2)	67.5 (2.2)			
Waist circumference (cm)	Control	87.8 (1.9)	86.1 (1.9)	0.950	0.929	0.384
	Intervention	87.1 (1.9)	86.5 (1.9)			
BMI (kg/m^2)	Control	28.2 (0.9)	28.3 (0.9)	0.571	0.707	0.291
	Intervention	27.5 (0.9)	27.4 (0.9)			
Body fat percentage	Control	38.6 (1.2)	37.2 (1.6)	0.036	0.372	0.003
	Intervention*	37.2 (1.2)	31.4 (1.6)			
Muscle mass (kg)	Control	22.6 (0.5)	22.7 (1.4)	0.054	0.652	0.028
	Intervention	23.3 (0.5)	27.2 (1.5)			

BMI, body mass index. Data are means (standard error of the mean). P values before adjustment for multiple comparisons.

*$P<0.01$, for post hoc analysis Pre vs. Post

Table 4. Effects of a 12-week intervention on physical fitness in women with fibromyalgia.

	Group	Pre	Post	*P* for Group effect	*P* for Time effect	*P* for Interaction effect
Chair sit and reach (cm)	Control Intervention	-13.2 (2.7) -11.0 (2.8)	-15.7 (2.9) -6.3 (3.0)	0.114	0.460	0.064
Back scratch test (cm)	Control Intervention	-7.3 (2.4) -6.5 (2.4)	-9.3 (2.4) -5.8 (2.5)	0.522	0.578	0.198
Handgrip strength (kg)	Control Intervention	15.7 (1.0) 18.1 (1.0)	17.3 (1.0) 18.4 (1.1)	0.220	0.729	0.251
Chair stand test (n)	Control Intervention	7 (0.5) 8 (0.5)	8 (0.5) 10 (0.5)	0.024	0.897	0.114
8 feet up & go (s)	Control Intervention	8.3 (0.3) 7.6 (0.3)	7.8 (0.3) 6.8 (0.3)	0.048	0.318	0.440
30-s blind flamingo (failures)	Control Intervention	10 (1) 10 (1)	11 (1) 9 (1)	0.764	0.922	0.246
6 minute walk (metres)	Control Intervention	456.6 (12.7) 448.7 (13.5)	457.0 (13.1) 480.9 (13.8)	0.649	0.764	0.041

Data are means (standard error of the mean). P values before adjustment for multiple comparisons.

Table 5. Effects of a 12-week intervention on psychological outcomes assessed in women with fibromyalgia.

	Group	Pre	Post	*P* for Group effect	*P* for Time effect	*P* for Interaction effect
FIQ						
Total score	Control	70.1 (2.1)	74.0 (2.8)	0.004	0.399	0.001
	Intervention*	66.9 (2.9)	56.0 (3.1)			
Physical function	Control	4.3 (0.3)	4.8 (0.4)	0.247	0.703	0.005
	Intervention	4.4 (0.4)	3.6 (0.4)			
Feel good	Control	8.3 (0.4)	8.8 (0.4)	0.002	0.347	0.010
	Intervention	7.6 (0.4)	6.1 (0.5)			
Pain	Control	7.3 (0.3)	8.0 (0.3)	0.009	0.788	0.010
	Intervention	6.9 (0.4)	6.1 (0.3)			
Fatigue	Control	8.2 (0.3)	8.5 (0.3)	0.001	0.539	0.009
	Intervention	7.8 (0.4)	6.5 (0.3)			
Sleep	Control	8.0 (0.3)	8.11 (0.4)	0.149	0.687	0.004
	Intervention	8.4 (0.3)	6.4 (0.4)			
Stiffness	Control	7.6 (0.4)	7.9 (0.4)	0.020	0.603	0.077
	Intervention	6.6 (0.4)	6.0 (0.5)			
Anxiety	Control	7.4 (0.4)	7.9 (0.4)	0.002	0.075	0.016
	Intervention	6.2 (0.5)	5.2 (0.5)			
Depression	Control	6.1 (0.5)	7.0 (0.5)	0.087	0.007	0.020
	Intervention	5.7 (0.6)	4.9 (0.6)			
SF-36						
Physical function	Control	39.1 (3.5)	38.0 (3.0)	0.499	0.907	0.091
	Intervention	38.1 (3.8)	44.8 (3.2)			
Physical role	Control	5.2 (3.3)	3.3 (2.6)	0.224	0.382	0.375
	Intervention	6.8 (3.6)	10.0 (2.8)			
Bodily pain	Control	21.8 (2.8)	22.2 (2.2)	0.017	0.538	0.906
	Intervention	30.1 (3.1)	30.9 (2.4)			
General health	Control	26.5 (3.0)	29.0 (3.1)	0.124	0.960	0.998
	Intervention	33.0 (3.2)	35.6 (3.4)			
Vitality	Control	18.1 (2.8)	19.0 (2.9)	0.121	0.125	0.476
	Intervention	22.6 (3.0)	26.4 (3.2)			

Social functioning	Control	44.4 (4.4)	36.7 (3.7)	0.029	0.888	0.024
	Intervention	49.2 (4.8)	55.6 (4.0)			
Emotional role	Control	33.4 (8.0)	38.0 (8.1)	0.437	0.786	0.675
	Intervention	39.4 (8.8)	48.8 (8.9)			
Mental health	Control	45.4 (3.6)	44.9 (4.2)	0.094	0.323	0.092
	Intervention	50.8 (3.9)	57.9 (4.6)			
VPMI						
Passive coping	Control	24.7 (0.8)	24.2 (0.7)	0.017	0.669	0.063
	Intervention	23.2 (0.9)	20.7 (0.7)			
Active Coping	Control	16.1 (0.7)	16.1 (0.7)	0.868	0.756	0.602
	Intervention	16.5 (0.7)	16.0 (0.7)			
HADS						
Anxiety	Control	11.2 (0.8)	11.0 (0.8)	0.131	0.997	0.891
	Intervention	9.4 (0.9)	9.1 (0.9)			
Depression	Control	9.3 (0.7)	9.0 (0.8)	0.105	0.554	0.902
	Intervention	7.5 (0.8)	7.3 (0.9)			
SELF-EFFICACY	Control	25.0 (1.3)	25.5 (1.3)	0.248	0.363	0.624
	Intervention	26.9 (1.4)	27.9 (1.4)			
RSES	Control	28.2 (1.1)	25.4 (1.2)	0.335	0.895	0.037
	Intervention	28.4 (1.2)	28.3 (1.3)			

FIQ = Fibromyalgia Impact Questionnaire; SF-36 = Short Form 36; VPMI = Vanderbilt Pain Management Inventory; HADS = Hospital Anxiety and Depression Scale; RSES = Rosenberg Self-Esteem Scale.

Data are means (standard error of the mean). P values before adjustment for multiple comparisons.

*P<0.01, for post hoc analysis Pre vs. Post.

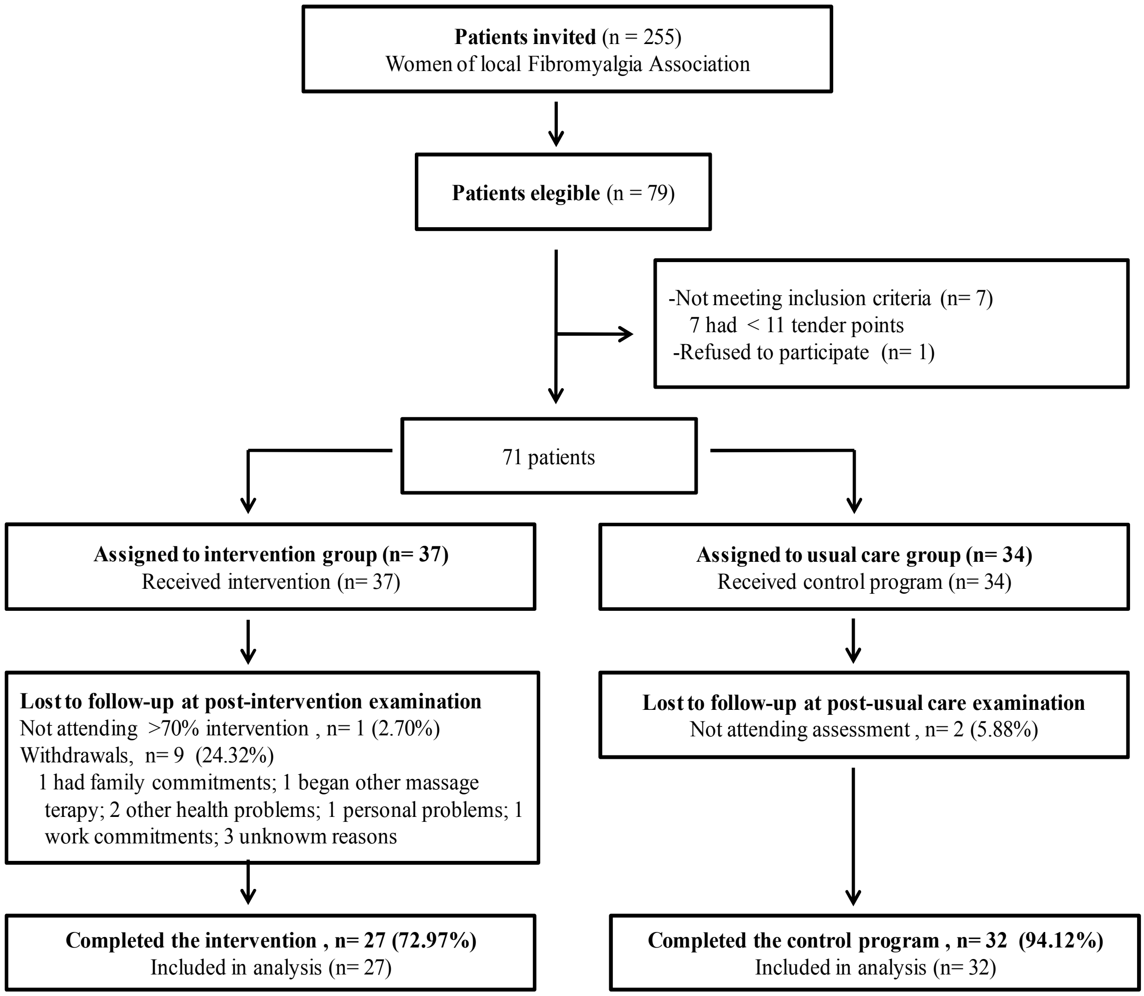

Figure 1. Flow of patients throughout the trial.

PRELIMINARY FINDINGS OF A 4-MONTH TAI CHI INTERVENTION IN MEN WITH FIBROMYALGIA

Carbonell-Baeza A, Romero A, Aparicio VA, Ortega FB, Tercedor P, Delgado-Fernández M, Ruiz JR

Submitted

V

Preliminary findings of a 4-month Tai Chi intervention in men with fibromyalgia

Running head: Tai Chi intervention in fibromyalgia

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ABSTRACT

Objective: To determine the effects of a 4-month Tai Chi training program in men with fibromyalgia (FM). We also analyzed the effects of a 3-month detraining period.

Methods: Six men with FM (age: 52.3 ± 9.3y) followed a 4-month Tai Chi intervention (3 sessions per week). The outcome variables were pain threshold and physical fitness (30-s chair stand, handgrip strength, chair sit and reach, back scratch, blind flamingo, 8 ft up and go and 6-min walk test). The psychological outcomes included the Fibromyalgia Impact Questionnaire, Short-Form Health Survey 36, Vanderbilt Pain Management Inventory, Hospital Anxiety and Depression Scale, General Self Efficacy Scale and Rosenberg Self-Esteem Scale.

Results: Pain threshold, algometer score and tender point count did not significantly change after the intervention period or after the detraining phase. Likewise, physical fitness and psychological outcomes did not significantly change during the intervention period or the detraining phase.

Conclusions: A 4-month Tai Chi training did not have any effect on pain, physical fitness and psychological outcomes in men with FM.

Key words: Fibromyalgia; tender point; physical fitness; pain.

Introduction

There is growing evidence that exercise plays a key role in the management of fibromyalgia (FM) (1-4). FM is characterized by the concurrent existence of chronic, widespread musculoskeletal pain and multiple sites of tenderness (5). Core symptoms include debilitating fatigue, sleep disturbance, and joint stiffness (5-7), and patients may also experience conditions such as anxiety and depression (6, 7). Due to these circumstances, exercise intervention programs in these patients are of low impact and intensity nature in order to avoid any side effect.

Tai Chi, an ancient Chinese form of exercise derived from the martial arts, is a low-speed and low-impact exercise (8). Tai-Chi is a 'balanced' exercise that integrates key components of exercise training, cardiorespiratory function, strength, balance and flexibility (8, 9). Furthermore, Tai Chi integrates the movements with deep breathing and incorporates elements of relaxation and mental concentration (10). Therefore, Tai Chi exercises combined aspect of mind-body therapy and physical exercise (10).

Overall, Tai Chi seems to have physiologic and psychosocial benefits and appears to be safe and effective in promoting balance control, flexibility, and cardiovascular fitness for patients with chronic conditions (11, 12). Therefore, it is potentially beneficial to FM patients but further research is needed to support the evidence-based practice (10). A recent meta-analysis concluded that Tai Chi has a positive, yet small, effect for reducing pain and improving disability in people with arthritis (13).

Descriptive data as well as exercise intervention studies in men with FM are lacking (2, 4). To our knowledge, only one study examined the effect of exercise training (walking and upper and lower body light dumbbell resistance training) in two male patients (14). Whether Tai Chi intervention influences pain, functional capacity and quality of life in men with FM is unknown.

The purpose of the present study was to determine the effects of 4-month Tai Chi training program 3 times per week on pain, physical fitness and psychological outcomes in men with FM. We also analyzed the effect of a 3-month detraining period on these parameters. Since exercise has positive effects in patients with FM and Tai Chi has physiologic and psychosocial benefits in patients with chronic conditions, we hypothesized that a Tai Chi training program has overall positive effects on health in men with FM.

Materials and Methods

Study participants

We contacted a total of 27 Spanish male members from a local aassociation of Fibromyalgia Patients. Nine potentially eligible patients responded, and gave their written informed consent after receiving detailed information about the aims and study procedures. The inclusion criteria were: (i) meeting the American College of Rheumatology criteria: widespread pain for more than 3 months and pain with 4 kg/cm of pressure for 11 or more of 18 tender points (5); (ii) not to have other severe somatic or psychiatric disorders, such as stroke or schizophrenia, or other diseases that prevent physical loading: and (iii) no to be attending another type of physical therapy at the same time. Three patients were not included in the study because did not have 11 of the 18 tender points. Therefore, a total of 6 men with FM (mean±SD; age: 52.3±9.3 years, weight: 78.2 ± 5.4 kg; height: 171.1 ± 7.9 cm) participated in the study.

Study design

Originally, we aimed to assess a control group of age- and gender-matched patients. However, it was not possible to recruit such a group as none of the others male patients contacted were willing to participate and did not give their permission to recruit information. Thus, though a control group would have strengthened the experimental design, for logistic reasons, this was not possible. Despite the lack of a 'formal' control group, our study used a controlled design as each patient served as his own control to compare pre-, post- at 3 and 4 months and detraining results after 3 months.

The research protocol was reviewed and approved by the Ethics Committee of the Hospital *Virgen de las Nieves*. The study was developed between september 2008 and september 2009, following the ethical guidelines of the Declaration of Helsinki, last modified in 2000.

Intervention

The Tai Chi program was based on the classical Yang Style. The characteristics of Yang Tai Chi are: extended and natural postures, slow and even motions, light and steady movements, and curved, flowing lines of performance (15). Patients participated in three 60-minute Tai Chi sessions conducted weekly for 16 weeks. Each session included: 15 minutes of warm up while stretching, mobility and breathing techniques; 30 minutes of Tai Chi exercises principles and techniques and finally, 15 minutes of various relaxation methods. The program consisted of 8 forms from classic Yang Style Tai Chi, with minor modifications that were suitable for patients with FM. For example, the first month some exercises were realized with the participants sitting to avoid too much fatigue.

A master Tai Chi instructor was present during the sessions to supervise the participants and also assist with movements/exercises. The first two weeks of the 16-week intervention focused on learning fundamental movement patterns. The participants then began learning the sequential movements of 8-Form, Yang Style Tai Chi for the following weeks.

Outcome measures

Tender points

We assessed 18 tender points according to the American College of Rheumatology criteria for classification of FM using a standard pressure algometer (EFFEGI, FPK 20, Italy) (5). The mean of two successive measurements at each tender point was used for the analysis. Tender point scored as positive when the patient noted pain at pressure of 4 kg/cm^2 or less. The total count of such positive tender points was recorded for each participant. The algometer score was calculated as the sum of the minimum pain-pressure values obtained for each tender point.

Physical fitness

Weight (kg) and height (cm) were measured using standard procedures and body mass index (BMI) was calculated as weight (in kilograms) divided by height (in meters) squared.

Fitness tests were part of the Functional Senior Fitness Test Battery (16). Additionally, we also measured the handgrip strength and the blind flamingo test, which have been used in patients with FM (17).

Lower body muscular strength. The "30-s chair stand test" involves counting the number of times within 30 s that an individual can rise to a full stand from a seated position with back straight and feet flat on the floor, without pushing off with the arms. The patients carried out 1 trial after familiarization (16).

Upper body muscular strength. "Handgrip strength" was measured using a digital dynamometer (TKK 5101 Grip-D;Takey, Tokyo, Japan) as described elsewhere (18). Patient performes (alternately with both hands) the test twice allowing a 1-minute rest period between measures. The best value of 2 trials for each hand was chosen and the average of both hands was registered.

Lower body flexibility. In the "chair sit and reach test", the patient seated with one leg extended, slowly bends forward sliding the hands down the extended leg in an attempt to touch (or past) the toes. The number of centimeters short of reaching the toe (minus score) or reaching beyond it (plus score) are recorded (16). Two trials with each leg were measured and the best value of each leg was registered, being the average of both legs used in the analysis.

Upper body flexibility. The "back scratch test", a measure of overall shoulder range of motion, involves measuring the distance between (or overlap of) the middle fingers behind the back (16). This test was measured alternately with both hands twice and the best value was registered. The average of both hands was used in the analysis.

Static balance. It was assessed with the blind flamingo test (19). The number of trials needed to complete 30 s of the static position is recorded, and the chronometer is stopped whenever the patient does not comply with the protocol conditions. One trial was accomplished for each leg and the average of both values was selected for the analysis.

Motor agility/dynamic balance: the "8 ft up and go test" involves standing up from a chair, walking 8 ft to and around a cone, and returning to the chair in the shortest possible time (16). The best time of two trials was recorded and used in the analysis.

Aerobic endurance. We assessed the "6-min walk test". This test involves determining the maximum distance (meters) that can be walked in 6 min along a

45.7 meters rectangular course (16, 20-22). The 6-minute walk test is a reliable measure in people with FM (20-22).

Psychological outcomes

Fibromyalgia Impact Questionnaire (FIQ). It was designed to evaluate the severity of FM on daily activities (23). This is a self-administered questionnaire, comprising 10 subscales of disabilities and symptoms, and has been validated for Spanish FM population (24). The total score, being the mean of the 10 subscales, and the subscales for physical function, feel good, pain, fatigue, morning tiredness, stiffness, anxiety, and depression were applied in the study. The questionnaire is scored from 0 to 100, in which a higher score indicates a greater impact of the syndrome (24).

The Short-Form Health Survey 36 (SF36). This is a generic instrument assessing health related quality of life. It contains 36 items grouped into 8 subscales: physical functioning, physical role, bodily pain, general health, vitality, social functioning, emotional role, and mental health. The range of scores is between 0 and 100 in every subscale, where higher scores indicate better health. In this study we used the Spanish version of SF-36 (25).

Hospital Anxiety and Depression Scale (HADS). This contains 14 statements, ranging from 0 to 3, in which a higher score indicates a higher degree of distress. The scores build 2 subscales: anxiety (0–21) and depression (0–21) (26). The Spanish version of the scale was used in this study (27).

Vanderbilt Pain Management Inventory (VPMI). The Vanderbilt Pain Management Inventory (28) adapted into Spanish version (29) was used to assess coping strategies. The scale has 18 items divided into two subscales designed to assess how often chronic pain sufferers use active and passive coping.

Rosenberg Self-Esteem Scale (RSES). It is a self-report measure designed to assess the concept of global self-esteem (30). In this study we used the Spanish version (31).

General Self-Efficacy Scale. It was evaluated with a Spanish version of this scale translated by Bäßler and Schwarzer (32, 33). The scale assesses the individual beliefs in her/his own capabilities to attain aims.

Participants performed the tests just before treatment (pretest, week 0), after 12 weeks of treatment (post- 12 weeks), after 16 weeks of treatment (post-16 weeks) and after 12 weeks of a detraining period during which the patients did not engage in any structured exercise program.

The tests were performed out on two separate days with at least 48 hours between each session. This was done in order to prevent fatigue and flare-ups (acute exacerbation of symptoms) in the patients. The assessment of the tender-points, blind flamingo test, chair stand test and psychological outcomes were completed on the first visit. Body composition, chair sit and reach, back scratch, 8 feet up & go, hand grip strength and 6-minute walk on the second day.

Data analysis

As previously mentioned, it was not possible to use a true experimental design, i.e., randomized controlled trial with 2 groups of patients: a treatment (training) group and a usual care (non-training) group. Thus, we applied a quasi-experimental reversal design, i.e., lacking a control group. The use of this type of design in scientific research has grown considerably in recent years, especially in those settings/group of diseases where it is very difficult to have a 'control' group.

The purpose of the research design used was to determine a baseline measurement, evaluate a treatment (Tai Chi exercise training), and evaluate a return to a non-treatment condition (detraining) in the same group of participants. One practical advantage of this type of design is its applicability to real world settings (in which random assignment is sometimes impossible) while still controlling internal validity as best as possible. This type of design particularly controls participant bias well, as the same individual is used at each testing time point. We used a one-factor (time) analysis of covariance (ANCOVA) with repeated measures to assess the training effects on the outcome variables (tender points, physical fitness and psychological measures) after adjusting for age. Multiple comparisons were adjusted for mass significance (34). Analyses were performed using the Statistical Package for Social Sciences (SPSS, v. 16.0 for WINDOWS; SPSS Inc, Chicago).

Results

Adherence to the intervention was 79.5 % (range 61.5 – 97.4%). There were no major adverse effects and no major health problems in the male patients during the training and detraining periods.

Mean values of pain thresholds, algometer score and tender point count at pre, post- 12 weeks and 16 weeks, and detraining are shown in **Table 1**. Pain thresholds, algometer scored and tender point count did not significantly change after the intervention period or the detraining phase **(Table 2)**. Likewise, after adjustment for multiple comparisons, physical fitness **(Table 3)** and psychological status **(Table 4)** did not significantly change during the intervention period or the detraining phase.

Baseline characteristics of participants and those who did not meet the inclusion criteria were similar except for tender points (16.0 $\pm$ 2.8 vs. 4.0 $\pm$ 3.6 ; P=0.018) and algometer score (47.65 vs. 82.23; p=0.020).

Discussion

The main finding of present study was that a 4-month Tai Chi training program does not significantly affect pain, physical fitness and psychological outcomes in male FM patients. Likewise, these outcomes did not change after the detraining phase. The Tai Chi training program was well tolerated and did not have any deleterious effects on patients' health. The lack of statistical changes may indicate that the intervention was potentially successful by maintaining the levels of physical and psychological outcomes studied. Moreover, there was a clinical improvement in some of the outcome variables such as the 6-min walk test (~60 meter), lower flexibility (~9 cm), and the subscale of FIQ anxiety (8.1 vs 5.9, pre vs. post-4 month respectively). Whether the outcomes studied might have changed (impaired) over time in a non-treated group of male FM patients is not known. Further randomized controlled trials will be able to answer this issue.

The findings of the present study should be taken as preliminary due to the small sample size and the lack of a control group. To note is that this is the first study that analyzed the effect of a Tai Chi intervention in a group of male FM patients. The assessment of a large range of physical and psychological measures, which are very limited in other studies, is a strength of this study.

Due to the lack of studies of this nature, and given the uniqueness of our study population, it is difficult to directly compare our results with other studies in male FM patients. To our knowledge, only one study analyzed the physical and psychosocial effects of a moderate exercise program on two men with FM (14). They completed a 14-month training program (3 days per week, 40-45 min per session) based on walking and upper and lower body light dumbbell resistance training. Reported changes at the 8th and 14th month included: handgrip strength, 32 vs 40 vs 42 kg, respectively, in participant 1, and 47 vs 55 vs 61 kg, respectively in participant 2; and chair stand test, 6 vs 11 vs 11 stand in participant 1 and 12 vs 16 vs 16 stand in participants 2 (14). We did not observe significant improvement in any of these tests. Similarly, we did not observe a significant improvement on the 6-min walk test, yet, patients were able to walk for on average ~45 meters more after 3 months and ~60 meters more after 4 months of intervention. After the detraining period, this improvement was not totally stable, and the distance walked was only ~20 meters more compared to baseline.

Two studies analyzed the effect of Tai Chi intervention in female FM patients on psychological outcomes (10, 35). Hammon and Freeman (35) included Tai Chi as part of the sessions combined with stretch, strengthening exercises and education, and compared this program (2 times/week for 10 weeks) with a relaxation program (considered as control group). They reported a significant improvement in total score of FIQ after treatment, self-efficacy for managing pain and other symptoms in comparisons with a relaxation intervention group, but these changes were not sustained after the detraining period. To note is that the severity of FM in our male patients was higher than that observed in the female patients (total score FIQ: 76.1 ± 14.6 vs 56.9 ± 12.5 respectively) enrolled in the study by Hammon and Freeman (35). Taggard *et al.* (10) implemented a program of Tai Chi (Yang style) 1 hour twice weekly classes for 6 weeks in women with FM. They observed significant improvement in the dimensions of SF-36 physical functioning, bodily pain, general health, vitally and role emotional and in the subscales physical function, days feel good, pain, morning tiredness, stiffness and anxiety of the FIQ. This study did not report the total FIQ score or tender point count and they did not establish as inclusion criteria the American College of Rheumatology diagnosis criteria for FM. Therefore, it is not possible to know the level of severity in these patients.

The effect of a Tai Chi intervention program has been studied in other chronic pain conditions (36-38). Wang (37) studied the effect of a 12-week Tai Chi (Yang style) intervention in adults with rheumatoid arthritis (n=10, 2 males) and observed an improvement in the subscale of vitality (SF-36), depression index and disability index compared with control group, but they did not find improvement in physical fitness. Fransen *et al.*(38) compared the effects of a 12-week Tai Chi intervention (twice a week, 24 forms from the Sun Style; n=56, 18 males) or hydrotherapy in adults with hip or knee osteoarthritis. Both programs achieved significant improvements in the SF-12 physical component summary score, but only hydrotherapy achieved significant gains in physical performance. Wang *et al.*(36) reported improvement in physical component summary of SF-36 and chair stand time compared with control group after 12-week Tai Chi intervention (twice a week, 10 modified forms from Yang style) in adults (n=20, 4 males) with knee osteoarthritis. In the 6-min walk test, body mass index and balance they did not obtain significant change (36). Lee *et al.*(39) implemented a 8-week Tai Chi Qigong training program (twice a week, n=29, 2 males) and observed improvements on mental and physical components of SF-36 compared with the control group.

Overall, complementary and alternative therapies are still in the ongoing process of being evaluated by scientific research (40). Qigong, other Chinese mind-body therapy has been also used in the management of FM. Astin *et al.*(41) did not find that a 8-week multimodal mind-body intervention (mindfulness meditation plus Qigong) in FM was superior to education and support as a treatment option in FM. Likewise, Manerkorpi & Arndorw (42) did not observe improvement for FM symptoms or physical function after 3-month therapy of body awareness combined with Qigong. In contrast, Haak & Scott(43) found improvement on pain and psychological outcomes after 7 weeks of Qigong intervention. A recent review concluded that no positive evidence could be identified for Qigong, biofeedback and body awareness therapy in FM (40). Mind body therapies are commonly used in a wide range of medical conditions, but future research is needed for better understanding of the potential efficacy of this type of treatments (44).

In summary, a 4-month Tai Chi intervention program (3 times per week) did not have any effect on pain, physical fitness and psychological outcomes in men with FM. Information on the usefulness of intervention programs in men with FM is specially lacking and future studies are needed.

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Disclosure statement

The authors have declared no conflicts of interest.

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Table 1. Sociodemographic characteristics of male with fibromyalgia.

Variable	Training group (n=6)
Years since clinical diagnosis, n (%)	
≤ 5 years	3 (50.0)
> 5 years	3 (50.0)
Marital status, n (%)	
Married	5 (83.3)
Unmarried	1 (16.7)
Educational status, n (%)*	
Primary school	2 (20.0)
Secondary school	3 (32.0)
Occupational status, n (%)	
Working	1 (16.7)
Retired	5 (83.3)
Income, n (%)	
< 1200,00 €	2 (33.3)
1201,00 – 1800,00 €	1 (16.7)
> 1800,00 €	3 (50.0)

*One missing data.

Table 2. Effects of 16-week Tai Chi intervention on tender points in men (n=6) with fibromyalgia.

	Pre (A)	Post 12 weeks (B)	Post 16 weeks (C)	Detraining 12 weeks (D)
Occiput R	2.62 (0.31)	2.36 (0.16)	1.87 (0.25)	2.17 (0.03)
Occiput L	2.73 (0.41)	2.25 (0.28)	2.16 (0.23)	2.21 (0.11)
Anterior cervical R	2.17 (0.27)	1.95 (0.18)	2.09 (0.19)	1.70 (0.14)
Anterior cervical L	2.12 (0.24)	2.08 (0.15)	2.10 (0.22)	2.67 (0.15)
Trapezius R	2.79 (0.39)	2.67 (0.33)	2.80 (0.28)	2.34 (0.23)
Trapezius L	2.79 (0.40)	2.69 (0.26)	3.10 (0.24)	2.62 (0.35)
Supraspinatus R	3.34 (0.49)	3.11 (0.32)	3.34 (0.41)	3.18 (0.26)
Supraspinatus L	3.30 (0.42)	3.11 (0.28)	3.49 (0.37)	3.19 (0.31)
Second rib R	2.46 (0.29)	2.17 (0.26)	2.27 (0.25)	1.89 (0.14)
Second rib L	2.55 (0.29)	2.20 (0.20)	2.44 (0.29)	2.16 (0.25)
Lateral epicondyle R	2.00 (0.28)	1.82 (0.15)	1.84 (0.22)	2.17 (0.22)
Lateral epicondyle L	2.02 (0.31)	2.21 (0.24)	2.07 (0.15)	2.20 (0.16)
Gluteal R	2.94 (0.31)	3.61 (0.31)	3.67 (0.25)	3.57 (0.24)
Gluteal L	3.15 (0.47)	3.61 (0.40)	3.89 (0.33)	3.60 (0.33)
Great trochanter R *	2.43 (0.36)	3.43 (0.41)	3.32 (0.33)	3.21 (0.43)
Great trochanter L	2.63 (0.50)	3.29 (0.39)	3.55 (0.29)	3.45 (0.36)
Knee R	2.80 (0.33)	2.43 (0.29)	2.52 (0.42)	2.69 (0.22)
Knee L	2.80 (0.29)	2.57 (0.31)	2.40 (0.33)	2.37 (0.18)
Algometer score	47.65 (5.28)	47.57 (4.15)	49.04 (4.33)	49.71 (5.31)
Total number points	16.00 (0.10)	16.17 (1.11)	16.17 (0.95)	16.33 (0.84)

Data are means (standard error of the mean) R, right; L, left.

*$P<0.001$ for A vs B.

Table 3. Effects of 16-week Tai Chi intervention on physical fitness in male (n=6) with fibromyalgia.

	Pre	**Post 12 weeks**	**Post 16 weeks**	**Detraining 12 weeks**
Weight (kg)	78.2 (5.4)	77.4 (5.2)	77.3 (4.8)	78.7 (5.3)
Waist circumference (cm)	90.9 (6.4)	91.0 (7.3)	90.3 (5.6)	92.4 (8.3)
BMI (kg/m^2)	26.8 (2.1)	26.5 (1.9)	26.5 (1.9)	27.0 (1.9)
Chair sit and reach (cm)	-12.3 (4.5)	-4.8 (3.3)	-3.3 (3.3)	-0.5 (5.8)
Back scratch test (cm)	-5.9 (4.3)	-3.9 (6.6)	-3.6 (7.3)	-2.9 (6.6)
Handgrip strength (kg)	28.5 (4.0)	33.7 (7.8)	31.3 (6.7)	33.9 (6.6)
Chair stand test (n)	9 (1)	10 (0.5)	10 (0.5)	10 (1)
8 feet up & go (s)	7.0 (0.2)	5.6 (0.5)	6.3 (0.8)	6.3 (0.6)
30-s blind flamingo (failures)	7 (1)	6 (2)	7 (1)	5 (1)
6 minute walk (m)	485.3 (15.1)	531.0 (13.3)	547.4 (44.8)	506.4 (24.9)

Data are means (standard error of the mean).

Table 4. Effects of 16-week Tai Chi intervention on psychological outcome measured in men (n=6) with fibromyalgia.

	Pre	**Post 12 weeks**	**Post 16 weeks**	**Detraining 12 weeks**
FIQ				
Total score	76.1 (6.4)	78.2 (2.6)	73.7 (2.4)	71.2 (3.2)
Physical function	6.2 (1.0)	6.8 (0.4)	5.8 (0.7)	6.7 (0.2)
Feel good	8.6 (0.7)	8.3 (0.8)	8.1 (0.8)	7.9 (0.8)
VAS Pain	8.6 (0.7)	7.2 (0.4)	8.1 (0.5)	7.7 (0.5)
VAS Fatigue	8.4 (0.6)	8.2 (0.4)	8.2 (0.4)	8.0 (0.8)
VAS Morning tiredness	8.8 (0.8)	7.8 (1.4)	9.0 (0.3)	8.9 (0.4)
VAS Stiffness	8.9 (0.6)	8.8 (0.5)	7.8 (0.3)	8.4 (0.6)
VAS Anxiety	8.1 (0.4)	8.3 (0.6)	5.9 (1.1)	5.5 (0.1)
VAS Depression	7.3 (0.6)	8.1 (0.7)	6.6 (0.9)	5.6 (1.1)
SF-36				
Physical function	32.5 (9.5)	35.8 (7.2)	35.8 (6.6)	39.2 (9.4)
Physical role	4.2 (4.0)	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)
Bodily pain	15.5 (3.2)	15.5 (4.2)	25.0 (5.2)	25.0 (6.0)
General health	26.7 (5.6)	26.6 (6.7)	20.0 (5.7)	28.3 (5.5)
Vitality	20.0 (6.1)	18.3 (5.6)	24.2 (7.7)	28.3 (6.4)
Social functioning	31.2 (8.8)	43.3 (6.8)	32.9 (8.1)	48.3 (7.5)
Emotional role	22.2 (13.1)	33.3 (12.5)	27.8 (14.3)	33.3 (12.5)
Mental health	33.3 (5.8)	50.7 (5.4)	49.3 (9.9)	53.3 (9.5)
VPMI				
Passive coping	27.3 (2.7)	24.2 (1.8)	26.3 (3.3)	22.7 (1.2)
Active Coping	17.0 (1.1)	17.5 (1.7)	16.8 (1.6)	15.8 (1.4)
HADS				
Anxiety	10.2 (1.6)	9.7 (1.9)	10.0 (2.1)	10.5 (2.1)
Depression	10.8 (1.1)	8.3 (1.1)	8.8 (1.8)	8.0 (0.8)
SELF-EFFICACY	24.8 (2.5)	25.3 (2.9)	25.5 (1.3)	28.2 (2.2)
RSES	29.2 (1.2)	29.7 (1.1)	30.8 (1.0)	29.0 (1.4)

Data are means (standard error of the mean).

FIQ = Fibromyalgia Impact Questionnaire; SF-36 = Short Form 36; VPMI = Vanderbilt Pain Management Inventory; HADS = Hospital Anxiety and Depression Scale; RSES = Rosenberg Self-Esteem Scale.

MULTIDISCIPLINARY AND BIODANZA INTERVENTION FOR THE MANAGEMENT OF FIBROMYALGIA

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Submitted

VI

Multidisciplinary and Biodanza intervention for the management of fibromyalgia

Running head: Physical interventions in fibromyalgia

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Multidisciplinary and Biodanza intervention for the management of fibromyalgia

ABSTRACT

Objective: To evaluate and compare the effectiveness of a 16-week multidisciplinary (exercise plus psychological therapy) and Biodanza intervention in women with fibromyalgia (FM).

Desing: Thirty-eight women with FM were distributed to a 16-week multidisciplinary (3-times/week) intervention (n=21) or Biodanza (1-time/week) intervention (n=17). We assessed tender point, body composition, physical fitness and psychological outcomes (Fibromyalgia Impact Questionnaire, the Short-Form Health Survey 36 questionnaire (SF-36), the Hospital Anxiety and Depression Scale, Vanderbilt Pain Management Inventory (VPMI), Rosenberg Self-Esteem Scale and General Self-Efficacy Scale).

Results: We observed a significant group*time interaction effect for the scales of SF-36 physical role (P=0.038) and social functioning (P=0.030) and for the passive coping scale in VPMI (P=0.043). Post hoc analysis revealed a significant improvement on social functioning (P=0.030) in the multidisciplinary group whereas it did not change in the Biodanza group. The physical role scale improved in the multidisciplinary group and decreased in the Biodanza group, yet these changes were not significant (P=0.069 and P=0.341 respectively). Post hoc analysis revealed a reduction in the use of passive coping (positive) (P<0.001) in the multidisciplinary group. There was no significant interaction or time effect in body composition and physical fitness.

Conclusions: 16 weeks of multidisciplinary intervention induced greater benefits for social functioning and coping strategies than a Biodanza intervention in women with FM.

INTRODUCTION

Patients with fibromyalgia (FM) have lower functional capacity for daily activities and health-related quality of life than healthy age- and sex-matched people [1], and incur in a considerably high annual total cost in the primary care setting [2]. Fibromyalgia is a complex and heterogeneous condition in which there is abnormal pain processing that results in a wide range of symptoms [3, 4]. The clinical manifestation of FM appears between the 40s and 50s, and is more common in women (~4.2%) than in men (~0.2%)[1].

The European League Against Rheumatism (EULAR) recommendations for the management of FM consider that optimal treatment requires a multidisciplinary approach with a combination of non-pharmacological and pharmacological treatment modalities [3]. Moreover, the recommendations deem that full understanding of FM requires comprehensive assessment of pain, physical function and psychosocial context.

The two most common non-pharmacological treatments are physical exercise and educational or psychological programs [5]. Both treatments together seem to induce improvements in self-efficacy and physical function, as well as in general well-being [5]. Despite these recommendations, many patients still prefer other treatments as complementary and alternative medicine therapies, which are increasing in popularity. Indeed, FM patients have high rates of complementary and alternative medicine use [6]. However, complementary and alternative medicine therapies are still in the ongoing process of being evaluated by scientific trials [7].

The aim of the present study was to evaluate and compare the effectiveness of a 16-week multidisciplinary (exercise plus psychological therapy) and an alternative-intervention (Biodanza) on pain, physical fitness and psychological outcomes in women with FM.

METHODS

Study participants

We contacted a local Association of Fibromyalgia Patients (Granada, Spain), and 44 potentially eligible patients responded. All gave their written informed consent after receiving detailed information about the aims and study procedures. The inclusion criteria were: (i) meeting the American College of Rheumatology criteria: widespread pain for more than 3 months, and pain with 4 kg/cm of pressure reported for 11 or more of 18 tender points [8], (ii) not to have other severe somatic or psychiatric disorders, or other diseases that prevent physical loading. A total of 5 patients were not included in the study because they did not have 11 of the 18 tender points. After the baseline measurements, 1 patient refused to participate due to incompatibility with job schedule. Therefore, a final sample of 38 women with FM participated in the study, and were distributed either to multidisciplinary (n=21) or Biodanza group (n=17). The study flow of participants is presented in Figure 1. Patients were not engaged in regular physical activity (>20 minutes on >3 days/week).

The research protocol was reviewed and approved by the Ethics Committee of the *Hospital Virgen de las Nieves* (Granada, Spain). The study was developed between January 2009 and June 2009, following the ethical guidelines of the Declaration of Helsinki, last modified in 2000.

Intervention

Multidisciplinary: The multidisciplinary program comprised 3 sessions per week for 16 weeks. The first two sessions of each week (Monday and Wednesday) were performed in a chest-high warm pool during 45 minutes, and the third session (Friday) included 45 minutes of activity in the exercise room and 90 minutes of psychological-educational therapy. The exercise sessions were carefully supervised by a fitness specialist and by a physical therapist. Each exercise session included a 10 minute warm-up period with slow walk, mobility and stretching exercises, followed by 25 minutes of exercise, and finished with a 10 minute cool-down period of stretching and relaxation exercises. Monday sessions involved strength exercises. Wednesday sessions included balance oriented activities and dancing aerobic exercises and Fridays included aerobic-type exercises and coordination using a circuit of different exercises. The psychological-educational sessions were conducted by a psychologist with experience in treating FM patients. The psychological therapy was based on the acceptance and commitment therapy developed by Hayes *et al.*[9]

These sessions included: (i) General information of the disease from a bio-psycho-social perspective, enhancing the role of physical activity; (ii) Assessment of individual life goals and promotion of actions to develop these goals, while trying to cope with the thoughts and feelings related to pain that act as barriers to achieve these goals; (iii) Relaxation exercises aiming to improve body awareness. The pedagogical approach was based on the active participation of the patients through discussions, practical exercises and role-playing. Educational materials were provided to improve patients' understanding of FM.

Intervention intensity was controlled by the rate of perceived exertion (RPE) based on Borg's conventional (6-20 point) scale. The medium values of RPE were 12 $\pm$ 2. These RPE values correspond to a subjective perceived exertion of 'fairly light exertion and somewhat hard exertion', that is, low-moderate intensity.

Biodanza: The program consisted of 16 sessions (one per week). Each session lasted 120 minutes and was divided into two parts: 1) a verbal phase of 35-45 minutes. In the first sessions, theoretical information about the program was provided, and from the 3rd session on, participants (seated in circle) were encouraged to express their feelings and to share with the group their experiences from the previous session; 2) the "vivencia" (living experience) itself (75-80 minutes), which involves moving/dancing according both to the suggestion given by the facilitator and the music played. The movements should express the emotions elicited by the songs (~12) as well as be a response to other peers' presence, proximity and feedback. Dances were performed in three different ways: (i) individually, (ii) in pairs, (iii) and with the whole group. The exercises proposed in each living experience were chosen according to the objective of the session and belong to 5 main groups: Vitality, sexuality, creativity, affectivity and transcendence. The Biodanza intervention took place once a week due to the fact that participants may feel these living experiences (“vivencias”) so intensely that they need at least one week to assimilate/integrate these experiences. The medium values of RPE were 11 $\pm$ 1. These RPE values correspond to a subjective perceived exertion of ‘fairly light exertion’, that is, low intensity.

Outcomes

Pre and post-intervention assessment were carried out on two separate days with at least 48 hours between each session. This was done in order to prevent patients’ fatigue and flare-ups (acute exacerbation of symptoms). The assessment of the tender-points, blind flamingo test, chair stand test and questionnaires was completed on the first visit. Body composition and the chair sit and reach, back scratch, 8 feet up & go, handgrip strength and 6-min walk tests on the second day.

We assessed 18 tender points according to the American College of Rheumatology criteria for classification of FM using a standard pressure algometer (EFFEGI, FPK 20, Italy) [8]. The algometer score was calculated as the sum of the minimum pain-pressure values obtained for each tender point. Tender point scored as positive when the patient noted pain at pressure of 4 kg/cm^2 or less. The total count of such positive tender points was recorded for each participant.

We performed a bioelectrical impedance analysis with an eight-polar tactile-electrode impedanciometer (InBody 720, Biospace)[10]. Weight (kg) and height (cm) were measured, and body fat percentage and skeletal muscle mass (kg) were estimated. Body mass index (BMI) was calculated as weight (in kilograms) divided by height (in squared meters).

Physical fitness was assessed by the tests included in the Functional Senior Fitness Test Battery [11]: the 30-s chair stand, chair sit and reach, back scratch, 8 ft up and go and 6 min walk tests [11]. For the chair sit and reach and back scratch test we recorded the average of both limbs for the final analysis and not only the dominant side. Additionally, we also measured the handgrip strength and the blind flamingo test, which have been used in FM patients [12]. The Handgrip strength was measured using a digital dynamometer adjusted to the individual’s hand size

[13]. The patients maintained the standard bipedal position during the entire test with the arm in complete extension and did not touch any part of the body with the dynamometer except the hand being measured. The best value of 2 trials for each hand was chosen and the average of both hands was used in the analysis. The "blind flamingo test"[14] registered the number of trials needed to complete 30 s of the static position. One trial was accomplished for each leg and the average of both values was selected for the analysis.

The Fibromyalgia impact Questionnaire (FIQ) is a self-administered questionnaire, comprising 10 subscales of disabilities and symptoms, that has been validated for Spanish FM population [15]. The Short-Form Health Survey 36 (SF-36) is a generic instrument assessing health related quality of life that contains 36 items grouped into 8 scales: physical functioning, physical role, bodily pain, general health, vitality, social functioning, emotional role, and mental health [16]. Furthermore, we also administered the following self-administered psychological questionnaires: (i) the Hospital Anxiety and Depression Scale (HADS) [17]; the (ii) Vanderbilt Pain Management Inventory (VPMI) [18] (assesses coping strategies); (iii) the Rosenberg Self-Esteem Scale (RSES) [19] to assess the concept of global self-esteem and (iv) the General Self-Efficacy Scale[20].

Data Analysis

Analyses of data included (i) a main analysis: per-protocol analysis, which included only those participants who complied with the study protocol (attendance at least 70% of the sessions), and (ii) secondary analysis: intention to treat (ITT), in which a patient was considered a study participant if she attended at least one treatment session. When post-test data were missing, baseline scores were considered post-test scores.

Independent t and chi-square tests were used to compare demographic variables between groups. We used a two-factor (group and time) analysis of covariance with repeated measures to assess the training effects on the outcome variables (pain, body composition, physical fitness and psychological outcomes) after adjusting for age. For each variable we reported the P value corresponding to the group (between-subjects), time (within-subjects) and interaction (group*time) effects. We calculated the P value for within-group differences by group when a significant interaction effect or time effect was present.

Analyses were performed using the Statistical Package for Social Sciences (SPSS, v. 16.0 for WINDOWS; SPSS Inc, Chicago).

RESULTS

The drop-out rates were 14.3% and 23.5% in the multidisciplinary and Biodanza interventions, respectively. One woman from the multidisciplinary and 3 women from the Biodanza group discontinued the program due to personal and health problems. Two women in the multidisciplinary group and one woman in the Biodanza group were not included in the analysis for attending less than 70% of the program sessions (attendance: 65.5, 45.2 and 58.3% respectively). Adherence to the multidisciplinary intervention was 85.3% (range 70 – 95%), and 85.4% (range 73 – 93%) for the Biodanza intervention. A total of 18 (85.7%) women from the multidisciplinary group and 13 (76.5%) from the Biodanza group completed the 4 month follow up and were included in the final (per-protocol) analysis.

During the study period, no participant reported an exacerbation of FM symptoms beyond normal flares, and there were no serious adverse events. No women changed from the multidisciplinary group to the Biodanza group or *vice versa*, and there were no protocol deviations from the study as planned. Sociodemographic characteristics of women with FM by group are shown in **Table 1**. There were no statistically significant differences at baseline between groups except for the occiput L and anterior cervical L tender points.

Per-protocol analysis

We did not observe a significant interaction effect (group*time) in pain threshold, algometer score and tender points count. We observed a significant time effect for the pain threshold on the left side of supraespinatus and the right side of knee tender point **(Table 2).** Post hoc analysis revealed that pain threshold on the left side of supraspinatus increased significantly in the multidisciplinary group and in the Biodanza group (P=0.003 and P=0.047, respectively) from pre-test to post-test. We observed no significant interaction or time effect in body composition or functional capacity **(Table 3).**

There was a significant interaction effect for the scales of SF-36, physical role and social functioning **(Table 4).** Post hoc analysis revealed that there was a significant improvement on the social functioning scale (P=0.030) in the multidisciplinary group whereas did not change in the Biodanza group. The physical role scale improved in the multidisciplinary group and decreased in the Biodanza group but these changes were not significant (P=0.069 and P=0.341 respectively). A time effect was found for total score of FIQ, for the subscales of feel good, pain, fatigue and depression and for the vitality scale of SF-36 **(Table 4)**. Post hoc analysis revealed that there was an improvement in the multidisciplinary and in the Biodanza group on total score of FIQ (P=0.002 and P=0.032, respectively) and the subscale pain (P=0.001 and P=0.003, respectively) from pre-test to post-test. The multidisciplinary group also showed an improving from pre-test to post-test in the subscales of FIQ fatigue (P=0.003) and depression (P=0.003). We observed a significant interaction effect for the passive coping scale of VPMI **(Table 5)**. Post hoc analysis revealed that there was a reduction in the use of passive coping (positive) (P<0.001) in the multidisciplinary group.

Intention to treat analysis

Thirty-eight patients were included in the ITT analysis (multidisciplinary group, n=21 and Biodanza group, n=17). We observed interaction (group*time) effects in the following outcomes: Pain threshold of lateral epicondyle (R) (P=0.027), subscale of FIQ anxiety (P=0.014), the scales of SF-36 physical role (P=0.009) and social functioning (P=0.011), the passive coping (P=0.030) and active coping scales from the VPMI (P=0.036) and anxiety of HAD (P=0.033). Significant time effects were found for pain threshold of supraespinatus R (P=0.009) and knee R (P=0.012) and for the subscales of FIQ feel good (P=0.011) and depression (P=0.011) and for the vitality scale of SF-36 (P=0.042).

DISCUSSION

The main finding of the present study is that 16-weeks of a multidisciplinary intervention obtained greater benefits on social functioning and coping strategies than a Biodanza intervention. The multidisciplinary group also improved the subscale of FIQ fatigue and depression. Total score of FIQ and the subscale of pain improved in both intervention groups in a similar manner. Due to the lack of control group we cannot know whether these improvements are attributed to the treatments or to others causes. Nevertheless, in previous studies in which we have analyzed the effect of 3 months of these types of interventions compared with control groups we observed no improvement in the control group and even worsening in some outcome variables [21, 22]. Both interventions were well tolerated and did not have any deleterious effects on patients' health.

The greater benefits in the multidisciplinary group on social functioning and coping strategies could be attributed to the psychological program included in this intervention. In the psychological program, the psychologist played an active role and encouraged patients to improve their communication with their social environment, to accept pain as well as to adopt active coping. In contrast, although there was a verbal part of the Biodanza session in which participants were encouraged to express their feelings and experience related to the last session, neither the facilitator nor the rest of the group intervened in the participants' comments.

Both interventions improved pain rating (FIQ), which is something to highlight considering that pain is the main symptom of FM [8, 23]. However, only the multidisciplinary intervention obtained improvements in fatigue and depression. Overall, chronic pain had been associated with higher level of anxiety and depression [24] and specifically in FM [1, 25]. In fact, FM patients reported higher scores of depression and anxiety than other chronic pain patients [24], and depression is the most common mental comorbidity condition (~38.6% of patients) [26]. Hence, we believe this improvement could be considered as clinically relevant. Jentoff *et al.* [27] compared 20-weeks (twice a week) of two types of physical interventions, one based on pool exercise and the other one on land-based exercise. They concluded that exercise in a warm-water pool may have additional positive effects on self-reported physical impairment and symptoms such as self-reported pain, depression, and anxiety compared with exercise performed in a gymnasium, which concurs with our results.

We did not obtain significant statistical change in tender points count and algometer score, albeit there was a reduction of ~1.2 points in the multidisciplinary group and ~ 2.6 points in the Biodanza group. Likewise, the algometer score increased 5.7 and 7.25 kg/cm^2 in the multidisciplinary and in the Biodanza intervention respectively. The fact that these improvements were slightly better in the Biodanza than in the multidisciplary intervention is somehow unexpected considering that the multidisciplinary intervention was carried out 3 times a week (versus once a week in the Biodanza intervention) and the exercise was performed in warm water. Hydrotherapy (with or without exercise) has been recommended for the management of FM because of the water buoyancy and warm temperature [28]. Despite of this, there is no clear evidence regarding the effect of pool exercise on tender points count, and whereas several studies[29, 30] reported improvement in tender points count, others did not [31-34]. Discrepancy among studies could be due to the fact that pain relief is related to a higher length and frequency of warm-water exercise sessions per week [33].

We did not observe any benefit in body composition nor in physical fitness, which might be expected due to the low intensity and frequency of the interventions. These findings do not concur with other studies that observed improvements after multidisciplinary interventions in the 6-min walk test [32, 35-37]. To note is that we used a relatively small swimming pool (4 x 7 meters), and a relatively low intensity program, which may explain why we did not obtain any significant change in physical fitness. Likewise, we did not observe improvements in muscular strength in the upper or lower extremities, which is in accordance with other pool exercise interventions [12, 29].

Multidisciplinary treatment showed greater benefits in social functioning and coping strategies and additional gains in fatigue and depression than Biodanza. However, considering the observed improvements in FM impact and pain after the Biodanza intervention, this alternative therapy could be recommended for (i) those patients who are sedentary and want to initiate a more active lifestyle, (ii) patients who have a low physical function or (iii) those with lack of free time. Further studies are needed to better understand the effectiveness of alternative and complementary therapies such as Biodanza [7, 36].

A limitation of our study it was not to randomize the participants into the multidisciplinary and Biodanza intervention, yet, there was no difference between groups in all the variables studied. Most of the effects reported in this study would become statistically non-significant after correction for multiple testing. However, we believe that to conclude negatively from a purely statistical point of view would be too stringent. We believe that most of the observed changes are informative and clinically relevant. Strengths include the comprehensive assessment of body composition and physical fitness measures, which are limited in others studies.

In summary, 16 weeks of multidisciplinary intervention induced greater benefits for social functioning and coping strategies than Biodanza intervention ion women with FM. Multidisciplinary group also obtained additional benefits on fatigue and depression. Both groups improved total score of FIQ and the subscale of pain but due to the lack of control group we can not assure that are as a result of the interventions.

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Table 1. Sociodemographic characteristics of women with fibromyalgia by group.

	Multidisciplinary (n=18)	**Biodanza** (n=13)	**P**
Age, years	50.9 (7.7)	54.5 (7.5)	0.207
Menopause (yes/no), n (%)	12/6 (66.7/33.3)	9/4 (30.8/69.2)	0.880
Years since clinical diagnosis, n (%)			0.171
≤ 5 years	10 (55.6)	4 (30.8)	
> 5 years	8 (44.4)	9 (69.2)	
Marital status, n (%)			0.821
Married	13 (72.2)	8 (61.5)	
Unmarried	2 (11.1)	2 (15.4)	
Separated /Divorced/ Widowed	3 (16.7)	3 (23.1)	
Educational status, n (%)*			0.064
Unfinished studies	0 (0.0)	2 (18.2)	
Primary school	9 (50.0)	1 (9.1)	
Secondary school	5 (27.8)	5 (45.5)	
University degree	4 (22.2)	3 (27.3)	
Occupational status, n (%)^			0.500
Housewife	10 (55.6)	7 (77.8)	
Working	6 (33.3)	1 (11.1)	
Unemployed	1 (5.6)	0 (0.0)	
Retired	1 (5.6)	1 (11.1)	
Income, n (%)			0.643
< 1200,00 €	8 (44.4)	8 (61.5)	
1201,00 – 1800,00 €	4 (22.2)	2 (15.4)	
> 1800,00 €	6 (33.3)	3 (23.1)	

*Two missing data in biodanza group. ^ Four missing data in the biodanza group.

Table 2. Effects of a 16-week of multidisciplinary and biodanza intervention on pain threshold (kg/cm^2), algometer score (kg/cm^2) and tender point count in women with fibromyalgia.

	Group	Pre	Post	*P* for Group effect	*P* for Time effect	*P* for Interaction effect
Occiput R	Multidisciplinary Biodanza	2.37 (0.13) 2.61 (0.18)	2.27 (0.11) 2.53 (0.15)	0.110	0.483	0.950
Occiput L	Multidisciplinary Biodanza	2.28 (0.14) 2.57 (0.19)	2.22 (0.14) 2.92 (0.19)	0.011	0.437	0.212
Anterior cervical R	Multidisciplinary Biodanza	1.66 (0.13) 1.98 (0.17)	2.03 (0.17) 2.58 (0.30)	0.837	0.102	0.063
Anterior cervical L	Multidisciplinary Biodanza	1.70 (0.13) 1.99 (0.17)	1.91 (0.14) 2.57 (0.19)	0.020	0.322	0.137
Trapezius R	Multidisciplinary Biodanza	2.49 (0.17) 2.70 (0.23)	2.86 (0.18) 3.02 (0.24)	0.494	0.181	0.829
Trapezius L	Multidisciplinary Biodanza	2.62 (0.14) 2.99 (0.18)	2.97 (0.19) 3.41 (0.25)	0.113	0.383	0761
Supraspinatus R	Multidisciplinary Biodanza	2.92 (0.18) 3.24 (0.24)	3.51 (0.20) 3.98 (0.27)	0.171	0.021	0.616
Supraspinatus L	Multidisciplinary Biodanza	2.92 (0.18) 3.42 (0.24)	3.60 (0.22) 3.99 (0.29)	0.138	0.055	0.743
Second rib R	Multidisciplinary Biodanza	1.90 (0.15) 2.28 (0.21)	2.33 (0.17) 2.67 (0.23)	0.141	0.682	0.918
Second rib L	Multidisciplinary Biodanza	1.83 (0.15) 2.26 (0.21)	2.32 (0.18) 2.79 (0.25)	0.085	0.399	0.887
Lateral epicondyle R	Multidisciplinary Biodanza	2.16 (0.17) 2.85 (0.22)	2.71 (0.21) 2.89 (0.29)	0.144	0.184	0.069
Lateral epicondyle L	Multidisciplinary Biodanza	2.31 (0.17) 2.81 (0.23)	2.70 (0.19) 3.14 (0.26)	0.096	0.188	0.818
Gluteal R	Multidisciplinary Biodanza	3.03 (0.25) 3.20 (0.33)	3.60 (0.26) 3.33 (0.35)	0.882	0.276	0.318

Gluteal L	Multidisciplinary Biodanza	3.17 (0.25) 3.45 (0.33)	3.71 (0.24) 3.86 (0.32)	0.549	0.658	0.750
Great trochanter R	Multidisciplinary Biodanza	2.89 (0.20) 3.09 (0.27)	3.24 (0.26) 3.32 (0.34)	0.694	0.262	0.699
Great trochanter L	Multidisciplinary Biodanza	3.04 (0.21) 3.17 (0.29)	3.39 (0.20) 3.64 (0.27)	0.537	0.364	0.703
Knee R	Multidisciplinary Biodanza	2.61 (0.22) 2.61 (0.29)	2.43 (0.19) 2.83 (0.25)	0.535	0.157	0.185
Knee L	Multidisciplinary Biodanza	2.63 (0.21) 2.58 (0.28)	2.47 (0.18) 2.57 (0.25)	0.943	0.024	0.565
Algometer score	Multidisciplinary Biodanza	44.55 (2.30) 48.80 (3.09)	50.26 (2.76) 56.05 (3.71)	0.163	0.093	0.885
Tender points count	Multidisciplinary Biodanza	17.02 (0.43) 16.36 (0.58)	15.83 (0.82) 13.80 (1.10)	0.176	0.272	0.210

Data are means (standard error of the mean). R, right; L, left.

Table 3. Effects of a 16-week of multidisciplinary and biodanza intervention on body composition and physical fitness in women with fibromyalgia.

	Group	Pre	Post	*P* for Group effect	*P* for Time effect	*P* for Interaction Effect
Weight (kg)	Multidisciplinary	68.3 (2.4)	68.3 (2.5)	0.958	0.469	0.337
	Biodanza	69.0 (3.1)	68.0 (3.3)			
Waist circumference (cm)	Multidisciplinary	86.9 (2.7)	88.1 (2.8)	0.788	0.068	0.100
	Biodanza	87.2 (3.4)	85.5 (3.5)			
BMI (kg/m^2)	Multidisciplinary	27.9 (1.1)	28.0 (1.2)	0.932	0.908	0.743
	Biodanza	27.8 (1.4)	27.8 (1.5)			
Body fat percentage	Multidisciplinary	38.4 (1.7)	37.8 (1.9)	0.491	0.790	0.968
	Biodanza	36.5 (1.9)	35.9 (2.2)			
Muscle mass (kg)	Multidisciplinary	22.3 (0.7)	27.4 (3.3)	0.559	0.296	0.225
	Biodanza	23.9 (0.8)	22.6 (3.9)			
Chair sit and reach (cm)	Multidisciplinary	-17.6 (4.5)	-7.7 (2.9)	0.813	0.793	0.823
	Biodanza	-15.7 (5.8)	-6.9 (3.7)			
Back scratch test (cm)	Multidisciplinary	-7.3 (2.4)	-9.3 (2.4)	0.699	0.921	0.973
	Biodanza	-6.5 (2.4)	-5.8 (2.5)			
Handgrip strength (kg)	Multidisciplinary	14.8 (1.6)	16.1 (1.3)	0.097	0.857	0.445
	Biodanza	17.9 (1.9)	20.4 (1.6)			
Chair stand test (n)	Multidisciplinary	8.0 (0.6)	8.2 (0.6)	0.864	0.101	0.643
	Biodanza	7.7 (0.8)	8.2 (0.7)			
8 feet up & go (s)	Multidisciplinary	8.1 (0.4)	7.9 (0.4)	0.133	0.525	0.080
	Biodanza	7.8 (0.5)	6.6 (0.5)			
30-s blind flamingo (failures)	Multidisciplinary	12.2 (1.1)	10.6 (1.3)	0.170	0.101	0.127
	Biodanza	9.6 (1.5)	9.6 (1.7)			
6 minute walk (metres)	Multidisciplinary	449.6 (16.3)	445.8 (14.6)	0.838	0.349	0.248
	Biodanza	443.9 (20.3)	461.0 (18.1)			

BMI, body mass index. Data are means (standard error of the mean).

Table 4. Effects of a 16-week of multidisciplinary and biodanza intervention on tender point count, Fibromyalgia Impact Questionnaire (FIQ) and Short Form 36 (SF-36), (primary outcomes) in women with fibromyalgia.

	Group	Pre	Post	*P* for Group effect	*P* for Time effect	*P* for Interaction Effect
FIQ						
Total score	Multidisciplinary Biodanza*	74.6 (3.1) 77.7 (3.9)	62.9 (3.7) 64.9 (4.7)	0.597	0.021	0.833
Physical function	Multidisciplinary Biodanza	5.4 (0.5) 4.4 (0.6)	4.0 (0.5) 4.3 (0.7)	0.758	0.144	0.156
Feel good	Multidisciplinary Biodanza	8.7 (0.5) 8.6 (0.6)	7.8 (0.7) 6.7 (0.8)	0.482	0.043	0.322
Pain	Multidisciplinary Biodanza	7.9 (0.4) 8.2 (0.6)	6.3 (0.4) 6.4 (0.5)	0.788	0.003	0.787
Fatigue	Multidisciplinary Biodanza	8.5 (0.4) 8.4 (0.6)	7.6 (0.5) 7.7 (0.6)	0.951	0.028	0.816
Sleep	Multidisciplinary Biodanza	8.3 (0.4) 8.9 (0.6)	8.1 (0.4) 8.3 (0.6)	0.489	0.269	0.589
Stiffness	Multidisciplinary Biodanza	7.6 (0.5) 8.3 (0.7)	6.1 (0.6) 7.0 (0.8)	0.357	0.159	0.883
Anxiety	Multidisciplinary Biodanza	8.5 (0.4) 7.7 (0.5)	5.9 (0.6) 6.9 (0.8)	0.827	0.135	0.056
Depression	Multidisciplinary Biodanza	7.0 (0.7) 7.8 (0.9)	4.9 (0.7) 6.3 (0.9)	0.331	0.009	0.614
SF-36						
Physical function	Multidisciplinary Biodanza	35.8 (4.7) 35.0 (6.0)	42.4 (4.8) 38.3 (6.2)	0.733	0.717	0.600
Physical role	Multidisciplinary Biodanza	0.0 (0.0) 9.1 (5.6)	9.7 (4.6) 4.5 (5.9)	0.742	0.205	0.038
Bodily pain	Multidisciplinary Biodanza	18.6 (3.0) 23.7 (3.8)	32.7 (4.8) 30.0 (6.1)	0.835	0.456	0.205

General health	Multidisciplinary	27.7 (3.2)	31.9 (3.3)	0.859	0.126	0.655
	Biodanza	26.0 (4.0)	31.9 (4.2)			
Vitality	Multidisciplinary	20.4 (4.0)	23.5 (3.5)	0.831	0.007	0.231
	Biodanza	16.2 (5.1)	25.2 (4.5)			
Social functioning	Multidisciplinary	31.7 (6.1)	51.6 (5.8)	0.784	0.531	0.030
	Biodanza	44.3 (7.8)	43.9 (7.5)			
Emotional role	Multidisciplinary	25.5 (8.5)	42.7 (10.3)	0.127	0.748	0.230
	Biodanza	15.8 (10.8)	12.0 (13.2)			
Mental health	Multidisciplinary	41.7 (4.5)	53.3 (4.6)	0.331	0.159	0.400
	Biodanza	37.3 (5.8)	44.0 (5.9)			

Data are means (standard error of the mean).

Table 5. Effects of a 16-week of multidisciplinary and biodanza intervention on coping strategies, anxiety and depression, self-efficacy and self-esteem in women with fibromyalgia.

	Group	Pre	Post	*P* for Group effect	*P* for Time effect	*P* for Interaction Effect
VPMI						
Passive coping	Multidisciplinary	25.6 (0.7)	21.4 (0.9)	0.665	0.124	0.043
	Biodanza	23.7 (0.9)	22.2 (1.2)			
Active Coping	Multidisciplinary	15.6 (0.9)	17.0 (0.9)	0.282	0.890	0.079
	Biodanza	15.9 (1.1)	14.2 (1.1)			
HADS						
Anxiety	Multidisciplinary	11.9 (1.0)	10.4 (1.0)	0.582	0.942	0.112
	Biodanza	12.1 (1.3)	11.9 (1.3)			
Depression	Multidisciplinary	9.6 (1.1)	8.5 (1.0)	0.891	0.212	0.668
	Biodanza	9.1 (1.4)	8.5 (1.3)			
SELF-EFFICACY	Multidisciplinary	26.1 (1.9)	27.1 (1.5)	0.240	0.753	0.422
	Biodanza	24.1 (2.4)	23.1 (1.9)			
RSES	Multidisciplinary	29.1 (1.4)	29.2 (1.3)	0.277	0.838	0.621
	Biodanza	26.4 (1.2)	27.1 (1.7)			

VPMI = Vanderbilt Pain Management Inventory; HADS = Hospital Anxiety and Depression Scale; RSES = Rosenberg Self-Esteem Scale.

Data are means (standard error of the mean).

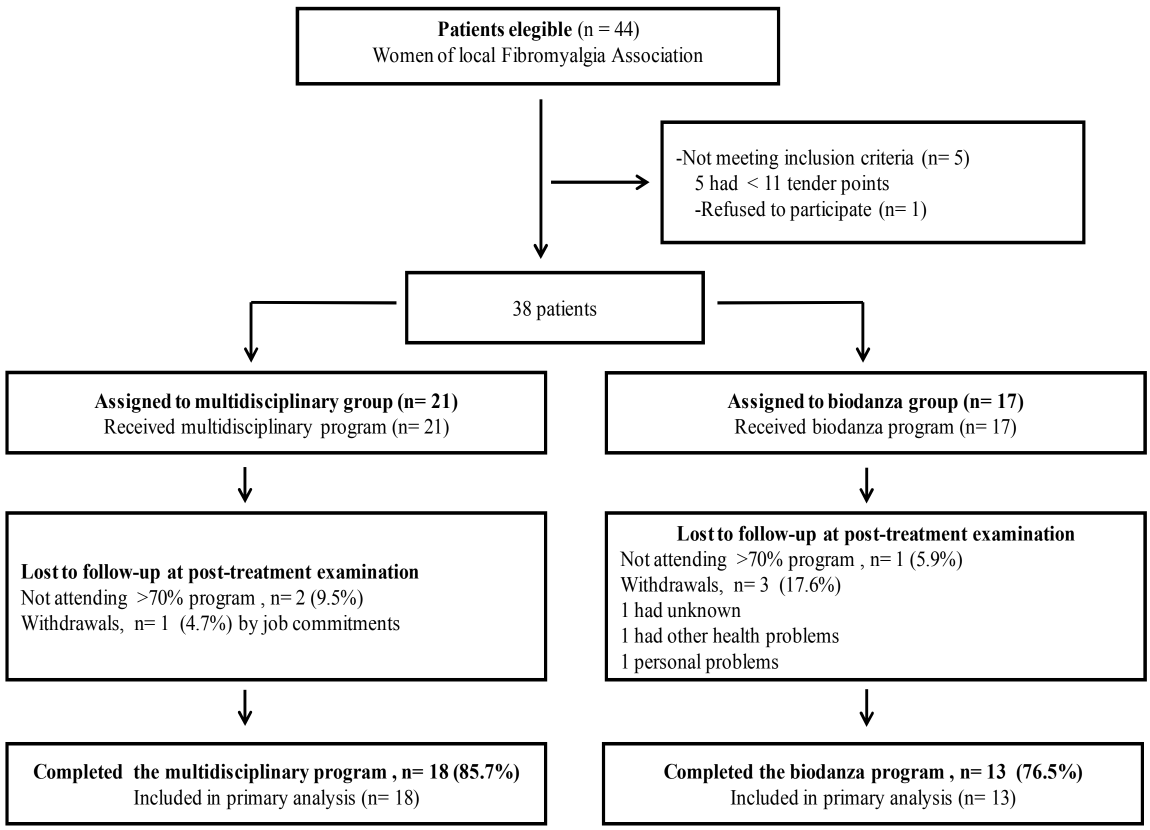

Figure 1. Flow of patients throughout the trial.

CONCLUSIONES

- Los pacientes con fibromialgia presentan en general una capacidad funcional reducida.
- La fuerza de tren inferior y la capacidad aeróbica están inversamente relacionadas con el dolor.
- Una intervención multidisciplinar de tres meses tiene un efecto positivo sobre el umbral de varios puntos de dolor, la fuerza de tren inferior, mejora la calidad de vida y reduce el impacto de la enfermedad en mujeres con fibromialgia.
- Tres meses de intervención de Biodanza reduce el dolor y el impacto de la fibromialgia en las pacientes.
- Una intervención de Tai Chi de cuatro meses de duración no tiene efectos significativos sobre el dolor, la condición física y variables psicosociales en hombres con fibromialgia.
- Una intervención multidisciplinar de cuatro meses de duración induce mayores beneficios que una intervención de Biodanza de la misma duración, en la función social y el uso de estrategias de afrontamiento de dolor en mujeres con fibromialgia.

Conclusión general:
Los resultados de la presente memoria de Tesis ponen de manifiesto la utilidad del ejercicio físico en el tratamiento de los síntomas de la fibromialgia.

CONCLUSIONS

- Patients with fibromyalgia had a reduced functional capacity.
- Lower limb muscular strength and aerobic capacity are inversely associated with pain in female with fibromialgia.
- A 3-month of low-moderate intensity multidisciplinary intervention program had a positive effect on pain threshold in several tender points, lower body flexibility, improves quality of life and reduces fibromyalgia impact, in women with fibromyalgia.
- A 3-month Biodanza intervention reduces pain and fibromyalgia impact in female patients.
- A 4-month Tai Chi intervention program did not have any significant effect on pain, physical fitness and psychological outcomes in men with fibromyalgia.
- A 4-month multidisciplinary intervention induced greater benefits than a Biodanza intervention for social functioning and coping strategies in women with fibromyalgia.

Overall conclusion:

The results of the present Thesis highlight the usefulness of physical interventions in the management of fibromyalgia symptoms.

CURRICULUM VITAE abreviado [Short CV]

Actividad Académica

- Licenciada en Ciencias de la Actividad Física y el Deporte. Universidad de Granada, Facultad de Ciencias de la Actividad Física y el Deporte (Junio 2004).
- Doctorado de Fisiología del Ejercicio aplicada el control del Rendimiento Deportivo y la Salud. Universidad de Granada. Facultad de Medicina (2004-2006).
- Máster en Dirección de Entidades e Instalaciones Deportivas. Universidad de Almería, Instituto Andaluz del Deporte (2005 – 2007).
- Estancia de investigación en la Facultad de Ciencias del Deporte de la Universidad de Extremadura, España. Departamento de Didáctica de la Expresión Musical, Plástica y Corporal (abril 2009-junio 2009).
- Estancia de investigación en el Karolinska Institutet. Department of Bioscience and Preventive Nutrition, Estocolmo, Suecia (septiembre-diciembre 2009).
- Estancia de investigación en la Facultad de Ciencias de Tetuán, Marruecos (14 marzo de 2010-19 de marzo de 2010).

Participación en proyectos de investigación

- Laboratorio ergonómico para el desarrollo y validación de un protocolo integral de la valoración de la calidad de vida en poblaciones adultas y mayores (ERGOLAB). (2005-2006). Programa de Fomento de la Investigación Técnica (PROFIT). Programa Nacional de Tecnología para la salud y el bienestar. CIT 300100-2005-23.
- Desarrollo, aplicación y evaluación de la eficacia de un programa terapéutico para adolescentes con sobrepeso y obesidad: Educación integral nutricional y de actividad física (EVASYON). (2005-2007). Fondos de

investigación sanitaria (FIS), Instituto de Salud Carlos III, Ministerio de Sanidad y Consumo. Proyecto coordinado. PI052369.

- Evaluación y promoción de la calidad de vida relacionada con la salud para enfermos de fibromialgia. (2008-2009). Instituto Andaluz del Deporte.
- Intervención para la mejora de la calidad de vida relacionada con la salud. (2008 -2010).Asociación Granadina de Fibromialgia (AGRAFIM).
- Cooperación en educación para la calidad de vida de mujeres mayores (2008-2010). CICODE. Vicerrectorado de Extensión Universitaria y Cooperación al Desarrollo.
- Evaluación de Los Hábitos de Salud y Calidad de Vida de Mujeres Peri y Menopáusicas tras Un Programa de Intervención Educativa Multidisciplinar (2008-2010). Consejería de Salud de la Junta de Andalucía. Ref: PI-0339.
- Mejora de la calidad de vida en personas con fibromialgia a través de programas de actividad física y multidisciplinares (2008-2009). CICODE. Vicerrectorado de Extensión Universitaria y Cooperación al Desarrollo.
- Efectos de programas de actividad física en la calidad de vida de personas con fibromialgia (EPAFI). 2010. Fundación MAPFRE. Ayudas a la investigación 2009.
- Efecto de hidrolizados proteicos vegetales procedentes de leguminosas sobre el metabolismo lipídico y energético en un modelo experimental de rata obesa. Interacción con el ejercicio físico aeróbico (2010-2013). Junta de Andalucia. P09-agr-4658
- Niveles de actividad física, condición física, salud y calidad de vida en población andaluza con fibromialgia: efectos del ejercicio físico y determinantes genéticos. (2010-2013).Consejería de Turismo, Comercio y Deporte. Modalidad Investigación en Medicina del Deporte.

Publicaciones científicas

Revistas Internacionales contempladas en el JCR.

1. Chillón P, Castro-Piñero J, Ruiz JR, Soto VM, **Carbonell-Baeza A**, Dafos J, Vicente-Rodríguez G, Castillo MJ, Ortega FB. Hip flexibility is the main determinant of the back-saver sit-and-reach test in adolescents. *Journal of Sports Sciences* 2010. First published on: 15 April
2. **Carbonell-Baeza A**, Aparicio VA, Ortega FB, Cuevas AM, Álvarez I, Ruiz JR, Delgado-Fernández M. Does a 3-month multidisciplinary intervention improve pain, body composition and physical fitness in women with fibromyalgia? *British Journal of Sport Medicine*. In press
3. **Carbonell-Baeza A**, Aparicio VA, Martins-Pereira CM, Gatto-Cardia MC, Ortega FB, Huertas FJ, Tercedor P, Delgado-Fernández M. Ruiz JR Efficacy of Biodanza in the treatment of women with fibromyalgia. *Journal of Alternative and Complementary Medicine*. In press.
4. **Carbonell-Baeza A**, Aparicio VA, Sjöström M, Ruiz JR, Delgado-Fernández M. Functional capacity in female and male fibromyalgia patients. Submitted.
5. **Carbonell-Baeza A**, Cuevas AM, Aparicio VA, Chillón P, Delgado-Fernández M, Ruiz JR. Effectiveness of multidisciplinary therapy in women with fibromyalgia. Submitted.
6. **Carbonell-Baeza A**, Romero A, Aparicio VA, Ortega FB, Tercedor P, Delgado-Fernández M, Ruiz JR. Preliminary findings of a 4-month Tai Chi intervention in men with fibromyalgia. Submitted
7. **Carbonell-Baeza A**, Ruiz JR, Aparicio VA, Martins-Pereira CM, Gatto-Cardia MC, Martinez JM, Ortega FB, Delgado-Fernández M. Multidisciplinary and biodanza intervention for the management of fibromyalgia. Submitted.
8. Aparicio VA, Ortega FB, Heredia JM, **Carbonell-Baeza A**, Sjöström M, Delgado, M. Handgrip strength assessment as a complementary tool in the diagnosis of fibromyalgia in women. Submitted.
9. Aparicio VA, **Carbonell-Baeza A,** Ortega FB, Ruiz-Ruiz J, Heredia JM, Delgado, M. Hand grip strength in men with fibromialgia. Submitted.

10. Parraca JA, Olivares PR, **Carbonell-Baeza A**, Aparicio VA, Adsuar JC, Narcis G. Test-Retest reliability of Biodex Balance SD on physically old people. Submitted.
11. **Carbonell-Baeza A**, Romero A, Aparicio VA, Tercedor P, Delgado-Fernández M, Ruiz JR. Tai chi intervention in men with fibromialgia: A multiple-patient case report. Submitted.
12. **Carbonell-Baeza A,** Ruiz JR, Aparicio VA, Ortega FB, Femia P, Tercedor P, Lucia A, Delgado-Fernandez M. Land- and water-based exercise intervention in women with fibromyalgia: The Al-Andalus physical activity Randomised Control Trial. Submitted.

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Aportaciones a Congresos científicos

(Únicamente se muestran las relacionadas con la presente Tesis).

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"El principio de la educación es predicar con el ejemplo" "El maestro deja una huella para la eternidad; nunca se puede decir cuando se detiene su influencia"

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"Lo que caracteriza al hombre y mujer de ciencia no es la posesión del conocimiento o de verdades irrefutables, sino la investigación desinteresada e incesante de la verdad."

"Lo desconocido define nuestra existencia. Buscamos constantemente, no solo respuestas a nuestras preguntas, sino también nuevas preguntas. Somos exploradores, exploramos nuestras vidas día tras día."

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