

UNIVERSIDAD POLITÉCNICA DE MADRID

**FACULTAD DE CIENCIAS DE LA ACTIVIDAD FÍSICA Y
DEL DEPORTE (INEF)**

**Evaluación de los efectos de un programa de actividad física
basado en el trabajo de fuerza en mujeres diagnosticadas de
fibromialgia (FM)**



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Graduada y Máster en Actividad Física y Salud

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**FACULTAD DE CIENCIAS DE LA ACTIVIDAD FÍSICA Y DEL DEPORTE
(INEF)**

Evaluación de los efectos de un programa de actividad física basado en el trabajo de fuerza en mujeres diagnosticadas de fibromialgia (FM)

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"Make things as simple as you can, but don't limit yourself to the simple"

(Albert Einstein)

“Haz las cosas lo más simple que puedas, pero no te limites a lo simple”

(Albert Einstein)

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**JESÚS JAVIER ROJO GONZÁLEZ, PROFESOR TITULAR DE LA
UNIVERSIDAD POLITÉCNICA DE MADRID,**

CERTIFICA:

Que la Tesis Doctoral titulada “*Evaluación de los efectos de un programa de actividad física basado en el trabajo de fuerza en mujeres diagnosticadas de fibromialgia (FM)*” que presenta Dña. **CRISTINA ASUNCIÓN MAESTRE CASCALES** al superior juicio del Tribunal que designe la Universidad Politécnica de Madrid, ha sido realizada bajo mi dirección durante los años 2015-2019. El trabajo presentado cumple con todos los criterios científicos y técnicos exigidos, y demuestra la capacidad de su autora para ser merecedora del Título de Doctora con Mención Internacional, siempre y cuando así lo considere el citado Tribunal.

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LIST OF ABBREVIATIONS

- ACR: American College of Rheumatology
ADL: Activities of Daily Living
AFIBROM: Fibromyalgia Association of the Community of Madrid
BPIQ: Brief Pain Inventory Questionnaire
CK: CreatinKinase
DOMS: Delayed Onset Muscle Soreness
EB: Elastic Bands
EL: External Loads
FD: Function Domain
FIQR: Revised Fibromyalgia Impact Questionnaire
FM: Fibromyalgia
HRQol: Quality of life
LTPAQ: Leisure Time Physical Activity Questionnaire
LPA: Light Physical Activity
Mgb: Myoglobin
MPA: Moderate Physical Activity
NSAIDs: Non-Steroidal Anti-Inflammatories Drugs
OID: Overall Impact Domain
OMNI-GSE: OMNI Global Session in Elderly
PA: Physical Activity
PID: Pain Intensity Domain
PITD: Pain Interference Domain
RM: Maximum repetition
SID: Symptoms Domain
SL: Strength by Self-Loads
SS: Symptom Severity
ST: Sedentary Time
STAI-S: State Anxiety-State Inventory
STP: Strength Training Programs
UPM: Universidad Politécnica de Madrid
VAS: Visual Analogue Scale
WPI: Widespread Pain Index

GRANTED RESEARCH PROJECTS AND FUNDING SUPPORT

The present doctoral thesis is focused on the “*Evaluation of the effects of a strength-based physical activity program on women diagnosed with fibromyalgia*”. The study aimed to develop a quasi- experimental study protocol in order to contribute with valuable data to strength training research in relation to symptomatology, functionality and fibromyalgia impact in women diagnosed with fibromyalgia residing in Region of Madrid (Spain). This study was not funded.

The following institutions collaborated:

1. Laboratory of Exercise Physiology Research Group (LFE). Faculty of Physical Activity and Sport Sciences of *Universidad Politécnica de Madrid* (UPM). Coordinator: Dr. Pedro José Benito Peinado and Francisco Javier Calderón Montero.
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Implication of the PhD candidate: Cristina Maestre Cascales was the main researcher for this study under the supervision of Dr. Jesús Javier Rojo González and the Dr. Javier Calderón Montero. She completed all the data collection, directed the intervention program of the study and conducted the data analysis. Finally, the PhD candidate wrote the specific papers included in this doctoral thesis, which are currently

in submission process for different scientific journals. At the present, the muscle-strengthening program in people with fibromyalgia continue to be developed.

The PhD candidate conducted a national research stay at the Training Analysis and Optimization Laboratory, Sports Research Center (SRC), Miguel Hernández University of Elche (UMH) with Dr. Diego Pastor, working on load control in a training program with elderly population. In addition, Cristina participated in another international stay at the University of Ulster in Belfast, United Kingdom with Dr. Ciara Hedges, working on '*Development and Piloting of a Prehabilitation Behavioural Change and Physical Activity Intervention for Fibromyalgia Syndrome*'. This international stay was carried out for the doctorate with international mention.

RESUMEN

Introducción: La fibromialgia (FM) es una enfermedad caracterizada por una sintomatología compleja con presencia de dolor musculoesquelético crónico generalizado junto con otros síntomas incapacitantes. Esta patología supone una elevada carga económica global para los pacientes, generando un problema de salud que conlleva a altas demandas económicas y de atención pública. Las consecuencias de la FM se ven agravadas por un gran número de limitaciones y un estilo de vida sedentario que conducen a una disminución de las capacidades físicas y a un aumento de riesgo de discapacidad. La mayoría de los pacientes afectados por esta patología tienen dificultades para realizar las actividades de la vida diaria, desencadenando en inactividad física. El tratamiento actual para la FM es paliativo, ya que no existe cura. Entre las estrategias utilizadas para aliviar los síntomas físicos y psicológicos y mejorar así la calidad de vida, se encuentra la actividad física. La mayoría de los estudios muestran los efectos del ejercicio físico llevados a cabo a través de programas de entrenamiento aeróbico y acuático en esta patología. A pesar de estas investigaciones, son escasos los estudios que valoran los efectos del entrenamiento de fuerza orientado a las actividades diarias como objetivo principal sobre el dolor, trastornos del sueño, fatiga y ansiedad tratando de especificar la intensidad, volumen y duración apropiada para alcanzar estos beneficios.

Objetivo: En este contexto, el objetivo general de esta tesis doctoral fue valorar los efectos de un programa de fortalecimiento muscular gradual y progresivo orientado a las actividades diarias con el fin de mejorar la sintomatología, funcionalidad física e impacto de la FM para alcanzar una mejor calidad de vida.

Métodos: Este estudio se caracterizó por ser cuasi experimental no aleatorio. El tipo de muestreo fue intencional y se llevó a cabo a través de la asociación de fibromialgia de la

Comunidad de Madrid (AFIBROM). Un total de 41 mujeres participantes formaron parte del estudio cumpliendo los criterios de inclusión. Todas ellas fueron sometidas a un mismo programa de intervención basado en el trabajo de fortalecimiento muscular gradual orientado a las actividades diarias iniciando con trabajo de autocarga, progresando a trabajo de fuerza con material de resistencia y finalizando a pesos libres. Este programa fue dirigido por una graduada en Ciencias del Deporte. La frecuencia de sesiones fue de dos días semanales (no consecutivos) con una duración total de 60 minutos cada sesión. La adherencia al programa fue de un 90%. El programa de intervención abarcó 24 semanas. Las valoraciones se llevaron a cabo una semana antes (pre), mitad de programa (semana 12) y una semana después de finalizar (semana 25). Las variables analizadas fueron: intensidad e interferencia de dolor mediante el Cuestionario Breve de Dolor (CBD), impacto de la FM, función física y sintomatología mediante el Cuestionario Revisado de Impacto de la Fibromialgia (CIFR) y ansiedad estado mediante el Cuestionario de Ansiedad (STAI). La carga interna de las sesiones se controló y estandarizó mediante la escala visual OMNI- GSE específica para población adulta en entrenamiento de fuerza.

Resultados: Se obtuvieron diferencias significativas y elevados efectos clínicos en todos los test de fuerza ($p<0,002$) y dominios que valoran la calidad de vida, en la semana 12 y al finalizar el programa de intervención (semana 25); función física; $p<0,001$, impacto general; $p<0,002$ y sintomatología, $p<0,003$ (**study I**). El programa de entrenamiento mejoró la condición física ($p<0,001$) en ambos grupos de edad (menores o igual a 55 y mayores o igual a 56 años). Además, el primer grupo mejoró significativamente las dimensiones del dolor (intensidad del dolor; $p<0,020$ e interferencia del dolor $p<0,030$). En cambio, el segundo grupo, no sólo mejoró las dimensiones del dolor (intensidad del dolor; $p<0,002$ e interferencia del dolor $p<0,001$), sino que también alcanzó diferencias

significativas en los dominios que valoran la calidad de vida, es decir, la sintomatología, la función física y el impacto general, todas $p<0,001$. Por otro lado, la capacidad aeróbica (valorada con el test de 2 minutos elevando rodillas) solamente alcanzó asociación inversa significativa con la intensidad del dolor ($p=0,04$), interferencia del dolor ($p=0,020$) y el impacto FM ($p=0,020$) en mujeres jóvenes (**study II**). En relación a los síntomas específicos de la fibromialgia, al finalizar las 24 semanas de intervención, las participantes alcanzaron diferencias significativas en calidad de sueño ($p<0,05$), hecho que no ocurrió para la ansiedad y fatiga, ambas $p>0,05$ (**study III**).

Conclusiones: **i)** El programa de fortalecimiento muscular gradual fue efectivo para mejorar la función física, sintomatología e impacto general a las 12 y 24 semanas en mujeres diagnosticadas de FM (**study I**); **ii)** Además, produjo mejorías en la condición física (a nivel de fuerza muscular y capacidad aeróbica) y dolor independientemente del grupo de edad. Sin embargo, la calidad de vida (función física, impacto y síntomas) sólo mejoró en el grupo de mujeres mayores de 56 años. Por otro lado, las mejoras en los niveles de fuerza se asociaron positivamente con la calidad de vida y el dolor en ambos grupos. Sin embargo, las mejoras en la capacidad aeróbica sólo se asociaron con una mayor calidad de vida (función física, impacto y síntomas) y dolor en el grupo de mujeres menores de 55 años. (**study II**); **iii)** El programa fue efectivo para mejorar la condición física, el dolor y la calidad del sueño. A pesar de mejorarlos niveles de la ansiedad y fatiga a las 12 semanas y al finalizar, el programa no fue efectivo para alcanzar diferencias significativas en ninguna de las dos fases (**study III**).

Palabras clave: incapacidad; comportamiento sedentario; fortalecimiento muscular; actividades diarias; dolor; sintomatología; función física.

ABSTRACT

Introduction. Fibromyalgia (FM) is a disease characterized by a complex symptomatology with the presence of generalized chronic musculoskeletal pain the prevailing disabling symptoms. This pathology generates high expenses not only for patients but also for the health care system. The consequences of FM are exacerbated by sedentary lifestyle that leads to a decrease in physical fitness and as a results most of the patients affected by this condition have difficulties in carrying out the activities of daily living which triggers physical inactivity and increased risk of disability. The current treatment for FM is palliative, as there is no healing. Among the strategies to reduce physical and psychological symptoms and thus to improve quality of life is physical activity. Most studies show the effects of physical exercise through aerobic and aquatic training programs on this pathology. Despite this research, few studies assessed the effects of strength training and the adequate combination of intensity, volume and duration aimed at improving daily activities and relieving pain, sleep disorders, fatigue, and anxiety.

Objective: In this context, the main aim of this doctoral thesis was to assess the effects of a gradual muscle strengthening program focused on daily activities in order to improve the symptomatology, physical functionality and impact of FM to achieve a better quality of life.

Methods: A quasi-experimental study was developed. The sampling was intentional and it was carried out in the fibromyalgia association of the Community of Madrid (AFIBROM). A total of 41 participants met the inclusion criteria. All of them, were enrolled in the aforementioned muscle-based intervention program aimed at improving daily activities. This muscle-strengthening program started with self-loads exercise and

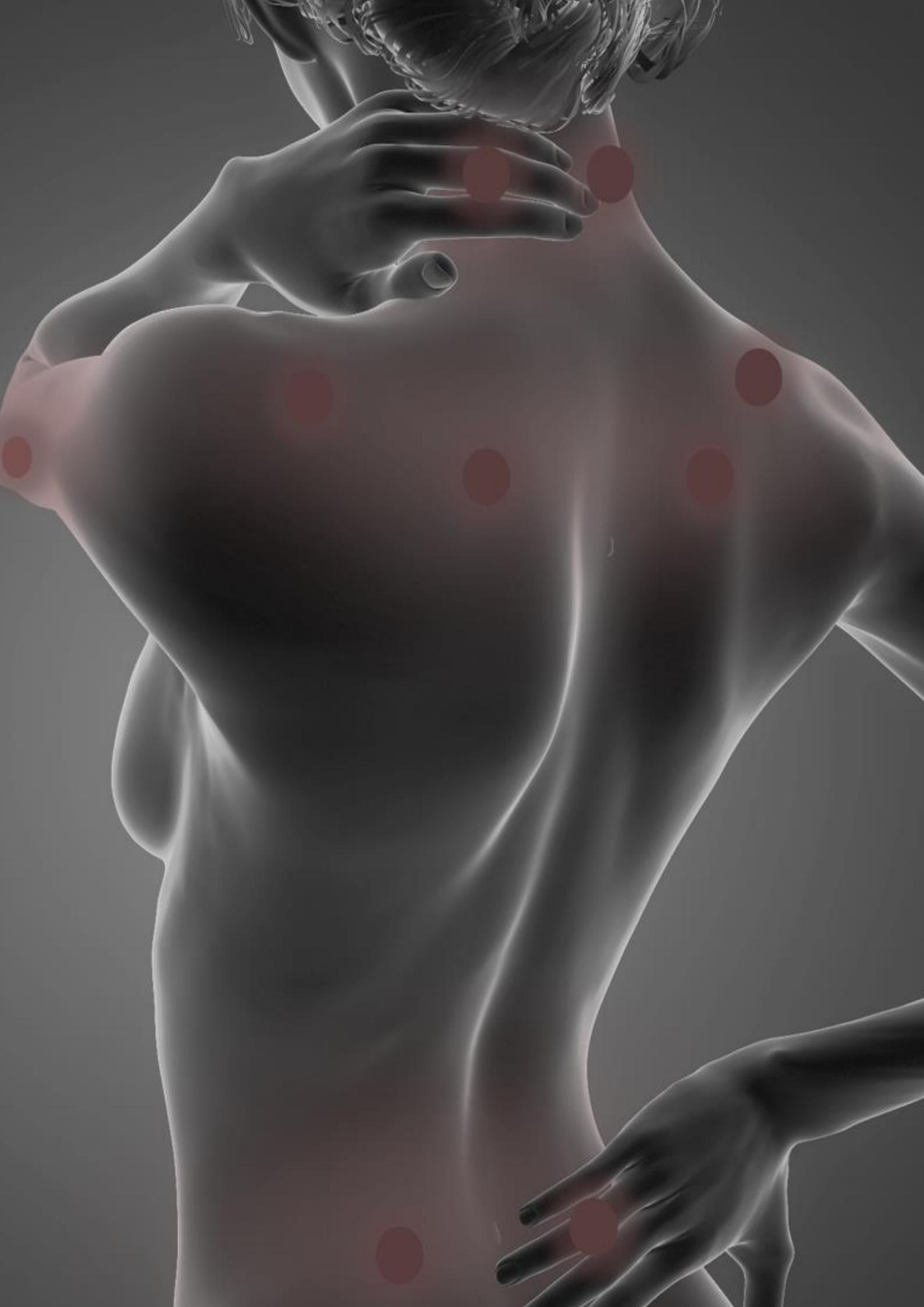
it was gradually progressing to strength work by using elastic bands and ending with free weights. A graduate student in Sports Science developed training sessions. The frequency of sessions was two days a week (not consecutive) with a total of 60 minutes/session. Adherence to the program was 90%. The intervention lasted 24 weeks and participants were evaluated in three occasions: one week prior (pre), in the middle (week 12) and one week after finishing the intervention program (week 25). The variables analysed were: pain intensity and pain interference using the Brief Pain Questionnaire (BPQ), FM impact, physical function and symptomatology using the Revised Fibromyalgia Impact Questionnaire (FIQR) and anxiety with the Anxiety Questionnaire Inventory (STAI). The internal load of the sessions was controlled and standardized by the use of OMNI-GSE visual scale specific for adult population in strength training.

Results: Significant differences and high clinical effects were obtained in all strength tests ($p<0.002$) and quality of life dimensions (physical function; $p<0.002$, overall impact; $p<0.002$, and symptomatology, $p<0.003$) at week 12 and 25 (intervention ended) (**study I**). The training program improved physical fitness ($p<0.001$) in both age groups (less than or equal to 55 and greater than or equal to 56 years). In addition, the first group significantly improved pain dimensions (pain intensity; $p<0.020$ and pain interference $p<0.03$). In contrast, the second group, not only improved pain dimensions (pain intensity; $p<0.002$ and pain interference $p<0.001$), but also achieved significant differences in domains that value quality of life, that is, symptomatology, physical function and overall impact, all $p<0.001$. Moreover, aerobic fitness (assessed with the 2-minute step test) only reached significant inverse association with pain intensity ($p=0.04$), pain interference ($p=0.02$) and FM impact ($p=0.02$) in younger women (**study II**). Regarding the specific symptoms of FM, at the end of 24 weeks intervention, participants reached significant

differences in sleep quality ($p<0.05$), a fact that did not occur for anxiety and fatigue, both $p>0.05$ (**study III**).

Conclusions: **i)** The gradual muscle-strengthening program was effective in improving physical function, symptomatology and FM impact at 12 and 24 weeks in women diagnosed with FM (**study I**); **ii):** This program produced improvements in physical fitness (both at the level of muscle strength and at the aerobic level) and pain regardless of age group. However, quality of life (physical function, impact and symptoms) only improved only in the group of women over 56 years of age. Moreover, improvements in aerobic fitness are only associated with increased quality of life (physical function, impact and symptoms) and pain in the group of women under the age of 55. (**study II**); **iii)** In addition, this program was effective in improving physical fitness (upper and lower limb strength, lower limb flexibility, and aerobic fitness), pain, and sleep quality. Despite improvement levels of anxiety and fatigue at 12 weeks and at the end of the muscle strengthening program (week 25). This was not effective in achieving significant differences in either phase (**study III**).

Key words: disability; sedentary behavior; muscle strengthening; daily activities; pain; symptomatology; physical function.



I. INTRODUCTION

I.1. CHARACTERISTICS OF FIBROMYALGIA

Fibromyalgia is a chronic disease, characterised by a variegated clinical picture (Gerwin, 2013). Until recently, it was a rather under-recognised entity, and some clinicians even doubted its actual existence. However, since 2010 the American College of Rheumatologists (ACR) has provided clear diagnostic criteria that can help clinicians to recognise this disease (Segura-Jiménez *et al.*, 2014; Triñanes *et al.*, 2014) and treat patients accordingly. One of the most important features is generalised pain that severely influences the quality of life. Moreover, these patients can also present with insomnia, depressive symptoms, gastrointestinal disturbances, etc.

I.1.1 *Definition*

Fibromyalgia is a chronic disease characterized by widespread musculoskeletal pain as the main symptom, associated with the presence of multiple locations of tender points (Wolfe *et al.*, 1990). Chronic widespread pain is defined as pain for at least three months in both sides of the body, both above and below the waist (Wolfe *et al.*, 1990, 1995) . This disease has been considered as a disorder regulation of unknown aetiology (Sarzi-Puttini *et al.*, 2008), characterized by increased sensitivity to painful stimuli (hyperalgesia) and lowered pain threshold (allodynia) (Staud and Domingo, 2001). However, fibromyalgia has recently been defined as a complex dimensional disorder with pain as main symptom (Wolfe *et al.*, 2013) associated with others of similar importance, such as fatigue, non-restorative sleep, mood alterations, stiffness, cognitive problems, depression, anxiety and poor health-related quality of life (HRQoL) (Silverman *et al.*, 2010; Segura-Jimenez *et al.*, 2015a; Wolfe, 2015).

I.1.2 Evolution of knowledge

Over the past 20 years, research in the clinical field as well as the neurophysiological basis for this disorder has been increasing. The clinical concept of FM was initially mentioned by Yunus *et al.*, (1981) in the publication of 1990 American College of Rheumatology (ACR) criteria for the FM classification (Wolfe *et al.*, 1990). An evolution of the clinical understanding of FM over the last two decades has emphasized the importance of symptoms beyond pain. In this context, it was necessary to establish criteria for a correct diagnosis.

Therefore, the new definition of FM affirms that symptoms are not an all-or-nothing with the possibility of presenting with varying severity (Wolfe *et al.*, 2011). The research setting has provided clinical specialists with the confidence to acknowledge a condition that presents with only subjective symptoms and no objective clinical findings (Perrot, Dickenson and Bennett, 2008). Furthermore, dysregulation of pain processing has been shown at various levels in the nervous system, but we still lack an objective test in the clinical setting to confirm a diagnosis or gauge response to treatments (Yunus, 1983; Perrot, Dickenson and Bennett, 2008).

The clinical challenge of this condition remains as there so that is still no objective clinical finding or test to confirm the diagnosis, or to assess the severity of physical and psychological symptoms. This has generated controversy and clinical uncertainty, and a diagnosis of FM is often only considered when other diagnostic possibilities have been excluded (Ghazan-Shahi, Towheed and Hopman, 2012). This insecurity by health care professionals may be a factor leading to frequent use of unnecessary investigations and can contribute to excessive medicalization of patients. It has been clearly documented

that a definite diagnosis of FM leads to reduced health care use and better global patient health (White *et al.*, 2002b; Hughes *et al.*, 2006).

In summary, FM is a constant struggle for different reasons. This disease usually has a burden that negatively impacts on people's daily living (Fontaine, Conn and Clauw, 2010; Goes *et al.*, 2012; Segura-Jimenez *et al.*, 2015a; Costa *et al.*, 2017). People with fibromyalgia often require more resources from the health care system which leads to a burden on the economy (Sicras-Mainar *et al.*, 2009). Given that the signs of FM are invisible (e.g., pain, fatigue and depression), society often has negative responses to people with FM by, for instance, accusation of malingering, disbelieving, and lack of understanding (Kool *et al.*, 2009, 2013; Cameron *et al.*, 2018). The condition leads to controversy for researchers and clinicians, as the predisposing, triggering, and perpetuating factors related to FM and its symptoms are not consensually determined as yet (Clauw, 2014).

This paucity of knowledge may be, at least, in part responsible for the lack of a treatment that universally, uniformly, and relevantly helps to reduce the impact of the disease long-term (Macfarlane *et al.*, 2017).

I.1.2 Epidemiology

The prevalence of fibromyalgia varies from 0.5 to 5% depending on the country (White and Harth, 2001). In Spain, approximately 2.4% of the general population over 20 years old are affected (Mas *et al.*, 2008). In absolute numbers, this means that 70,000 patients are affected by FM in our country. The percentage of people affected in the Community of Madrid is 5% (Ramos, 2017).

By sex, approximately 4.2% of women suffer from disorder, whereas only 0.2% of men are affected, which is a female: male ratio of 21:1 (Mas *et al.*, 2008). Regarding

the distribution in age groups, FM appears in all age groups, with a maximum prevalence between 40-50 years (4.9%), while it is relatively infrequent in people over 80 years of age (Mas *et al.*, 2008; Marques *et al.*, 2017). Due to the low number of diagnosed fibromyalgia in men, research has mainly been focused on women, somewhat ignoring the study of fibromyalgia in men.

Researchers affirm that the percentage of affected individuals can vary according to the level of academic achievement, with the prevalence in the uneducated population being 4.8%, 3% with primary education and 0.6% with university education. Social class is also inversely related to prevalence, in that people active employment have a lower prevalence (32.7%) than the rest of the population (52.3%) (Mas *et al.*, 2008).

I.1.4 Diagnosis and symptomatology: fibromyalgia is more than just pain

Fibromyalgia is present in a heterogeneous population; i.e., the clinical picture is highly variable among people (Alvarez-Gallardo *et al.*, 2017a). Even within a person, symptoms of FM usually fluctuate daily (Finan *et al.*, 2011; Vincent, Whipple and Rhudy, 2016). Initially, FM was considered to be a condition of pain, and this concept was reinforced by the ACR criteria in 1990 which only included a) widespread pain for at least 3 months, b) tenderness measured by a physical examination with the presence of 11 of 18 tender points $\leq 4 \text{ kg/cm}^2$ (Wolfe *et al.*, 1990). This ACR classification criteria created a crude definition of fibromyalgia as widespread pain by imposing the presence of 11 tender points (Wolfe *et al.*, 2010). As time passed, objections to the 1990 ACR criteria developed, with the bases that the presence of different tender points cannot be an objective assessment of whole body pain (Salaffi and Sarzi-Puttini, 2012). Furthermore, digital palpation instead of algometry is the most widely used method among examiners (Fitzcharles and Boulos, 2003). Without an objective instrument, the application of an

equal pressure of 4 kg is therefore doubtful (Fitzcharles and Boulos, 2003; Salaffi and Sarzi-Puttini, 2012). In addition, FM has been recognized as a disease that is related to pain and non-pain symptoms (Wolfe *et al.*, 2014, 2016).

Today, the understanding of FM acknowledges that patients with FM have complex physical and psychological symptoms characterized by more than pain, presenting with other complaints present of variable intensity, such as fatigue, stiffness, depression and cognitive problems among others (Silverman *et al.*, 2010; Wolfe *et al.*, 2013). Accordingly, an updated version of the diagnostic criteria had been proposed by Wolfe *et al.* (2010) and Salaffi and Sarzi-Puttini (2012).

Later, the ACR published in 2010 the following preliminary criteria, emphasizing that they do not correlate with functional impairment. The diagnostic criteria are composed by two dimensions: a) Widespread Pain Index (WPI) as measure of the number of painful body regions, with the patients being asked to indicate in which of 19 body areas, they had pain during the week before. The minimum total score of WPI is 0 and the maximum total score is 19, b) The Symptom Severity (SS) score is a measure of symptomatology where the patients are asked to indicate the severity of fatigue, trouble thinking or remembering and waking up tired (unrefreshed) over the previous week; and to answer whether (or not) they have had pain or craps in the lower abdomen, depression or headache during the previous 6 months. The minimum total score of SS is 0 and the maximum total score is 12. This preliminary diagnostic criteria establish 3 conditions: i) WPI ≥ 7 , and SS ≥ 5 , or WPI between 3-6 and SS ≥ 9 ; ii) Symptoms have been present at similar level for at least 3 months; and iii) The patients do not have a disorder that would otherwise explain the pain.

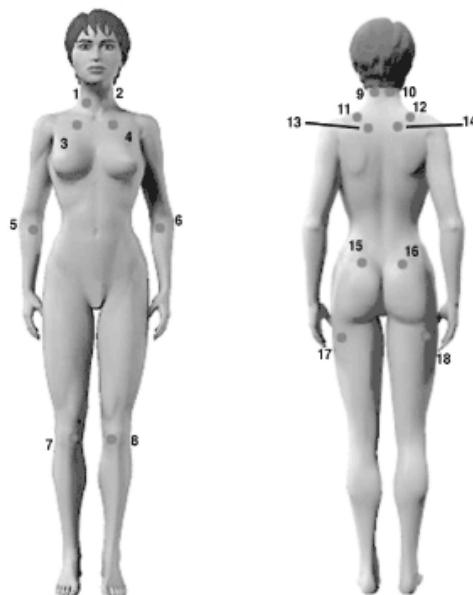


Figure 1. Distribution of trigger points in fibromyalgia (Villanueva Cerdá, Monsalve, Bayona, De Andrés, 2004).

Besides those mentioned above, other symptoms or associated conditions include restless legs syndrome, periodic limb movements in sleep, multiple chemical sensitivity and interstitial cystitis (Yunus, 2007a, 2007b). Each of these symptoms plays a variable role in the presentation of an individual patient and all contribute to a greater or lesser degree towards the overall effect of impaired quality of life and reduced functional activity.

All diagnostic criteria for FM include a compulsory presence of chronic pain (Wolfe *et al.*, 1990, 2014). It is assumed that hyperactivity of the central nervous system is a key player in processing stimuli that are usually not painful as painful (Lannersten and Kosek, 2010; Woolf, 2011). Researchers affirm that the concept of central sensitization is caused by different phenomena's such as the activation of painful pathways without an apparent stimulus causing the "non-nociceptive pain", due to the stimulation of fibers that lead to these painful sensations. That is, it is defined as an

anomaly in the perception of pain, so that stimuli that are usually not painful are perceived as painful (Plazier *et al.*, 2015).

The 2010/2011 ACR criteria correctly classify more than 87.033% of the cases that also met the previous criteria (ACR-1990) (Wolfe *et al.*, 1990). These criteria are a simple way of evaluating FM patients and allow for easier understanding and management of the pathology. However, the 1990 ACR criteria remain those accepted by the scientific community for the correct diagnosis of FM (Moyano, Kilstein and Alegre de Miguel, 2015). Moreover, the use of these criteria (ACR, 2010) (Wolfe *et al.*, 2010) is much discussed by rheumatologists, since it dispenses with physical examination and does not take into account any complementary study.

These 2010/2011 criteria generated disagreement regarding the erroneous classification of a small fraction of patients who did not present generalized pain (Egloff *et al.*, 2015). Misclassification occurs because the WPI, while indicating the number of painful sites, does not consider the spatial distribution of the sites. This problem can be obviated by imposing the requirement of meeting a widespread pain criterion, such as the 1990 criterion. However, the 1990 widespread pain criterion is often very restrictive (Wolfe, Egloff and Häuser, 2016). Therefore, the proposed criteria modifications now require the presence of what we have called “generalized pain,” to distinguish it from the 1990 definition of widespread pain.

An important consequence of this change is that one previous criterion for diagnosis, WPI of 3–6 and SSS ≥ 9 is not entirely correct since is now impossible to satisfy our modification with a WPI<4. The proposed generalized pain criterion is easier to use than the 1990 widespread pain, as it requires only a quick look by the clinician to decide if the patient meets the criterion. In the current (2016) revision of the criteria these areas

and headache and facial pain should not be included in the quadrant or region definition of generalized pain (Wolfe *et al.*, 2016).

FM may now be diagnosed in adults when all of the following criteria are met: (a) Generalized pain, defined as pain in at least 4 of 5 regions, is present, (b) Symptoms have been present at a similar level for at least 3 months, (c) Widespread pain index (WPI) \geq 7 and symptom severity scale (SSS) score \geq 5 or WPI of 4–6 and SSS score \geq 9, (d) A diagnosis of fibromyalgia is valid irrespective of other diagnoses. A diagnosis of FM does not exclude the presence of other clinically important illnesses (Wolfe *et al.*, 2016). Despite all this, there is no specific test for the diagnosis of FM, due to the fact that complementary explorations in these patients are intended to rule out the existence of other pathologies.

FM patients can experience important cognitive dysfunction, which is associated with pain, but not current depression or anxiety, and includes poor working memory, spatial memory alterations, free recall, and verbal fluency (Park *et al.*, 2001; Cánovas *et al.*, 2009; Rodríguez-Andreu *et al.*, 2009). Cognitive symptoms are present in FM even after adjusting data for age, medications, education, and depression (Cánovas *et al.*, 2009). However, cognitive changes were no different when compared to other pain patients, suggesting that pain may affect cognition (Walitt *et al.*, 2008). Although most patients experience associated symptoms to varying degrees, they are not a requirement for a diagnosis of FM.

FM may accompany other medical, neurological, or rheumatologic illnesses as a comorbid condition (Goldenberg, 2009). Conditions that have been associated with FM include amongst others various rheumatologic conditions such as systemic lupus, erythematosus and rheumatoid arthritis, as well as neurologic disorders such as multiple

sclerosis and post-polio syndrome (Trojan and Cashman, 1995; Goldenberg, 2009). It is important to appreciate that FM can coexist with these conditions in order to do a treatment appropriately. For example, a continuous complaint of pain due to FM in a patient with rheumatoid arthritis would be incorrectly treated by increasing treatments with disease modifying agents, rather than addressing the symptoms associated with FM (Plesner and Vaegter, 2018).

I.1.5 Treatment for fibromyalgia

Current evidence indicates that there is no unique ideal treatment that responds to the symptomatology of patients with FM, but there is a wide range of effective pharmacological (Sumpton and Moulin, 2008), cognitive behavioral (Castel *et al.*, 2012) and exercise-based interventions (Mannerkorpi and Henriksson, 2007; Goldenberg, 2008) and psychological-educative programs (Mannerkorpi and Henriksson, 2007; Castel *et al.*, 2012).

The **pharmacological treatment** is often used and among the most common are analgesics, non-steroidal anti-inflammatories, opioids and psychotropic drugs (Sumpton and Moulin, 2008; Fitzcharles, Ste-Marie and Pereira, 2013). Nutritional supplements are also commonly used (Tavoni *et al.*, 1987; Jacobsen, Danneskiold-samsøe and Andersen, 1991; Pate *et al.*, 1995). However, these treatments produce little benefit for the patient.

Medications should be used to complement a broad multidisciplinary program to address the treatment of fibromyalgia. The goal of treatment should be to achieve symptomatic relief, not the actual elimination of such symptoms. Patients should be fully informed of the various existing treatment modalities and should be able to freely adjust their own therapeutic plans, within reason. In these patients, polypharmacy is very common, and it should be avoided since it does not produce beneficial results. In addition,

all medication must be re-evaluated periodically, adjusting the dose in order to justify its continued use (Russell, 1996; Leventhal, 1999).

However, success in pharmacological treatment can be achieved if patients start with very low doses, increasing the dose until the desired therapeutic effect is achieved, or unacceptable side effects appear. According to **alternative medicines**, the mind-body exercise (which incorporates human biological and psychological aspects into treatment, with the intent of using the mind to affect physical functioning and promote health (Taggart *et al.*, 2003; Wang *et al.*, 2018) and relaxation therapies can increase pain tolerance in fibromyalgia patients (Carbonell-Baeza *et al.*, 2010; Carson *et al.*, 2010; Carbonell-Baeza *et al.*, 2011). Recently, there has been an increase in complementary and alternative modalities for managing fibromyalgia (some examples include: Tai-Chi, Biodanza, Yoga, breathing exercises) (Busch *et al.*, 2007; Rahman, Underwood and Carnes, 2014). These new approaches, with limited applicability not having scientific evidence, have been proposed in the last seven years (De Silva *et al.*, 2010; Oliveira *et al.*, 2017) so will require further investigation.

Evidence from the literature indicates that **non-pharmacological therapies**, particularly Physical Activity (PA) gradually and progressive of moderate intensity (Macfarlane *et al.*, 2016, 2017; Gavilán-Carrera *et al.*, 2018), provides the best outcomes for the treatment of fibromyalgia. This type of intervention must be incorporated into the treatment plan for each patient, as it has been shown to improve the psychological components of fibromyalgia, symptomatology and physical function (Busch *et al.*, 2008, 2013b; Busch, Webber, Brachaniec, Bidonde, Dal Bello-Haas, *et al.*, 2011; Nüesch *et al.*, 2012; Mist, Firestone and Jones, 2013; Bidonde, Busch, *et al.*, 2014; Bidonde, Busch, *et al.*, 2014b; Soriano-Maldonado, Ruiz, *et al.*, 2015; Cordoba-Torrecilla *et al.*, 2016; Jones, 2016; Bidonde, Busch, Schachter, Overend, Kim, Goes, *et al.*, 2017).

There is persuasive evidence that also induces positive changes in the brain areas associated with pain processing (Flodin *et al.*, 2015; Ellingson *et al.*, 2016). These findings raise the prospect that movement may be ‘disease modifying’ or at least affects key underlying physiologic perturbations. Recommending exercise in a clinic setting remains more of an ‘art’ than a ‘science’. Prescription of PA should be specific and targeted to the type of symptoms that these patients present (Jones, 2016b).

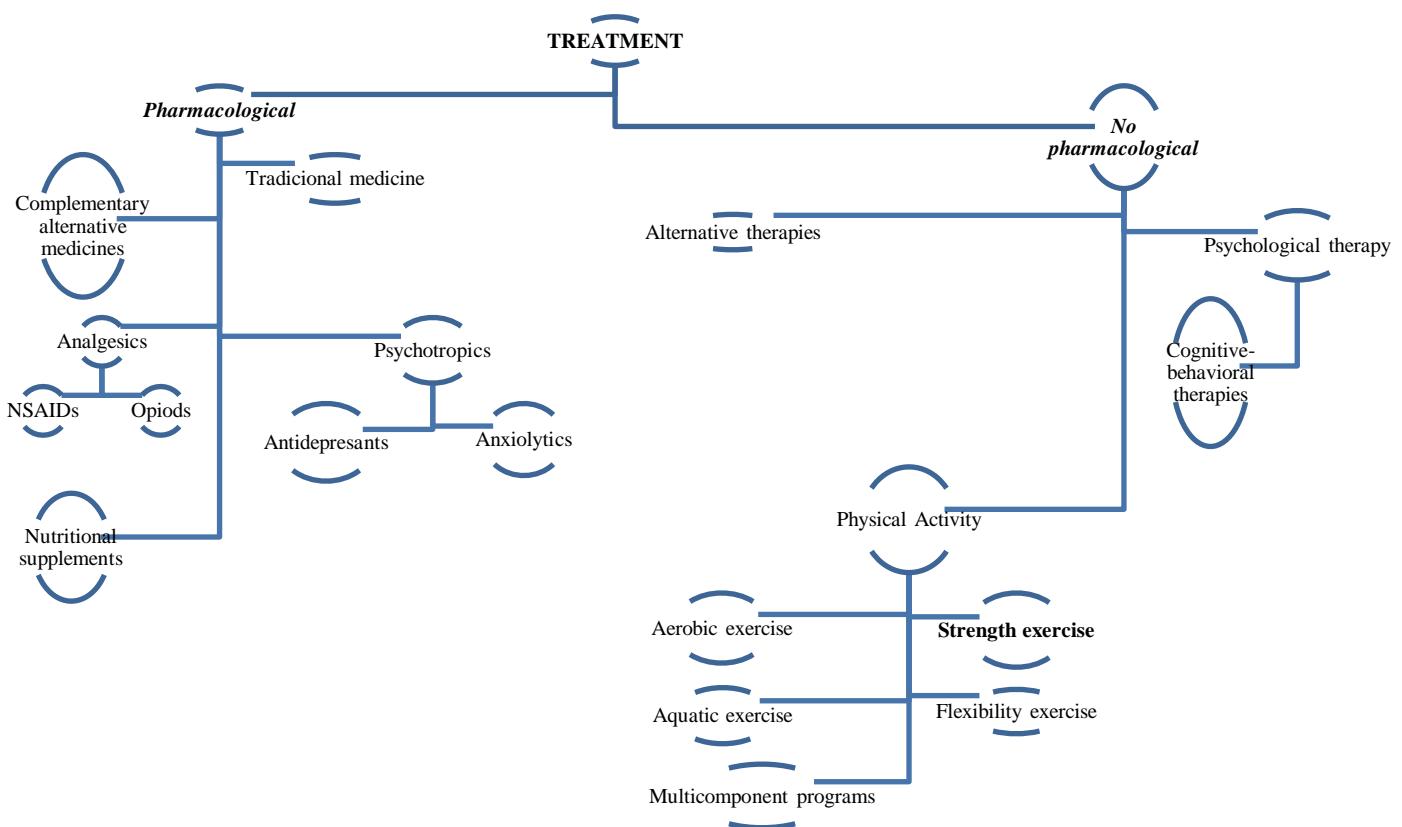


Figure 2. Classification of the different treatments applied to fibromyalgia.

Although there are several treatment options available, the optimal management for FM remains elusive. Clinical guidelines recommend a broad range of pharmacological and non-pharmacological therapies (Carville *et al.*, 2007; Häuser, Thieme and Turk, 2010). Nevertheless, there is evidence that physical exercise can have an impact on the clinical presentation of patients with FM. Indeed, exercise is considered to be the main non-pharmacological strategy in the management of FM.

I.2 QUALITY OF LIFE: AGING AND FUNCTIONAL LIMITATIONS IN FIBROMYALGIA PATIENTS

In general, not dependent on FM, as a result of the aging process, the efficacy of various physiological functions begins to decrease slightly until it becomes more evident at about 55 years of age (Pate *et al.*, 1995). Sarcopenia as consequence of the ageing process is associated with functional loss and disability and, as a consequence, poor quality of life and increased mortality (Doherty, 2003). The mechanism that explains the process of sarcopenia approaches that the decrease in muscle mass is associated with a decrease in muscle strength, which in turn decreases physical performance, limiting the performance of the usual activities of daily life, increasing disability and dependence (Koca *et al.*, 2016). From the age of 55, the slow decline in muscle mass and strength accelerates sharply, especially in sedentary people (Hughes *et al.*, 2002).

The consequences of FM are exacerbated by a host of comorbidities and a sedentary lifestyle leading to declines in physical abilities, functional impairments, and increased risk for disabilities (Clauw and Crofford, 2003; Mannerkorpi, Svantesson and Broberg, 2006; Bennett *et al.*, 2007a) leading to decreased levels of muscular strength and muscular resistance (Vandervoort, 2001). Patients with FM have functional limitations that are more debilitating or equal to those shown by persons with

osteoarthritis or rheumatoid arthritis (Hawley and Wolfe, 1991). They also demonstrate alterations in motor control associated with an increased risk of falls (Costa *et al.*, 2017). Furthermore, in people with FM (White *et al.*, 1999; Wolfe and Michaud, 2004), loss of function has been strongly associated with work disability.

Patients with FM need more time to complete activities of daily living (ADL) (walking and stair-climbing) and report more exertion compared to healthy volunteers (Huijnen *et al.*, 2015). It might be that the muscle recruitment pattern of patients with FM is altered resulting in a less efficient performance during daily activities. Therefore, these patients will need more energy to perform regular ADL (Vlaeyen and Linton, 2000), producing higher levels of fatigue in their daily life (Huijnen *et al.*, 2015).

Current evidence shows an association between physical fitness and symptoms of FM. According to Jones *et al.* (2008), reduced physical function is associated with pain intensity and fatigue in individuals with FM. Assumpcao *et al.* (2010) found certain association between pain intensity, pain threshold, and symptoms of FM, with muscular strength and dynamic balance. Also, changes in pain threshold and symptoms of FM could be caused by the effect of muscle strength and flexibility exercise, as the improvement in muscle strength, flexibility and dynamic balance produced a positive impact on overall pain. Since the evidence on physical exercise has been associated with a strong improvement in symptoms, a better knowledge of the relationship between physical function and severity of symptoms of FM is necessary in order to determine causality, as well as to design a guide for effective therapies.

The functional limitations produce a considerable impact on daily activities and quality of life. FM patients experience severe consequences on family environment due

to functional limitations, economic status, etc. In addition, the FM is often associated with constant changes in employment and job losses (Collado *et al.*, 2014).

It is therefore not surprising that FM shows a negative effect on the quality of life of affected patients (Wolfe *et al.*, 1997; Epstein *et al.*, 1999; Raphael *et al.*, 2004) as well as their relatives and spouses due to associated physical and psychological disorders (Tutoglu *et al.*, 2014). The ability to work can be considered an important aspect of quality of life. For patients with fibromyalgia, work is a way to contribute to society and meet other people, although it may present a burden when the symptoms of this disease affect the performance of job tasks, housework, and relationships with co-workers, among others (Palstam and Mannerkorpi, 2017; Amorós-Molina and Berlanga-Fernández, 2018).

Currently we find many sedentary work activities that involve little PA, such as spending many hours sitting, either in front of a computer, driving or attending a business. These aspects worsen the neuromuscular condition of the patient, which further aggravates the symptoms of fibromyalgia (Cathey, Wolfe and Kleinheksel, 1988; Collado *et al.*, 2014; Segura-Jimenez *et al.*, 2015b; Thieme *et al.*, 2015). Literature has shown that the majority of women presenting FM exhibit muscular desynchronization, being more susceptible to muscle damage with activity (Henriksson *et al.*, 1982; Bengtsson *et al.*, 1986; Panton *et al.*, 2006). Some authors have also found that one third of the women diagnosed with FM did not have the upper-body strength (force-generating capacity of a muscle) to carry out simple routine activities such as reaching high shelves or washing their hair (Wolfe *et al.*, 1990). Muscle strengthening exercise is an essential component of fitness, which refers an individual's ability to have the physical requirements for work and daily activities (Da *et al.*, 2000; Costa *et al.*, 2017).

I.3. PHYSICAL FITNESS IN FIBROMYALGIA PATIENTS

Levels of physical fitness (specifically, aerobic fitness and muscle strength) are powerful predictors of morbidity and mortality among in the general population (Blair *et al.*, 1989; Barry *et al.*, 2014) regardless of PA (Lee *et al.*, 2011; Eisenlohr-Moul *et al.*, 2015), age, smoking, adiposity, and other disease risk factors (Lee *et al.*, 2010). In fact, it is suggested that FM may have a larger impact on physical health rather than on psychological health (Segura-Jimenez *et al.*, 2015a). Among the physical impairments of FM patients, low levels of strength, endurance, flexibility, and poor balance are extremely relevant (Aparicio *et al.*, 2015; Muto *et al.*, 2015).

Theoretically, an association between fitness levels and pain can be expected based on modulating influences of the autonomic nervous system: low physical fitness may result in unbalanced autonomic nervous system function, which can impact on pain (Light *et al.*, 2009) or alternatively, pain may lead to a reduction in fitness, which brings about an unbalanced autonomic nervous system function (Geenen, Jacobs and Bijlsma, 2009).

Current evidence shows that the improvement of the already mentioned different components of the physical fitness are associated with lower levels of pain (de Bruijn *et al.*, 2011; Soriano-Maldonado *et al.*, 2015b), lower FM severity (Soriano-Maldonado, Henriksen, Segura-Jimenez, *et al.*, 2015; Collado-Mateo *et al.*, 2016) and better health-related quality of life (Carbonell-Baeza *et al.*, 2013; Soriano-Maldonado, Henriksen, Segura-Jimenez, *et al.*, 2015; Collado-Mateo *et al.*, 2016; Sener *et al.*, 2016). In addition, Aparicio *et al.* (2011, 2013b, 2015) suggested that physical fitness might be useful as a complementary tool in the diagnosis and monitoring of fibromyalgia (specially the

handgrip strength and 6 -min walk tests). Therefore, physical fitness might be considered a relevant health marker in people with fibromyalgia.

In this context, it is of clinical interest to provide standard reference values of different components of physical fitness using easy-to-use, inexpensive, feasible and reliable assessment tools for their quantification. The Senior Fitness Test battery (Rikli and Jones, 1999a,b) is a set of field-based tests widely used in patients with fibromyalgia (Carbonell-Baeza *et al.*, 2011; Cherry *et al.*, 2012; Aparicio *et al.*, 2013; Carbonell-Baeza *et al.*, 2015; Jones *et al.*, 2015; Soriano-Maldonado, Ruiz, *et al.*, 2015; Cordoba-Torrecilla *et al.*, 2016; Soriano-Maldonado *et al.*, 2016; Alvarez-Gallardo *et al.*, 2017b; Ofei-Dodoo *et al.*, 2018). Thus, it can be considered a feasible and reliable test to assess physical fitness in this population (Carbonell-Baeza *et al.*, 2015).

I.4 THE APPROACH TO PHYSICAL ACTIVITY IN FIBROMYALGIA.

Physical inactivity is one of the major public health problems of the 21st century (Blair, 2009) and several longitudinal studies have shown the negative consequences on health by leading a sedentary lifestyle (Thorp *et al.*, 2011; Katzmarzyk and Lee, 2012; Matthews *et al.*, 2012).

Several symptoms and functional limitations in daily life have been strongly associated with chronic pain, including deficient energy and muscular discomfort, physical mobility limitations, lifting groceries, climbing stairs and stooping (Björnsdóttir, Jónsson and Valdimarsdóttir, 2013). Moreover, female but not male, with chronic pain tend to refrain from PA (Björnsdóttir, Jónsson and Valdimarsdóttir, 2013). Pain-related fear in the fibromyalgia populations limits voluntary PA (Turk, Robinson and Burwinkle, 2004), and leads to fibromyalgia patients mostly spending their time in sedentary (Turk, Robinson and Burwinkle, 2004; Ruiz *et al.*, 2013).

Women with FM who are physically active seem to manage their ability to modulate pain better than those who are less active (McLoughlin, Stegner and Cook, 2011). It has also been suggested that peripheral mechanisms, such as abnormalities in microcirculatory capillaries (Morf *et al.*, 2004), irregularities in mitochondria (Castro-Marrero *et al.*, 2013) and alteration of muscle oxygen utilization (Shang *et al.*, 2012) might reduce peripheral tissue oxygenation and have an important role in central sensitization. In this context, an increase of tissue oxygenation following exercise could reduce peripheral and central sensitization and, consequently, reduce clinical pain (Hooten *et al.*, 2012).

Fibromyalgia patients can benefit from PA to maintain or improve their health (Busch, Webber, Brachaniec, Bidonde, Bello-Haas, *et al.*, 2011). International organizations support the use of PA-based interventions as a complementary tool in the therapeutic armamentarium against fibromyalgia (Brosseau, Wells, Tugwell, Egan, Wilson, Dubouloz, Casimiro, Robinson, McGowan and Busch, 2008). Fibromyalgia patients with active lifestyle patterns show greater physical function and lower levels of pain than those who tend to be physically inactive (Kop *et al.*, 2005; Fontaine, Conn and Clauw, 2010). This knowledge suggests the existence of a cyclic relation between PA and fibromyalgia symptoms (McLoughlin *et al.*, 2011). Despite the known benefits of PA on their symptomatology, fibromyalgia women are usually less physically active than control groups (McLoughlin *et al.*, 2011). Fibromyalgia patients decrease their PA levels due to fear of pain (Turk, Robinson and Burwinkle, 2004; Enlander, 2013; Nijs *et al.*, 2013) which will cause a worsening of symptom followed by higher levels of inactivity.

I.4.1 Strength training on symptomatology in FM patients

Exercise has been largely considered as a key component in a comprehensive treatment program for people with FM (Burckhardt, Clark and Bennett, 1993). The potential adverse effects of exercise depend on the level of exercise in relation to the participant's level of conditioning and age (Gearhart *et al.*, 2008; Cortez *et al.*, 2015). There is scientific evidence on the effects found following aerobic training programs (Nichols and Glenn, 1994; Wigers, Stiles and Vogel, 1996; van Santen *et al.*, 2002; Valim *et al.*, 2003; Ayan *et al.*, 2007; Günendi, Meray and Özdem, 2008; Thomas and Blotman, 2010; Sañudo *et al.*, 2010; Arcos-Carmona *et al.*, 2011; Hooten *et al.*, 2012; Cullinane *et al.*, 2014; Bardal, Roeleveld and Mork, 2015; Garcia-Hermoso, Saavedra and Escalante, 2015; Bidonde *et al.*, 2017), aquatic programs (Jespersen *et al.*, 2003; Gusi *et al.*, 2006; Tomas-Carus *et al.*, 2007; Bidonde, Busch, *et al.*, 2014), flexibility programs (Jones *et al.*, 2002; Matsutani, Assumpção and Marques, 2012) and those combined with others physical qualities (Jones *et al.*, 2000, 2002; Bircan *et al.*, 2008; Sevimli *et al.*, 2015) and also multicomponent programs (Hooten *et al.*, 2012). Several researchers studies have reported that strength training showed improvements in pain (Jones *et al.*, 2002; Valkeinen *et al.*, 2006; Figueroa *et al.*, 2007; Bircan *et al.*, 2008; Hooten *et al.*, 2012; Gavi *et al.*, 2014; Larsson *et al.*, 2015), physical function (Kingsley *et al.*, 2005; Valkeinen *et al.*, 2008; Gavi *et al.*, 2014; Palstam *et al.*, 2016), and sleep quality (Bircan *et al.*, 2008; Ericsson *et al.*, 2016; Andrade, Vilarino and Bevilacqua, 2017) , in addition to improvement in the quality of life of these patients.

In terms of emotional factors, it has been studied that low levels of well-being are clearly associated with the severity of fibromyalgia, fatigue, and pain (van Middendorp *et al.*, 2010; Estévez-López *et al.*, 2017). Previous studies suggest that women with fibromyalgia who present higher levels of strength achieved higher levels of subjective

well-being, specifically higher levels of positive affection and life satisfaction, as well as lower levels of negative affection (Maestre-Cascales *et al.*, 2019). Therefore, physical exercise programs that improve strength levels may not only provide physical but also psychological (i.e., higher levels of subjective well-being) benefits for women with fibromyalgia.

Most of the research related to physical exercise and FM has been done with the aim of improving the cardiorespiratory levels of patients. The idea of using strength training programs (STP) to relieve symptomatology is recent and was overlooked since it was believed that FM was directly caused by muscle trauma (Clark, Jones, Burckhardt and Bennett, 2001). Current research has shown that the etiology of FM may not be muscular, and therefore strength training may be beneficial. Fatigue is one of the first symptoms of FM (Geel and Robergs, 2002) and it is perceived at rest, during and after exercise, as well as days after exercise is restarted (Nørregaard *et al.*, 1994; Bendtsen *et al.*, 1997). In the first few seconds of exercise, the energy metabolism that takes the main contribution is phosphines, and it has been suggested that this metabolism is altered in people with FM (Geel and Robergs, 2002). Some authors (Geel and Robergs, 2002) showed that using STP, through exercises involving the body's most important muscle groups can normalize and reduce the amount of fatigue associated with exercise in people with FM (Bircan *et al.*, 2008; Ericsson *et al.*, 2016).

Muscle pain is the predominant symptom in people with FM (Karper, Hopewell and Hodge, 2001). Increases in myoglobin (Mgb) and creatinkinase (CK) are associated with muscle damage and pain (Nørregaard *et al.*, 1994). Studies that have investigated plasma Mgb and CK concentrations before and after exercise found no significant differences between people with FM compared to the controls group. These data suggest that although muscle pain is present, it may not be due to muscle damage (Bidonde,

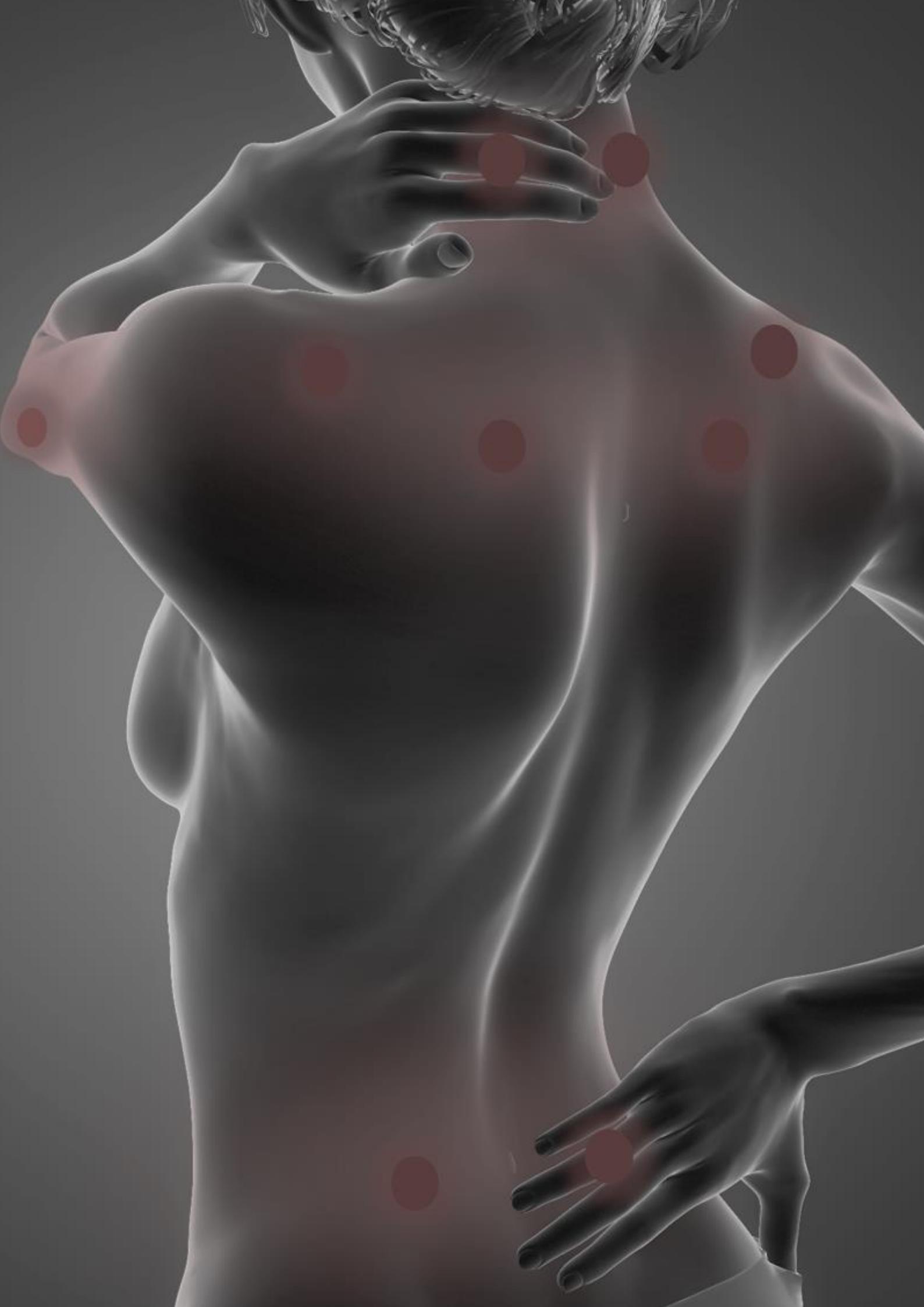
Angela Jean Busch, *et al.*, 2014a). However, studies that have used strength training programs have found that so-called delayed onset muscle soreness (DOMS) is clearly evident in people with FM (Clark, Jones, Burckhardt and Bennett, 2001; Karper, Hopewell and Hodge, 2001; Häkkinen *et al.*, 2002). This delayed pain is the acute effect of predominantly eccentric training (Sherman, 1992; Folland *et al.*, 2001). In the case of FM patients, it is suggested that the key to optimal strength training is the reduction of eccentric exercise and the inclusion of pauses at the end of each movement, which may help to avoid the appearance of some of these DOMS experienced by FM patients (Sherman, 1992; Clark, Jones, Burckhardt and Bennett, 2001).

Several studies have examined the effect of STP on the symptoms of patients with FM, however these studies have been conducted over short periods of time, generating discordance in the results obtained (Nichols and Glenn, 1994; Häkkinen *et al.*, 2001; Bircan *et al.*, 2008a; Hooten *et al.*, 2012; Gavi *et al.*, 2014; Roman, Campos and García-Pinillos, 2015; Andrade, Vilarino and Bevilacqua, 2017). However, the influence of ST in a progressive and long-lasting approach oriented to the daily activities on pain intensity and interference, anxiety state, impact disease, physical function, fatigue, and sleep quality has not been investigated deeply.

Since STP for the treatment of FM for the treatment of FM patients' symptoms, studies detailing exercise protocols are needed. The current study presents a possibly treatment option that can be used to alleviate the patient's symptoms by altering daily activities to improve the patient's quality of life. In clinical practice, the use of ST is feasible and requires few resources. Starting strength training programs at light intensities and then progressing to moderate, moderate-high intensities can help alleviate symptoms and provide global health benefits (Maestre-Cascales, Peinado Lozano and Rojo González, 2019).

MAIN EXPECTED CONTRIBUTION OF THIS THESIS

Gradual intervention programs based on muscle strengthening exercise and oriented towards ADL are needed in order to reduce the loss of functional ability, improve physical, psychological symptoms and the impact of fibromyalgia. The vast majority of the studies including training programs in FM people are focused on aerobic, flexibility, and combined exercise. So, there is little literature about gradual strength exercise on daily activities, being a major limitation in fibromyalgia patients. Regarding methodology, a 24- week's strength training program focused on daily activities with gradual and progressive intensity was applied. Moreover, the current study compared the different phases to assess the evolution of fitness, physical and psychological symptoms and FM impact. Therefore, we aim to contribute to the advancement of knowledge about the effects of a gradual muscle strengthening program (24 weeks) oriented to the ADL on the quality of life in people diagnosed with fibromyalgia.



II.HYPOTHESIS AND OBJECTIVES

II.1 HYPOTHESIS AND OBJECTIVES

The symptomatology, functionality, impact and severity of fibromyalgia can be improved through physical activity programs. People diagnosed with fibromyalgia present a sedentary lifestyle due to limitations caused by this disease. As a consequence of incapacity, fitness levels are low, in particular, muscle performance is impaired. Therefore, the main aim of this PhD. thesis was to contribute to the knowledge regarding the effect of gradual muscle strengthening program on quality of life in FM population. This PhD. thesis was composed by 3 sequential studies that represent the subsections of this thesis.

GENERAL HYPOTHESIS

Hypothesis: A gradual muscle strengthening program can improve symptoms, physical function, and overall impact in women diagnosed with FM.

GENERAL OBJECTIVE

Objective: To analyse the effects of a 24-week gradual muscle strengthening program oriented to daily activities on the symptomatology, physical function and overall impact in women diagnosed with FM residents in the Region of Madrid.

Hypothesis and objectives of Study I

Hypothesis: A gradual muscle strengthening program will increase strength levels and physical function decreasing overall symptoms and the impact of FM significantly in women diagnosed with FM.

Objective: To analyze the evolution of physical fitness (upper and lower limb), symptomatology, physical function and overall impact throughout the 24 weeks of a gradual muscle strengthening program.

Hypothesis and objectives of Study II

Hypothesis 1: A gradual muscle strengthening program will significantly increase fitness regardless of age. However, the group over 56 years of age will benefit most at the end of the program in their quality of life (physical function, symptoms, and impact) by attenuating the effects of sarcopenia that do not impact so heavily on women under 55 years of age.

Hypothesis 2: Strength-related fitness tests will show association with quality of life and pain as it has been suggested in the literature a gain in strength levels will improve these symptoms.

Objective 1: To evaluate the effects of strength training on physical fitness, pain, and quality of life (symptoms, physical function, and overall impact) in women with FM establishing a cut-off point on the basis of the beginning of the aging and muscle decline.

Objective 2: To determine the association between physical fitness and pain, impact, physical function, and symptomatology in both age groups.

Hypothesis and objectives of Study III

Hypothesis: A gradual muscle strengthening program will significantly improve anxiety, sleep quality, fatigue, pain intensity, and pain interference in women diagnosed with FM.

Objective: To examine the effect of a 24-weeks gradual muscle strengthening program oriented to daily activities on sleep quality, fatigue, pain domains, physical function and anxiety state in women diagnosed with FM.



III. MATERIAL AND METHODS

As mentioned before, the present PhD. thesis correspond to the intervention program (24 weeks) carried out in first person in collaboration with the Association of FM, Region of Madrid (AFIBROM). Figure 3 shows the timeline of all tasks performed during the 4 years of the doctoral program in relation to the present study.

Throughout this chapter, all materials and methods used to develop the publications related to this intervention program are detailed.

International Doctoral Thesis

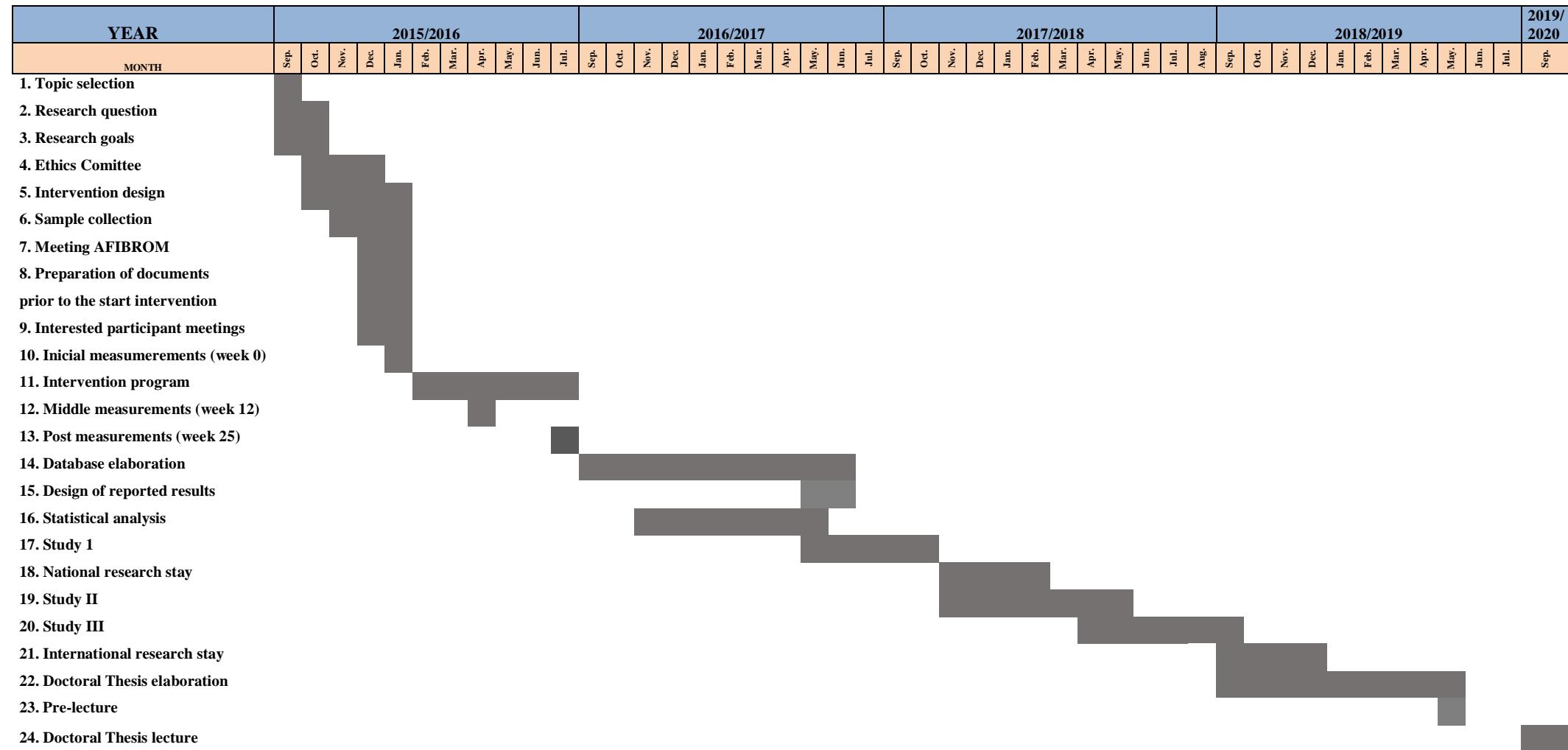


Figure 3. Timeline process for all task developed in this doctoral thesis.

III.1 DESIGN:

The studies were quasi-experimental uncontrolled trial with 24 weeks of intervention without control group. Data collection took place at three moments; (i) in week 0, before starting the intervention (January 2016); (ii) in week 12, midway through the intervention programme (April 2016); and (iii) week 25, at the end of the intervention (June 2016). The programme, as mentioned above, lasted 24 weeks, starting in week 1 and ending in week 24. The study was conducted in Madrid. Table 1 provides an overview of the timeline of this methodology and table 2 provides an overview of the methods of each study elaborated the PhD. thesis.

Regarding to the intervention program, from 21 March to 3 April (two weeks intervention) coincided with holiday's period. Therefore, in order to maintain the adherence of the participants, a special program of exercises was designed specifying: the methodology of work (being the same as in previous face-to-face sessions), the intensity, recovery intervals, exercises for the activation and relaxation phase, and specific exercises belonging to the elastic bands phase (**APPENDIX IV**).

Also, at the end of this period (week 25), a program was designed with all the characteristics worked during the 24 weeks of intervention; phases of exercise, intensity, series, recovery period, exercise intervals, in order to maintain adherence during summer holidays and to be able to incorporate again in September for the following course (**APPENDIX V**).

Table 1. Timeline of data collection and the intervention program.

2016*					
JANUARY	FEBRUARY	MARCH	APRIL	MAY	JUNE
1-3	1-7	1-6	4-10	2-8	6-12
18-24 Pre-data collection (i) Week 0	8-14	7-13	11-17 Middle-data collection (ii) Week 12	9-15	13-19
25-31 Pre-data collection (i) Week 0	15-21	14-20	18-24	16-22	20-26 End intervention Week 24
18-24 Start intervention Week 1	22-28	21-27 CATHOLIC HOLIDAYS	25-1	23-29	27-30 Post-data collection (iii) Week 25
25-31	29	28-3 CATHOLIC HOLIDAYS		30-5	

* The months are divided into weeks, from Monday to Sunday.

Table 2. Summary of doctoral thesis methods.

Study	Design ^a	Sample ^a	Main variables studied	Instruments
I	Quasi-experimental (week 0 VS week 12 VS week 25)	41 FM cases	Physical function, FM FIQR domains, OMNI-impact, symptomatology, GSE scale, fitness tests total score FIQR, physical fitness (upper and lower limb strength in dominant and non-dominant side).	arm curl and handgrip in dominant and non-dominant plus 30-s chair stand).
II	Quasi-experimental (week 0 VS week 25)	17 FM ≤ 55 years, 24 FM ≥ 56 years	Pain intensity, pain interference, physical function, impact FM, symptomatology, physical fitness (upper and lower limb strength in dominant and non-dominant side, and handgrip strength).	FIQR, BPIQ, OMNI-GSE scale, fitness tests (arm curl, 30-s chair stand, 2-minute step and handgrip strength)
III	Quasi-experimental (week 0 VS week 12 VS week 25)	41 FM cases	Pain intensity, pain interference, physical function (upper and lower limb strength, and flexibility), anxiety state, fatigue, and sleep quality.	FIQR, BPIQ, OMNI-GSE, scale, STAI-S fitness tests (sit and rich, arm curl, 30-s chair stand and 2-minute step).

ACR, American College Rheumatology fibromyalgia diagnostic criteria modified in 2010; BPIQ, Brief Pain Inventory Questionnaire; FIQR, Revised Fibromyalgia Impact Questionnaire; RCT, Randomised Controlled Trials; SWLS, Satisfaction with Life Scale; MMSE, Mini Mental State Examination; OMNI-GSE, OMNI Global Session in Elderly; STAI-S, State Anxiety-State Inventory.

a All the participants were women.

III.2 PARTICIPANTS

The study began with 55 women, of whom 14 participants withdrew from the study for different reasons (25%): 6 (11%) not meeting inclusion criteria, 4 (7%) other reasons, 3 (5%) incorporation to work due to medical discharge, 1 (2%) injuries due to a work accident. Finally, a total of 41 women with FM participated in the study. All of them were recruited by the FM association, Region of Madrid, AFIBROM (Spain) and were chosen using convenience sampling, that is, they were selected according to their availability and willingness to participate in the study. Figure 4 shows the participants who completed the study.

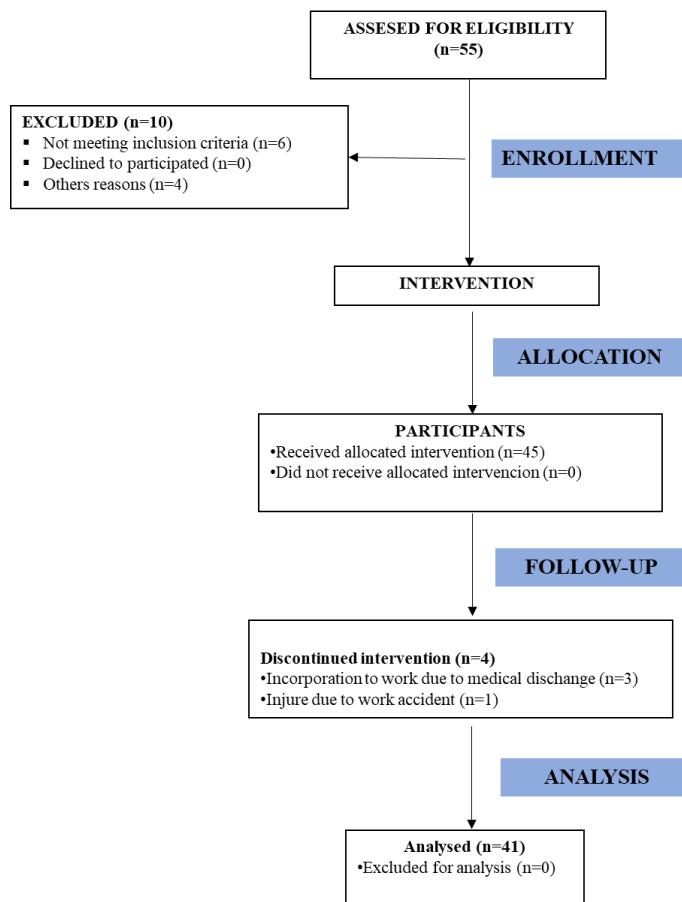


Figure 4. Consolidated standards of reporting trials flow diagram.

The inclusion criteria for people with fibromyalgia were: a) Women aged between 20 and 75 years old; b) Diagnosed with FM by a rheumatologist and meeting the American College of Rheumatology (ACR) criteria on examination according to the criteria of the American College of Rheumatology (Wolfe *et al.*, 1990); c) no physical disabilities; d) report no physical activity practise or a maximum of 1 weekly session, and e) able to communicate effectively with the study staff. Participants were excluded if they a) are male; b) disease that could be exacerbated by the practice of physical activity, such as cancer or heart disease; c) are in a gestational state; and d) change from usual care therapies during the intervention period.

III.3 ETHICAL CONSIDERATIONS

The Ethics Committee of the Universidad Politécnica de Madrid (Madrid, Spain) approved the studies of the current PhD. Thesis research project. The ethical guidelines of the Declaration of Helsinki (modified in 2000) were followed for all studies and all participants provided written informed consent before taking part in the studies (**APPENDIX III**).

III.4 PROCEDURE

Firstly, the fibromyalgia association of the community of Madrid was contacted to show them the design of the project and the importance of getting participants interested in participating in it (**APPENDIX I**). Then, all members of AFIBROM were informed via e-mail about the project to be carried out. Those interested attended a face-to-face meeting at the association where all formal aspects of the intervention were presented (training program contents, objectives, measurements, inclusion/exclusion criteria, etc.) (**APPENDIX II**). It was also mentioned that they would be subjected to a series of tests (non-invasive) and questionnaires at different times during the program. Then,

members interested in participating signed the informed consent and then filled out the sociodemographic questionnaire (related to personal and disease information). Once the questionnaires were collected, participants who did not meet the inclusion criteria were excluded. Measurements were performed on three different time points, as mentioned in the study design by the same researcher in order to reduce inter-examiners error. The first time point (week 0), the two weeks prior to the start of the intervention, baseline measurements were carried out, establishing a rigorous order in the protocol. First of all, the Revised Fibromyalgia Impact Questionnaire (FIQR), the Brief Pain Inventory Questionnaire (BPIQ), the State Anxiety Inventory (STAI-S), were completed. Then, the anthropometric measurements were assessed and finally, the Senior Fitness Test battery and dynamometry were used to evaluate physical fitness. For the second time point (week 12) and the third (week 25) the same evaluation protocol that was used that in week 0 was repeated.

III.5 INSTRUMENTS

QUESTIONNAIRES OUTCOMES

Sociodemographic and clinical data

The participants filled out an initial questionnaire designed by the researchers that included questions about gender, age, marital status, educational level, current occupational status, and time since diagnosis, drugs, therapies, years of onset of symptoms, year of diagnosis, pain-sensitive points, level of pain on a Visual Analogue Scale (VAS) of 0-100 and presence/absence of acute or terminal illness (such as cancer, stroke, recent cardiomyopathy, severe coronary disease, schizophrenia, or any other disabling injury).

The Revised Fibromyalgia Impact Questionnaire (FIQR)

The FIQR is a self-administered questionnaire, comprising 21 individual questions with a rating scale of 0 to 10. The questions compose 3 different domains; function (FD), overall impact (OID) and symptoms (SD) score (ranging 0-30, 0-20 and 0-50 respectively (Bennett *et al.*, 2009). The FIQR total score range from 0 to 100, with a higher score indicating greater effect of the condition on the person's life. We used the Symptom Impact Questionnaire with control participants. The SIQR (Friend and Bennett, 2011) is a slightly modified version of the FIQR used with non-fibromyalgia patients. Number of questions, domains and scoring is the same as the FIQR. We used the Spanish version (Salgueiro *et al.*, 2013).

The Brief Pain Inventory (BPI)

The BPI is a validated self-report measure of pain (Cleeland and Ryan, 1994) in two domains. Firstly, pain intensity/ severity domain (PID) through 4 items, and second, pain interference on daily functions domain, encompassing 7 items with a recovery period of the last 24 h (PITD). Both domains are scored with a numerical rating scale of 0-10 (0 pain and no interference, 10 pain is as bad as you can imagine and completely interfere) and were calculated as the mean of the element responses in each of both domains. The BPI has been used extensively in fibromyalgia studies (Arnold *et al.*, 2005; Bennett *et al.*, 2007a; Chappell *et al.*, 2008; Russell *et al.*, 2008; Mease *et al.*, 2011; Williams and Arnold, 2011). The pain intensity/severity domain was used to represent the symptom domain of pain.

The State Anxiety Inventory (STAI-S)

The STAI-S was used to assess the level current anxiety-state (Anxiety-S). This is a 20-item self-administered scale of current feelings “at this moment”: 1) not at all, 2) somewhat, 3) moderately so, and 4) very much so, using items that measure subjective feelings of apprehension, tension, nervousness, worry, and activation/arousal of the autonomic nervous system. The range of score is 20-80, with higher indicating a greater level of anxiety (White *et al.*, 2002a; Spielberger *et al.*, 2017).

The effort perception scale OMNI-GSE (Silva-Grigoletto *et al.*, 2013)

The OMNI-GSE scale was used to control and standardize the overall internal load based on which participants were asked to choose a score that reflected their perceived degree of effort previously, during and after training. The range is through VAS of 0-10 with the help of faces that represent the effort, with 0; being extremely easy and 10; extremely hard. This was developed to be used in collective classes (intermittent) with adult populations.



Figure 5. Participants filling the sociodemographic questionnaire.

CLINICAL MEASURES

Anthropometry and body composition

We used a portable eight-polar tactile-electrode impedanciometer (InBody R20, Biospace, Seoul, Korea) to measure body weight (kg), body fat (kg and %), skeletal muscle mass (kg) and Body Mass Index (%) (BMI). This last measurement was made at least two hours after the last lunch, with participants released from clothing and metal objects and having remained standing at least five min before the assessment. Following the manufacturer's recommendations, we asked them not to have a shower, not to practice intense physical exercise, and not to ingest large amounts of fluid in the hour before the measurement. The validity and reliability of this instrument are adequate (Malavolti *et al.*, 2003; Segura-Jimenez *et al.*, 2014).

Height (cm) was measured using a stadiometer (Seca 22, Hamburg, Germany). The waist and hip circumference (cm) was measured with the participant standing up. For the waist, the midpoint between the ribs and the crest of the ileum was used as a reference. And for the hip, the most prominent part of the gluteus above the symphysis pubis was used as a reference (Holtain Ltd) (Cruz, Armesilla and de Lucas, 2009).



Figure 6. Waist circumference measurement.

PHYSIOLOGICAL MEASURES

Blood Pressure and Heart Rate (HR) were evaluated at rest with a tensiometer (Omron PL-100 Pro Logic, United Kingdom) and a fingertip pulse oximeter (Beurer PO-30, Ulm, Germany) was used to measure oxygen saturation and it also showed the pulse rate.



Figure 7. Oxygen saturation and resting pulse

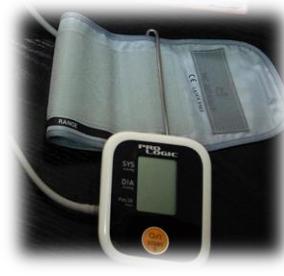


Figure 8. Blood Pressure and Heart Rate measurements with Omron PL-100 Pro Logic, United Kingdom.

PHYSICAL FITNESS TESTING

The Functional Senior Test battery was used because it is relatively easy to administer, safe, and requires minimal equipment and space (Rikli and Jones, 2013). It has shown no ceiling and floor effects, which is a relevant aspect for this study due to the heterogeneity of fibromyalgia patients (Wilson, Robinson and Turk, 2009). Therefore, the tests used are feasible to perform in clinical and community settings, and psychometric properties of these tests are adequate (Aparicio *et al.*, 2015; Carbonell-Baeza *et al.*, 2015). Furthermore, we also used the handgrip strength test which is commonly used when evaluating fibromyalgia patients (Carbonell-Baeza *et al.*, 2011). The main functional capacity components studied were:

Lower-body muscular strength

- The “**30-s chair-stand test**” involves counting the number of times within 30 seconds 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 arms were crossed at the chest level (Rikli and Jones, 1999). Higher scores indicate better performance.



Figure 9. 30-seconds chair-stand test.

- The **handgrip** strength test is valid, reliable and feasible (Nordenskiold and Grimby, 1993; Valkeinen *et al.*, 2008) as it provides useful information about the participant's overall muscle strength. It was evaluated using a TKK hand dynamometer as the systemic bias is small and has been shown to have the most reliable results when repeated measurements with known weights are used. The grip range is adjustable, using the formula suggested by Ruiz *et al.* (2006) to calculate the optimal grip distance: $y=x/5+1.5$; “x” being the hand size, and “y” the grip length. The participant squeezed gradually maintaining at least 2 seconds, performing the test with the right and left hand in turn. Each patient made two attempts with each hand, with the arm fully extended, forming an of 30° angle with respect to the trunk (Ruiz-Ruiz *et al.*, 2002). The maximum score in kilograms (kg) for each hand was recorded. For analysis, the mean score of the

left and right hand or as independent variables, dominant side and non-dominant side was used. Higher scores indicate better performance.



Figure 10. Handgrip strength test with dynamometer TKK.

Upper-body muscular strength

- The “**arm curl test**” which measures the number of times that, with the person seated, a hand weight (for women 2 kg or 1 kg if the test was adapted) can be curled through full range of motion within 30 seconds (Rikli and Jones, 1999). Patients performed one trial with both hands. For the analysis, the mean score of the left and right hand or as independent variables, dominant arm and non-dominant arm was used. Higher scores indicate better performance.



Figure 11. Arm curl test in resting position.



Figure 12. Arm curl test in maximum flexion.

Lower body flexibility

- The “**box sit-and-rich**” test involves sitting on the floor with legs stretched out straight ahead. Shoes should be removed. The soles of the feet are placed flat against the box. Both knees should be locked and pressed flat to the floor - the tester may assist by holding them down. With the palms facing downwards, and the hands-on top of each other or side by side, the participant reaches forward along the measuring line as far as possible. Ensure that the hands remain at the same level, none reaching further forward than the other. After some practice reaches, the participant reaches out and holds that position for a one-two seconds while the distance is recorded. Two attempts were recorded, collecting the best score achieved. Higher scores indicate a better performance.



Figure 13. Box sit-and-rich test.

Aerobic fitness

- The “**2-minute step test**” requires that the participant to walk in place, lifting her knees to an intermediate point between her kneecap and the iliac crest. Participants could use a wall or chair to maintain balance, if necessary. This test consists of completing cycles (1 cycle is 2 knee lifts, one with each leg) for two minutes. A higher step count indicates better cardiovascular fitness. The participants were asked to perform as fast as they could, keeping in mind their functional limitations. Higher scores indicate a better performance.



Figure 14. 2-minute step test.

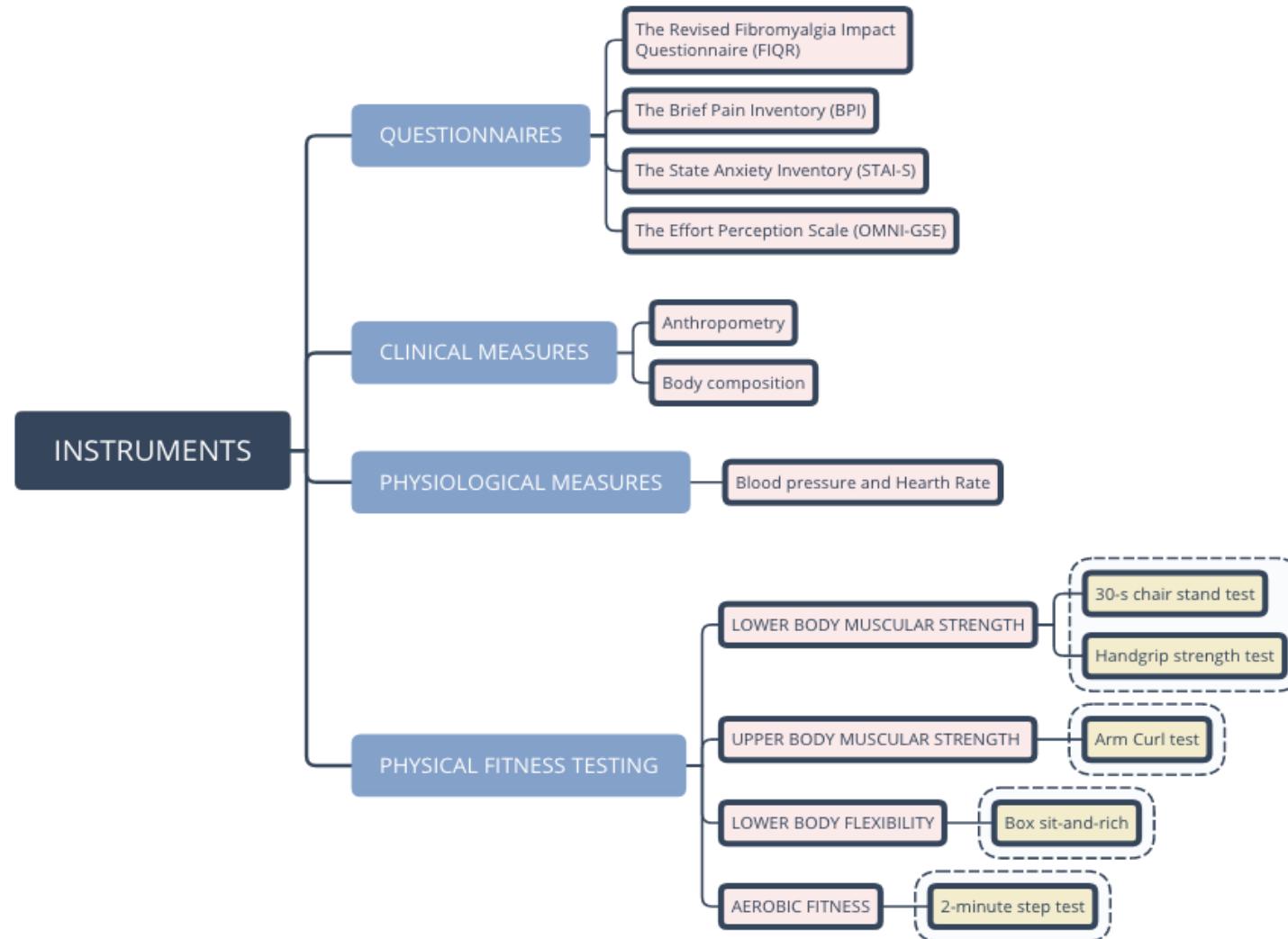


Figure 15. Instruments applied in this current study.

TRAINING PROGRAM

The program consisted of 24 weeks of supervised muscle strengthening in a group setting, progressively increasing in intensity (according to patient's tolerance), and transferable to the actions of daily life with exercise performed in the standing, sitting, and lying positions, in order to improve their physical fitness, in particular overall strength (Bircan *et al.*, 2008a). The frequency was two days a week with a duration of 60 minutes for each session. Volume and intensity were controlled throughout the program as described below (figure 5). The intensity was controlled by means of the OMNI - Global Session in the Elderly Scale (OMNI-GSE) (Silva-Grigoletto *et al.*, 2013) used in inexperienced people or in elderly populations, taking into account their incidence at the functional level (Gearhart *et al.*, 2009; Guidetti *et al.*, 2011; Colado *et al.*, 2012). Also, heart rate monitoring was performed by using a pulse oximeter (Beurer PO-30, Ulm, Germany) at the beginning, middle, and the end of each session.

The program included three different phases of progressive exercise in volume and intensity (Busch *et al.*, 2013a; Jones, 2016b). **1st phase (SL)** (*five weeks*): strength by self-loads including balance, coordination, and postural control. The intensity of effort was between 3-4 of the OMNI-GSE scale; **2nd phase (EB)** (*seven weeks*): elastic bands were included as resistance material along with the content of the first phase. The intensity was between 4-5 of OMNI-GSE scale, and **3rd phase (EL)** (*twelve weeks*): external loads together with the contents of the previous phases. The intensity was between 6-8 of OMNI-GSE scale.

The first 10 minutes of the session were devoted to joint mobility and movement. Then, 40 minutes of strength exercise including balance, coordination, and postural control and finally, 10 minutes of stretching and relaxation. The dynamic exercise was

through circuits. Each session covered two different circuits (six exercises each). Two series per circuit were performed in each session (Sanudo *et al.*, 2011). The initial work time was 30 seconds per exercise, increasing 5 seconds every two weeks until the participant reaches one minute of work per exercise (week 14). For the last 10 weeks the working time was kept at 1 minute. Recovery time was 30 seconds between exercise, 2-min between series and 5-min between circuits. At the beginning of the session an explanation/ demonstration of each exercise was provided in order to reduce the possibility of harmful movements.

In the 3rd phase, the load was set at a level that patients could easily manage. However, as in previous studies (Van Santen *et al.*, 2002; Kingsley *et al.*, 2005; Gearhart *et al.*, 2008; Sanudo *et al.*, 2011), during the course of this phase the level gradually increased according to the patient's tolerance, the individual knowledge of the symptoms and the level of general fatigue. At the beginning, during and end of every sessions the pulse and oxygen saturation was measured by oximeter as a safety precaution, as some participants presented feeling of fatigue or drowning during the exercise. The OMNI-GSE scale previously mentioned was administered.

The evolution of the load in this third phase, from week 13 to the end, week 24, depended on the characteristics of the participants (Sanudo *et al.*, 2011). The progression of the absolute load in the main muscle groups was from 0.2 to 2.0 for upper limb. Specifically, back work out ranged from 0.5 to 5.0, and finally, for lower limb the load varied from 1.5 to 3.0.

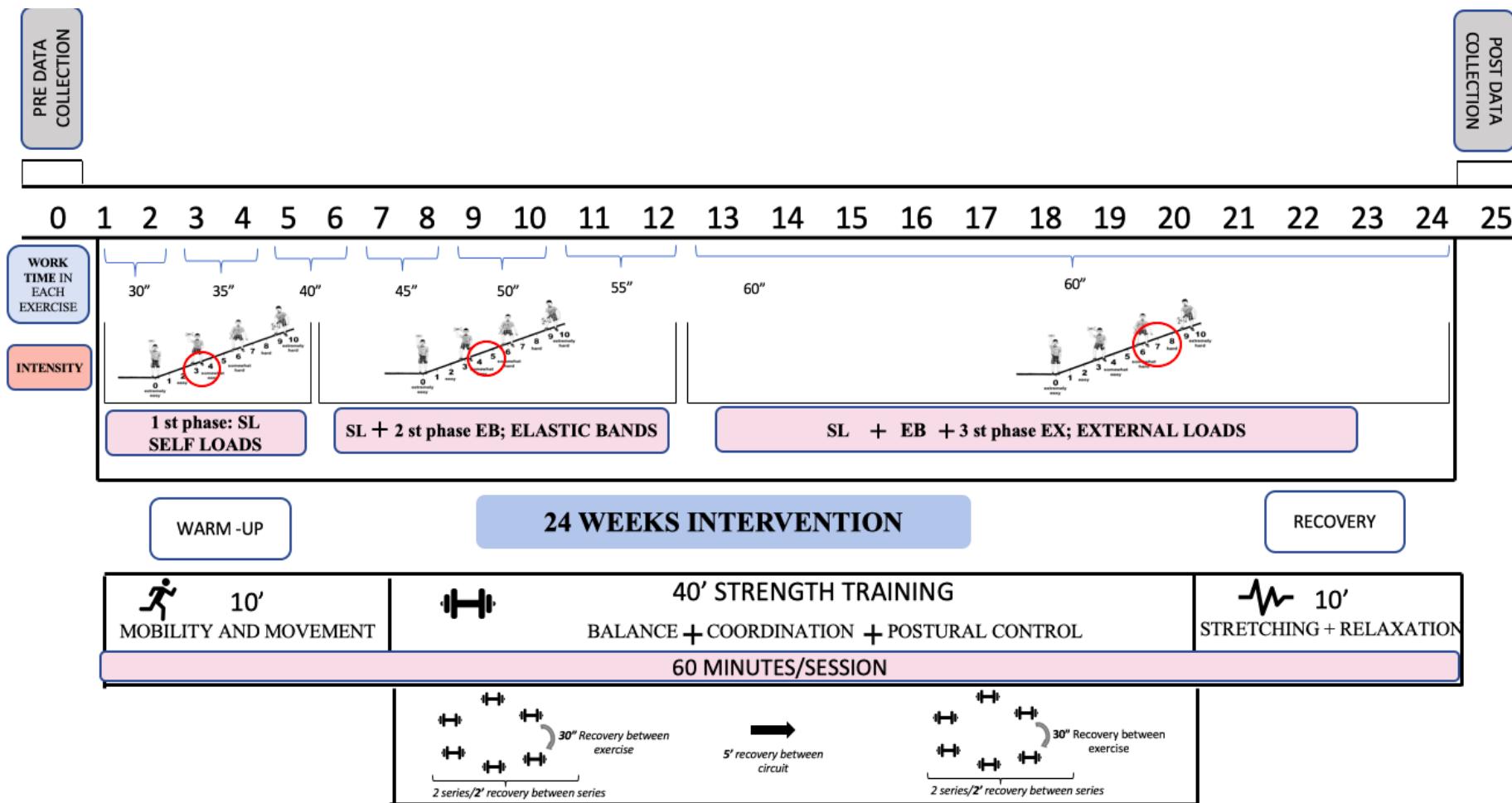
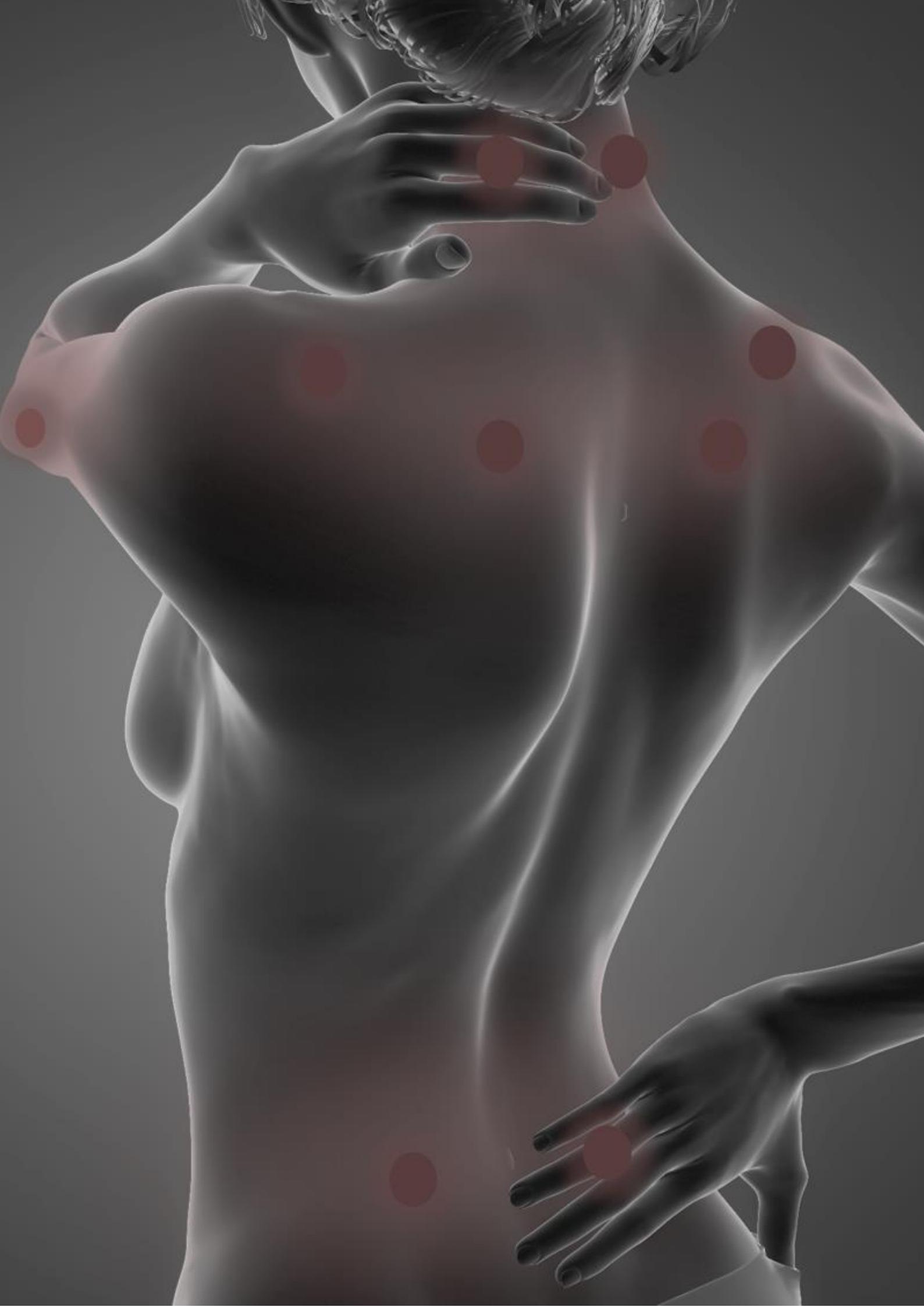


Figure 16. Intervention protocol based on strength training oriented to daily activities.



Figure 17. Strength training exercises in each protocol phase.

RESULTS are presented below for each contribution that constitutes the present doctoral thesis



IV. RESULTS

The results shown below are presented in the format of 3 research articles, which have been already published or submitted. Each article contains introduction, discussion and results independently.

The sections of each article depend on the format of each journal.

STUDY I

EFFECTS OF A STRENGTH TRAINING PROGRAM ON DAILY LIVING IN WOMEN WITH FIBROMYALGIA

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ABSTRACT

Background. Fibromyalgia, among other symptoms, is associated with poor physical fitness regarding the loss of muscle, which leads to an increase in muscle disability. This directly affects health because it causes limitations to perform daily living tasks.

Objective. The aim was to analyse the effect of a progressive strength training program on components that affect quality of life and to evaluate the changes produced as a result of the program. **Design.** Controlled quasi-experimental analytical study evaluating the response to the intervention program at three specific moments. **Methods.** 41 women with fibromyalgia fulfilling inclusion criteria participated in this study. Participants completed a total of 24 weeks of a training program based on strength work oriented towards daily living activities. The program consisted of a total of 3 progressive and controlled phases in volume and intensity in order to improve muscle strength that affects the performance of daily living activities. **Results.** We obtained statistical differences ($p<0.001$) and high clinical effects ($d>0.60$) in all strength test and all domains of the Revised Fibromyalgia Impact Questionnaire at the end of the intervention. **Conclusions.**

The improvement in functional capacity allowed them to perform tasks that were previously unfeasible. The muscle strengthening program based on strength exercise twice a week on non-consecutive days with a total duration of 1 hour, improves quality of life related to health, symptomatology, physical function, and severity of the condition.

1. INTRODUCTION

Fibromyalgia (FM) is a chronic disorder of unknown aetiology not only characterized by multiple painful regions in at least 12 weeks, but also by a series of added symptoms such as rigidity, loss of strength in extremities, non-refreshing sleep, fatigue, alteration of the mood, anxiety and depression (Carmona *et al.*, 2001; Sener *et al.*, 2016) and poor healthy associated quality of life (Casanueva *et al.*, 2016). Regarding prevalence in Spain is approximately 4.2 % of women suffer from this disorder, whereas only 0.2% of men are affected. Regarding to the distribution in age groups, FM appears with a maximum prevalence between 40-50 years old (4.9%) (Mas *et al.*, 2008; Marques *et al.*, 2017).

Most of FM patients are sedentary, so their current symptomatology is exacerbated by their poor physical fitness regarding muscle strength (Omoigui, 2007). As a consequence of the increasing muscle disability, these patients suffer from a deficit in their daily living performance and labour, social and family relationships are directly affected (Burckhardt, Clark and Bennett, 1993; Carmona *et al.*, 2001). It is also interesting to show that this incapacity is also preceded by manual grip strength poor levels (Nordenskiold and Grimby, 1993).

The most beneficial treatment for FM requires a multidisciplinary approach combining education, pharmacological treatment, exercise and cognitive behavioural therapy (Wolfe *et al.*, 1997; Sanudo *et al.*, 2011; Arnold *et al.*, 2012). Few studies have researched how this pathology affects physical function measurements, symptomatology, and overall impact on quality of life implementing a strength training program that includes types of resistance, intensities, frequencies and progression. Given the lack of clarity regarding which parameters are best suited for this population, there are

reservations about the prescription of physical activity mainly because the individuals who suffer from this pathology present different initial levels of physical fitness. Some of them can start with a moderate-high intensity, while for others such intensity can worsen the pain, raising the need to assess individual condition before starting any exercise program in order to adjust for exercise intensity (van Santen *et al.*, 2002). However, the findings of these studies indicate that strengthening exercises to regulate inflammation and muscle quality (Hwi-Ryun *et al.*, 2010) and could face limitations in the capacity to perform the routine tasks of daily life that have been observed in these patients (Kingsley *et al.*, 2005; Bircan *et al.*, 2008a).

The aim was to analyse the effect of a progressive strength training program including parameters of multiple dimensions of quality of life in women with FM and to evaluate the changes produced during the intervention comparing the same group at different time periods.

2. MATERIAL AND METHODOLOGY

2.1 PARTICIPANTS

All participants were part of the exercise group. The study began with 55 women, of who 14 withdrew from the study for different reasons (25%): 11% not meeting inclusion criteria, 7% other reasons, 5% incorporation to work due to medical discharge, 2% injuries to work accident. Finally, 41 women with FM participated in the study. The inclusion criteria were: a) women aged between 20 and 75 years; b) diagnosed with FM by a rheumatologist according to the criteria of the American College of Rheumatology (Wolfe *et al.*, 1990); c) not present disabilities, d) report no physical activity practise or a maximum 1 weekly session reported, and e) able to communicate effectively with the study staff. Participants were excluded if they a) are male; b) disease that could be

exacerbated by the practice of physical activity; c) are in a gestational state, and e) change from usual care therapies during the weeks of treatment. All participants were informed about the risks and benefits of the study. This study was approved by the Human Research Review Committee of the Universidad Politécnica de Madrid in accordance with the Declaration of Helsinki.

The contact with these participants was established through the Association of Fibromyalgia of the Community of Madrid (AFIBROM). The participants included in the study were chosen using convenience sampling, that is, they were selected according to their availability and willingness to participate in the study.

2.2. STRENGTH EXERCISE

The participants completed a total of 24 weeks of a gradual strength training program oriented to improve the ADL. The participants attended twice a week in non-consecutive days (1h/ session). The program consisted of three progressive and consecutive exercise phases, controlling volume and intensity in order to improve muscle strength that affects the performance of these activities. The intensity was controlled by means of the OMNI - Global Session in the Elderly Scale (OMNI-GSE) (Silva-Grigoletto *et al.*, 2013) used in inexperienced people or in elderly populations, considering their incidence at the functional level (Gearhart *et al.*, 2009; Colado *et al.*, 2012). The program involved a *1st phase* (SL): strength exercise by self-loads including balance, coordination and postural control (five weeks) whose intensity of effort was between 3-4 of the OMNI-GSE scale; *2nd phase* (EB): the first phase and including elastic bands as a training method to increase strength (seven weeks). The intensity was between 4-5 of OMNI-GSE scale, and *3rd phase* (EL): the first and second phase and including strength exercise with

external loads (twelve weeks). The intensity was between 6-8 of OMNI-GSE scale. All the participants completed the three phases at the same time.

The exercise session started with ten minutes of warm-up followed by some circuit work described below and finally ten minutes for cool down with stretching exercises. Each session covered two different circuits (six exercises each). Two series per circuit were performed in each session. The initial work time was 30 seconds per exercise, increasing 5 seconds of work every two weeks until the participant reaches one minute of work per exercise (week 14). For the last 10 weeks, the working time was kept at 1 minute. Recovery time was 2 min between the same circuits and 5 min between different ones. At the beginning of the session, a correct exercise explanation was provided in order to avoid harmful gestures.

In the *3rd phase*, the load was set at a level easily manageable for the patients. However, following the recommendations of the other authors (Kingsley *et al.*, 2005; Bircan *et al.*, 2008a; Gearhart *et al.*, 2009; Sanudo *et al.*, 2011), during the course of the study, the level gradually increased according to the patient's tolerance, knowledge of the symptoms and the level of general fatigue. At the beginning, during and end of all exercise sessions measurements of pulse and oxygen saturation by oximeter were taken due to feelings of fatigue or drowning in some participants. The OMNI-GSE scale previously mentioned was also used.

2.3 MEASURES

PHYSIOLOGICAL AND ANTHROPOMETRICS MEASUREMENTS

Height was measured with a stadiometer (Seca 22, Hamburg, Germany) and weight was assessed with a scale (InBody 720, Biospace, Seoul, Korea). Blood Pressure and Heart Rate (HR) were evaluated at rest with a tensiometer (Omron PL-100 Pro Logic, United Kingdom) and an oximeter fingertrip (Beurer PO-30, Ulm, Germany) was used to measure oxygen saturation.

QUESTIONNAIRE OUTCOMES

The sociodemographic questionnaire was used to obtain information about demographic and clinical variables as number of tender points and grade of pain. In addition, the Revised Fibromyalgia Impact Questionnaire (FIQR) in Spanish version (Salgueiro *et al.*, 2013) was used to evaluate domains as physical function (FD), overall impact (OID), symptoms (SID) and total score (TS). All questions were classified between 0-10 each one through numeric scale.

FITNESS TESTING

In order to measure physical fitness, a Senior Fitness Functional Test was selected because these tests are relatively easy and safe to administer and score and also require minimum of material and space. Among them we can find; the "30-s chair stand test", this consisted in counting the number of times within 30 seconds 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 "arm curl adapted test" (repetitions in dominant and non-dominant side with a weight 2 kg or 1 kg if the test was adapted, during 30 seconds sitting in the chair). This test to consider as a measure functional performance.

The participants were asked to perform as fast as they could considering the functional limitations.

Additionally, we also evaluated handgrip strength by using a hand-held dynamometer TKK 5101 Grip D; Takey (Tokyo, Japan). Each patient with the arm fully extended in a standing position performed two attempts with each hand (30° with respect to the trunk). The maximum score in kilograms for each hand was recorded.

3. STATISTICAL ANALYSIS

Descriptive statistics were used to present the characteristics of the sample (table 3). The Kolmogorov Smirnov test was used to determine normality. Normal distribution was assumed when the p-value was higher than 0.05. Differences between moments at week 0, week 12 and week 24 about characteristics were evaluated by comparing mean using the independent sample Student's T for parametric test. We used mix linear model for repeated-measures to analyse the evolution of strength levels ("30-s chair stand test", "arm curl adapted test" and "handgrip strength") throughout of training program phases (week 0, week 12 and week 24) on and how influences these changes in the quality of life using the domains (FD, OID, SID) and the total score of the questionnaire (TS) during the program. Secondly, Standardised Cohen'd effect size (ES) was calculated to verify the magnitude of the mean differences between program phases. The ES were interpreted based on the following criteria: <0.2 = trivial, 0.2 to 0.6 = small effect, >0.6 to 1.2 = moderate effect, >1.2 to 2.0 = large effect, and >2.0 = very large (Hopkins, 2006). The 90% confidence interval (CI) was also calculated. Magnitude Based Inferences were carried out to determine the beneficial, trivial or harmful effect, of the strength training phases. When a clear interpretation was possible, a qualitative inference was given as follows: 0.5% to 5%, very unlikely; 5% to 25%, unlikely; 25% to 75%, possibly; 75% to

95%, likely; 95% to 99.5%, very likely; and >99.5%, most likely (Batterham and Cox, 2006). SPSS version 22 (IBM; Armonk, NY, USA) and Microsoft Excel (Microsoft, Redmond, WA) were used to perform the statistical analyses. All tests were conducted with a 5% significance level ($p<0.05$). All data are presented as mean (SD).

4. RESULTS

General characteristics of the participants are summarized in table 3. Table 4 shown the evolution of questionnaire domains (FIQR) along the training program. Significantly different in all moments of measurements except the function domain between week 0-12 and overall impact between weeks 12-24 were observed. Figure 17 shown the evolution of strength levels where we obtained significant differences in all ($p<0.001$) test except the handgrip strength in both side between weeks 12-24.

Table 3. Baseline characteristics of women diagnosed with FM.

Variable (n=41)	Week 0 Mean (SD)
Age (yr)	56.36 (8.72)
Height (cm)	159.94 (5.72)
Body Mass Index (kg/m ²)	26.67 (5.38)
Weight (kg)	68.12 (14.04)
Heart Rate at Rest (bpm)	76.19 (10.31)
Systolic Blood Pressure (mm Hg)	122.24 (15.88)
Diastolic Blood Pressure (mm Hg)	72.56 (10.90)
Oxygen Saturation (%)	97.59 (1.90)

Notes

SD; Standard Deviation, bpm, beats per minute; mm Hg, millimetre of mercury; yr, years; cm, centimetres.

Table 4. Evolution of the Revised Fibromyalgia Impact Questionnaire (FIQR) domains along the strength training program.

Variable (n=41)	Week 0	Week 12	Week 24
	Mean (SD)	Mean (SD)	Mean (SD)
FD (Score)	57.17 (16.60)	52.19 (15.17)	46.97 ^{#\$} (15.64)
OID (Score)	13.0 (4.52)	10.76* (4.39)	9.44 [#] (4.12)
SID (Score)	68.927 (15.07)	62.95* (13.10)	53.39 ^{#\$} (13.10)
TS (Score)	139.10 (33.23)	125.90* (30.08)	112.78 ^{#\$} (29.88)

Notes

**p* between weeks 0-12, # *p* between weeks 0-24, \$ *p* value between weeks 12-24. SD, Standard Deviation, FD: Function Domain, OID: Overall Impact Domain, SID: Symptoms Domain; TS: Total Score domains.

Interaction between time of measurement about the strength tests in table 5 were found for strength levels significant results. Values relative to arm curl in dominant side ($F_{(2, 42.389)}=123.697$; $p<0.001$), for non-dominant side ($F_{(2, 41.166)}=105.597$; $p<0.001$), 30-s chair stand test ($F_{(2, 40.690)}=63.6910$; $p<0.001$), handgrip strength in dominant side ($F_{(2, 4.194)} = 46.671$; $p<0.001$) and finally, non-dominant side ($F_{(2, 40.690)} = 123.697$; $p<0.001$). The effect was greater at 24 weeks than at 12 weeks ($d>0.8$) except arm curl test in non-dominant size (in week 24; $d=0.60$ versus week 12; $d=0.13$) and the effect was considered small ($d=0.5$) in 12 weeks of training program. Moreover, in table 6 shown relevant results about the interaction between time of measurement and questionnaire domains during the evolution of training program. Values as function domain ($F_{(2, 40.477)}=9.070$; $p<0.001$), overall impact domain ($F_{(2, 40.545)}=10.932$; $p<0.001$), symptom domain ($F_{(2, 40.474)}=13.623$; $p<0.001$) and total score of three domains ($F_{(2, 40.622)}=4.208$; $p<0.001$). The effect size was large ($d>0.8$) when the 24 weeks ended except the function domain where the effect was medium ($d>0.5$ and $d<0.8$).

Table 5. Pairwise comparison of strength in upper and lower body in women diagnosed with fibromyalgia and their evolution throughout the intervention program. Results expressed as statistical significance, ES and magnitude-based inference.

Variable	Intervention program	ES (90% CI) ^c	P-value ^c	Chances of being positive/trivial/negative
Dominant	Week 0 vs Week 12	2.60 (1.56, 3.63)	<0.001 ^a	99.9/0/0
	Week 0 vs Week 24	3.57 (2.84, 4.30)	<0.001 ^a	100/0/0
	Week 12 vs Week 24	0.97 (0.44, 1.55)	<0.001 ^a	99.3/0/0
Non-dominant	Week 0 vs Week 12	1.95 (0.68, 3.21)	<0.001 ^a	99.2/0.5/0.4
	Week 0 vs Week 24	3.00 (1.97, 4.02)	<0.001 ^a	100/0/0
	Week 12 vs Week 24	1.05 (0.32, 1.78)	<0.001 ^a	98.5/1.2/0.3
30-s chair stand test	Week 0 vs Week 12	1.03 (0.31, 1.74)	<0.001 ^a	98.5/1.2/0.3
	Week 0 vs Week 24	1.60 (0.72, 2.48)	<0.001 ^a	99.5/0.3/0.2
	Week 12 vs Week 24	0.57 (0.04, 1.11)	0.001 ^a	93.3/6.0/0.7
Dominant-handgrip strength	Week 0 vs Week 12	0.59 (0.19, 0.99)	<0.001 ^a	97.2/2.6/0.2
	Week 0 vs Week 24	0.96 (0.39, 1.53)	<0.001 ^a	99.1/0.8/0.2
	Week 12 vs Week 24	0.37 (0.00, 0.74)	0.19 ^b	85.6/13.9/0.5
Non-dominant-handgrip strength	Week 0 vs Week 12	0.13 (-0.28, 0.53)	<0.001 ^a	32.8/62.7/4.5
	Week 0 vs Week 24	0.60 (0.24, 0.97)	<0.001 ^a	92.8/1.7/0.1
	Week 12 vs Week 24	0.48 (0.01, 0.95)	0.07 ^b	90.6/8.7/0.7

Notes. ES, effect size; CI, confidence interval. a. Significant pairwise comparisons; b. Non-significant pairwise comparisons; c. The Bonferroni correction.

Table 6. Pairwise comparison of the different dimensions of the overall impact of the disease in women diagnosed with Fibromyalgia and their evolution throughout the intervention program. Results expressed as statistical significance, ES and magnitude-based inference.

Variable	Intervention program	ES (90% CI) ^c	P-value ^c	Chances of being positive/trivial/negative	Qualitative inference
Function Domain (FD)	Week 0 vs Week 12	0.61 (0.17, 1.05)	0.001 ^a	67.6/24.8/7.6	Possibly Harmful
	Week 0 vs Week 24	0.63 (0.18, 1.17)	0.001 ^a	32.5/33.9/33.6	Possibly Beneficial
	Week 12 vs Week 24	-0.03 (-0.41, -0.46)	0.001 ^a	5.6/24.1/70.3	Possibly Beneficial
Overall Impact Domain (OID)	Week 0 vs Week 12	0.50 (0.06, 0.94)	0.001 ^a	100/0/0	Most likely Harmful
	Week 0 vs Week 24	0.82 (0.37, 1.27)	<0.001 ^a	100/0/0	Most likely Harmful
	Week 12 vs Week 24	0.77 (0.32, 1.23)	0.05 ^b	98.9/1/0.1	Very likely Harmful
Symptoms Domain (SID)	Week 0 vs Week 12	0.42 (-0.02, 0.86)	0.001 ^a	33.6/32.6/33.8	Possibly Beneficial
	Week 0 vs Week 24	0.81 (0.36, 1.26)	<0.001 ^a	10.8/15.8/73.4	Possibly Beneficial
	Week 12 vs Week 24	0.42 (-0.02, 0.86)	0.002 ^a	2.2/10.9/86.9	Likely Beneficial
Total Score (TS)	Week 0 vs Week 12	0.41 (-0.03, 0.85)	0.001 ^a	54.5/30.9/14.6	Possibly Harmful
	Week 0 vs Week 24	0.82 (0.37, 1.28)	<0.001 ^a	16.8/25.6/57.5	Possibly Beneficial
	Week 12 vs Week 24	0.22 (-0, 0.87)	0.001 ^a	2.3/11.8/85.8	Likely Beneficial

ES, effect size; CI, confidence interval; a. Significant pairwise comparisons; b. Non-significant pairwise comparisons; c. The Bonferroni correction.

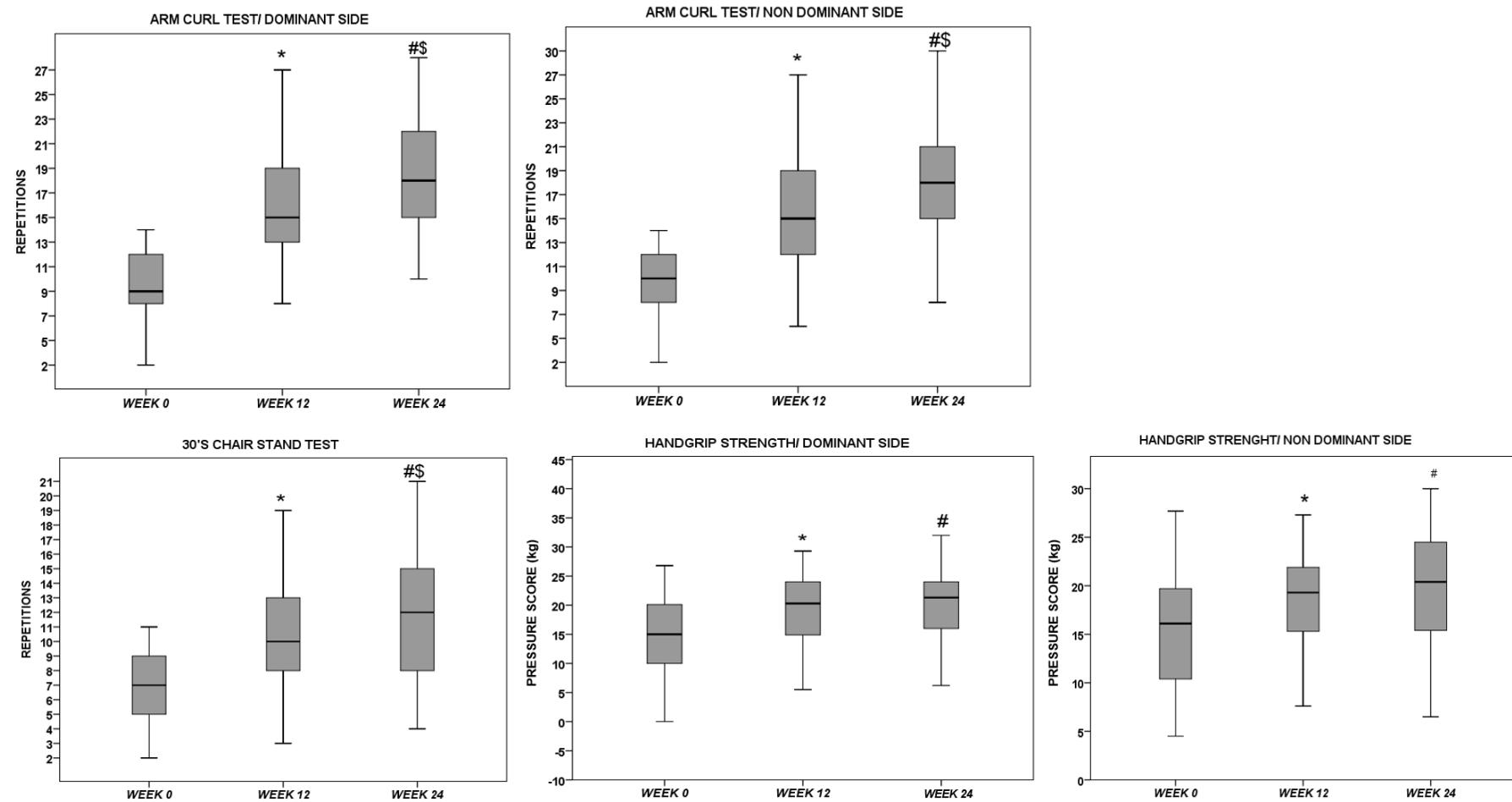


Figure 18. Median and interquartile evolution of strength levels through the training program expressed by repetitions in arm curl test (dominant and non-dominant side), handgrip strength (dominant and non-dominant side) and 30-s chair stand test. *P-value between weeks 0-12; #P-value between weeks 0-24; \$ P-value between weeks 12-24 weeks.

5. DISCUSSION

The main finding of this study was that the 24 weeks of gradual strength exercise oriented to daily activities was effective in improving the quality of life of women diagnosed with fibromyalgia. There is little consensus in the literature about the importance of exercise protocol in FM; however, there is some evidence that exercise interventions of longer duration are most effective (Valim *et al.*, 2003; Sanudo *et al.*, 2011; Bardal, Roeleveld and Mork, 2015). In our data, the benefits obtained at 24 weeks were greater than at 12 weeks, a fact that supports the finding provided by the authors mentioned. The idea of using strength training to improve physical and psychological symptoms is recent because it was overlooked due to its direct relationship to muscle trauma. Currently, several scientific studies has been suggesting that strength training could curb the poor physical fitness of the females affected (Jones, Clark and Bennett, 2002), although their treatment continues to be limited to a few studies (Valkeinen *et al.*, 2004; Kingsley *et al.*, 2005; Bircan *et al.*, 2008). Our data showed differences in symptom domains with the training program. The symptom improvement in these women with fibromyalgia, observed after completion of the 24 weeks intervention, would not have been as noticeable after an intervention of 12 weeks only.

Few previous studies have used a similar training program like the one implemented in the current study and also used the FIQR as their primary outcome. In one of these studies, a slight improvement in FIQ scores was shown after 12 weeks, but no statistical significance was reached (Kingsley *et al.*, 2005). Thus, a prolonged strength training programme, like the one used in our study would be necessary in order to achieve clinical and statistical improvements in female patients with FM. Another study compared the effectiveness of a strengthening program versus a flexibility program and showed

statistically and clinically significant changes in Fibromyalgia Impact Questionnaire (FIQ) score in the strengthening group only (Jones, Clark and Bennett, 2002). This finding confirms the results of our study where it was shown that important changes occurred in the total score domain (TS). In the same way other researchers also showed a reduction in number of active tender points, a tendency towards improvement in pain, sleep, and fatigue after 21 weeks of strength training and improvements in some FM symptoms after 8 weeks of strength training (Sanudo *et al.*, 2011).

These results are in line with ours, where it was observed that a 12-week program is already effective to reduce such symptoms. In addition, our results also indicate this effect to be greater with longer duration of the program similarly to the interventions mentioned above (Valkeinen *et al.*, 2004; Sanudo *et al.*, 2011). This effect is also reflected by the effect size in relation to the symptom domain obtained in our study. On the other hand, previous studies on resistance training found that women with FM who practiced strength and resistance training for 16 to 21 weeks improve in terms of ability to do normal activities, pain, tenderness, muscle strength, and overall well-being (Rebutini *et al.*, 2013; Dominguez, Garnacho-Castano and Mate-Munoz, 2016). In our study, no significant differences were obtained at 12 weeks and a medium clinical effect was observed with respect to the function domain dimension that encompasses the ability to perform activities. However, at 24 weeks there were highly significant and clinical differences. Furthermore, our results suggest that strength training programs might be a relevant component of physical fitness in this population.

Although exercise programs rarely focus on specific strength training, the present study provides evidence for future intervention based on strength exercise, since it is a component associated an increase in quality of life, specifically, physical function and

ability to perform daily activities, and a decrease in symptoms and impact of the disease (Kingsley *et al.*, 2005; Bircan *et al.*, 2008a). Considering these factors, we have designed a specific, adapted, and controlled strength training program, thus obtaining more representative and significant results than similar studies previously conducted (Kingsley *et al.*, 2005). The improvement percentages obtained in relation to the strength levels were in the lower limb 12%, in the dominant arm 139%, non-dominant arm 123%, dominant handgrip strength 46% and non-dominant 40%. The improvement of strength in the study was followed by very low changes in the body mass index (BMI) obtaining a loss of 1%.

More research is needed in this area to determine if women with fibromyalgia have the ability to increase the percentage of body mass through training programs. The clinical manifestations of FM usually appear when patients are in their 40 or 50 years of age. Hence, we can affirm that the majority of these patients are in the perimenopause stage. Body composition during this period of life is characterized by increased fatty tissue, particularly abdominal fat, undoubtedly due to the loss of oestrogen and the decrease in physical activity (Hwi-Ryun *et al.*, 2010). This phenomenon has been related to any number of metabolic disorders, such as dyslipidaemia, insulin resistance, high blood pressure, and an increase in coronary heart diseases (Folsom *et al.*, 2000).

In relation to the handgrip strength, is a common measurement used in the assessment of hand function. It can be used as an indicator of improvement to value the effectiveness and ability to realize daily activities (function domain) (Nordenskiold and Grimby, 1993). In previous studies, improvements in handgrip strength were observed at the end of the program (Valkeinen *et al.*, 2004). In our results, handgrip strength was initially lower than of the healthy control group analysed in other recent studies (Koklu *et al.*, 2016). In the dominant side, it was produced a high clinical effect at 24 weeks and

medium effect in 12 first weeks. In the no dominant side, a high clinical effect was established at 24 weeks and a medium effect in the first 12 weeks. In the no dominant side, the clinical effect in the first 12 weeks was null, and at the 24 weeks and the last 12 weeks the effect was medium. Being a musculature that is not greatly involved in life tasks, the improvement is proportional to the duration of the program that is, the longer the program, the greater the strength levels improvement. In contrast, in the dominant musculature, being constantly involved in daily activities, the effect is greater in the first weeks of the program, stabilizing with time.

Considering previous studies on handgrip strength, logistic regression analysis showed that handgrip strength 23.1kg or less was associated with 33.8 times higher odds for having FM after adjustment for age, and handgrip strength 16.9kg or less was associated with 5.3 time's higher odds for having severe FM (Aparicio *et al.*, 2011). Therefore, our results showed that the participants started with a severe FM (mean; 15.4 kg) and ended with a mean of 19.7 improving the impact of the pathology and moving to moderate FM.

The level of exercise adherence was high in our study given that patients who completed the study attended all of the exercise sessions. However, reduction in exercise adherence is common once supervised exercise programs are completed. Our research program continued one more year with the same line of work, achieving a 50% adherence among participants from the previous year, which would allow assessing possible improvement over the previous year. Another aspect to consider is exercising in a group setting, which provided additional benefits through increased social support within the group.

A major limitation of the study is the lack of inclusion of a "no treatment" control group. However, the previously described exercise intervention was compared across distinct time periods with time being an intragroup factor. These recommendations are largely approved in clinical settings and also from an ethical stance. Gains in functionality, symptomatology, and impact of the disease observed in the intervention might have been due to the goal of the study. Initially the participants consented to take part in a study that would prescribe and counsel them about strength exercise with the objective to increase fitness and improve life quality.

Considering the variety of symptoms and limitations due to fibromyalgia, the wide prevalence, and increasingly earlier onset of the disease, it is crucial to establish the domains, limitations, or affection points according to age group in order to design, prescribe, and treat the disease in a more specific manner within the different affected subgroups.

6. CONCLUSIONS

In conclusion, the results of this study demonstrate that a muscle strengthening program based on strength work twice a week on non-consecutive days with a total duration of 1 hour, improves quality of life related to health, symptomatology, physical function, and severity of the disease.

7. FUNDING

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8. ACKNOWLEDGEMENTS

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to all the participants who showed their interest in being part of this research. The experiments comply with the current laws of the country in which they were performed (Spain).

8. CONFLICT OF INTEREST

The authors declare that no conflict of interest exists.

9. AUTHORS CONTRIBUTIONS

CMC was involved in the conception and design of the study, the data acquisition, the analysis and interpretation of the data, ABP created the draft article or critical review of the content intellectual and JJR gave final approval to the version being presented. All co-authors have contributed to the published work and agree to its publication in JHSE

STUDY II

AGE-DEPENDENT RESPONSE TO EXERCISE IN WOMEN WITH FIBROMYALGIA

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ABSTRACT

To assess the association between physical fitness and pain, functionality, impact and symptoms in both age groups. This quasi-experimental study was conducted on 41 women diagnosed with fibromyalgia. All were recruited from the fibromyalgia association of the community of Madrid, Madrid. Data were gathered between January 18 and June 30, 2016. Both age groups received the strength intervention program. Physical fitness, pain and quality of life were evaluated using the Revised Fibromyalgia Impact Questionnaire (FIQR), the Brief Pain Inventory (BPI) and senior fitness test battery plus dynamometer, respectively. Physical fitness ($p<0.001$), pain intensity ($p<0.111$) and pain interference ($p<0.023$) improved significantly in both groups. However, the second group achieved significant differences also achieved differences in quality of life ($p<0.001$). Aerobic fitness only showed association with pain intensity and interference, and FM impact in younger women, all $p<0.05$. The program improves physical fitness (strength and aerobic fitness) and pain in both groups. Although the program has improved the quality of life in both groups, only in the older women group has it done so significantly because of those lower levels of baseline quality of life.

Key words: Strength-training, functionality, aging, aerobic fitness, fibromyalgia

1. INTRODUCTION

Fibromyalgia (FM) is a chronic disorder of unknown aetiology focused on the nervous system, characterized by widespread pain at least for 12 weeks, as well by series of additional symptoms such as rigidity, non-refreshing sleep, fatigue, alteration of the mood, anxiety and depression, memory problems and poor health associated to the quality of life (Carmona *et al.*, 2001; Perrot, Dickenson and Bennett, 2008; Casanueva *et al.*, 2016; Sener *et al.*, 2016). According to the maximum prevalence, FM seems to appear between 40-50 years old (4.9%) (Mas *et al.*, 2008; Marques *et al.*, 2017). In the Spanish population, approximately 4.2 % of women suffer from this disorder, whereas only 0.2% of men are affected.

Physical fitness of women with FM has been previously studied. Among the physical impairments of FM patients, extremely low levels of strength in upper and lower limbs, aerobic fitness and handgrip strength have been reported, often due to their sedentary lifestyles, reaching efforts dangerously close to their maximum ability level during normal activities (Muto *et al.*, 2015; Roman, Campos and Garcia-Pinillos, 2015; Segura-Jiménez *et al.*, 2015). In fact, it is suggested that FM may have a larger impact on physical than on psychological health. In this regard, physical fitness is reduced by the associated physical and psychological symptoms (Segura-Jimenez *et al.*, 2015b; Soriano-Maldonado, Estévez-López, *et al.*, 2015). The improvement of physical fitness (i.e., cardiorespiratory fitness, speed-agility, flexibility, and muscular strength) has been reported to be associated with lower levels of pain (de Bruijn *et al.*, 2011; Soriano-Maldonado, Henriksen, Segura-Jiménez, *et al.*, 2015), lower FM severity (Soriano-Maldonado, Henriksen, Segura-Jimenez, *et al.*, 2015) and better health-related quality of life (Carbonell-Baeza *et al.*, 2013; Sener *et al.*, 2016). In addition, researches revealed that physical fitness might serve as a complementary tool in the diagnosis and monitoring

of this disease (Aparicio et al., 2013; Aparicio et al., 2011; Rikli and Jones, 1999; Rikli and Jones, 2013).

According to the literature, aging-related sarcopenia is associated with a functional loss and disability and, as a consequence, a poor quality of life and a higher mortality (Doherty, 2003). The mechanism which explains these consequences appear to follow a logical order in which the decrease in muscle mass is associated with a decrease in muscle strength, which, in turn, decreases physical performance, making difficult to carry out the usual activities of daily life, and enhancing disability and dependence (Koca *et al.*, 2016). From the age of 55 onwards, the slow decline in muscle mass and strength accelerates sharply, especially in sedentary people (Hughes *et al.*, 2002). Moreover, several authors consider that from the age of 55, the aging period starts (Datan *et al.*, 1977). Therefore, the effectiveness of several physiological functions begins to decline slightly until it becomes more obvious at approximately 55 years old (Pate *et al.*, 1995).

The limitations of FM also have a considerable impact on daily activities and quality of life. In particular, it has been frequently shown that fatigue in this pathology may be severe enough to reduce physical activities and lead to a sedentary lifestyle by reducing physical abilities and increasing the risk of disabilities (Bennett *et al.*, 2007a; Jones *et al.*, 2008; Ghavidel-Parsa *et al.*, 2015). Furthermore, it has been shown that the loss of function could be strongly associated with work disability in these patients (White *et al.*, 1999; Wolfe and Michaud, 2004). It is also interesting to show that this incapacity is also preceded by poor levels of strength that affect to the performance of these activities (Koklu *et al.*, 2016).

Low levels of physical fitness, and the susequent limitations of physical inactivity, depend on physiological processes (e.g. sarcopenia) and symptoms associated (e.g.

intensity of pain, anxiety, fatigue, etc.). It has recently been reported that as part of the diagnosis, it is important to know the functional and symptomatic effects of age-related physical exercise on strength training (Marques *et al.*, 2017). However, few studies have investigated the effects of strength training on symptomatology, physical function and impact as a function of age group.

The main aim of this study was to evaluate the effects of strength training on physical fitness, pain, and quality of life (symptoms, physical function, and overall impact) in women with FM establishing a cut-off point on the basis of the beginning of the aging and muscle decline. A secondary purpose was to determine the association between physical fitness and pain, impact, physical function, and symptomatology in both age groups.

2. METHODS

2.1 PARTICIPANTS

41 women with FM participated in the study as shown in flow diagram (figure 1). The sample was divided in 2 groups according to their age, women ≤ 55 years old ($n=17$) and women ≥ 56 ($n=24$). The cut-off point was determined in 55 years due to the notable decrease in muscle strength levels and the decline in physiological functions associated with the aging process. All participants completed the test and the attendance was high (90%). Data from 17 of the 21 women allocated in the ≤ 55 year's old group were analysed, meaning a loss of 15%. For the ≥ 56 group, allocated 24 women without any loss (figure 1). The recruitment started in December 2015, and the study ended in June 2016. Both groups participated in the training program. The inclusion criteria were: a) women aged between 20 and 75 years; b) diagnosed with FM by a rheumatologist according to the criteria of the American College of Rheumatology; c) did not present

disabilities, d) physical activity practise or a maximum 1 weekly session reported, and e) were able to communicate effectively with the study staff. Participants were excluded if they a) were male; b) presented diseases that could be exacerbated by the practice of physical activity; c) were in a gestational state, and d) changed their usual care therapies during the 8 weeks of treatment. All participants signed the informed consent and were informed about the risks and benefits of the study. This study was approved by the Human Research Review Committee of the Universidad Politécnica de Madrid in accordance with the Declaration of Helsinki.

The contact with these participants were conducted through the FM association, Region of Madrid (AFIBROM). The participants included in the study were chosen using convenience sampling, that is, they were selected according to their availability and willingness to participate in the study.

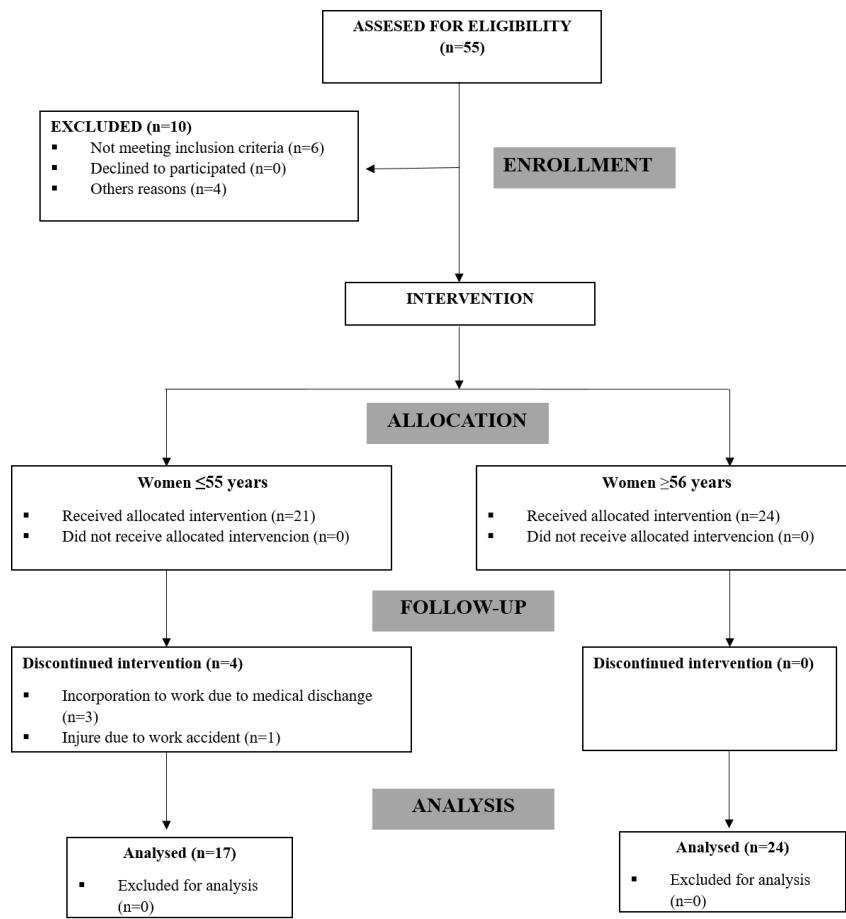


Figure 19. Consolidated standards of reporting trials flow diagram.

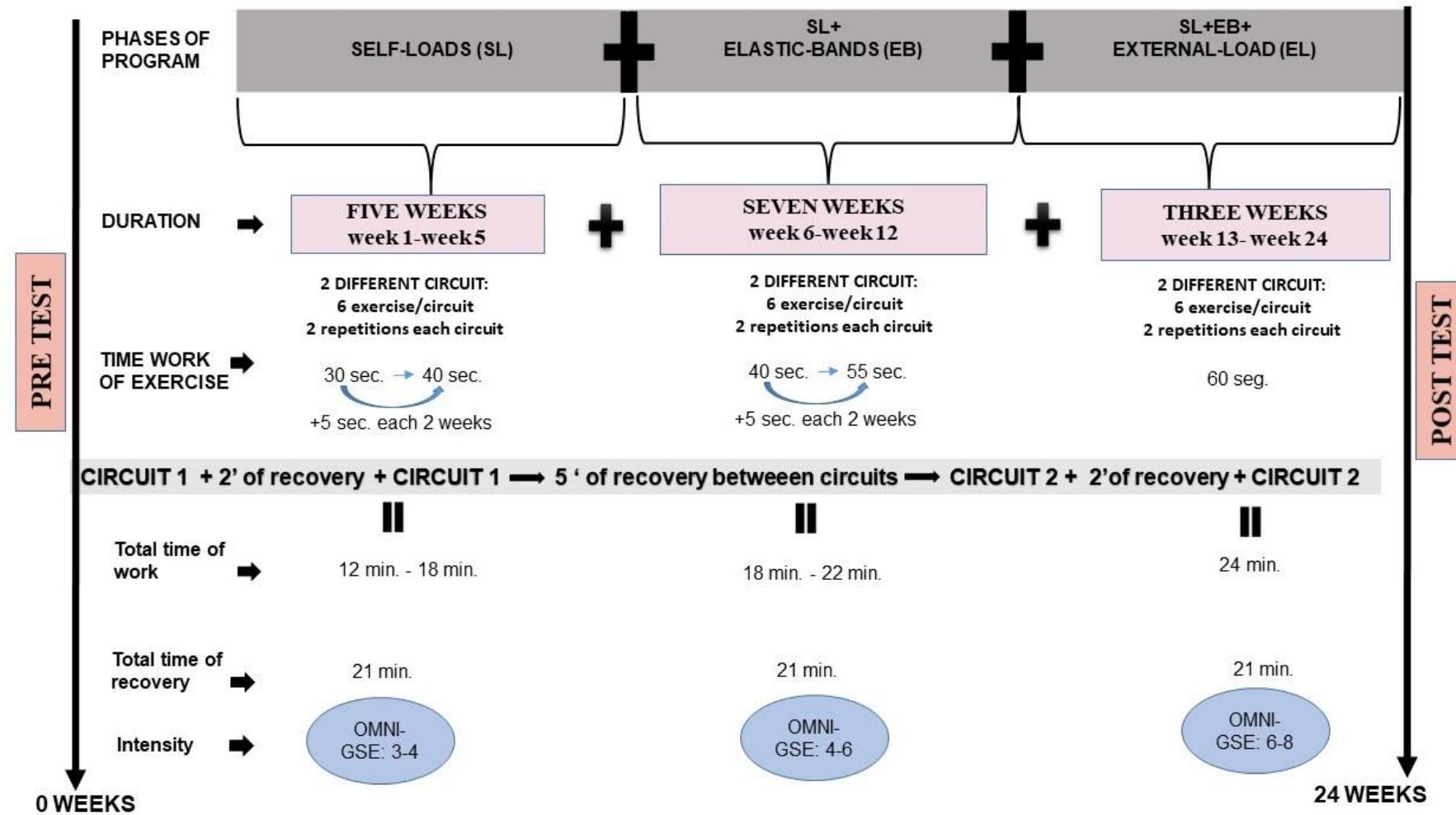
2.2 STRENGTH EXERCISE

The program consisted of 24 weeks of gradual strength training transferable to the actions of daily life in order to improve physical fitness, in particular general strength. The frequency was two days a week with a duration of 60 minutes each session, volume and intensity were controlled throughout the program as described below (figure 1). The intensity was controlled on the basis of the OMNI - Global Session in the Elderly Scale (OMNI-GSE) (Silva-Grigoletto *et al.*, 2013) used in inexperienced people or in elderly populations, taking into account their incidence at the functional level (Gearhart *et al.*, 2009; Guidetti *et al.*, 2011; Colado *et al.*, 2012).

The program involved a 1st phase (SL) (five weeks): strength by self-loads including balance, coordination, and postural control. The intensity of effort was between 3-4 of the OMNI-GSE scale; 2nd phase (EB) (seven weeks): elastic bands were included as resistance material along with the content of the first phase. The intensity was between 4-6 of OMNI-GSE scale, and 3rd phase (EL) (eleven weeks): external loads together with the contents of the previous phases. The intensity was between 6-7 of OMNI-GSE scale.

The first 10 minutes of each session were aimed at mobility and movement. Then, 40 minutes of strength exercise including balance, coordination, and postural control and finally, 10 minutes of stretching. The exercise dynamic consisted of circuits. Each session covered two different circuits (six exercises each). Two series per circuit were performed in each session. The initial work time was 30 seconds per exercise, increasing 5 seconds of work each two weeks until you reach one minute of work per exercise (week 14). For the last 10 weeks the working time was kept at 1 minute. Recovery time was 2 min between series of the same circuit and 5 min between different ones. At the beginning of the session a correct exercise explanation was provided in order to avoid harmful gestures.

In the 3rd phase, the load was set at a level that patients could easily manage. However, as a reference in previous studies (van Santen *et al.*, 2002; Kingsley *et al.*, 2005; Gearhart *et al.*, 2006, 2008, 2009; Sanudo *et al.*, 2011), during the course of the study the level gradually increased according to the patient's tolerance, the individual knowledge of the symptoms and the level of general fatigue. At the beginning, during and end of all sessions was measured the pulse and oxygen saturation was controlled by oximeter because some participants presented feeling of fatigue during the exercise. The OMNI-GSE scale previously mentioned was administered.

**Figure 20.** Protocol of strength training program for both age groups.

2.3 MEASURES

PHYSIOLOGICAL AND ANTHROPOMETRIC MEASUREMENTS

Height was measured with a stadiometer (Seca 22, Hamburg, Germany) and weight was assessed with a scale (InBody R20, Biospace, Seoul, Korea). Blood Pressure and Heart Rate (HR) were evaluated at rest with a tensiometer (Omron PL-100 Pro Logic, United Kingdom) and an oximeter fingertrip (Beurer PO-30, Ulm, Germany) was used to measure oxygen saturation.

QUESTIONNAIRE OUTCOMES

The sociodemographic questionnaire was used to elicit information about demographic and clinical variables as number of tender points and grade of pain. Also, the Revised Fibromyalgia Impact Questionnaire (FIQR) (Bennett et al., 2009) was used to evaluate domains as physical function (FD), overall impact (OID) and symptomatology (SID). This self-administered instrument that included scales classified between 0-10 each one related to physical deterioration, feeling good, work lost, work, pain, fatigue, rest, rigidity, anxiety and depression. We used the Spanish version of the Revised Fibromyalgia Impact Questionnaire (FIQR) (Bennett *et al.*, 2009). In addition, we used the Brief Pain Inventory Questionnaire (Williams and Arnold, 2011) to evaluate the pain in two dimensions: pain intensity (PID) and pain interference in daily activities (PITD).

PHYSICAL FITNESS TESTING

Some tests from the Functional Senior Fitness Test battery were selected to measure the physical fitness due to their safety and ease to administer and score (Jones, Rikli and Beam, 1999; Rikli and Jones, 2013). In addition, minimal equipment and space are required (Salgueiro *et al.*, 2013; Alvarez-Gallardo *et al.*, 2017b). Therefore, these tests

are feasible to be performed in clinical and community settings (Carbonell-Baeza *et al.*, 2015). Among them we used: the ‘30-s chair stand test’, that consists in accounting the number of times within 30 seconds 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 ‘arm curl adapted test’ that consists in performing repetitions in dominant side for 30 seconds while sitting on the chair. For this test, we used a weight of 2 kg or 1 kg if the test was adapted and it is considered a representative measure of functional performance (Jones, Rikli and Beam, 1999). Finally, the ‘2-minute step test’, that requires individuals to walk in their place, lifting their knees to a midway target between their kneecap and the iliac crest. Individuals may use a wall or chair for balance as needed. This test consists of completing cycles (1 cycle is 2 knee lifts, one with each leg). A higher step count indicates better cardiovascular fitness. The participants were asked to perform as fast as they could, keeping in mind their functional limitations.

Additionally, we also evaluated handgrip strength by using a hand-held dynamometer TKK 5101 Grip D; Takey (Tokyo, Japan) (Carbonell-Baeza *et al.*, 2015). Each patient with the arm fully extended in a standing position performed two attempts with each hand (30° with respect to the trunk). The maximum score in kilograms for each hand was recorded.

2.4 PROCEDURES

TESTING PROTOCOL

All measurements were carried out in two moments, in week 0, and at the end of 24 weeks. The protocol order was the following: the participant was in a completely silent room with light in a supine and relaxed position for 5 minutes and then, another 5 minutes in sitting position in order to decrease HR and to be in a resting state for a correct

and valid measuring socket. After that, weight, height, blood pressure, heart rate and oxygen saturation were measured. Afterwards, they completed the questionnaires and the physical fitness test. The same researcher evaluated each test.

3. STATISTICAL ANALYSIS

SPSS, version 16 was used for statistical analyses. The Kolmogorov-Smirnov test was applied to verify normal distribution of the data. Data were analysed using independent samples Student's test. In addition, two-way analysis of variance (ANOVA) (time X age as independent variables) for repeated measures (at baseline week 0, week 12, week 24) was used for assess the mean differences, interaction factors and influential variable. Post-hoc Bonferroni tests were used when ANOVA was significant. Cohen's d effect size (ES) was calculated to verify the magnitude of the mean differences between weeks of training. The ES were interpreted based on the following criteria: $d < 0.5$ = small effect, 0.5 to 0.8 = medium effect, > 0.8 = large effect (Cohen, 1988). The 95% confidence interval (CI) was also calculated. Finally, bivariate correlations were used to analyse the association between fitness and impact, pain, symptomatology and functionality in each age group. The p value less than .05 was considered statistically significant.

4. RESULTS

Significant differences in age ($p < 0.001$) and body mass index ($p = 0.049$) were observed in the unpaired Student's t-test at baseline (table 7). The mean of age for the first group (FM women's aged group ≤ 55) was 47.54 ± 7.98 and for the second (FM women's aged group ≤ 56) was 61.81 ± 5.68 . The results shows in the two-way ANOVA or repeated measures analysis (table 8) achieved significant differences intragroup in all physical fitness test in both groups ($p < 0.001$). For the first group, pain interference ($p = 0.011$) and pain intensity ($p = 0.03$) showed statistical differences. However, for the

second group significant differences were reached in pain intensity ($p=0.001$), pain interference ($p <0.001$), functionality ($p <0.001$), overall impact ($p <0.001$) and symptoms ($p <0.001$).

Regarding differences between both groups (intergroup), strength in upper limb ($p=0.001$), strength in lower limb ($p=0.023$), aerobic fitness ($p=0.047$), and physical function ($p=0.029$) showed significant differences (figure 21). In addition, high effect size was observed ($d>0.8$) in all physical fitness tests of both groups. The results on the interaction of the study's independent variables showed significant differences in aerobic fitness ($p=0.003$) and FM impact ($p=0.014$).

The pain intensity dimension was higher in women ≤ 55 ($d=0.92$) and moderate effect in women ≥ 56 ($d=0.76$). The opposite situation occurs regarding pain interference during daily activities where the effect was lower in women ≤ 55 ($d=0.75$) than in women ≥ 56 ($d=0.99$). About the FIQR domains, in general the clinical effect was smaller in women ≤ 55 ($d<0.5$) than in women ≥ 56 ($d>0.8$). Figure 20 shows the variables where we obtained statistically significant differences through the interaction between group and strength training program.

Pearson's correlation between fitness tests and pain dimensions, physical function, disease impact and symptomatology parameters in both age groups are shown in table 9 and table 10. For the first group, when the women were sedentary (i.e. at the beginning of the program, week 0) there was no correlation between the variables studied. Nevertheless, at the end of the intervention program (post), the upper limb strength correlated inversely with physical function, impact and symptomatology. Upper limb strength only with physical function. Aerobic fitness with intensity and pain interference and with FM impact. Finally, handgrip strength did not correlate with any. For the second

group, at the beginning, lower limb strength correlated significantly intensity, interference pain and physical function. Aerobic fitness with interference pain and handgrip strength with physical function, FM impact and symptoms. At the time the training program ended, this group showed inverse correlations between upper limb strength with FM impact and symptomatology, lower limb strength with interference pain, physical function, FM impact and symptomatology. Finally, handgrip strength with pain interference, physical function, FM impact and symptoms.

Table 7. Characteristics at baseline of two groups participants in the study.

	FM women's aged group ≤ 55 (n=17)	FM women's aged group ≥ 56 (n=24)	<i>p</i> [#]
(n= 41)	Mean (SD)	Mean (SD)	
Age (yr)	47.54 (7.98)	61.81 (5.68)	<0.001
Height (cm)	161.66 (6.09)	158.72 (5.24)	0.106
Body Mass Index (kg/m ²)	24.71 (5.21)	28.04 (5.15)	0.049
Weight (kg)	64.68 (15.45)	70.54 (12.72)	0.192
Heart Rate at Rest (bpm)	77 (7.05)	75.62 (12.22)	0.698
Sistolic Blood Pressure (mm Hg)	117.23 (10.65)	125.79 (18.11)	0.098
Diastolic Blood Pressure (mm Hg)	69.82 (9.42)	75.50 (11.63)	0.197
Numer of tender points (0 minium-18 maximum)	14.41 (2.91)	15.88 (2.64)	0.102
Grade of pain (0 minium-100 maximum)	71.47 (19.66)	67.71 (16.08)	0.505

FM, Fibromyalgia, bpm; beats per minute, mm Hg; millimetre of mercury, yr; years, cm; centimetres, SD; Standard Deviation, [#]*p* of analysis using unpaired Student's t-test (intergroup factor), **p*<0.001; ***p*<0.05.

Table 8. Analysis of variance results (two-factors ANOVA) after 24-weeks strength training program on women's group ≤ 55 versus ≥ 56 diagnosed with FM.

Measure	FM women's aged group ≤ 55							FM women's aged group ≥ 56								
	PRE		POST		MD	ES*	<i>p</i> [#]	PRE		POST		MD	ES*	<i>p</i> [#]	<i>p</i> group ⁺	<i>p</i> interaction [¶]
	Mean	(SD)	Mean	(SD)				Mean	(SD)	Mean	(SD)					
Arm curl test	11.24	(3.78)	21.24	(4.53)	-10.0	2.34 ^c	<0.001	8.0	(2.60)	17.1	(4.2)	-9.1	2.57 ^c	<0.001	0.001	0.503
30-s-chair stand test	8.12	(3.06)	13.65	(5.45)	-5.35	1.22 ^c	<0.001	6.08	(2.38)	10.79	(3.36)	-4.67	1.58 ^c	<0.001	0.023	0.415
2-minute step test	44.06	(21.64)	96.0	(28.72)	-51.95	1.99 ^c	<0.001	41.83	(17.64)	71.88	(24.56)	-30.04	1.38 ^c	<0.001	0.047	0.003
Handgrip strength	14.98	(5.63)	15.24	(6.79)	-5.53	1.0 ^c	<0.001	15.13	(6.26)	20.81	(5.37)	-3.38	0.61 ^c	<0.001	0.945	0.514
IPD	25.53	(4.88)	20.77	(5.26)	-4.77	0.92 ^c	0.010	25.50	(5.88)	20.46	(7.14)	-5.05	0.76 ^b	0.001	0.912	0.904
IND	47.06	(13.33)	39.29	(11.97)	-7.77	0.75 ^b	0.029	49.63	(11.80)	37.08	(13.02)	-12.55	0.99 ^c	<0.001	0.957	0.294
FD	49.06	(15.73)	43.24	(17.71)	-5.82	0.35 ^a	0.124	62.917	(14.97)	46.5	(13.46)	-13.29	0.91 ^c	<0.001	0.029	0.084
OID	11.0	(5.18)	9.65	(4.86)	-1.36	0.26 ^a	0.235	14.42	(3.44)	9.29	(3.61)	-5.12	1.43 ^c	<0.001	0.177	0.014
SID	63.41	(14.49)	56.53	(13.98)	-6.89	0.47 ^a	0.052	72.83	(14.51)	58.0	(12.72)	-14.83	1.07 ^c	<0.001	0.159	0.084

FM; Fibromyalgia, MD; Mean Difference.

*Effect Size intergroup; a. Small effect size (cohen's d<0.5), b. Medium effect size (cohen's between 0.5 and 0.8), c. Large effect size (cohen's d>0.8).

p differences intragroup.+*p* differences intergroup.¶ *p* differences interaction between group-training program.

Table 9. The correlations of physical fitness with pain domains, physical function, FM impact and symptomatology parameters in the age group ≤ 55 .

Measure	FM women's aged group ≤ 55															
	Arm curl test				30-s-chair stand test				2-minute step test				Handgrip strength			
	PRE		POST		PRE		POST		PRE		POST		PRE		POST	
	r	p	r	p	r	p	r	p	r	p	r	p	r	p	r	p
IPD	NS		-0.47	0.05*	NS		-0.45	0.07*	NS		-0.49	0.04		NS		
IND	NS		NS		NS		NS		NS		-0.55	0.02		NS		
FD	NS		-0.55	0.02	NS		-0.53	0.03	NS		-0.45	0.07*		NS		
OID	NS		-0.56	0.02	NS		-0.44	0.07*	NS		-0.57	0.02		NS		
SD	NS		-0.50	0.04	NS		NS		NS		NS		NS		NS	

NS; Not inversely correlation significant. * Tended to be significant.

IPD; Intensity pain domain, IND; Interference pain domain, FD; Function domain, OID; Overall impact domain, SD; Symptom domain.

FM; Fibromyalgia.

Table 10. The correlations of physical fitness with pain domains, physical function, FM impact and symptomatology parameters in the age group ≥ 56 .

Measure	FM women's aged group ≥ 56															
	Arm curl test				30-s-chair stand test				2-minute step test				Handgrip strength			
	PRE		POST		PRE		POST		PRE		POST		PRE		POST	
	r	p	r	p	r	p	r	p	r	p	r	p	r	p	r	p
IPD	NS		NS		-0.46	0.02		NS		NS		-0.34	0.06*		NS	
IND	NS	-0.97	0.07*	-0.55	0.01	-0.51	0.01	-0.41	0.04	NS		NS		-0.47	0.02	
FD	NS	-0.39	0.06*	-0.47	0.02	-0.51	0.01		NS		-0.53	0.01	-0.47	0.02		
OID	NS	-0.63	<0.01		NS		-0.63	<0.01		NS		-0.48	0.02	-0.42	0.04	
SD	NS	-0.49	0.01	-0.40	0.05*	-0.60	<0.01		NS		-0.42	0.04	-0.43	0.04		

NS; Not inversely correlation significant. *Tended to be significant

IPD; Intensity pain domain, IND; Interference pain domain, FD; Function domain, OID; Overall impact domain, SD; Symptom domain.

FM; Fibromyalgia.

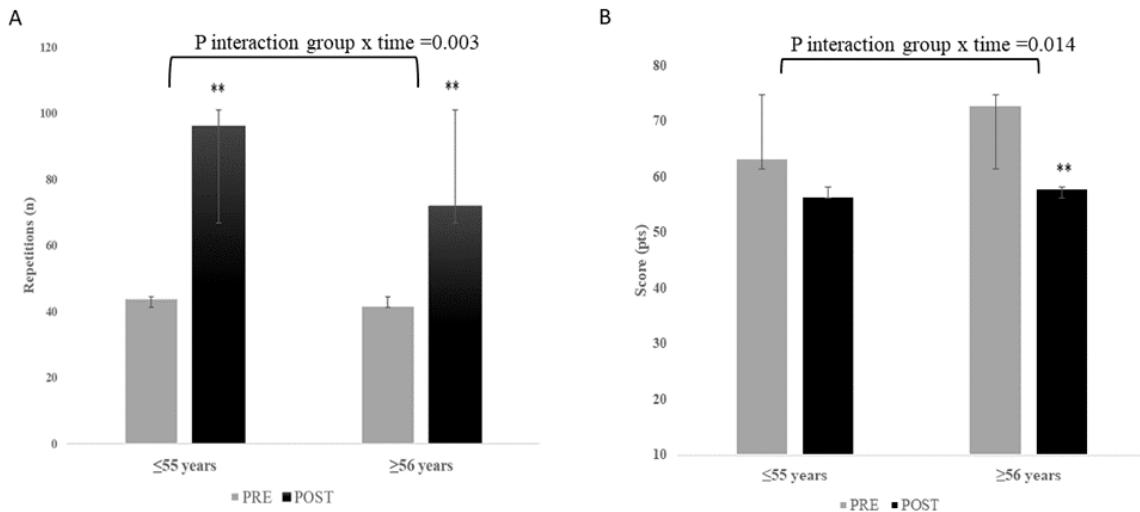


Figure 21. Effects of the interaction between group and training program. **A.** 2-minute step test graphic; **B.** Overall impact domain graphic. ** Significant differences intergroup with $p<0.001$.

5. DISCUSSION

The present study aimed to assess the effects of strength training on physical fitness, pain, and quality of life (symptoms, physical function, and overall impact) in women with FM establishing a cut-off point on the basis of the beginning of the aging and muscle decline. A secondary purpose was to determine the association between physical fitness and pain, impact, physical function, and symptomatology in both age groups.

The results of the present study showed that the baseline physical fitness of women with FM was more deteriorated in the age group ≥ 56 years, with no notable difference observed with respect to the initial values in the first group, which is in agreement with a previous study (Alvarez-Gallardo et al., 2017). Our interpretation of this finding is that physical fitness in patients with FM is deeply deteriorated already at young ages, in other words, these patients have might be aging earlier. Therefore, during the lifespan, the consequences of ageing are notably manifested, which is reflected in the deterioration of physical fitness.

A core starting-point of our study was that both groups significantly improved their fitness levels (strength and aerobic fitness) at the end of the program. Even so, significant differences can be seen in both groups. Regarding pain, both groups also achieved significant improvements, starting the program with similar pain levels. However, the quality of life of younger women was again less deteriorated than that of older women. Although the strength program improved the quality of life (symptoms, impact and physical function) in both, only in the group of older women was the improvement significant due to the aforementioned lower levels of quality of life at baseline. It would be interesting to see whether a program based on higher intensity or volume would achieve significant improvements in the quality of life.

Concerning the youngest group, strength in upper and lower limb was negatively associated with pain intensity, symptoms and the impact of FM, and positively with physical function. These results are in line with the recent studies where they show that the improvement of fitness are associated with less impact of FM (Soriano-Maldonado, Henriksen, Segura-Jimenez, *et al.*, 2015; Collado-Mateo *et al.*, 2016), pain (Bruijn *et al.*, 2011; Soriano-Maldonado, Ruiz, *et al.*, 2015), better health-related quality of life (Carbonell-Baeza *et al.*, 2013; Soriano-Maldonado, Henriksen, Segura-Jiménez, *et al.*, 2015; Collado-Mateo *et al.*, 2016; Sener *et al.*, 2016) and lower symptomatological impact (Bircan *et al.*, 2008; Martinsen *et al.*, 2018). In the case of upper limb strength, it did not correlate with symptoms. This result does not support what was previously found by Segura-Jiménez *et al.*, 2017. This could explain that the increase strength levels the upper limb would be determinant in the improvement of the general pathology symptoms.

Older patients with FM have a lower level of physical fitness than healthy subjects of the same age (Alvarez-Gallardo *et al.*, 2017b). Regarding our results, the women's group ≥ 56 years old, at the beginning of the study, upper limb strength was inversely

correlated with pain intensity and interference, physical function and symptomatology. In addition, handgrip strength correlated with all except pain interference. These associations were not shown for the women's group ≤ 55 . This could be because older participants were sedentary, and as a consequence, in the younger women's group, the physical fitness was deteriorated as in the women's group ≥ 56 (Alvarez-Gallardo *et al.*, 2017b), so the level of physical fitness will not be determinant in the improvement of symptomatology, impact and physical function. A further reason could be the fact that consequences of sarcopenia do not seem to be as aggravated (Doherty, 2003; Koca *et al.*, 2016).

Recently, Rikli and Jones (2013) proposed fitness standards (for people between 60 and 94 years of age) that are associated with the physical fitness levels needed to perform the types of everyday activities required to remain physical independence until late in life. When comparing our results in women's group ≥ 56 with the physical fitness standards (Rikli & Jones, 1999; Rikli & Jones, 2013) we found that our findings are even more alarming given that the physical fitness of most of people with FM in our study did not meet the physical fitness standards for their age and it is similar to the physical fitness of 30 years older people without FM people. These results are consistent with those of a previous study (Jones *et al.*, 2014), indicating an early risk for disability in women with FM. At the end of the training program, considering that women with FM were already physically active and that their physical fitness had improved, our data showed an inverse correlation between strength levels and pain intensity and interference, physical function, symptomatology and FM impact (Palstam *et al.*, 2016).

The association between aerobic fitness and pain appears to show some controversy because previous studies reported that aerobic fitness, measured through the 6-minute walking test, was inversely associated with pain sensitivity (Assumpção *et al.*,

2010), pain intensity and pain interference (Mannerkorpi, Svantesson and Broberg, 2006). Our results indicated for the group under 55 years, that increased aerobic fitness measured with the 2-minute step-test is consistently associated with lower levels of pain intensity, pain interference and impact (regardless of the method used to assess pain) (Soriano-Maldonado, Ruiz, *et al.*, 2015). Theoretically, an association between fitness levels and pain can be expected based on modulating influences of the autonomic nervous system: low physical fitness may result in unbalanced autonomic nervous system function, which can impact pain (Light *et al.*, 2009) or alternatively, pain may lead to reduce the fitness, which brings about an unbalanced autonomic nervous system function (Geenen, Jacobs and Bijlsma, 2009).

The majority of studies analysing the association between aerobic fitness and quality of life have been with a population between 45-50 years, which corresponds to our reference group of women under 55 years. As a result of these studies, they have found direct associations between both variables which would be in line with the findings from the present study (Busch *et al.*, 2007, 2013a; Hooten *et al.*, 2014; Garcia-Hermoso, Saavedra and Escalante, 2015; Soriano-Maldonado, Henriksen, Segura-Jimenez, *et al.*, 2015).

In contrast, the older group showed no association between aerobic fitness and quality of life (physical function, impact and symptoms). This could explain that increased aerobic fitness has an influence on the improvement in pain and impact of FM in younger women, while in older women, aerobic fitness does not seem to have an influence on the improvement of symptoms. No scientific literature has been found that analyses the associations between quality of life and aerobic fitness in this age range in population with FM (mean age 62 years). Therefore, to the best of our knowledge, it is the first time that the sample of FM female patients is analysed distributed in two age

groups according to our criterion. We have not found a relationship as it was presumably expected to be the same as in the younger group. To affirm that the improvement of aerobic fitness do not improve the symptoms of FM in older women, further studies are required to analysing in isolation the response of aerobic fitness after an improvement of this with quality of life (physical function, impact and symptoms).

An issued to address in future studies would be the early identification of physical decline and appropriate interventions which may help to prevent functional impairments, such the ones observed in walking and stair climbing (Collado-Mateo *et al.*, 2016), that often result in falls and physical frailty (Fiatarone *et al.*, 1994; Spirduso, Francis and MacRae, 1995). A goal for fitness practitioners should be the early identification of individuals at risk in order to avoid the loss of physical independence by tools as the aforementioned Senior Fitness Test (Rikli and Jones, 1999; Rikli and Jones, 2013).

6. LIMITATIONS

The present study included only women, so studies with men are required to assess the impact of this program in both age groups. In addition, the applied training program is strength training, so future studies comparing different training programs based on different age ranges are needed to determinate the orientation between age groups and training programs. Moreover, specific aerobic programs in elderly population (mean age 60) to determine the association between quality of life and aerobic fitness by achieving improvements in physical fitness levels. Another important limitation is the fact that no more subgroups of ages are used to try to profile associations throughout the aging process.

7. CONCLUSIONS

A muscle strengthening program produces non-age-dependent improvements in physical fitness (both at the level of muscle strength and at the aerobic level) and pain. However, quality of life (physical function, impact and symptoms) only improves in the older women group.

Additionally, strength training provides a non-age-related tool to positively change quality of life and pain. However, despite the quality of life seems to be improved by increasing aerobic fitness in younger women with FM, to confirm the effects in older women further research is needed.

8. ACKNOWLEDGMENTS

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9. DECLARATION OF INTEREST

The authors of this manuscript not shown conflict of interests.

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STUDY III

GRADUAL STRENGTH TRAINING IMPROVES QUALITY OF SLEEP, PHYSICAL FUNCTION AND PAIN IN PATIENTS WITH FIBROMYALGIA

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ABSTRACT

Introduction. Fibromyalgia (FM) is characterized by chronic and generalized musculoskeletal pain. There is currently no cure for FM, but alternative treatments are available. Among them, gradual strength training program (STP) focused on daily activities is a valid option to improve some of the pronounced symptoms of FM that affect their quality of life, such as, fatigue, pain, sleep quality and physical function. However, more information is needed to develop better training programs and improve anxiety and fatigue symptoms. **Objective.** To analyse the effects of 24 weeks of the gradual and progressive ST on sleep quality, fatigue, pain domains, physical function and anxiety-state. **Methods.** Forty-one women with FM participated in the 24 weeks of intervention based on gradual and progressive ST. Participants performed two training sessions of 60 minutes per week and they were evaluated before (week 0), week 12 and at the end of ST program (week 24). The Revised Fibromyalgia Impact Questionnaire was used to assess sleep quality and fatigue scales. Anxiety-state was evaluated with the State Anxiety Inventory, and pain domains by means of the Brief Pain Inventory. Senior Fitness Test was used for physical function measurements. One-way analysis of variance (ANOVA) was applied to assess the mean differences between phases, and Pearson's correlation was used to check the associations between physical and psychological symptoms, and physical function. **Results.** The results show that 24 weeks of ST improves physical function, sleep quality and pain domains ($p<0.05$). Higher anxiety and pain interference scores were related to a low physical function. **Conclusions.** Gradual ST significantly improves sleep quality, pain and physical function, but not anxiety and fatigue. Current research shows that for the improvement of these symptoms, training programs must be combined with other cognitive behavioural therapies.

Keywords: Fitness, functionality, symptoms, life quality.

1. INTRODUCTION

Fibromyalgia (FM) is a chronic disease characterized by generalized skeletal muscle pain (Wolfe *et al.*, 1990, 2016), and others common symptoms include fatigue, sleep disorder, inability, and excessive anxiety (Wolfe *et al.*, 2010; Borchers and Gershwin, 2015; Häuser *et al.*, 2015; McDowell, Cook and Herring, 2017). The pathogenesis of FM is still not well understood (Andrade *et al.*, 2018), and it is considered by some researchers to be a neurobiological disease caused by abnormal processing of pain (Sluka and Clauw, 2016). Owing to the lack of markers of that can identify the disease, the diagnosis is made through clinical examination, according to the guidelines of the American College of Rheumatology (Wolfe *et al.*, 1990, 2010, 2016).

As FM has no cure, treatments are palliative, and multidisciplinary approaches involving the use of medications, physical exercise (PE), and psychological treatments are recommended (Arnold, 2006; Häuser *et al.*, 2009; Langhorst *et al.*, 2013; Poole and Siegel, 2016; McDowell, Cook and Herring, 2017). PE has been advised in several studies and guidelines for the treatment of FM (Brosseau, Wells, Tugwell, Egan, Wilson, Dubouloz, Casimiro, Robinson, McGowan and Busch, 2008; Brosseau, Wells, Tugwell, Egan, Wilson, Dubouloz, Casimiro, Robinson, McGowan, Busch, *et al.*, 2008; Bidonde *et al.*, 2017; Sanz-Baños *et al.*, 2018), and inclusion of aerobic, strength, and water exercises has been strongly recommended (Brosseau, Wells, Tugwell, Egan, Wilson, Dubouloz, Casimiro, Robinson, McGowan and Busch, 2008; Brosseau, Wells, Tugwell, Egan, Wilson, Dubouloz, Casimiro, Robinson, McGowan, Busch, *et al.*, 2008; Busch *et al.*, 2013b; McDowell, Cook and Herring, 2017). The severity of FM symptoms can affect the level of physical fitness, and patients commonly perform little physical activity because of pain (Musumeci, 2015; Segura-Jimenez *et al.*, 2015b, 2016).

The relationship between ST in and psychophysical symptoms has been investigated in FM (Bircan *et al.*, 2008; Akyol *et al.*, 2013; Soriano-Maldonado, Henriksen, Segura-Jimenez, *et al.*, 2015). However, no studies have been found using ST from a gradual and progressive approach. In addition, the duration of previous interventions is no longer than 21 weeks (Hakkinen *et al.*, 2002; Kingsley *et al.*, 2005; Bircan *et al.*, 2008b; Gavi *et al.*, 2014; Ericsson *et al.*, 2016). However, our intervention program records the effects of 24 weeks, analysing also the effect at 12 weeks. Recent studies have attempted to better understand the effects of ST in patients with FM (Larsson *et al.*, 2015; Nelson, 2015; Ericsson *et al.*, 2016; Andrade, Vilarino and Bevilacqua, 2017), noting there are psychophysical symptoms that cannot be improved through progressive and gradual strength training, such as fatigue and anxiety. Hence, to improve these symptoms, it is likely that STP will need to be combined with cognitive behavioral therapies or education programs. The aim of this study was to analyse the effects of 24 weeks gradual and progressive ST on sleep quality, fatigue, pain domains, physical function and anxiety-state.

2. MATERIAL AND METHODS

2.1 PARTICIPANTS

55 women started the study, of whom 14 participants withdrew from the study for different reasons (25%). Finally, forty-one women diagnosed with fibromialgia who met the American College of Rheumatology (ACR) criteria (Wolfe *et al.*, 1990) for FM classification were included in this study. Participants were recruited from the FM association, Region of Madrid (AFIBROM). Exclusion criteria were; a) not be a female, b) the presence of serious disease that could be exacerbated by the practice of physical activity, c) to be pregnant, and d) change from usual care therapies during the treatment.

period. The study was approved by the Ethics Comitte of the Universidad Politécnica de Madrid (Madrid, Spain). All patients gave their informed consent prior to their inclusion in the study. All participants were part of the STP and exercised two times per week with a duration of 60 minutes per session. The intervention lasted 24 weeks.

2.2 STRENGTH EXERCISE

STP was focused of daily activities with a progressive increase in intensity (according to patient's tolerance). Exercise was performed in the standing, sitting and lying position. It was focused on the strengthening of the upper and lower limb muscles and trunk muscles. The intensity was controlled by means of the OMNI-Global Session in the Elderly Scale (OMNI-GSE) (Silva-Grigoletto *et al.*, 2013) used in inexperienced people or in elderly population. In addition, heart rate monitoring was controlled using a pulse oximeter in three different moments; at the beginning, middle, and the end of each training session.

The program involved three different and progressive phases; *1st phase (SL)* (5 weeks), free weights and body weight were used for STP, including including balance, coordination, and postural control. The intensity in this phase was between 3-4 (OMNI-GSE); *2nd phase (EB)* (7 weeks), elastic bands were included along with the contents of the first phase. The intensity was between 4-5 (OMNI-GSE); *3rd phase (EL)* (12 weeks), external loads were used with the contents of the preious phases. The intensity was beteen 6-8 (OMNI-GSE). The dynamic exercise was by means of circuits. Each session consisted of two different circuits (six exercises each), which were performed twice. Participants started with 30 seconds of work (week 1) progressively increasing to reach 1 minute of work per exercise (week 14). During the remaining 10 weeks, the time was kept at 1

minute of work. Recovery was 30 sec. between exercise, 2 min between series of a circuit, and 5 min between different circuits.

Exercise sessions began with a low intensity warm up (10 minutes) of marching in place, and joint mobility, followed by 30-40 min of STP, and concluded with 10 min of cool down (stretching and relaxation).

2.3 PROCEDURE

Patients were evaluated in three different times; week 0, week 12, and week 24 by the same examiner. Outcome measures were the intensity of fibromyalgia-related symptoms (fatigue, sleep quality, anxiety-state, pain domains and pain interference) and physical fitness (strength in upper and lower limb, aerobic fitness and flexibility in lower limb. The testing protocol followed this sequence: firstly, the anthropometrics and physiological parametres were measured. Secondly, participants completed the questionnaires. Finally, the physical fitness test were assessed.

2.4 INSTRUMENTS

Body Mass Index (%, IMC) was measured with a bioelectrical impedance analyser (Inbody R20;Biospace, Seoul, South Korea). The measurement was made at least two hours after the last lunch, with participants released from clothes and metal objects and having remained standing at least five min before the assessment. In addition, we asked them not to shower, not to do intense physical exercise and not to ingest large amounts of liquid in the hour before the measurement. The validity and reliability of this instrument are adequate (Malavolti *et al.*, 2003; Segura-Jimenez *et al.*, 2014).

A sociodemographic questionnaire was completed by participants. This contains different items on personal data and in relation to fibromyalgia (e.g., year of diagnosis, number of pain points, other alterations, etc.).

Fatigue and sleep quality was assessed by means of the Revised Fibromyalgia Impact Questionnaire (FIQR). FIQR contains two subscales of symptoms: fatigue and sleep quality. These range from 0 to 10, with higher scores indicating more fatigue and poor sleep quality.

The State Anxiety Inventory (STAI-S) Questionnaire was used to assess state anxiety (i.e., the level of current anxiety). Scores from this 20-item self-administered questionnaire range from 20-80 points, with higher scores indicating more anxiety (Spielberger *et al.*, 2017).

The Brief Pain Inventory (BPI) (Cleeland and Ryan, 1994) is a questionnaire that assesses two domains; pain intensity with 4 items, and second, pain interference in daily activities with 7 items. Both domains are scored of 0-10 indicating higher scores greater pain. Furthermore, these were calculated as the mean of the element responses in each one.

Physical fitness was assessed using the Senior Fitness Test battery (Carbonell-Baeza *et al.*, 2015). This battery assesses physical fitness parameters associated with functional mobility: flexibility (the ‘chair sit-and-reach’), muscular strength (the ‘30-s chair stand’ and “30-s arm curl” tests) and cardiorespiratory fitness (2-minute step test). Psychometric properties of these tests are adequate (Aparicio *et al.*, 2015; Carbonell-Baeza *et al.*, 2015).

-The chair sit-and-reach test involves sitting on the floor with legs stretched out straight ahead. Shoes should be removed. The soles of the feet are placed flat against the

box. Both knees should be locked and pressed flat to the floor - the tester may assist by holding them down. With the palms facing downwards, and the hands on top of each other or side by side, the participant reaches forward along the measuring line as far as possible. Ensure that the hands remain at the same level, not one reaching further forward than the other. After some practice reaches, the participant reaches out and holds that position for at one-two seconds while the distance is recorded. Two attempts were recorded, collecting the best score achieved. Higher scores indicate better performance.

The 30-s chair stand test. From a sitting position and with arm folded across chest, the participant stands up to a fully standing position. The test performed once for 30 seconds. The score is the count of full stands. Higher scores indicate better performance.

The 30-s arm curl test. In a sitting position, the participant curls up a hand weight (for women 2 kg or 1.5 kg if they test was adapted). The test is performed once for 30 seconds with each arm. The score of this test is the average count of hand weight curls through the full range of motion. Higher scores indicate better performance. Higher scores indicate better performance.

The 2-minute step test requires that the participant to walk in place, lifting her knees to an intermediate point between her kneecap and the iliac crest. Participants could use a wall or chair to maintain balance, if necessary. This test consists of completing cycles (1 cycle is two knee lifts, one with each leg) for two minutes. A higher step count indicates better cardiovascular fitness. The participants were asked to perform as fast as they could, keeping in mind their functional limitations. Higher scores indicate better performance.

2.5 STATISTICAL ANALYSIS

Characteristic variables were analysed using descriptive analysis. Study variables assumed a normal distribution through Kolmogorov Smirnov test. Therefore, for the analysis of the results, parametric tests were used. One-way analysis of variance (ANOVA) was used for assess the mean differences between phases intervention program (week 0, week 12, and week 24). Port-hoc Bonferroni tests were used when ANOVA was significant.

Pearson's correlation were computed in order to examine the relationships among physical fitness and physical-physiological symptoms (pain, state anxiety, and fatigue). Statistical significance was set at $p<0.05$. The Statistical Package for Social Science software (IBM SPSS for Mac, version 25; Armonk, NY, USA) was used for all analysis.

3. RESULTS

Six women discontinued the program due to not meeting inclusion criteria, seven by others reasons, three incorporations to the work by medical discharge and one injurie to work accident. Adherence to the intervention was 90%. A total of 41 women completed the 24-week follow-up. There were no major adverse effects and no major health problems in the patients during the training and rest periods.

Baseline characteristics of women with FM are shown in table 11. The effects of muscle strengthening exercise oriented to daily activities are showed in table 12. Regarding differences between week 0-week 12 significant differences were found in pain intensity and pain interferences strength in upper and lower limb ($F_{(2,122)}>5.708$; $p <0.015$). Moreover, between week 0 - week 24 differences were found in pain intensity and pain interference, sleep quality, flexibility in lower limb, strength in upper and lower limb and aerobic fitness ($F_{(2,122)}>3.083$; $p<0.044$). Finally, between week 12-week 24

significant differences were achieved in pain intensity and pain interference, strength in upper and lower limb and aerobic fitness ($F_{(2,122)} > 5.708$; $p < 0.015$). Figure 21 show the evolution of pain dimensions and sleep quality throughout the 24 weeks, achieving significant differences between phases ($p < 0.05$).

Pearson's correlation between physical and physiological symptoms, and physical function measured through physical fitness test are presented in table 13. The results showed negative and significant associations between anxiety-state and upper and lower limb strength. Also, pain interference was associated with upper limb strength and aerobic fitness.

Table 11. Characteristics of the participants (n=41).

Variables		Mean	SD
Age, years		56.36	8.72
Body mass index (kg/m ²)		26.67	5.38
Total tender points (11-18)		15.87	2.82
Symptoms (questionnaires)			
Pain intensity (0-40 score)		25.40	5.44
Pain interference (0-70 score)		48.62	12.51
FIQR-Sleep quality (0-10 score)		6.30	2.34
Anxiety-State (20-80 score)		31.45	9.31
FIQR- Fatigue (0-10 score)		6.70	2.12
Physical fitness tests			
Muscular fitness			
Upper body	30-s arm curl test (repetitions)	9.32	3.51
Lower body	30-s chair stand test (repetitions)	6.95	2.86
Flexibility			
Lower body	Chair sit and reach test (cm)	-4.77	7.78
Aerobic fitness	2-min step test (step)	43.47	18.84

All participants were women. SD, Standard Desviation.

Table 12. Effects of strength training program in women diagnosed with FM.

	Week 0			Week 12			Week 24		
	Mean	SD	95%CI	Mean	SD	95%CI	Mean	SD	95%CI
Anxiety-State	31.40	9.31	28.47 to 34.42	27.36	11.78	23.64 to 31.08	26.59	11.72	22.94 to 30.24
Fatigue	6.70	2.12	6.01 to 7.38	6.04	1.97	5.42 to 6.67	5.61	1.99	4.99 to 6.24
Pain intensity	25.40 ^a	5.44	23.65 to 27.14	22.68 ^b	6.43	20.65 to 24.71	20.83 ^c	6.48	18.81 to 22.85
Pain interference	48.62 ^a	12.51	44.62 to 52.62	40.24 ^b	14.39	35.70 to 44.78	37.59 ^c	12.61	33.66 to 41.52
Sleep quality	6.30	2.34	5.55 to 7.04	7.36	2.15	6.68 to 8.04	7.69 ^c	1.78	7.13 to 8.24
Sit and rich	-4.77	7.7	-7.33 to -2.21	-2.35	8.05	-4.97 to 0.25	-0.30 ^c	8.13	-2.87 to 2.26
30-s arm curl test	9.32 ^a	3.51	8.19 to 10.45	15.46 ^b	4.44	14.06 to 16.86	18.61 ^c	4.89	17.09 to 20.14
30-s chair stand test	6.95 ^a	2.86	6.03 to 7.86	10.68 ^b	3.75	9.49 to 11.86	11.88 ^c	4.50	10.47 to 13.28
2-min step test	43.47 ^a	18.84	37.44 to 49.50	73.51 ^b	28.12	64.63 to 82.39	81.76 ^c	28.32	72.93 to 90.58

All analysis included bonferroni correction; CI, Confidence interval; SD, Standard Desviation.

^aSignificative differences between week 0- week 12; ^b Significative differences between week 12- week 24; ^csignificative differences between week 0-week 24.

Table 13. Pearson's correlation coefficient analysis between muscle strength and pain domains, fatigue, anxiety-state, and sleep quality after strength training program in patients with FM (n=41).

	Anxiety-State		Fatigue		Pain intensity		Pain interference		Sleep quality	
	r	p	r	p	r	p	r	p	r	p
Sit and rich	-0.01	0.976	-0.21	0.194	-0.18	0.249	-0.05	0.743	0.12	0.431
30-s arm curl test	-0.32	0.035	-0.22	0.157	-0.30	0.056	-0.32	0.036	0.16	0.314
30-s chair stand test	-0.35	0.022	-0.34	0.028	-0.29	0.061	-0.29	0.064	0.09	0.560
2-min step test	-0.27	0.087	-0.10	0.501	-0.16	0.300	-0.32	0.040	0.10	0.496

Statistically significant with $p<0.05$

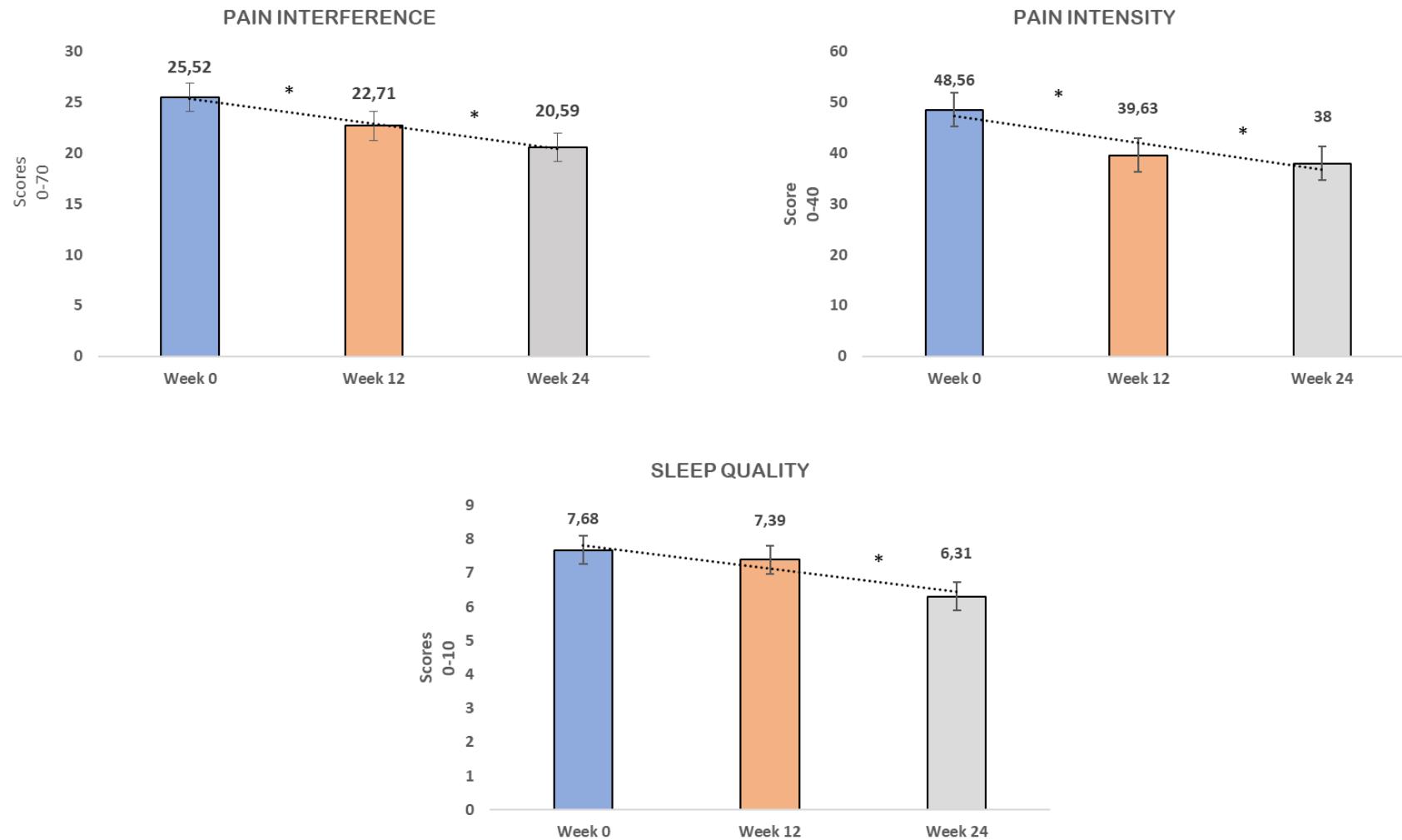


Figure 22. Evolution of pain dimensions and sleep quality throughout the 24 weeks of strength training focused on daily activities. *Significant differences ($p<0.05$) between program phases.

4. DISCUSSION

Our study showed that women with FM had significant improvement in associated symptoms as pain, sleep quality and physical function after 24 weeks of strength training focused on daily activities. However, this program did not show improvements in anxiety and fatigue. These results demonstrated the importance of gradual STP in this population but there are still gaps that need to be investigated.

Andrade *et al.* (2018) performed a meta-analysis of the effects of ST in patients with FM which included 22 studies. The authors concluded that STP had positive effects on physical and psychological symptoms in terms of reducing pain and improving muscle strength, sleep quality and physical function. In addition, these researchers showed that interventions programs should start at low intensity and gradually increase the intensity, working the main muscles groups. With regard to the symptoms, pain is the main of these one in FM. It is associated with others such as sleep disorders, and poor quality of life (Ericsson *et al.*, 2016; Andrade, Vilarino and Bevilacqua, 2017). Hence, to find treatments that improve these symptoms are of crucial clinical relevance for patients.

Literature indicates that patients with FM have less strength and reduced physical function compared with healthy individuals of the same age and without the disease (Larsson *et al.*, 2018). The reduced muscle strength of patients with FM may be related to pain; because of pain, it is common for patients to avoid making physical efforts; Thus, our results demonstrated that 24 weeks of ST improved the quality of life regarding to pain, sleep quality and physical function in patients with fibromyalgia. Similar results were found in other studies where the improvements of pain (Jones *et al.*, 2002; Valkeinen *et al.*, 2006; Figueroa *et al.*, 2007; Bircan *et al.*, 2008; Hooten *et al.*, 2012; Gavi *et al.*, 2014; Larsson *et al.*, 2015; Palstam *et al.*, 2016), sleep quality (Ericsson *et al.*, 2016; Andrade,

Vilarino and Bevilacqua, 2017) and physical function (Jones *et al.*, 2002; Valkeinen *et al.*, 2004, 2006; Kingsley *et al.*, 2005; Figueroa *et al.*, 2007; Bircan *et al.*, 2008; Panton *et al.*, 2009; Gavi *et al.*, 2014; Larsson *et al.*, 2015) were significant after STP. Despite favorable results, previous research did not observe significant improvements in pain (Kingsley *et al.*, 2005; Panton *et al.*, 2009). However, ability to perform daily activities showed improvements. The fact that the authors did not observe significant differences can be attributed to the sample size or the intervention program design. In our study, patients performed an intervention program focused on daily activities, with progressive and gradual increases in intensity.

Patients with FM also commonly have sleep disorders (Diaz-Piedra *et al.*, 2015). However, few studies have investigated the effects of STP on this variables (Häkkinen *et al.*, 2001; Jones *et al.*, 2002; Bircan *et al.*, 2008a; Busch *et al.*, 2013a; Ericsson *et al.*, 2016; Andrade, Sieczkowska and Vilarino, 2019a). Our results showed significant differences in sleep quality from week 13 of strength training, which concides with the external loads phase. These results support those found in previous studies (Jones *et al.*, 2002; Bircan *et al.*, 2008; Ericsson *et al.*, 2016). However, other studies did not find significant benefits in sleep disturbances (Häkkinen *et al.*, 2001; Andrade, Sieczkowska and Vilarino, 2019a) due to short intervention program (4 weeks) and planning design based on Maximum Repetition (RM).

Another noteworthy finding is the fact that fatigue and anxiety did not improve at the end of the intervention program. Regarding anxiety-state, among the studies investigating the effects of muscle strength for this symptom, previous research has not yet shown significant improvements after strength training program (Bircan *et al.*, 2008; Gavi *et al.*, 2014; Ericsson *et al.*, 2016). On the opposite, these significant changes have been shown through an intervention programme based on flexibility exercise during 15

weeks (Gavi *et al.*, 2014). The effect of exercise on psychological status of patients with FM is controversial. In the current study, the anxiety-state scores lowered, but were not enough to reach significant differences after 24 weeks. Fatigue is a symptom with a great negative effect on daily life in women with FM (Guymer and Clauw, 2002; Sallinen *et al.*, 2010; Wuytack and Miller, 2011). Previous literature have investigated the effect of STP on global fatigue assessed with a scale (Bircan *et al.*, 2008; Ericsson *et al.*, 2016) and significant improvements have been found. The results of the present study are not in line with previous studies because no significant differences were found throughout the strength training program (neither at 12 weeks nor at the end of 24 weeks of STP).

Variables that have been previously found to be associated with physical and physiological symptoms, and physical function were included in the correlation analyses. However, at the end of STP, only a few variables appeared to be associated. The fatigue, anxiety-state and pain intensity did not seem to have influence on physical function. Conversely, anxiety levels seem to be associated with upper and lower limb strength. These results are partially in line with what others results (Cordoba-Torrecilla *et al.*, 2016) where they found an inverse relationship between upper-body strength, as measured by the arm-curl test, and anxiety (confirmed only as measured by the FIQR-anxiety). This fact is noteworthy because this psychological variable showed no improvement at the end of the strength training program focused on daily activities. These findings indicate that the gradual STP oriented to the ADL does not improve anxiety levels. Then, if the program had factors that improved anxiety, for example, greater flexibility component (Gavi *et al.*, 2014) or strength training combined with cognitive behavioral therapies (Macfarlane *et al.*, 2016) or educational programs (Mannerkorpi *et al.*, 2000; Valim *et al.*, 2003), at the end of the program, the values of anxiety would be probably significant. This could have improved even more, if possible, the strength of upper and lower limbs. Therefore the

physical functionality and ability that affect the quality of life of women suffering from FM.

Regarding pain interference, it was negatively associated with upper limb strength and aerobic fitness. This fact supports the effects previously found the intervention program, since participants with higher levels of upper limb strength and aerobic fitness will achieve less pain interference. Therefore, this program has been shown to be effective in reducing pain interference, which will also improve strength in this way.

The present study supports the idea of FM as a multidimensional condition. This is reflected in an altered perception of musculoskeletal pain, which in turns causes fatigue, disability, anxiety, sleep disorders and poor physical function. In this context, diverse physical exercise intervention programs have proved their efficacy reducing fibromyalgia symptomatology (Busch, Webber, Brachaniec, Bidonde, Dal Bello-Haas, *et al.*, 2011), being even more effective than pharmacology therapies (Rahman, Underwood and Carnes, 2014). Results from the present study reinforce the idea that treatments should focus on both physical and emotional dysfunctions, with an especial emphasis on the physical domain, since it shows the greatest differences. Furthermore, as some psychological components (e.g.,anxiety) influence the level of disability in fibromyalgia (Verbunt, Pernot and Smeets, 2008), their proper treatment might lead to an improvement physical function. Therefore, multidisciplinary interventions (Carbonell-Baeza *et al.*, 2011) combining exercise and cognitive behavioral therapies could achieve the greatest benefits in this context (Rahman, Underwood and Carnes, 2014). However, there are some symptoms that should be treated with specifically programs since multidisciplinary interventions do not seem to be able to improve all FM-related symptoms.

5. STUDY LIMITATIONS

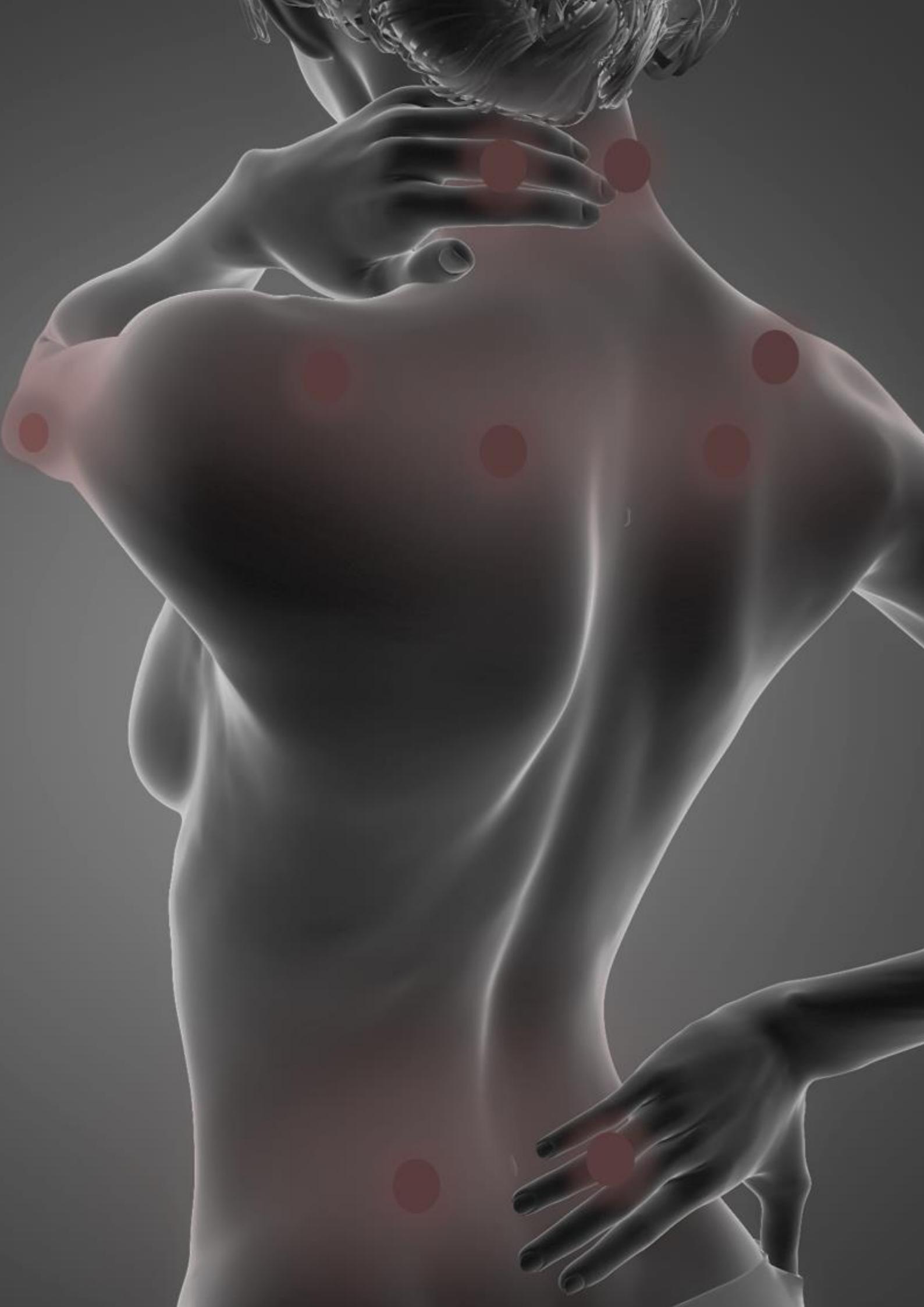
This study had some limitations. Firstly, the patients were not randomized. Additionally the intensity of the exercise was controlled in a subjective way, so it is possible that not all the participants were carrying out the program with the same percentage of load. Upper limb flexibility was not measured in the study. Additional studies with a larger number of participants, and randomization should be conducted to better understand the effect of ST in these patients.

6. CONCLUSIONS

After 24 weeks of STP focused on daily activities, patients with FM showed significant reduction in pain and sleep quality (scale scores), and greater physical function related to increased levels of upper and lower limb strength, lower limb flexibility and aerobic fitness. In contrast, these improvements did not occur for anxiety and fatigue. Hence, programs should probably be combined with cognitive behavioral therapies or educational programs to achieve significant changes in these symptoms. Finally, anxiety correlated negatively and significantly with upper and lower limb strength. In the other side, pain interference correlated negatively and significantly with upper limb strength and aerobic fitness.

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We would like to express our gratitude to the EXERNET study Group (Research Network on Exercise and Health in Special Populations), which has been supported by the Ministerio de Educación y Ciencia, and the participants of the FM association, Region Madrid (AFIBROM) their patience and involvement in the study.



V GENERAL DISCUSSION

The results obtained in this doctoral thesis show that women diagnosed with fibromyalgia are sedentary, a reason which undoubtedly favours muscular deterioration and general physical fitness. This can be observed in the **table 8 of study II** and in **tables 11 and 12 of study III**, where the initial values of physical fitness tests are lower than values found by Rikli & Jones (1999) in elderly women (60-80 years) using the same test for the assessment (Senior Fitness Test Battery). This is due to physical decline, because the symptoms worsen and limitations to perform daily activities, work, social and family are generated increase, as indicated by other findings in the literature (Roos, Rice and Vandervoort, 1997; Jones *et al.*, 2009; Assumpção *et al.*, 2010; Dailey *et al.*, 2016).

A relevant contribution in the current PhD. thesis is the assessment of the effects of a gradual and progressive strength-training program on symptoms, physical function, impact and physical fitness in order to improve quality of life. The designing of this program rooted in the fact that physical disability triggered by the loss of muscle mass is the main symptom of FM (Thompson, 1994; Okumus *et al.*, 2006; Nelson, 2015) being the fundamental consequence the limitation to carry out daily activities. The term “strength” in this patients generates “fear” and “frustration” because of the disability they present (Bennett *et al.*, 2007b). Patients with FM show to have lower functional capacity than women aged 60 to 80 years (Jones *et al.*, 2009). This is an important characteristic since the symptoms of FM could easily lead to inactivity, which with increasing age, would diminish physical function (Vøllestad and Mengshoel, 2005) and quality of life (Bennett, 2005; Henriksson, Bäckman, Henriksson, & de Laval, 1996).

Our results may suggest that lower levels of physical fitness are associated with greater risk for death and disability later in life, which is in line with recent studies (Ruiz *et al.*, 2009; Höglström, Nordström and Nordström, 2016; Henriksson *et al.*, 2019) and

with findings found in the study “*Associations of sedentary time and physical activity with physical fitness in women with fibromyalgia: an isotemporal substitution approach*” (**APPENDIX VII**, not yet published). These results show that sedentary time registered or presented by FM patients people during one day is much longer than the time performingin light, moderate, or vigorous physical activity.

The results obtained from the isotemporal models (Mekary *et al.*, 2009) determine the temporary substitution of sedentary behaviours for physical activities and suggest a key role for moderate physical activity in the maintenance or improvement of all components of physical fitness, which seems to be in line with the general advice of moderate physical activity to improve health in fibromyalgia (ACSM, 2012). This explains the benefits found in our study, which could be due to the intensity applied in the intervention program. That is, the training program was gradual and progressive in intensity, starting with light intensities and gradually reaching moderate to reach moderate-high intensities with the objective of achieving potentially significant benefits in **symptoms, impact, physical function and physical fitness**.

Previous research has analysed the effects of strength training in FM patients. People is vague and global improvements has been noticed in **symptomatology** (Bircan *et al.*, 2008a), as well as **physical function** (Valkeinen *et al.*, 2004; Kingsley *et al.*, 2005; Panton *et al.*, 2009; Gavi *et al.*, 2014), **reduction in pain points** (Hakkinen *et al.*, 2002; Jones *et al.*, 2002; Kingsley *et al.*, 2005; Figueroa *et al.*, 2007; Bircan *et al.*, 2008a; Hooten *et al.*, 2012; Kayo *et al.*, 2012), **increase strength levels** (Jones *et al.*, 2002; Kingsley *et al.*, 2005; Valkeinen *et al.*, 2006; Figueroa *et al.*, 2007; Bircan *et al.*, 2008a; Panton *et al.*, 2009; Larsson *et al.*, 2015), **fatigue** (Häkkinen *et al.*, 2001; Bircan *et al.*, 2008; Ericsson *et al.*, 2016) and **sleep** (Bircan *et al.*, 2008a; Ericsson *et al.*, 2016; Andrade, Vilarino and Bevilacqua, 2017). These results are partially in line with those

found in the present thesis, because, at the end of the 24-week intervention, the participants showed an improvement in sleep quality, symptomatology and greater physical function related to increased strength levels of the upper and lower extremities, flexibility of the lower extremities and aerobic fitness.

On a different note, our study not only improved pain intensity, but also improved the incidence of pain in the performance of daily activities, a variable that has not been studied previously. On the contrary, regarding fatigue, our results showed decreases in scores, without reaching statistically significant differences. This could be due to the fact that progressive strength training oriented to daily activities does not provide benefits in this symptom. Probably, to improve fatigue, strength base programs should be combined with aerobic training (Nichols and Glenn, 1994; Dinler *et al.*, 2009; Hooten *et al.*, 2012), cognitive-behavioural therapies (Macfarlane *et al.*, 2017), or educational programs (Mannerkorpi *et al.*, 2000). This WAS suggested by different studies in which the combination of psychopedagogical interventions with strength exercise improved feelings of tiredness and anxiety (Carville *et al.*, 2007; Macfarlane *et al.*, 2016, 2017). Aerobic exercise programs have also shown decreases in pain and fatigue (Nichols and Glenn, 1994; Dinler *et al.*, 2009; Hooten *et al.*, 2012) as well as notable improvements in quality of life (Häuser, Thieme and Turk, 2010) and physical function (Cullinane *et al.*, 2014).

Despite the fact that at the end of 24 weeks there were no significant differences in the decrease of anxiety, in comparison to baseline, anxiety was negatively and significantly correlated with upper limb strength and lower limb strength. Significant differences in anxiety may require combining strength training with other qualities or therapies, such as flexibility (Gavi *et al.*, 2014), cognitive-behavioural therapies

(Macfarlane *et al.*, 2017), or educational programs (Mannerkorpi *et al.*, 2000), at the end of the program.

In addition, studies about aquatic training in people with FM showed associations with improvements in pain (Mannerkorpi *et al.*, 2009; Tomas-Carus *et al.*, 2009), quality of life (Mannerkorpi *et al.*, 2009) and physical function (Mannerkorpi *et al.*, 2009). In contrast, the results of this PhD. thesis, not only showed significant improvements in these variables, but also notable differences in sleep quality and pain interference in daily activities performance.

Multidisciplinary programs (swimming pool, ground training and psychoeducational sessions) have also shown improvements in lower body severity and flexibility, but not in physical fitness (Sanudo *et al.*, 2010). This could be due to the low intensity applied in the intervention program because no differences in physical fitness were revealed at the end of the program was found, or also, by intolerance to high water temperature which aggravates the symptoms and impairs physical fitness. However, our results showed improvements in lower limb flexibility, upper and lower limb strength, and aerobic fitness achieving an optimal level of physical fitness.

Given the age-related loss of muscle mass, it is not surprising that there is an associated loss of muscle strength when comparisons are made across the adult age span (Doherty, Vandervoort and Brown, 1993; Grabiner and Enoka, 1995; Porter, Vandervoort and Lexell, 1995). In the **study II** of this PhD. thesis was to evaluate the effects of strength training on physical fitness, pain, and quality of life (symptoms, physical function, and overall impact) in women with FM establishing a cut-off point on the basis of the beginning of the aging and muscle decline.

The results of the present study showed that the initial physical fitness of women with fibromyalgia was more deteriorated in the group older than or equal to 56 years. This finding is in line with the results found in others studies (Alvarez-Gallardo et al., 2017; Alvarez-Gallardo et al., 2017). Despite this, both groups significantly improved their fitness levels (strength and aerobic fitness). Regarding pain, both groups also achieved significant improvements, starting the program with similar pain levels. However, the quality of life of younger women was less deteriorated than that of older women. Although the strength program improved the quality of life (symptoms, impact and physical function) in both, only in the group of older women has it done so significantly due to those lower levels of baseline quality of life. It would be interesting to see whether a more intensive program or a more volume or both would achieve significant improvements in the quality of life.

In terms of group association in women under or equal to 55 years of age, strength in upper and lower limb was negatively associated with pain intensity, symptoms and the impact of FM, and positively with physical function. In the same group, upper limb strength, it did not correlate with symptoms. Moreover, in this group, the increase of aerobic fitness measured with the 2-minute step test is consistently associated with lower levels of intensity, interference, and pain impact (regardless of the method used to assess pain) (Soriano-Maldonado, Ruiz, et al., 2015) which would be in line with previous studies (Busch *et al.*, 2007, 2013a; Hooten *et al.*, 2014; Garcia-Hermoso, Saavedra and Escalante, 2015; Soriano-Maldonado, Henriksen, Segura-Jimenez, *et al.*, 2015).

For the group greater than or equal to 56 years of age, at the end of the training program, considering that women with FM were already physically active and that their physical fitness had improved, our data showed an inverse correlation between strength levels and pain intensity and interference, physical function, symptomatology and FM

impact (Palstam et al., 2016). As opposed to the first group, no association was found between aerobic fitness and quality of life (physical function, impact and symptoms). This may explain that increased aerobic fitness influences pain improvement and the impact of fibromyalgia in younger women, while in older women, aerobic fitness does not appear to influence symptom improvement. No previous studies have been found that determine the associations between quality of life and aerobic fitness in fibromyalgia in older ages. Therefore, to confirm that improvement in aerobic condition will not improve fibromyalgia symptoms in older women is still bold and we suggest that further studies analyze in isolation the association of aerobic condition after an improvement in aerobic condition with quality of life (physical function, impact and symptoms).

Over the course of this PhD. thesis, it has been observed that achieving optimal muscle performance has a positive influence on the symptoms of women diagnosed with fibromyalgia. This has been evidenced in subsequent studies (Maestre-Cascales *et al.*, 2019) (**APPENDIX VI**), with the aim of confirming that FM patients who achieved higher levels of strength, and as a result, achieved greater functionality to perform daily activities, and as a consequence, these participants had a beneficial effect not only on their physical health but also on their psychological health. Thus, physical activity can promote better mental health that enables to succeed in daily activities was indicated in available researches (Kanning and Schlicht, 2010). In addition, it is also contributes to meet the needs that will lead to a greater subjective well-being in women with FM, which is also concluded by other authors (Palagini *et al.*, 2016; Ruiz-Cabello *et al.*, 2017; Carvalho *et al.*, 2018; Borges-Cosic *et al.*, 2019).

VI. CONCLUSIONS

CONCLUSIONS

The overall aim of this PhD. thesis was to assess the effect of a gradual muscle strengthening program oriented to daily activities on the symptomatology, functionality, and impact of FM in women diagnosed with fibromyalgia. Therefore, conclusions presented according to the three studies of it.

Conclusions of Study I

Conclusion 1: The gradual muscle strengthening program was effective to improve strength levels, physical function, general symptoms, and overall impact at 12 and 24 weeks in women diagnosed with FM.

Conclusion 2: The quality of life of people diagnosed with fibromyalgia improved clinically and significantly at the end of the strength program (24 weeks).

Conclusions of Study II

Conclusion 1: A muscle strengthening program produced improvements in physical fitness (both at the level of muscle strength and at the aerobic level) and pain regardless of age group. However, quality of life (physical function, impact and symptoms) only improved only in the group of women over 56 years of age.

Conclusion 2: Improvements in strength levels are positively associated with quality of life and pain in both groups. However, improvements in aerobic fitness are only associated with increased quality of life (physical function, impact and symptoms) and pain in the group of women under the age of 55.

Conclusions of Study III

Conclusion 1: The gradual muscle strengthening program was effective to improve physical fitness (upper and lower limb strength, lower limb flexibility and aerobic fitness), pain and sleep quality.

Conclusion 2: Despite improvement levels of anxiety and fatigue at 12 weeks and at the end of the muscle strengthening program (week 25). This was not effective in achieving significant differences in either phase.

CONCLUSIONES

El objetivo general de esta tesis doctoral fue evaluar el efecto de un programa de fortalecimiento muscular gradual orientado a las actividades cotidianas sobre la sintomatología, función física e impacto de la FM en mujeres diagnosticadas de fibromialgia. Por lo tanto, las conclusiones que se presentan a continuación corresponden a cada uno de los tres estudios que componen las subsecciones de esta tesis.

Conclusiones estudio I

Conclusión 1: El programa de fortalecimiento muscular gradual fue efectivo para mejorar la función física, sintomatología e impacto general a las 12 y 24 semanas en mujeres diagnosticadas de FM.

Conclusión 2: La calidad de vida de las personas diagnosticadas de FM mejoró clínicamente y significativamente al finalizar el programa de fortalecimiento muscular (24 semanas).

Conclusiones estudio II

Conclusión 1: Un programa de fortalecimiento muscular gradual produjo mejorías en la condición física (a nivel de fuerza muscular y capacidad aeróbica) y dolor independientemente del grupo de edad. Sin embargo, la calidad de vida (función física, impacto y síntomas) sólo mejoró en el grupo de mujeres mayores de 56 años.

Conclusión 2: Las mejoras en los niveles de fuerza se asocian positivamente con la calidad de vida y el dolor en ambos grupos. Sin embargo, las mejoras en la capacidad aeróbica sólo se asocian con una mayor calidad de vida (función física, impacto y síntomas) y dolor en el grupo de mujeres menores de 55 años.

Conclusiones estudio III

Conclusión 1: El programa de fortalecimiento muscular gradual fue efectivo para mejorar la condición física (fuerza del miembro superior e inferior, flexibilidad del miembro inferior y capacidad aeróbica), el dolor y la calidad del sueño.

Conclusión 2: A pesar de mejorarlos niveles de la ansiedad y fatiga a las 12 semanas y al finalizar el programa de fortalecimiento muscular (semana 25). Este no fue efectivo para alcanzar diferencias significativas en ninguna de las dos fases.

VII. STRENGTHS AND LIMITATIONS

STRENGTHS

Several strengths of study and this thesis should be highlighted:

- Participants who completed the intervention and were included in present PhD thesis had an adherence of 90% to exercise sessions.
- Intervention was conducted by a collaboration of the regional FM association (AFIBROM, Region of Madrid), where sessions were developed along with the data collection.
- In the supervised groups, throughout the 24 weeks, participants were monitored by certified trainer with Exercise and Health Master degree, ensuring the correct execution during all the training sessions.
- In order to obtain short-term feedback on the intervention program, small face-to-face interviews were conducted approximately every two weeks. Moreover, to know the possible traumas that trigger fibromyalgia (if any).
- The inclusion of a third measurement (week 12) in the intervention program allowed to bring greater scientific quality to the final results.
- Adherence for the following three years was 30%, and for the fourth year (2018/2019) 22%.
- The proposed program is easily reproducible as no specific installations or sophisticated equipment are required. In addition to the low cost that would entail the implementation of specific facilities for it.

- The number of study participants. Thanks to AFIBROM, the people who have carried out this program, exceeds with 25% the average of participants in similar studies.

LIMITATIONS

After carrying out the project, analyzing the data, discussing and comparing our results with other studies, we present a critical view of our work, listing the main limitations below:

- The no inclusion of a non-exercising group to control for confounding psychosocial effects such as peer support, encouragement, and attention afforded participants. However, the magnitude of the symptom abatement is far in excess of any placebo reported in other studies conducted under similar experimental conditions. Moreover, this study was designed to test the response of a group of patients to exercise.
- Daily activities were not recorded with accelerometer.
- Evolution of pain points with algometer was not measured.
- The gender effect was not tested.
- The program was not validated via experts' criteria.
- The intervention program was controlled and directed by the same person who is doing this doctoral thesis.

VIII. FUTURE RESEARCH LINES

FUTURE RESEARCH LINES

This PhD thesis has given the possibility to study the effects of strength training oriented to daily activities with the aim of improving the quality of life of women diagnosed with fibromyalgia. Learning from it and having a wider view of similar projects, future studies should take into consideration the following issues:

- Future research lines may include other illnesses with psychological disorders as a control group.
- Add male participants to the intervention program to assess the response to strength training on quality of life.
- Organize multi-center collaborations (associations, primary healthcare centers, rheumatologists, etc.) in order to obtain a larger sample size to ensure enough statistical power.
- Include accelerometer measures in order to control for the activity at home, work time, free time (physical activity sessions), and the sedentary time with the aim of adjust the training intensities.
- Includes instruments to measure intensity such as: heart rate monitors during training sessions to see if there is a linear relationship between strength training and heart rate. Also, Velocity-Based Resistance Training is another parameter for monitoring and evaluating strength training.
- Include blood samples for inflammatory markers.
- Add cognitive-behavioral therapy to intervention sessions.

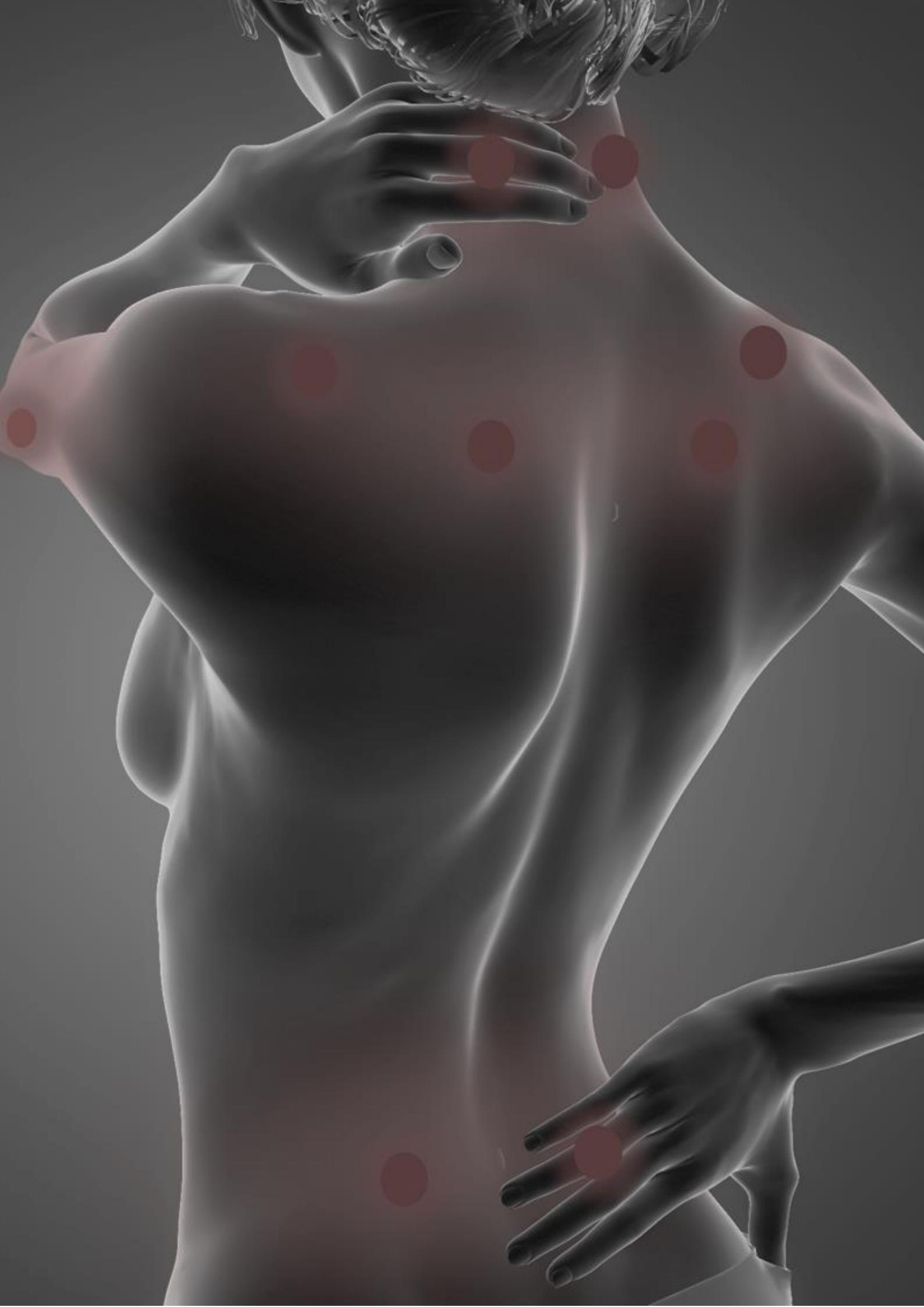
IX. PRACTICAL APPLICATIONS

PRACTICAL APPLICATIONS

Experts in Sport Science and practicing trainers have suggested before that well designed, controlled and supervised exercise with certified trainers is the best way to do exercise in order to improve the muscle performance in women diagnosed with fibromyalgia. In our study, physical activity recommendations have also promoted some health benefits, but our results support the suggestion of the experts and demonstrate a greater effect of supervised interventions for some aspects.

Below, we highlight some practical applications from current findings:

- Training programs aimed at improving muscle performance, physical function, impact and general symptomatology should be progressive and gradual in volume and intensity with a minimum duration of 12 weeks.
- Strength training oriented to daily activities does not appear to be able to enough stimuli to improve levels of anxiety and fatigue.
- Strength training aimed at daily activities improves symptoms such as pain and sleep quality, while to improve symptoms such as anxiety, it is not effective.
- The current program improves the physical fitness of FM patients regardless of age. However, the quality of life despite improving in both age groups, women older than or equal to 56 years reach more drastic improvements.
- Organize multidisciplinary program with physiotherapists, psychological, and nutritional sessions for the treatment of fibromyalgia.



X. REFERENCES

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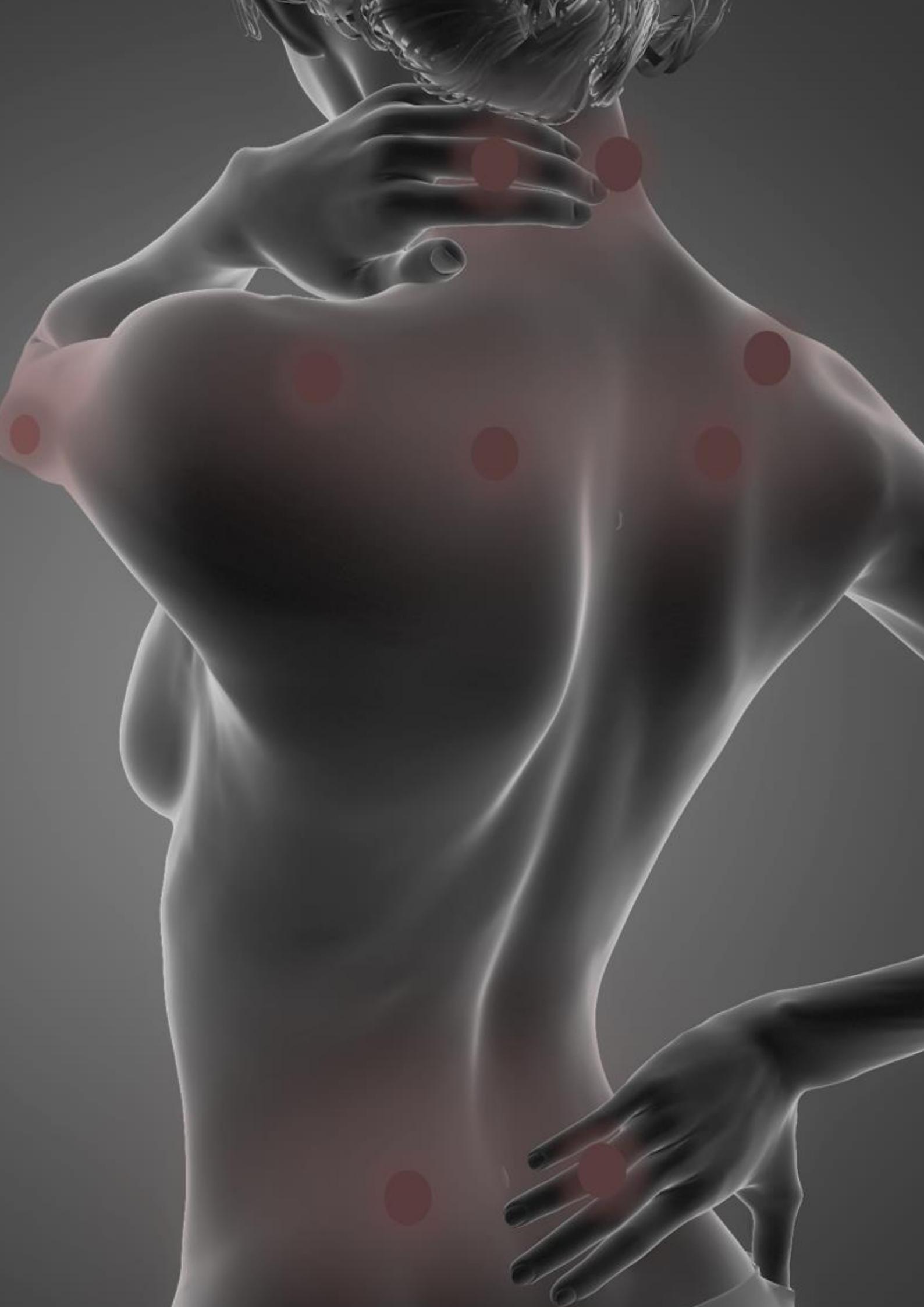
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XI. CV SUMMARIZED

SHORT CV

CRISTINA ASUNCIÓN MAESTRE CASCALES

Personal e-mail: cmcascales@hotmail.com

FPI Research fellow

Member of Laboratory of Exercise Physiology Research Group (*LFE*)

Universidad Politécnica de Madrid (Spain)

Dept. of Health and Human Performance

Faculty of Physical Activity and Sport Sciences (INEF)

Member of the EXERNET research network

Academic training

2015-current	PhD student in Physical Activity and Sport Science. Universidad Politécnica de Madrid, Spain.
2016-2017	Master's Degree (MSc) in Physical Education Teacher Training. Miguel Hernández University of Elche (UMH), Spain
2014-2015	Master's degree (MSc) in Promotion of Public Health through Physical Activity. University of Extremadura, Spain.
2010-2014	Graduate degree (BSc) in Research in Physical Activity and Sport Science. Catholic University of Valencia (UCV), Spain.

Complementary academic training

2018	Course on the psycho-pedagogical bases of cooperative learning: group work in the classrooms. Organization: University Camilo José Cela (UCJC). Madrid (Spain). <i>110 hours</i>
2018	Teaching Digital Competence Course: School 2.0 as a didactic tool in the development of digital competences. Organization: University Camilo José Cela (UCJC). Madrid (Spain). <i>110 hours</i>
2015-2016	National Swimming Coach Course. Organization: Spanish Royal Swimming Federation. <i>1 year</i> .
2014	Attendance to the 1st conference on the Prevention of Adaptation of Sport Injuries in Physical Activity and Sport. Organization: JAM SPORTS. Alboraya (Valencia). <i>12 hours</i> .
2014	International Certification Course in Anthropometry Level I. Organization: International Society for the Advancement of Kinanthropometry (ISAK). Valencia (Spain). <i>24 hours</i>

Research projects

2016-current	<p>Iron Femme project</p> <p><i>Funder:</i> Ministerio de Economía, Industria y Competitividad, Convocatoria de Ayudas I+D 2016, Programa Estatal de Investigación Científica y Técnica y de Innovación 2013-2016 (Grant code DEP2016-75387-P).</p> <p>Laboratory of Exercise Physiology Research Group (LFE). Universidad Politécnica de Madrid (Spain).</p> <p><i>Supervisor:</i> Ana Belén Peinado Lozano and Rocío Cupeiro Coto.</p>
2012-2014	<p>Effects of fatigue on physical-cognitive performance in the military.</p> <p>Research Institute in Physical Activity and Sport Sciences.</p> <p><i>Supervisor:</i> Carlos Pablos Abella</p> <p>Catholic University of Valencia (UCV), Spain.</p>
2012-2014	<p>Effects of exercise programs on cognitive performance in older people</p> <p>Research Institute in Physical Activity and Sport Sciences.</p> <p><i>Supervisor:</i> Carlos Pablos Abella</p> <p>Catholic University of Valencia (UCV), Spain.</p>
2012-2014	<p>Effects of a dance intervention programme on mood and life satisfaction in people with Parkinson's disease.</p> <p>Research Institute in Physical Activity and Sport Sciences.</p> <p><i>Supervisor:</i> Carlos Pablos Abella</p> <p>Catholic University of Valencia (UCV), Spain.</p>

Grants

2017-2019	<p>FPI Research and Teaching (Predoctoral) Fellowship</p> <p><i>Funding:</i> Universidad Politécnica de Madrid-Programa Propio-Santander Universidades</p> <p><i>Affiliation:</i> Department of Health and Human Performance</p>
2012-2014	<p>Collaborative grant at the Institute for Research in Physical Activity and Sport Sciences.</p> <p><i>Funding:</i> Catholic University of Valencia (UCV), Spain</p> <p><i>Affiliation:</i> Institute for Research in Physical Activity and Sport Sciences.</p> <p><i>Supervisor:</i> Carlos Pablos Abella</p>

Visiting researcher

2018-2019	Institute of Nursing and Health Research Ulster University, Belfast, United Kingdom <i>Date: 14/9/2017-14/12/2018 (3 months)</i>
2017-2018	Center for Research in Sports Sciences (CID) Load Analysis and Optimization Laboratory Miguel Hernández University of Elche (UMH), Spain <i>Date: 1/11/2017-23/02/2018 (3 months, 23 days)</i>

Informative publications

2016	Journal “fibromyalgia al día” nº 24. Cuerpo y mente. Primer Semestre de 2016. Pages 14-15. “El fomento de la Actividad Física mejora el estado de ánimo de las personas con fibromialgia”.
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Teaching assistant

2019-2020	Subject: Kinesiology and Systematics of Physical Activity Bsc in Physical Activity and Sport Science, Universidad Politécnica de Madrid (Spain).
2019-2020	Postgrade degree in Sport and Women Subject: Physical Activity and Fibromyalgia. Universidad Politécnica de Madrid (Spain). <i>(5 hours)</i>
2018-2019	Subject: Kinesiology and Systematics of Physical Activity Bsc in Physical Activity and Sport Science, Universidad Politécnica de Madrid (Spain).
2018-2019	Postgrade degree in Sport and Women Subject: Physical Activity and Fibromyalgia. Universidad Politécnica de Madrid (Spain). <i>(3 hours)</i>
2018-2019	Subject: Physiology of Systems Bsc in Biotechnology, Universidad Politécnica de Madrid (Spain).

2017-2018	Subject: Physiology of Systems Bsc in Biotechnology, Universidad Politécnica de Madrid (Spain).
2016-2017	Subject: Physical Activity and Health Bsc in Physical Activity and Sport Science, Universidad Politécnica de Madrid (Spain).

Congress Organazing Committe

2018	Organizing Committee member of the X International Symposium in Strength Training in Faculty of Physical Activity and Sports Science (INEF). Universidad Politécnica de Madrid, 14th---15 th December 2018.
2017	Organizing Committee member of the X International Symposium in Strength Training in Faculty of Physical Activity and Sports Science (INEF). Universidad Politécnica de Madrid, 16th---17 th December 2017.

Congresses Contributions

2013	Yuste, F., Ballester, R., Bermejo, J., Maestre, C.A. , Moratal, C., & Llorens, F. Does physical out of school activity compromise the academic performance of youth people?. 18TH ANNUAL CONGRESS OF THE ECSS. BARCELONA (ESPAÑA).
2013	Bermejo, J., Ballester, R., Yuste, F., Llorens, F., Maestre, C.A. , & Huertas, F. Does fitness level modulate vigilance of youth people?. 18TH ANNUAL CONGRESS OF THE ECSS. BARCELONA (ESPAÑA).
2013	Huertas, F., Yuste, F., Ballester, R., Maestre, C.A. , Llorens, F., Moratal, C., Llorens, F.& Sanabria, D. Relación entre vigilancia y práctica deportiva en la etapa prepuberal ¿condición física o especialización atencional? RECA. PALMA DE MALLORCA (ESPAÑA).
2014	Huertas, F., Bermejo, J.L., Ballester, R., Palma, V., Maestre, C. & Pablos, C. Effect of about of strength exercise until failure on heart rate variability. IV NSCA INTERNATIONAL CONFERENCE 2014. MURCIA (ESPAÑA).
2014	Huertas, F., Ballester, R., Yuste, F.J., Llorens, F., Bermejo, J.L., Maestre, C. , & Sanabria, D. Be fit and smart: team sports practice improves physical fitness, sustained attention and academic achievement in adolescence. IV NSCA INTERNATIONAL CONFERENCE 2014. MURCIA (ESPAÑA).

- 2014** Huertas, F., Bermejo, J.L., Ballester, R., Palma, V., **Maestre, C.** & Pablos, C. **Heart rate variability perform after an exercise of power with muscular optimal load.** **19TH ANNUAL CONGRESS OF THE ECSS.** AMSTERDAM (HOLANDA).
- 2015** Gusi N, Collado-Mateo D, Dominguez-Muñoz FJ, Olivares PR, **Maestre-Cascales C**, Adsuar JC. **Sit- to-stand-to-sit performance in women with fibromyalgia compared with healthy controls.** **11TH ANNUAL MEETING AND 6TH CONFERENCE OF HEPA EUROPE.** ISTANBUL (TURKEY).
- 2018** Romero-Parra, N., Cupeiro R., Alfaro-Magallanes VM., Rael B., Rojo-Tirado MA., **Maestre-Cascales C.**, Peinado AB. **Muscle soreness and range of movement after exercise-induced muscle damage in eumenorrheic women.** **XI INTERNATIONAL SYMPOSIUM IN STRENGTH TRAINING.** MADRID (SPAIN).
- 2018** Alfaro-Magallanes, V.M., Barba-Moreno, L., Cupeiro, R., Romero-Parra, N., Rael, B., **Maestre-Cascales, C.**, Sánchez-Díaz, C., Bodoque, M., Salmerón, C., Peinado, A.B. **Iron metabolism regulation in women after an endurance protocol depending on ferritin status.** **23ND ANNUAL CONGRESS OF THE EUROPEAN COLLEGE OF SPORT SCIENCE.** MADRID (SPAIN).
- 2018** Barba, L., Cupeiro, R., Dían, A.E., Santiago, E., Alfaro, V., Rael. B., **Maestre-Cascales, C.**, Orellana, J., Peinado, A.B. **Menstrual Cycle Influence on Hepcidin Secretion and Inflammatory Responses in Female Athletes. IronFEMME Pilot Study.** **65ND AMERICAN COLLEGE OF SPORTS MEDICINE.** MINNEAPOLIS, MINNESOTA (USA).
- 2019** Maestre Cascales, C., Gavilán-Carrera, B., Acosta-Manzano, P., Borges-Cosic, B., Soriano-Maldonado, A., Hughes, CM., Estévez-López, F. **Association of sedentary time and physical activity with physical fitness in women with fibromialgia: an isotemporal substitution approach.** **EUROPEAN CONGRESS OF RHEUMATOLOGY.** MADRID (SPAIN).
- 2019** Estévez-López, F., **Maestre-Cascales, C.**, Russell, D., Álvarez-Gallardo, IC., Rodriguez-Ayllon, M., Hughes, CM., Davison, GW., Sañudo, B., McVeigh, JG. **Effectiveness of exercise in the management of fatigue and sleep quality in fibromyalgia: a systematic review and metaanalysis.** **EUROPEAN CONGRESS OF RHEUMATOLOGY.** MADRID (SPAIN).

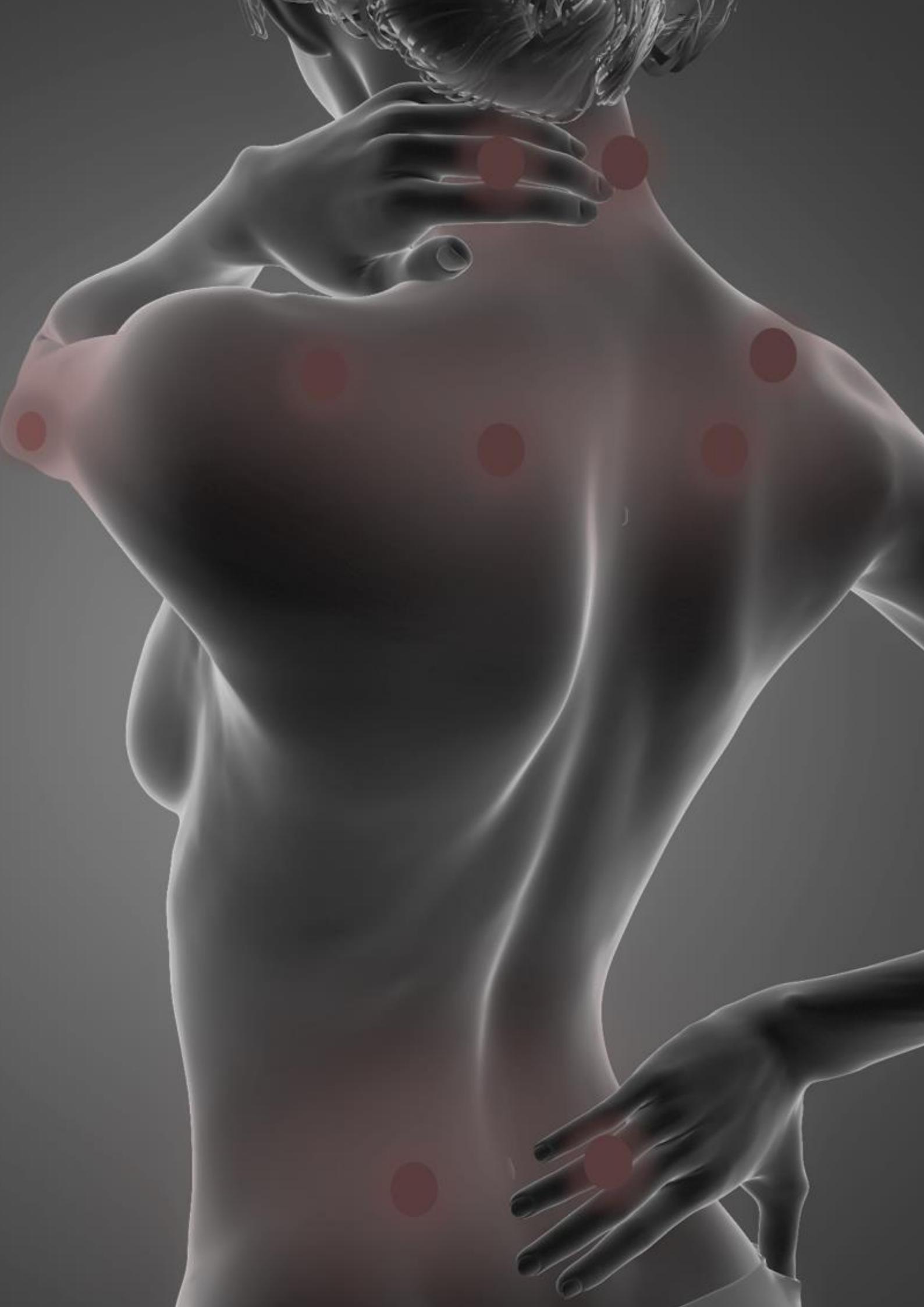
Oral Congresses Contributions

2015	Maestre Cascales, Cristina. Traducción a lengua de signos española de cuestionarios de calidad de vida y actividad física en base web. I CONGRESO MULTIDISCIPLINAR DE JÓVENES INVESTIGADORES EXTREMEÑOS. CÁCERES (SPAIN).
2017	Maestre-Cascales, C., Calderón-Montero, J., Rojo-González, J.J. EFFECT OF a progressive and monitored muscle strengthening program on the development of upper limb strength in people diagnosed with fibromyalgia. 22ND ANNUAL CONGRESS OF THE EUROPEAN COLLEGE OF SPORT SCIENCE. 5TH - 8TH JULY, METROPOLISRUHR (GERMANY).
2018	Maestre Cascales, C., Pastor, D., Carbonell-Hernández, L., Rojo-González, J.J. effect of a strength program about pain interference and other symptom in women with fibromyalgia. XXVI JORNADAS NACIONALES DE TRAUMATOLOGÍA DEL DEPORTE. 8-9 MARZO, MURCIA (ESPAÑA).
2018	Maestre Cascales, C., Pastor, D., Rojo-González, J.J. EFFECT OF A twenty-four-weeks strength trainin program about pain intensity and interference with daily activities in two different groups of women diagnosed with fibromylgia. 23ND ANNUAL CONGRESS OF THE EUROPEAN COLLEGE OF SPORT SCIENCE. 4-7TH JULY, DUBLIN (IRELAND).
2018	Maestre Cascales, C., Pastor, D., Romero-Parra, N., Benito, PJ., Rojo-González, J.J. age-dependent response to exercise in women with fibromyalgia. XI INTERNATIONAL SYMPOSIUM IN STRENGTH TRAINING. 14-15 TH DECEMBER, MADRID (SPAIN).

International Publications

2016	Maestre-Cascales, C, Girela-Rejón, M.J., Sánchez-Gallo, D.P.-, Acosta-Manzano, P., Gavilán-Carrera, B., García-Rodríguez, I., Rojo-González, J.J. & Aparicio,V.A. (2019) ‘Association of handgrip strength and well-being in women with fibromyalgia’, <i>Revista Internacional de Ciencias del Deporte</i> , 15(58), pp. 307–322. doi: 10.5232/ricyde. In press.
2019	Maestre-Cascales, Cristina; Peinado Lozano, Ana Belén; Rojo González, Jesús Javier. Effects of a strength training program on daily living in women with fibromyalgia. <i>Journal of Human Sport and Exercise</i> , [S.l.], p. in press , jan. 2019. ISSN 1988-5202. Available at: < https://www.jhse.ua.es/article/view/2019-v14-n4-strength-training-program-daily-living-women-with-fibromyalgia >. Date accessed: 24 apr. 2019. doi: https://doi.org/10.14198/jhse.2019.144.03 .

- 2019 **Maestre Cascales**, C., Gavilán-Carrera, B., Soriano-Maldonado, A., Hughes, C.M., Rojo-González, J.J., Segura-Jiménez, V. & Estévez-López, F. Associations of sedentary time and physical activity with physical fitness in women with fibromyalgia: an isotemporal substitution approach. **Submitted.**
- 2019 Estevez-Lopez, F., **Maestre-Cascales**, C., Russell, D., Álvarez-Gallardo, I.C., Rodriguez-Ayllón, M., Hughes, C.M., Davison, G.V., Sañudo, B. & McVeigh, J.G. Effectiveness of exercise in fatigue and sleep quality in fibromyalgia: a systematic review and meta-analysis of randomised trials. **Submitted in Sports Medicine.**
- 2019 **Maestre-Cascales**, C., Calderón Montero, J. & Rojo-González, J.J. Gradual strength training improves quality of sleep, physical function and pain in patients with fibromyalgia. **Submitted in Clinical and Experimental Rheumatology.**
- 2019 **Maestre-Cascales**, C., Pastor, D., Romero-Parra, N., José Benito, J., Alfaro-Magallanes, VM. & Rojo-González, J.J. Age-dependent response to exercise in women with fibromyalgia. **Submitted in Women & Health.**



XII. APPENDIXES

APPENDIX I



UNIVERSIDAD POLITÉCNICA DE MADRID
FACULTAD DE CIENCIAS DE LA ACTIVIDAD
FÍSICA Y DEL DEPORTE
C/ Martín Fierro, s/n. 28040 Madrid

Dña. Cristina Maestre Cascales, graduada en Ciencias de la Actividad Física y del Deporte y Máster en Promoción de la Salud mediante la Actividad Física, se encuentra realizando, bajo mi dirección, su trabajo de tesis doctoral, consistente en diseñar y desarrollar distintos programas de ejercicio en personas con fibromialgia. La finalidad del estudio es comprobar que tipo de trabajo proporciona un mayor bienestar en las personas diagnosticadas de esta patología.

Para poder realizar un estudio que siguiendo el método científico lleve a conclusiones fidedignas, es necesario un número elevado de participantes por lo que nos sería de gran utilidad la ayuda que desde esa asociación nos pudieran dar, fundamentalmente dando a conocer el estudio entre sus asociados, animándolos para que participen como voluntarios.

Agradeciendo su atención. Reciba un cordial saludo,

Fdo. Dr. Jesús J. Rojo González

A handwritten signature in black ink, appearing to read "Jesús J. Rojo González".

Madrid a 14 de septiembre del 2015

APPENDIX II

EVALUACIÓN DE LOS EFECTOS DE UN PROGRAMA DE ACTIVIDAD FÍSICA BASADO EN EL TRABAJO DE FUERZA EN MUJERES DIAGNOSTICADAS DE FIBROMIALGIA.

Investigador/es principal/es: Jesús Javier Rojo González, Javier Calderón Montero y Cristina Maestre Cascales

Se ha demostrado que existe un tratamiento alternativo considerado como terapias **complementarias no farmacológicas como es la actividad física**, donde en la actualidad se ha demostrado tener un efecto muy positivo en la sintomatología física y psicológica y con ello una mejora de la calidad de vida necesaria para realizar cualquier tarea de la vida cotidiana.



“El ejercicio regular debe incorporarse dentro de la rutina como tratamiento en todos los pacientes con FM ya que se observan mejoras a corto plazo reduciendo el dolor mediante entrenamiento de fuerza” (Andrade, Sieczkowska and Vilarino, 2019b).



:POR QUÉ BASADO EN EL TRABAJO DE FUERZA?

“LA MEJORA DE LA FUERZA MUSCULAR PUEDE TENER UN IMPACTO POSITIVO EN LA CALIDAD DE VIDA DE LOS PACIENTES QUE PRESENTAN FIBROMIALGIA”

“EL FORTALECIMIENTO DE LOS PRINCIPALES GRUPOS MUSCULARES PUEDEN REDUCIR SIGNIFICATIVAMENTE LOS SÍNTOMAS TRANSFERIBLES A LAS ACTIVIDADES DE LA VIDA COTIDIANA”

- ✓ *Mejoras significativas* (mayores al 30%) mediante un entrenamiento exclusivo de fuerza en el dolor, bienestar general y depresión; sin embargo, estos estudios también han mostrado beneficios en ansiedad, calidad de vida, función física, fatiga y estado de ánimo (Kingsley *et al.*, 2005).
- ✓ La FM afecta a la capacidad funcional, por tanto, el objetivo fundamental que queremos conseguir es que la persona mantenga y/o mejore su capacidad funcional con los beneficios que esto conlleva en el desarrollo de su vida diaria y en el bienestar psicológico y social (Cerón-Lorente *et al.*, 2018)

¿CUÁLES SON NUESTROS OBJETIVOS?

1. Conocer el impacto (síntomas y funcionamiento físico) de un programa de Actividad Física 24 semanas basado en el trabajo de fuerza gradual sobre la FM y orientado a las actividades de la vida diaria.
2. Valorar la evolución de diferentes aspectos clínicos como el dolor (intensidad e interferencia en las actividades), ansiedad, fatiga y sueño a lo largo de las 24 semanas de entrenamiento de fuerza gradual.
5. Mejorar el nivel de condición física de los sujetos mediante el programa de fortalecimiento muscular gradual.
 - 5.1 Aumentar los niveles de fuerza en tren superior como en inferior.
 - 5.2 Disminuir la rigidez mediante el trabajo de flexibilidad
 - 5.3 Mejorar la capacidad cardiorrespiratoria

¿QUÉ ASPECTOS SE VAN A MEDIR?

1. VARIABLES FISIOLOGICAS

- ✓ TENSIÓN ARTERIAL
- ✓ FRECUENCIA CARDIACA EN REPOSO
- ✓ SATURACIÓN DE OXÍGENO

2. CUESTIONARIOS

- ✓ VARIABLES SOCIODEMOGRÁFICAS
- ✓ CUESTIONARIO REVISADO IMPACTO FIBROMIALGIA (CIFR)
- ✓ CUESTIONARIO BREVE PARA LA EVALUACIÓN DEL DOLOR (CBD)
- ✓ CUESTIONARIO ANSIEDAD- ESTADO (STAI-E)

3. TALLA Y PESO

4. ANTROPOMETRIA

5. PRUEBAS FÍSICAS

- ✓ FUERZA MIEMBRO SUPERIOR E INFERIOR
- ✓ FLEXIBILIDAD MIEMBRO SUPERIOR
- ✓ RESISTENCIA AERÓBICA

- **MEDICIONES EN 3 MOMENTOS TEMPORALES:**
 - ✓ SEMANA PREVIA AL INICIO DEL PROGRAMA (SEMANA 0).
 - ✓ A MITAD DEL PROGRAMA (SEMANA 12).
 - ✓ FINAL DEL PROGRAMA (SEMANA 25).
 - ✓
- **“DIARIO PACIENTE A LO LARGO DEL PROGRAMA”**
 - ✓ CONTROLAR LA INTENSIDAD
 - ✓ OBTENER INFORMACIÓN A CORTO PLAZO
 - ✓ INDIVIDUALIZAR LAS CARACTERÍSTICAS DEL PROGRAMA A LAS NECESIDADES DEL SUJETO

Los criterios de inclusión y exclusión que se establecerán para formar parte del estudio serán los siguientes:

CRITERIOS DE INCLUSIÓN

- a) Ser mujer con edades comprendidas entre 20-75 años.
- b) Estar diagnosticada de FM por un reumatólogo cumpliendo con los criterios de la American College of Rheumatology, 1990.
- c) No presentar discapacidades físicas.
- d) No practicar otra actividad en el momento de la intervención o 1 hora semanal como máximo.
- e) Capacidad de comunicarse con el medidor

CRITERIOS DE EXCLUSIÓN

- f) a) Ser varón.
- g) b) Haber sido diagnosticadas de enfermedades que contraindiquen la práctica de Actividad Física
- h) c) Encontrarse en estado gestacional.
- i) d) Cambio de terapia en el periodo de la intervención



¿EN QUE COSISTE EL PROGRAMA DE FORTALECIMIENTO?

- ✓ DURACIÓN: 24 SEMANAS + 3 DE VALORACIONES
- ✓ FRECUENCIA SEMANAL: 2 DIAS SEMANALES

PROGRAMA DE FORTALECIMIENTO MUSCULAR	
CALENTAMIENTO- 15 minutos	
Generalmente incluirá dos bloques de ejercicios: trabajo aeróbico mediante desplazamiento y movilidad articular mediante ejercicios rítmicos.	
PARTE PRINCIPAL-30 minutos	
Trabajo de fuerza gradual distribuido en 3 FASES :	
<ul style="list-style-type: none"> ❖ 1^a fase: AUTOCARGAS. ❖ 2^a fase: MATERIAL DE RESISTENCIA: BANDAS ELÁSTICAS. ❖ 3^a fase: CARGAS EXTERNAS 	
Trabajo de equilibrio, coordinación, control postural, estabilidad e interacción sensorial mediante material inestable durante las 3 fases de trabajo.	
CARACTERÍSTICAS:	
*Trabajo en circuito: 2circuitos, 2 series/circuito, tiempo de trabajo inicial:30'', tiempo de recuperación entre ejercicios; 30'', tiempo de recuperación entre circuitos: 5', tiempo de recuperación entre series: 2'.	
VUELTA A LA CALMA-15 minutos	
La última parte de la sesión consistirá en estiramientos, incidiendo en las zonas más comunes de rigidez debido a la propia FM, así como actividades posturales, de relajación y respiración.	

A LO LARGO DEL PROGRAMA DE INTERVENCIÓN SE TENDRÁ EN CUENTA EL FACTOR MOTIVACIONAL PARA CONSEGUIR Y MANTENER LA ADHERENCIA A LO LARGO DEL MISMO.



- CONTROL Y MONITORIZACIÓN AL INICIO, MITAD Y FINAL DE CADA SESIÓN DE LAS SIGUIENTES VARIABLES FISIOLÓGICAS:
 - RECUENCIA CARDIACA EN REPOSO
 - SATURACIÓN DE OXÍGENO
 - TENSIÓN ARTERIAL

APPENDIX III

HOJA DE INFORMACIÓN AL PARTICIPANTE

Título del proyecto:

EVALUACIÓN DE LOS EFECTOS DE UN PROGRAMA DE ACTIVIDAD FÍSICA
BASADO EN EL TRABAJO DE FUERZA EN MUJERES DIAGNOSTICADAS DE
FIBROMIALGIA.

Investigador principal: MAESTRE CASCALES, CRISTINA

Directores: ROJO GONZÁLEZ, JESÚS JAVIER ROJO y CALDERÓN MONTERO, FCO. JAVIER

Centros participantes: Laboratorio de Fisiología del Esfuerzo (LFE), Facultad de Ciencias de la Actividad Física y el Deporte y Asociación de Fibromialgia de la Comunidad de Madrid (AFIBROM).

Paciente	Cod.
----------	------

LEA DETENIDAMENTE LA INFORMACIÓN CONTENIDA EN ESTE DOCUMENTO Y ASEGÚRESE QUE ENTIENDE ESTE PROYECTO DE INVESTIGACIÓN. POR FAVOR SI ESTÁ DE ACUERDO EN PARTICIPAR EN ESTE ESTUDIO, FIRME ESTE DOCUMENTO. POR SU FIRMA RECONOCE QUE HA SIDO INFORMADO DE LAS CARACTERÍSTICAS DEL PROYECTO, DE SUS REQUISITOS Y SUS RIESGOS Y QUE ACEPTE LIBREMENTE PARTICIPAR EN ÉL.

• **OBJETO DEL ESTUDIO**

La Fibromialgia (FM) es un síndrome de etiología desconocida, caracterizada por un estado de dolor crónico y generalizado, que presenta una elevada comorbilidad que repercute en la calidad de vida, siendo la fatiga y el dolor los síntomas más frecuentes en esta enfermedad.

En las personas con fibromialgia, la práctica de actividad física produce los mismos efectos que en los individuos sanos: mejora de la función cardiorrespiratoria, reducción de los factores de riesgo de enfermedad coronaria, disminución de la mortalidad y morbilidad cardiovascular y mejora de la función psicosocial. También produce un incremento de la fuerza muscular, movilidad articular y mejoras en el equilibrio y control postural, facilitando una mejor capacidad funcional para el desarrollo de las actividades de la vida cotidiana. Existiendo diversas publicaciones que donde informan sobre la

mejoría de personas con fibromialgia al someterse a programas de Actividad Física, usted ha sido invitada a participar en un estudio de investigación estableciendo los siguientes objetivos:

1. Conocer el impacto (síntomas y funcionamiento físico) de un programa de Actividad Física basado en un programa de 24 semanas basado en el trabajo de fuerza gradual sobre la FM.
2. Valorar la evolución de diferentes aspectos clínicos como el dolor (intensidad e interferencia en las actividades), ansiedad, fatiga y sueño a lo largo de las 24 semanas de entrenamiento de fuerza gradual.
5. Mejorar el nivel de condición física de los sujetos mediante el programa de fortalecimiento muscular gradual.
 - 5.1 Aumentar los niveles de fuerza en tren superior como en inferior.
 - 5.2 Disminuir la rigidez mediante el trabajo de flexibilidad
 - 5.3 Mejorar la capacidad cardiorrespiratoria

• **PROCEDIMIENTO Y DURACIÓN DEL ESTUDIO**

- ❖ La duración del programa abarcará un periodo de 6 meses (24 semanas + 3 semanas de mediciones/valoraciones), trabajándose en grupos de 10 personas (máximo).
- ❖ En cuanto al orden y protocolo de las evaluaciones mediante prueba e instrumentos específicos tanto pre, mitad y post al programa de intervención será importante establecer un orden riguroso de medición, por tanto, se citará a cada persona en franjas de una hora para poner en marcha el siguiente procedimiento.

1º: Toma de tensión arterial, frecuencia de pulso (FCR) y saturación de oxígeno en reposo.

2º: Cumplimentar cuestionarios:

- ✓ CUESTIONARIO SOCIODEMOGRÁFICO (edad, ocupación, estado actual de salud y otras relacionadas con la patología)
- ✓ CUESTIONARIO REVISADO IMPACTO FIBROMIALGIA (CIFR)
- ✓ CUESTIONARIO BREVE PARA LA EVALUACIÓN DEL DOLOR (CBD)
- ✓ CUESTIONARIO ANSIEDAD- ESTADO (STAI-E)

3º Mediciones no invasivas: antropometría (protocolo ISAK) y valoración de la condición física (capacidad aeróbica, equilibrio, fuerza y flexibilidad) mediante las pruebas mencionadas a continuación.

- ❖ Cada prueba de medición estará distribuida en diferentes postas con un mismo medidor por cada una de ellas para todos los sujetos.
- ❖ Tras comprobar la condición física de partida de cada sujeto, se diseñará un programa personalizado en función de las variables biológicas medidas con anterioridad cuya duración abarcará un periodo de 24 semanas.

- ❖ A mitad y final del programa, se repetirá en protocolo de evaluación realizado en las evaluaciones iniciales.
- **CARACTERÍSTICAS DEL PROGRAMA- FORTALECIMIENTO MUSCULAR-**
 - ❖ Trabajo de fuerza gradual distribuido en **3 FASES:**
 - ✓ 1^a fase: **AUTOCARGAS.**
 - ✓ 2^a fase: **MATERIAL DE RESISTENCIA: BANDAS ELÁSTICAS+F1.**
 - ✓ 3^a fase: **CARGAS EXTERNAS+F1+F2**
 - ❖ Trabajo de equilibrio, coordinación, control postural, estabilidad e interacción sensorial mediante material inestable durante las 3 fases de trabajo.
 - ❖ Trabajo en circuito: 2 circuitos, 2 series/circuito, tiempo de trabajo inicial:30”, tiempo de recuperación entre ejercicios; 30”, tiempo de recuperación entre circuitos: 5’, tiempo de recuperación entre series: 2’.
 - ❖ Al inicio, mitad y final de cada sesión se controlarán variables fisiológicas medidas anteriormente: (frecuencia cardiaca en reposo, saturación de oxígeno y pulso)
 - ❖ Cada sujeto cumplimentara un “diario-paciente” compuesto por diferentes escalas visuales analógicas (VAS) que a continuación detallaremos, con el fin de obtener un feedback directo a corto plazo de aquellas variables que consideramos de mayor relevancia en el desarrollo del programa.
 - ❖ El diario se cumplimentará cada tres-cuatro semanas **AL FINALIZAR LA SESIÓN.**
 - ❖ El investigador recogerá el diario una vez cumplimentado con el fin de obtener información a medida que va evolucionando y poder realizar pequeñas modificaciones en función de las exigencias individuales. Se realizarán entrevistas personales si fuese necesario.

- **CRITERIOS DE INCLUSIÓN Y EXCLUSIÓN**

Los criterios de inclusión y exclusión que se establecerán para formar parte del estudio serán los siguientes:

Criterios de inclusión

- j) Ser mujer con edades comprendidas entre 20-75 años.
- k) Estar diagnosticada de FM por un reumatólogo cumpliendo con los criterios de la American College of Rheumatology, 1990.
- l) No presentar discapacidades físicas.
- m) No practicar otra actividad en el momento de la intervención o 1 hora semanal como máximo.
- n) Capacidad de comunicarse con el medido.

Criterios de exclusión:

- a) Ser varón.
- b) Haber sido diagnosticadas de enfermedades que contraindiquen la práctica de Actividad Física
- c) Encontrarse en estado gestacional.
- d) Cambio de terapia en el periodo de la intervención.

• **INSTRUMENTOS**

PULSIOXIMETRIA- OXIOMETRÍA DE PULSO

Método no invasivo para determinar el porcentaje de saturación de oxígeno que hay en sangre durante la realización de ejercicio físico.

TENSIOMETRIA

Método no invasivo de medición de la presión arterial mediante esfigmomanómetro.

PULSOMETRIA-FRECUENCIA DE PULSO

Técnica no invasiva y sencilla en la cual se realiza toma del pulso con el objetivo de monitorizar individualmente a cada sujeto.

CUESTIONARIO DE VARIABLES SOCIO-DEMOGRÁFICAS

Se recogeran datos personales y cuestiones relacionadas con la propia patología.

CUESTIONARIO IMPACTO DE LA FIBROMIALGIA EN SU VERSIÓN REVISADA (CIF-R) (Salgueiro *et al.*, 2013).

Cuestionario para evaluar tres conjuntos de dominios: a) Función física, b) Impacto general y

- c) Síntomas.

CUESTIONARIO BREVE DE DOLOR (CBD) (Badia *et al.*, 2003)

Evaluación de dos dimensiones básicas relacionadas con el dolor: la intensidad del dolor y la interferencia del dolor en las actividades diarias del paciente.

CUESTIONARIO DEL ESTADO DE ANSIEDAD [STATE ANXIETY INVENTORY (STAI-E)] (Spielberger *et al.*, 2017).

Evaluación de la ansiedad en relación con el sentimiento de tensión (ansiedad estado).

ANTROPOMETRIA (ISAK, 2001)

Técnica no invasiva para la medición de peso, talla, envergadura, ocho pliegues cutáneos, cuatro diámetros y seis perímetros para la estimación de la composición corporal mediante un método no invasivo.

BATERIA SENIOR FITNESS TEST (SFT) (Jones, Rikli and Beam, 1999; Roberta E Rikli and Jones, 1999; Rikli and Jones, 2013)

Batería para valorar la condición funcional de la persona. Se seleccionarán tres pruebas:

- ❖ Evaluación fuerza miembro superior (ARM CURL TEST): flexiones de codo con mancuerna de 2kg durante 30' en lado derecho e izquierdo.
- ❖ Evaluación fuerza miembro inferior (CHAIR STAND TEST): sentarse y levantarse de una silla durante 30'
- ❖ 2- Minutos Marcha (2- MINUTE STEP TEST) : Evaluación de la resistencia aeróbica.

SIT AND REACH (Wells & Dillon, 1952)

Es una prueba de valoración de la flexibilidad de la parte baja de la espalda, extensores de la cadera y músculos flexores de la rodilla. Esta información es esencial para la puesta en práctica de programas específicos de trabajo en función de la situación de partida.

DINAMOMETRÍA

Test para valorar la fuerza muscular estática máxima mediante dinamómetro digital manual. Estas herramientas expresan la fuerza de prensión y tracción del sujeto en kg.

DIARIO PACIENTE

Contiene:

- ❖ Escalas visual analógicas (0-10) de: mejora, dolor, rigidez, esfuerzo, rendimiento y frustración
- ❖ Escalas para evaluar la carga de trabajo (0-20): rendimiento (grado de cumplimiento de los objetivos); esfuerzo (cantidad de esfuerzo físico y mental) y nivel de frustración (sensación de presión, desánimo, inseguridad... durante la realización de la tarea)
- ❖ Escala visual analógica de gravedad en la fatiga (0-7) (FSS) (Tellez *et al.*, 2005) e impacto de la fatiga (0-4) (D-FIS) (Martinez-Martin *et al.*, 2006).

- **PARTICIPACIÓN**

Ha de saber que tiene derecho a retirarse del estudio por cualquier razón personal o médica en cualquier momento y sin tener que dar explicaciones.

Si así lo desea, tras ponerse en contacto con los investigadores, será informado de los resultados de la investigación, y tendrá derecho a utilizar el programa que para Ud. será diseñado. Todos los participantes firmaran el consentimiento informado siendo el estudio aprobado por el Comité de ético de la Universidad Politécnica de Madrid (UPM).

- **RIESGOS DERIVADOS DE LA PARTICIPACIÓN EN EL ESTUDIO**

Los riesgos asociados al estudio son prácticamente nulos, limitándose a las comunes derivadas de la realización de actividad física: agujetas, cansancio o lesiones musculares agudas, siendo nuestra intención minimizar la posibilidad de que esto ocurra.

Dado que se incluirá en el trabajo de investigación el estudio de la concentración de distintos iones en sangre, será necesario realizarle tres extracciones de una pequeña cantidad de sangre, lo que en algún caso conlleva un pequeño hematoma.

- **BENEFICIOS**

Los beneficios que le brinda la participación en este proyecto serán tanto a nivel clínico como físico. Además, contribuirá a que este tipo de programas se pueda aplicar al resto de la población con enfermedad de Fibromialgia, mejorando su condición física, dolor y ansiedad, repercutiendo en la mejora de la Calidad de Vida.

- **COSTES**

El coste de las pruebas que se realizarán en el estudio no repercutirá sobre Ud.

La participación en el proyecto no será recompensada económica mente.

- **CONFIDENCIALIDAD**

El protocolo de recogida de datos será archivado, y a cada participante se le asignará una clave de tal modo que no pueda relacionarse la información obtenida con la identidad del sujeto.

El investigador principal del proyecto se compromete a que la confidencialidad de los datos que se puedan obtener en dicho proyecto será escrupulosamente observada, y que los datos personales de los sujetos participantes no serán conocidos por los investigadores

del proyecto. Si se obtuvieran datos que pudieran influir sobre su estado de salud o su calidad de vida, aparte de los buscados en el proyecto, será informado por el investigador principal ya que será la única persona con capacidad para poderle identificar.

Los resultados del estudio pueden ser publicados en revistas científicas o publicaciones de carácter general. No obstante, la información concerniente a su participación será mantenida como confidencial y los resultados responderán al conjunto de participantes, no pudiendo ser Ud. identificado en ningún momento.

• DERECHOS DEL VOLUNTARIO

Los principales investigadores son Cristina Maestre Cascales y Jesús Javier Rojo González.

Pueden dirigirse a ellos en estas direcciones electrónicas
cmcascales@hotmail.com, jesusjavier.rojo@upm.es

y en la siguiente dirección:

Departamento de Salud y Rendimiento Humano.
Facultad de Ciencias de la Actividad Física y el Deporte
Calle Martín Fierro, 7,
28040 Madrid
Tfno.: 91 336 4128; 91 336 4026

HOJA DE CONSENTIMIENTO DEL PARTICIPANTE

Cod. : _____

Título del proyecto: EVALUACIÓN DE LOS EFECTOS DE UN PROGRAMA DE ACTIVIDAD FÍSICA BASADO EN EL TRABAJO DE FUERZA EN MUJERES DIAGNOSTICADAS DE FIBROMIALGIA.

Investigador/es principal/es: Jesús Javier Rojo González, Cristina Maestre Cascales, Francisco Javier Calderón Montero

Centros participantes: Facultad Ciencias de la Actividad Física y el Deporte.

Yo,
(Nombre y Apellidos)

DECLARO:

- Haber leído la hoja informativa que acompaña a este consentimiento, habiendo podido preguntar libremente cuantas dudas me han surgido.
- Haber recibido respuestas y aclaraciones sobre las cuestiones que he planteado.
- Haber sido informado sobre cómo se va a cuidar mi anonimato y de las medidas tomadas a fin de cumplir con la Ley Orgánica 15/1999 de protección de datos de carácter personal, y si es el caso de la Ley 41/2002 reguladora de la autonomía del paciente y del derecho y obligaciones en materia de información y documentación clínica.
- Haber sido informado sobre el uso de los datos obtenidos.

COMPRENDO que mi participación es voluntaria pudiendo retirarme del estudio cuando lo desee, sin tener que dar explicaciones y sin que ello pueda tener repercusión sobre mi salud ni mis intereses.

DOY LIBREMENTE MI CONFORMIDAD PARA PARTICIPAR EN EL PROYECTO:
Evaluación de los efectos de un programa de actividad física basado en el trabajo de fuerza en mujeres diagnosticadas de fibromialgia.

En

En

Lugar y Fecha

Lugar y Fecha

Firma:

Firma

Nombre del participante

Nombre del investigador

APPENDIX IV

PROGRAMA ACTIVIDAD FÍSICA: EJERCICIOS FORTALECIMIENTO MUSCULAR

CRISTINA MAESTRE CASCALES

- **MOTIVO:** TRABAJO AUTÓNOMO EN CASA
- **LUGAR:** CASA/AIRE LIBRE
- **DURACIÓN:** DESDE JUEVES 22 DE DICIEMBRE- 9 ENERO
- **REALIZACIÓN:** DOS DÍAS A LA SEMANA NO CONSECUTIVOS (DESCANSO ENTRE SESIONES).

CONTENIDOS:
FASE:2^a MATERIAL
DE RESISTENCIA

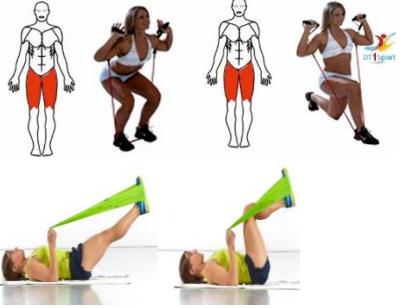
SESIÓN:	CALENTAMIENTO: 10 MINUTOS (EJERCICIOS FOLLETO)
45'	EJERCICIOS FUERZA: 20 MIN (MIRAR EJERCICIOS TABLA)
	ESTIRAMIENTOS-RELAJACIÓN: 10 MINUTOS (5' ESTIRAMIENTOS + 5' TUMBADOS RESPIRACIÓN)

ESCOGER 5 EJERCICIOS VARIADOS

SERIES/CIRCUITO: 2

ESTIRAMIENTOS-RELAJACIÓN: 10 MINUTOS (5' ESTIRAMIENTOS + 5' TUMBADOS RESPIRACIÓN)

2 CIRUITOS

TRÍCEPS	BÍCEPS
  <p>RECOMENDACIONES</p> <ul style="list-style-type: none"> ❖ El ejercicio de tríceps se puede realizar frente a la pared, fijando un extremo de la banda en la pared y el otro en la mano que ejecuta el movimiento: <u>fijando codo</u>, llevo la mano desde atrás extendiendo todo el codo hacia la altura del pecho. ❖ También podemos realizar los fondos en pared que hemos hecho en clase y vamos jugando con la inclinación. ❖ Recordad, cuanta mayor inclinación tengamos, ¡¡más nos costará el ejercicio!! 	 <p>RECOMENDACIONES</p> <ul style="list-style-type: none"> ❖ También podéis realizar el movimiento alternando los brazos.
PECTORAL	ESPALDA
 <p>RECOMENDACIONES</p> <p>*Velocidad de ejecución: lenta</p>	 <p>RECOMENDACIONES</p> <ul style="list-style-type: none"> ❖ Espalda apoyada en la pared ❖ Abdomen contraído ❖ Coordinar respiración: Inspiro/espiro
HOMBRO	CUADRICEPS
 <p>RECOMENDACIONES</p> <ul style="list-style-type: none"> ❖ No pasar la altura del hombro para que no sufran las cervicales, ¡cuidado! 	 <p>RECOMENDACIONES</p> <ul style="list-style-type: none"> ❖ También podemos sentarnos y levantarnos en una silla como hemos hecho en clase. ❖ Recordad la línea recta entre rodilla y tobillo en todo el recorrido. ❖ ¡Las rodillas NO se meten hacia dentro!

CUADRICEPS/ISQUIOTIBILIALES-EQUILIBRIO

RECOMENDACIONES

Ejercicio de desplazamiento lateral:
Flexionando rodillas, manos en la cintura, pelvis hacia delante, espalda recta, abro y cierra piernas desplazandome hacia el lado.

Tener en cuenta:

- Espalda recta
- No levantar talones
- Gluteos atrás
- Contracción abdominal

GLÚTEO

Posición inicial

Posición final

RECOMENDACIONES

- ❖ Abdomen traído
- ❖ No vascular cadera
- ❖ Tobillo en flexión
- ❖ Aducción de escáپulas
- ❖ Hombros relajados

GEMELOS

1.

2.

RECOMENDACIONES

1. Se puede realizar sin banda, con manos en cintura o apoyadas en pared
2. Elevar talones.
3. .Espalda: apoyada en pared

ABDUCTORES

RECOMENDACIONES

- ❖ Espalda apoyada en pared
- ❖ Palmas de la mano apoyadas en el suelo

ESTIRAMIENTOS (5' ESTIRAMIENTOS + 5' TUMBADOS RESPIRACIÓN)

EN CUANTO A LOS ESTIRAMIENTOS; PODÉIS ESCOGER LOS QUE MUESTRA EN LA PARTE (A). SI NO LOS ENTENDÉIS (PORQUE HAY ALGUNOS QUE NO HEMOS REALIZADO EN CLASE), OS DEJO EN LA SEGUNDA PARTE DE ESTE APARTADO (B) LOS QUE SOLEMOS HACER EN CLASE:

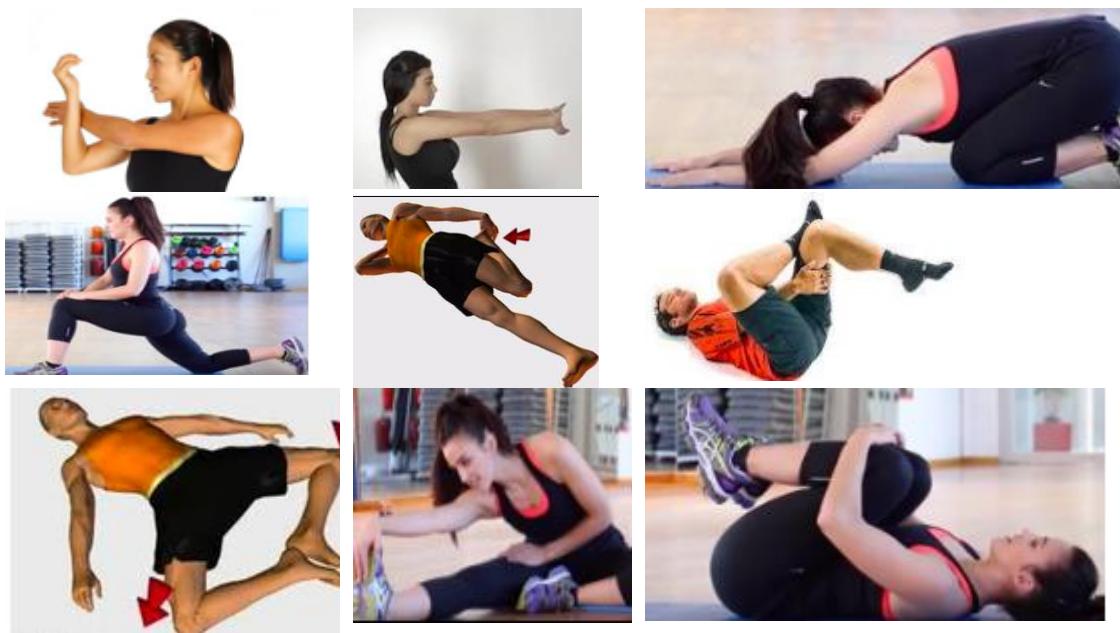
RECOMENDADIONES

- ❖ Mantener 30 segundos en cada posición.
- ❖ Movimientos al límite máximo (sin llegar al dolor).
- ❖ Percibir sensación agradable.
- ❖ Mínimo un ejercicio de cada grupo muscular.
- ❖ Al finalizar la parte de estiramientos. Nos tumbamos en una posición cómoda y aislada de ruidos, Manos en la zona del abdomen, controlando la respiración con la técnica que realizamos en clase.

A



B



PROGRAMA FORTALECIMIENTO MUSCULAR



OBJETIVO

- ❖ Mejorar las limitaciones funcionales.
- ❖ Mejorar el rendimiento muscular.
- ❖ Mejorar la sintomatología propia de la FM.
- ❖ Disminuir la rigidez
- ❖ Mejorar los niveles de condición física.



“EL ÉXITO ES LA SUMA DE PEQUEÑOS ESFUERZOS REPARTIDOS DIA TRAS DIA”



Cristina.maestre@upm.es



XXXXXX



<http://www.afibrom.org/>



@AFIBROM
afibrom

EXPERIENCIAS PREVIAS

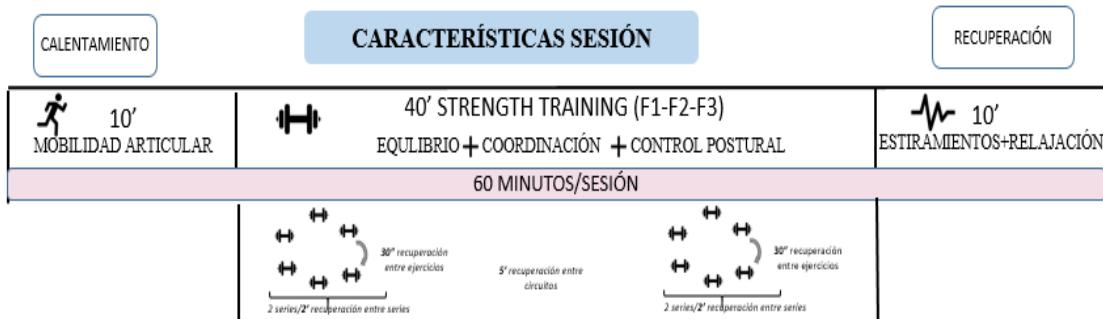
“Desde el comienzo de la actividad, mi estado general ha mejorado considerablemente. Siento menos rigidez, dolor más suave y estado anímico bastante mejor”

“Me cuesta a veces hacer algunos ejercicios, pero salgo como nueva y me siento con ganas de seguir haciendo cosas.”



CARACTERÍSTICAS GENERALES

- **2- 3 DÍAS SEMANALES DE FORMA INTERMITENTE**
- **CARACTERÍSTICAS DE UNA SESIÓN**



La pérdida de fuerza y masa muscular, menor capacidad cardiorrespiratoria, limitaciones articulares y un elevado deterioro de equilibrio junto con la sintomatología característica de esta patología afectan de manera negativa para llevar a cabo las actividades de la vida diaria

La inactividad física y el sedentarismo es uno de los principales factores en la pérdida y deterioro de la función física, por lo tanto, hay evidencias de que el programa de entrenamiento basado en el trabajo de fuerza es de los más eficaces para reducir las limitaciones funcionales y mejorar la sintomatología física y psicológica de las personas con fibromialgia. Considerando el cuadro clínico de esta patología, el entrenamiento de fuerza debe ser progresivo y gradual en intensidad para no agravar ningún síntoma asociado a esta patología.

A lo largo de estos documentos se muestran ejercicios de cada una de las fases que se muestran en el siguiente apartado (F1/F2/F3) para que sea un trabajo progresivo. Todos estos ejercicios llevan asociados una descripción específica.

¡NO OLVIDE REALIZAR UNA DIETA SALUDABLE E DESPUÉS DEL EJERCICIO FÍSICO PARA ASEGURAR UNA MAYOR EFICACIA DEL PROGRAMA DE ENTRENAMIENTO! ¡ánimo chicas!



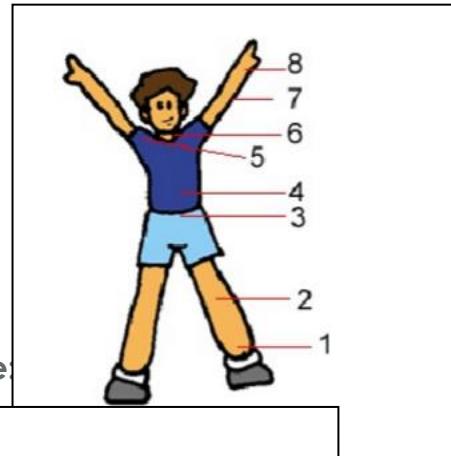
CALENTAMIENTO

EJERCICIOS DE MOVILIDAD ARTICULAR

Consiste en realizar un movimiento de manera repetida en cada una de las articulaciones. El objetivo de esta parte es alcanzar la máxima amplitud. Existen dos formas de realizar estos ejercicios de movilidad articular, el primero es de forma ascendente, empezando por los tobillos y finalizando en muñecas. El segundo es de forma descendente, iniciándose en las muñecas para finalizar en tobillos.

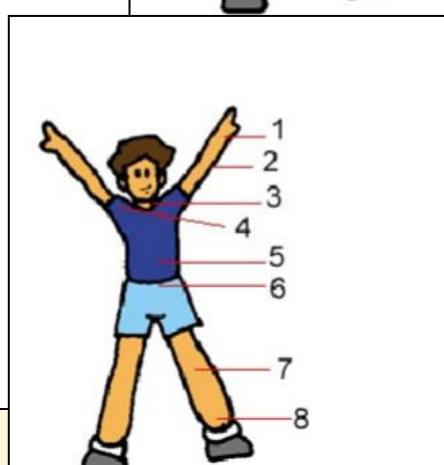
Movilidad articular en sentido ascendente:

1. Tobillos
2. Rodillas
3. Cadera
4. Tronco
5. Hombros
6. Cuello
7. Codos
8. Muñeca



Movilidad articular en sentido descendente

1. Muñeca
2. Codos
3. Cuello
4. Hombros
5. Tronco
6. Cadera
7. Rodilla
8. Tobillo



RECOMENDACIONES

1. Se deben realizar ejercicios de movilidad articular previo a cualquier actividad deportiva.
2. A continuación te ofrecemos algunos ejercicios de movilidad articular que se hacen de forma individual.
3. Los ejercicios deben hacerse con calma, contando cada una de las repeticiones y siguiendo el orden de sentido ascendente o descendente.



Circunducción de Tobillos
16 veces cada pie



Flexión y Extensión de
Rodillas y Caderas
16 veces



Rotación Externas y Flexión de
Cadera
16 veces



A Fondo Lateral
16 veces por cada lado



Flexión y Extensión de Tronco y
Cadera
16 veces



Inclinación lateral del Tronco
16 veces cada lado



Rotación de Tronco
16 veces cada lado



Flexión de Hombros
16 veces cada hombro



Extensión de Hombros
16 veces



Circunducción de Hombros
16 veces adelante y
16 veces atrás



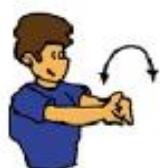
Flexión y extensión lateral del
cuello
16 veces cada lado



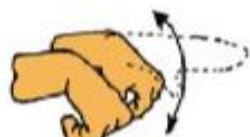
Rotación del Cuello
16 veces cada lado



Flexión y extensión de Cuello
16 veces



Circunducción de muñecas
16 veces cada una



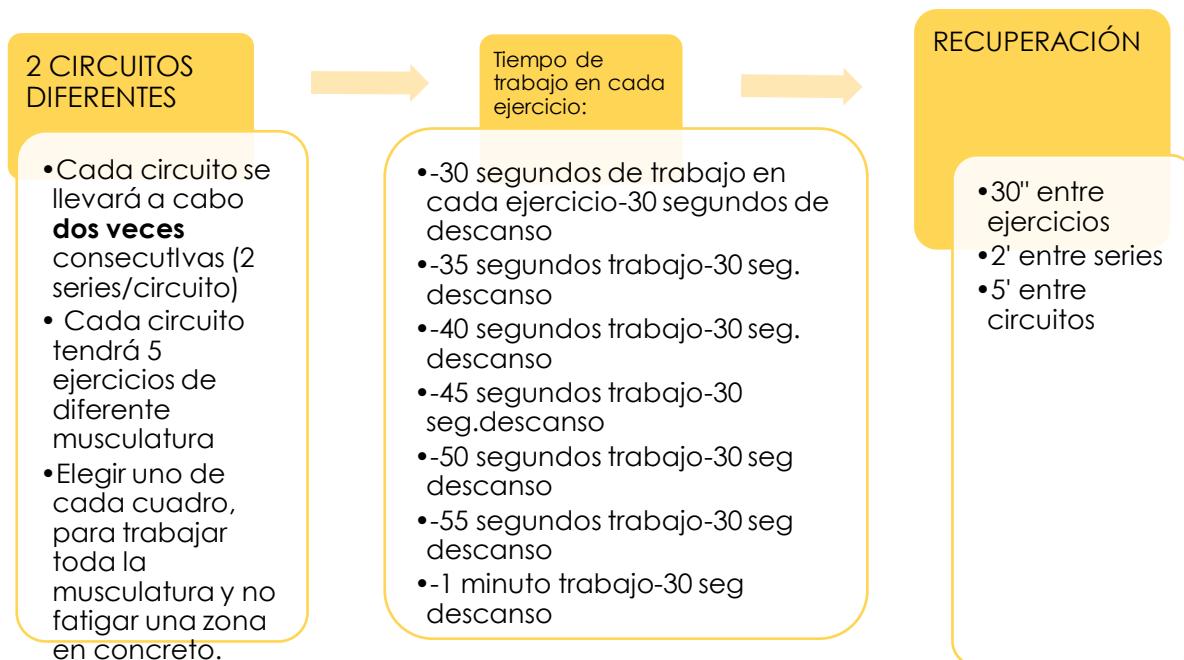
Flexión y Extensión de muñecas
16 veces cada una

CARACTERÍSTICAS ESPECÍFICAS DEL ENTRENAMIENTO DE FUERZA

- EL TRABAJO DE FUERZA ES IMPORTANTE QUE SE TRABAJE DE MANERA

PROGRESIVO EN TRES FASES:

- **F1^a: AUTOCARGA- EQUILIBRIO-PROPIOCEPCIÓN**
- **2^a: MATERIAL DE RESISTENCIA + F1**
- **3^a CARGAS EXTERNAS + F1 +F2**



El incremento de tiempo deberá realizarse cada dos –tres semanas de trabajo
aproximadamente *Dependerá de las condiciones de la persona.





FASE 1: AUTOCARGA

FUERZA

EJERCICIOS DE PRENSIÓN EN LAS MANOS

A

Ejercicio A:

Coja una pelota de goma o antiestrés con la mano y apriétela poco a poco tan fuerte como pueda. Relaje su mano. Una vez acabadas las series descanse y repita con la otra mano.



Ejercicio B:

Enrolle una toalla pequeña dándole una forma de tubo. Coja la toalla por los extremos y con ambas manos realice un movimiento similar al de escurrir una toalla empapada de agua. Apriete poco a poco, pero tan fuerte como pueda. Empiece con el ejercicio A. Cuando pueda realizar 20 movimientos de prensión con la pelota de manera fácil y de forma ininterrumpida, incorpore el ejercicio B.

B

EJERCICIO EN POSICIÓN SENTADA DE MÚSCULOS DEL PIE Y PANTORRILLAS



Póngase de puntillas hasta llegar a lo más alto posible y manténgase en esta posición durante 3 segundos. Baje poco a poco hasta apoyar los talones en el suelo. En el caso de que resulte demasiado fácil realizar el ejercicio, coloque una tobillera lastrada (ya vienen rellenas de arena o de otra sustancia pesada) o sujeté un peso con una correa a su tobillo (con cuidado para que no caiga). Inicio Determinación del peso: escoga un peso que le permita realizar el ejercicio correctamente y sin interrupciones unas 30 veces aproximadamente, pero con el que note que hace un esfuerzo al terminarlo. En el caso de que resulte muy difícil realizarlo con peso adicional se realizará sin carga.

EJERCICIO EN POSICIÓN SENTADA DE EXTENSIÓN DE LA RODILLA SIN CARGA



Extienda horizontalmente una pierna procurando mantenerla lo más recta posible (como en la imagen). Repita con la otra pierna una vez haya acabado las series recomendadas.

EJERCICIO DE PIE, PARA LOS MÚSCULOS DE PANTORRILLAS

Colóquese de pie delante de una mesa o del respaldo de una silla, con los pies separados y alineados con los hombros (la separación de los pies ha de ser, aproximadamente, la distancia entre los dos hombros). Póngase de puntillas hasta llegar lo más alto posible y manténgase en esta posición durante 3 segundos. Si pierde el equilibrio, apóyese en la mesa o en la silla; no se apoye si mantiene bien el equilibrio. Baje poco a poco hasta apoyar los talones en el suelo.



EJERCICIO DE SEPARACIÓN DE CADERAS

Sitúese de pie y, si lo precisa, apoye los brazos en una silla firme o mesa. Con la espalda recta, separe una pierna de la otra sin doblar la rodilla (como en la imagen). Ha de mantener las piernas rectas y los pies mirando hacia delante (no hacia los laterales). Vuelva a la posición inicial. Repita estos movimientos el número de veces indicado.



EJERCICIO DE LA PARTE POSTERIOR DEL MUSLO

Sitúese de pie y, si lo precisa, apoye los brazos en una silla firme o mesa. Con la espalda recta, flexione la rodilla manteniendo el pie hacia atrás. Vuelva a la posición inicial. Repita con la otra pierna una vez haya acabado las series indicadas.



EJERCICIO DE FLEXIÓN CON PIERNAS SIN SILLA

Sitúese de pie detrás de una mesa. Empiece que agacharse flexionando las caderas y rodillas como si fuera a sentarse; luego vuelva a la posición inicial. Si lo cree necesario, coloque una silla detrás suya para tener mayor seguridad.



EJERCICIO DE FLEXIÓN DE PIERNAS EN SILLA

Siéntese en una silla firme con brazos. Apoye bien los pies en el suelo y levántese sin apoyarse en los brazos de la silla. En el caso de que no pueda hacerlo, apóyese solo con un brazo y, si no puede, hágalo con la ayuda de los dos brazos. Manténgase 1 segundo de pie y vuelva a sentarse.



EJERCICIO DE SUBIR Y BAJAR ESCALERAS

Suba y baje escaleras los primeros días, al comienzo ayudándose de la barandilla, posteriormente se puede progresar subiéndolas sin ayuda o incluso de dos peldaños en dos peldaños.



EQUILIBRIO

EJERCICIO DE CAMINAR CON LOS PIES EN LÍNEA

Sitúese de pie, cerca de una mesa, pared o familiar suyo. Coloque el talón de un pie en contacto con la punta del otro pie. Se trata de hacer pequeños pasos en línea recta, poniendo el talón del pie que adelantamos justo delante de la punta del otro pie (vea la imagen). Si se siente más seguro, sitúese de pie apoyado en una mesa o barandilla.



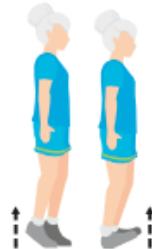
EJERCICIO DE EQUILIBRIO SOBRE UNA PIerna Y CON LOS BRAZOS CRUZADOS

Sitúese de pie. Cruce los brazos encima del pecho (como en la imagen). Flexione una pierna mientras la otra sigue estirada y manténgala elevada unos 5 segundos; baje la pierna y haga lo mismo con la otra.



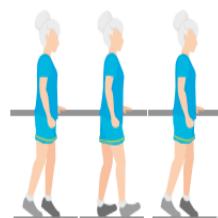
EJERCICIO DE EQUILIBRIO PUNTA – TALÓN

Sitúese de pie. Mantenga el equilibrio apoyando su peso solo sobre las puntas de los pies. Permanezca en esta posición unos segundos y, a continuación, mantenga el equilibrio apoyándose solo en los talones. Si se siente más seguro, sitúese de pie apoyado en una mesa o barandilla.



EJERCICIO DE CAMINAR DE PUNTAS Y CON TALONES CON AYUDA

Sitúese de pie apoyado al lado de una mesa o barandilla. Camine apoyando su peso solamente en las puntas de los pies. Haga una pausa y reinicie la marcha, pero ahora apoyándose en los talones.

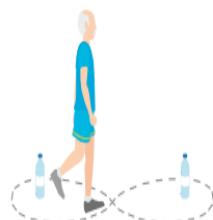


EJERCICIO DE CAMINAR REALIZANDO CAMBIOS DE DIRECCIÓN (“REALIZANDO OCHOS”) SORTEANDO PEQUEÑOS OBSTÁCULOS

Caminar realizando cambios de dirección, por ejemplo, en ocho.

Inicio

- Camine contando hasta 10.
- Realice un descanso no inferior a un minuto, ni superior a 3 minutos.
- Repita de nuevo la serie.



EJERCICIO DE CAMINAR SORTEANDO PEQUEÑOS OBSTÁCULOS

Coloque pequeños obstáculos que tengan una altura de unos 10-15 cm, como por ejemplo cajas de zapatos, zapatillas deportivas, etc. en un recorrido corto. Sitúese de pie apoyado al lado de una mesa o barandilla. Camine y pase por encima de los obstáculos que encuentre en su camino sin pisarlos. Es recomendable realizar este ejercicio con la ayuda de otra persona.



Inicio

Con y sin apoyo por encima de pequeños obstáculos de 10-15 cm.

- Camine de manera relajada y pase por encima de los obstáculos.
- Coloque 5 obstáculos para empezar.
- Cuando llegue al fin del recorrido, empiece de nuevo. Repita 8 veces.



Progresión:

Cuando note que mejora su capacidad, aumente la dificultad e incorpore algunas de estas indicaciones:

- Modifique la posición de los brazos; por ejemplo, cruce los brazos o colóquelos en forma de cruz.
- Realice los ejercicios sobre diferentes superficies, por ejemplo, encima de una alfombra.
- Cierre los ojos, pero solo si alguien está junto a usted para ayudarle.

REALIZAR EJERCICIOS HACIENDO MULTITAREAS, POR EJEMPLO, COMBINANDO EJERCICIOS DE EQUILIBRIO Y PASAR UNA PELOTA.

Realizar los anteriores ejercicios haciendo multitareas complejas (por ejemplo, ejercicios de equilibrio y pasar una pelota)



Inicio

- Camine contando hasta 10.
- Realice un descanso no inferior a un minuto, ni superior a 3 minutos.
- Repita de nuevo la serie.

FASE 2: BANDAS ELÁSTICAS

FUERZA

EJERCICIO EN POSICIÓN SENTADA DE LOS MÚSCULOS ABDUCTORES DE CADERA CON CINTA ELÁSTICA (SON LOS MÚSCULOS QUE USAMOS PARA SEPARAR LAS PIERNAS)

Coloque, centrada sobre las rodillas, la cinta elástica (como en la imagen). Agarre firmemente la cinta elástica apretándola contra cada una de las rodillas. Separe las rodillas poco a poco hasta que ya no pueda hacerlo más.



Inicio

Determinación de la resistencia de la cinta: escoja una cinta que le permita realizar el ejercicio correctamente y sin interrupciones unas 30 veces aproximadamente, pero con el que note que hace un esfuerzo al terminarlo.

EJERCICIO EN POSICIÓN SENTADA DE APERTURA DE BRAZOS EN DIAGONAL CON UNA CINTA ELÁSTICA

Coja una cinta elástica por los extremos y enróllela adecuadamente para evitar lesiones. A la altura de las rodillas, empiece a separar los brazos en diagonal realizando una extensión del codo (como en la imagen).



Inicio

Determinación de la resistencia de la cinta: escoja una cinta que le permita realizar el ejercicio correctamente y sin interrupciones unas 30 veces aproximadamente, pero con el que note que hace un esfuerzo al terminarlo.

EJERCICIO EN POSICIÓN SENTADA DE APERTURA DE BRAZOS EN HORIZONTAL CON UNA CINTA ELÁSTICA

Coja una cinta elástica por los extremos y enróllela adecuadamente para evitar lesiones. A la altura del pecho estire la cinta y separe los brazos realizando una extensión total del codo (como en la imagen).



Inicio

escoja una cinta que le permita realizar el ejercicio correctamente y sin interrupciones unas 30 veces aproximadamente, pero con el que note que hace un esfuerzo al terminarlo.

EJERCICIO EN POSICIÓN SENTADA DE FLEXIÓN Y EXTENSIÓN DE LOS BRAZOS CON UNA CINTA ELÁSTICA

Coloque el centro de la cinta elástica debajo de ambos pies. Agarre los dos extremos de la cinta con las manos a la altura de las rodillas. Flexione los brazos hacia los hombros manteniendo las muñecas firmes y evitando separar los codos del tronco (como en la imagen).

Inicio



Determinación de la resistencia de la cinta: escoja una cinta que le permita realizar el ejercicio correctamente y sin interrupciones unas 30 veces aproximadamente, pero con el que note que hace un esfuerzo al terminarlo.

EJERCICIO DE PIE CON FLEXIÓN DE CADERA Y FLEXIÓN DE RODILLAS

Coloque los pies a la anchura de las caderas. Inclina el tronco hacia delante haciendo una flexión de cadera, manteniendo la espalda recta y los omoplatos aducidos. Pasa la banda por la placa de los pies sujetando ambos extremos de esta en cada una de las manos. Flexiona el codo atrás quedando las muñecas a la altura del pecho. Ejecuta una extensión de codo atrás quedando el brazo lo más extendido posible.



Variante

El ejercicio de tríceps se puede realizar frente a la pared, fijando un extremo de la banda en la pared y el otro extremo en la mano que realiza el movimiento: fijando codo, llevo la mano desde atrás extendiendo todo el codo hacia la altura del pecho.

REMO – PARADO CON BANDAS ELÁSTICAS



Asegura la banda elástica en un lugar bajo, ponte de pie y sujetá las agarraderas con tus manos, los brazos extendidos enfrente de tus caderas, con las palmas apuntando una hacia la otra. Tira de las agarraderas hacia atrás, en dirección a tu abdomen y permítele retornar lentamente luego de una breve pausa. Mantén tu espalda recta y firme durante el movimiento.

REMO CON BANDAS ELÁSTICAS – SENTADO



Asegura la banda elástica en un lugar bajo, siéntate con tus piernas extendidas y sujetá las agarraderas con tus manos por encima de tus rodillas, con las palmas apuntando una hacia la otra. Tira de las agarraderas hacia atrás, en dirección a tu abdomen y permítele retornar lentamente luego de una breve pausa. Mantén tu espalda recta y firme durante el movimiento.

EXTENSIONES CON BANDAS ELÁSTICAS - BRAZOS-PIERNAS

Asegura la banda a tus pies, arrodíllate sobre la rodilla del otro costado y sujetla la agarradera con la mano de ese mismo costado. Estira la banda elástica extendiendo tu pierna y brazo hasta que esté paralelo al suelo y permítelle retornar lentamente luego de una breve pausa. Mantén tu espalda recta.



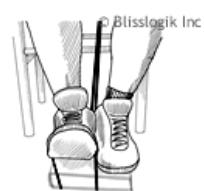
EVERSIÓN DE TOBILLOS CON BANDAS ELÁSTICAS

Siéntate sobre el suelo, con las piernas extendidas y ata tus pies, próximos uno del otro con una banda elástica. Lleva el área de las puntas de tus pies hacia afuera, alejándolas una de la otra estirando la banda elástica y luego de una breve pausa retorna a la posición inicial. Mantén tus talones presionados durante todo el movimiento.



ELEVACIÓN DE TALONES CON BANDAS ELÁSTICAS

Siéntate sobre un banco, coloca el talón de tu pie sobre un bloque pequeño y asegura la banda elástica entre las puntas de tus pies y dicho bloque. Lleva el área de la punta de tu pie hacia arriba estirando la banda elástica y luego de una breve pausa retorna a la posición inicial. Mantén tus talones firmes.



SENTADILLAS CON BANDAS ELÁSTICAS

Asegura la banda elástica debajo de tu pie, agáchate y sujetla las agarraderas con tus manos a cada lado de tus hombros, con las palmas apuntando hacia adelante. Empújate a ti mismo hacia arriba extendiendo tus piernas y bája lentamente luego de una breve pausa. Mantén tus pies firmes en su lugar a lo largo de todo el movimiento.



FLEXIONES DE BÍCEPS CON BANDAS ELÁSTICAS

La banda elástica bajo tu pie y sujetela las agarraderas con tus manos, los brazos extendidos y las palmas hacia arriba. Tira de las agarraderas hacia tus hombros flexionando tus codos y permitiéndoles lentamente volver luego de una breve pausa. Mantén inmóvil la parte superior de tus brazos durante el movimiento.



FLEXIONES DE MUÑECA CON BANDAS ELÁSTICAS

Siéntate sobre un banco, la banda elástica bajo tu pie y sujetela la agarradera con tu mano por encima de tu rodilla, la palma hacia arriba y el codo encima de tu muslo. Tira de la agarradera flexionando la muñeca y permitiéndole volver. Mantén inmóvil tu antebrazo durante el movimiento.



FASE 3: CARGAS EXTERNAS

FUERZA

EJERCICIO DE SEPARACIÓN DE CADERAS CON CARGA

Coloque una tobillera lastrada (ya vienen rellenas de arena o de otra sustancia pesada) o sujeté un peso con una correa a su tobillo (con cuidado para que no caiga). Sitúese de pie y, si lo precisa, apoye los brazos en una silla firme o mesa. Con la espalda recta, separe una pierna de la otra sin doblar la rodilla (como en la imagen). Ha de mantener las piernas rectas y los pies mirando hacia delante (no hacia los laterales). Vuelva a la posición inicial. Repita estos movimientos el número de veces indicado.



Inicio

Determinación del peso: escoja un peso que le permita realizar el ejercicio correctamente y sin interrupciones unas 30 veces, pero con el que note que hace un esfuerzo al terminarlo.

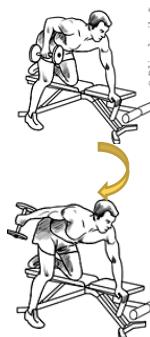
EJERCICIO DE LA PARTE POSTERIOR DEL MUSLO

Sitúese de pie y, si lo precisa, apoye los brazos en una silla firme o mesa. Con la espalda recta, flexione la rodilla manteniendo el pie hacia atrás. Vuelva a la posición inicial. Repita con la otra pierna una vez haya acabado las series indicadas.



PATADA DE BURRO DE TRÍCEPS

Coloca tu rodilla y tu mano sobre un banco y coge una mancuerna con tu otra mano, con la palma apuntando hacia tu cuerpo, y la parte superior de tu brazo paralela a tu cuerpo.



Empuja la mancuerna hacia atrás mediante la extensión de tu codo y vuelve lentamente luego de una breve pausa. Mantén firmes las partes superiores de tus brazos durante todo el movimiento.

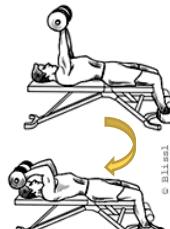
EXTENSIONES DE TRÍCEPS ACOSTADO

Acuéstate de espalda sobre un banco y sujetá una mancuerna en cada mano, con las palmas apuntando hacia arriba, y las partes superiores de tus brazos apuntando al techo. Eleva las mancuernas mediante la extensión de tus codos y luego de una breve pausa, vuelve al punto de partida.



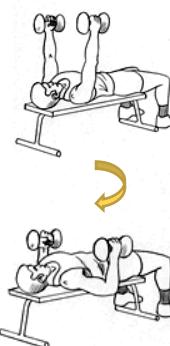
EXTENSIONES DE TRÍCEPS ACOSTADO

Acuéstate de espalda sobre un banco y sujetas una mancuerna en cada mano, con las palmas apuntando hacia arriba, y las partes superiores de tus brazos apuntando al techo. Eleva las mancuernas mediante la extensión de tus codos y luego de una breve pausa, permíteles retornar al punto de partida. Mantén firmes las partes superiores de tus brazos durante todo el movimiento.



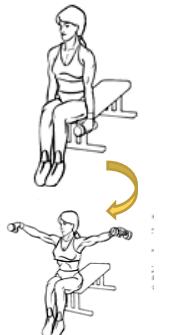
TRICEPS: PRENSA EN BANCO

Recuéstate de espalda sobre un banco y sujetas las mancuernas a los costados de tu cuerpo, justo por encima de tu pecho, con las palmas apuntando una a otra. Empuja las mancuernas hacia arriba hasta que tus brazos estén casi totalmente extendidos y luego de una breve pausa bájalas. Exhala al empujar las mancuernas hacia arriba e inhala al bajarlas.



VUELOS LATERALES SENTADO

Siéntate sobre uno de los extremos del banco o silla y sujetas una mancuerna con cada mano, hacia abajo y a ambos lados de tu cuerpo. Eleva las mancuernas hacia los costados, hasta que tus brazos estén cerca de quedar paralelos al suelo y bájalas lentamente luego de una breve pausa. Mantén tu espalda recta a lo largo del movimiento. Intenta mantener los ángulos en tus codos durante todo el movimiento. -Si hay molestias, elevar a 90º o menos.



REMO VERTICAL

Ponte de pie y sujetas una mancuerna en cada mano enfrente de tus muslos. Levanta ambas mancuernas hasta que tus brazos estén casi paralelos al suelo y bájalas lentamente luego de una breve pausa. Ten cuidado de NO mover tu espalda en el intento de ayudar a levantar las mancuernas.



REMO PARA DELTOIDES POSTERIORES, AGACHADO

Agáchate flexionando tus caderas y rodillas y coge una mancuerna con cada mano, cerca de tus rodillas, con las palmas apuntando hacia atrás. Eleva las mancuernas hacia arriba de forma recta hasta que tus codos formen un ángulo de 90 grados y bájalas luego de una breve pausa. Intenta concentrarte en sólo mover tus brazos durante el ejercicio



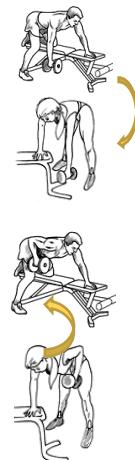
Variantes: Misma posición, pero glúteos apoyado en pared.

REMO A UN BRAZO

Coloca tu rodilla y mano sobre un banco y coge una mancuerna con tu otra mano. Eleva la mancuerna sin mover otra cosa que tu brazo y bájala luego de una breve pausa. Exhala al levantar la mancuerna e inhala al retornar a la posición inicial.

Variantes:

Colócate en posición de pie inclinada hacia adelante enfrente de un banco, mientras sostienes una mancuerna con una mano (con el brazo extendido) tal y como muestra la imagen.

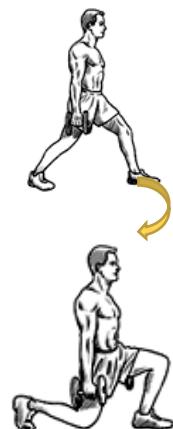


ESTOCADAS ESTÁTICAS

Ponte de pie con un pie al frente, el otro atrás y sujetas una mancuerna en cada mano a los costados de tu cuerpo, con las palmas apuntando una hacia la otra. Baja sin mover tus pies hasta que tu rodilla forme un ángulo de 90 grados y luego de una breve pausa elévate a ti mismo. Mantén tu tronco firme durante todo el movimiento.

Variedad:

Se puede colocar el peso dentro de una bolsa de la compra y alternar en cada brazo cada 5-6 repeticiones.



PESO MUERTO-PIERNAS RECTAS

Ponte de pie y sujetas una mancuerna en cada mano contra los costados de tu cuerpo, con las palmas apuntando una hacia la otra. Baja las mancuernas mediante la flexión de tus caderas hacia adelante y elévate nuevamente hacia arriba luego de una breve pausa. Mantén tu espalda recta durante todo el movimiento.

-Mirada hacia abajo y adelante, siguiendo la trayectoria e inclinación del tronco.



ESTIRAMIENTOS

SEMANA	SERIES Y REPETICIONES	INTENSIDADES
1-12	2 series de 3 repeticiones (manteniendo 10 segundos la posición)	<ul style="list-style-type: none"> Estirar hasta donde sienta cierta tensión y ahí mantener la posición durante los 10 -12 segundos Estirar sin realizar excesivos alongamientos musculares o tensiones articulares Todos los días. Después de los ejercicios de fuerza y potencia muscular o de cardiovascular
12-24	3 series de 3 repeticiones (manteniendo 10 segundos la posición)	



SÍNTOMAS INTOLERANCIA EJERCICIO FÍSICO

A continuación, se indican algunos signos y síntomas de intolerancia al ejercicio físico que deberían ser contralados durante la realización de ejercicio físico. En el caso de tener alguno de ellos debería de parar la práctica inmediatamente y consultar su médico.

SENSACIÓN FALTA DE AIRE

DOLOR/PRESIÓN EN EL PECHO

PALPITACIONES

¡CUIDADO!

MAREOS/PÉRDIDA DE CONCIENCIA

DIFICULTAD PARA MANTENER UNA COVERSACIÓN CONSTANTE EN EL MOMENTO SE REALIZA EL EJERCICIO FÍSICO

FATIGA ANORMAL

COLOR AZUL/MORADO EN LABIOS O UÑAS

NÁUSEAS/VOMITOS

PIEL PÁLIDA, HÚMEDA O FRÍA.



RECOMENDACIONES

Previo al inicio de la práctica de estos ejercicios en casa/gimnasio o cualquier otra instalación, es importante que lea los consejos que se muestra a continuación. Considerarlos y asumirlos es importante para conseguir una buena práctica.

El cumplimiento de los ítems que se proponen a continuación favorecerá la adherencia y minimizará el riesgo de lesión.

NO DOLOR ANORMAL. Si durante la práctica de los ejercicios aumenta el grado de dolor comparado con el inicio de la sesión o siente respiración dificultosa, mareos, taquicardias, etc. PARE!

UTILICE UNA INSTALACIÓN ADECUADA. Sin obstáculos por enmedio que dificulten la práctica óptima de actividad física ni riesgo de sufrir caídas. Tenga a mano una silla como ayuda externa si fuese necesario en los ejercicios que no lo indica.

¡RECUERDA!



BUEN CALZADO. Asegurese de que el calzado que utilice tenga la superficie completamente plana, sin tacón y no resbaladizas.

UTILIZA ROPA CÓMODA.

RESPIRACIÓN REGULAR. No realice apneas mientras ejecutas los ejercicios. Respire de manera acompasada. Inspirando antes de realizar el esfuerzo, espirando durante el mismo y al acabarlo

Utilice **material adecuado** y seguro para ejecutar los ejercicios.

Respete la parte de calentamiento y flexibilidad/respiración al finalizar una sesión.

No realizar elongamientos musculares o tensiones articulares, es decir, no los estire bruscamente.



**“EL ÉXITO EN LA VIDA NO SE MIDE POR LO QUE
LOGRAS, SINO POR LOS OBSTÁCULOS QUE
SUPERAS”**

APPENDIX VI



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Asociación entre fuerza de prensión manual y bienestar en mujeres con fibromialgia

Association of handgrip strength and well-being in women with fibromyalgia

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Resumen

La fibromialgia es una enfermedad caracterizada por una sintomatología compleja con presencia de dolor crónico generalizado junto con otros síntomas incapacitantes como fatiga y problemas de memoria. Como consecuencia, suelen verse deteriorados sus niveles de bienestar. Por lo tanto, es necesario encontrar factores modificables mediante terapia para mejorar el bienestar en la fibromialgia. En esta población, la fuerza de prensión manual es un conocido marcador relevante de salud física, pero se desconoce si también lo es de salud psicológica. Objetivo. Analizar la asociación entre los niveles de fuerza de prensión manual con el bienestar subjetivo en mujeres con fibromialgia. Métodos. Este estudio transversal incluyó a 465 mujeres pertenecientes a la Comunidad de Andalucía (España). La fuerza se midió a través del test de prensión manual. Las dos dimensiones (i.e., afectiva y cognitiva) del bienestar subjetivo se midieron con cuestionarios, Positive and Negative Affect Scale (PANAS) para el afecto positivo y negativo y Satisfaction with Life Scale (SWLS) para la satisfacción con la vida. La asociación de la fuerza de prensión manual con estas dimensiones se analizó mediante regresiones lineales ajustadas por la edad y el consumo de medicamentos. Resultados. Mayores niveles de fuerza se asociaron con mayor afecto positivo ($p<0,001$), menor afecto negativo ($p<0,001$) y mayor satisfacción con la vida ($p<0,05$). Conclusión. En una muestra representativa de la población andaluza de mujeres con fibromialgia, este estudio ha identificado que los niveles de fuerza están positivamente asociados con puntuaciones más favorables de bienestar subjetivo (i.e., afecto positivo, afecto negativo y satisfacción con la vida). En general, la fuerza de estas asociaciones fue débil. Para esclarecer la causalidad de nuestros hallazgos se requieren futuros estudios longitudinales y experimentales.

Key words: actividad física, condición física, estado de ánimo, felicidad, fibromialgia.

Abstract

Fibromyalgia is a disease characterized by a complex symptomatology including presence of widespread chronic pain and other disabling symptoms such as fatigue and poor memory. Thus, fibromyalgia often supposes a considerable burden for well-being. Therefore, finding factors that may be modifiable by therapy is of interest in order to enhance well-being among people with fibromyalgia. Objective. To analyse the association between levels of handgrip strength with well-being in women with fibromyalgia. Methods. This cross-sectional study included 465 women with fibromyalgia from community of Andalusia. Strength was measured by means of the handgrip strength test. The two dimensions (affective and cognitive) of subjective well-being were measured with questionnaires, positive and negative affect was assessed by the Positive and Negative Affect Scale (PANAS) and satisfaction with life by the Satisfaction with Life Scale (SWLS). The association between the handgrip strength test and positive affect, negative affect and satisfaction with life was analysed by linear regression models adjusted for age and consumption of medications (for depression, pain and sleep). Results. Higher levels of strength were associated with higher positive affect ($p<0.001$), lower negative affect ($p<0.001$) and higher life satisfaction ($p<0.05$). Conclusion. Conducted in a representative sample of the Andalusian population of women with fibromyalgia, the present study has identified that muscular strength levels are positively associated with more favorable scores in all dimensions of subjective well-being (i.e., positive affect, negative affect, and life satisfaction). Overall, the strength of these associations was weak. In order to elucidate the causality of our findings, future longitudinal and experimental studies are required.

Palabras clave: fibromialgia, happiness, physical activity, physical fitness, physical function.

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Introducción

La fibromialgia es una enfermedad que se caracteriza por la presencia de dolor crónico, acompañada por otros síntomas como niveles elevados de fatiga, dificultades cognitivas y sueño no reparador (Clauw, 2014). Por ello, la fibromialgia supone una carga elevada para los pacientes, siendo un problema de salud pública de primer orden ya que genera altas demandas en el sistema sanitario y supone un incremento relevante en los costes económicos (Sicras-Mainar, Rejas, Navarro, Blanca, Morcillo, Larios, y Villarroya, 2009). Investigaciones recientes se han centrado en aspectos emocionales de la fibromialgia. En concreto, se ha mostrado que las personas con fibromialgia tienen niveles muy deteriorados de bienestar subjetivo (Hassett, Simonelli, Radvanski, Buyske, Savage, y Sigal, 2008; van Middendorp, Lumley, Jacobs, Bijlsma y Geenen, 2010). Además, los niveles bajos de bienestar están claramente asociados a la gravedad de la fibromialgia, la fatiga y el dolor (Estevez-Lopez, Segura-Jimenez, Alvarez-Gallardo, Borges-Cosic, Pulido-Martos, Carbonell-Baeza, y Delgado-Fernandez, 2017; van Middendorp y col., 2010).

Actualmente ha aumentado el interés por mejorar la aceptación personal y desarrollar estrategias de adaptación a la enfermedad. Esto requiere un proceso dinámico necesario para reequilibrar las nuevas circunstancias y el correcto mantenimiento de las funciones psicológicas (Stanton, Revenson y Tennen, 2007). Tradicionalmente, la investigación se ha centrado en respuestas no adaptativas (factores de vulnerabilidad) como, por ejemplo, la catastrofización del dolor que se define como la tendencia de prestar excesiva atención a las sensaciones de dolor (Estevez-Lopez, 2018; López, 2018). Sin embargo, los factores adaptativos, deseables para gestionar bien la fibromialgia, han recibido menos atención. Entre estos factores, conocidos como resiliencia, el bienestar subjetivo es uno de los más importantes. El bienestar subjetivo se define como la evaluación de la vida tanto a nivel afectivo (e.g., afecto positivo y afecto negativo) como cognitivo (e.g., satisfacción con la vida) (Diener, Suh, Lucas, y Smith, 1999). Entre estas dimensiones del bienestar subjetivo, el afecto positivo es de especial relevancia para favorecer la adaptación a esta patología crónica (Estévez-López, Gray, Segura-Jiménez, Soriano-Maldonado, Álvarez-Gallardo, Arrayás-Grajera, y Pulido-Martos, 2015).

Dado que el bienestar subjetivo en personas con fibromialgia es, en promedio, bajo (Hassett y col., 2008), es necesario encontrar factores modificables que estén relacionados con el bienestar subjetivo para adaptar y focalizar mejor los programas de intervención en fibromialgia. En este contexto, Mannerkorpi, Svantesson y Broberg (2006) sugirieron que los test de condición física podrían servir como complemento a las herramientas actuales empleadas en la valoración clínica cuando se planifica el tratamiento orientado a pacientes con fibromialgia. Estos mismos autores, indicaron que la fuerza de prensión manual es de especial interés en fibromialgia. Desde un punto de vista clínico, nuestro grupo ha mostrado la capacidad diagnóstica y pronostica del test de fuerza de prensión manual para valorar la presencia y severidad de esta patología (Aparicio, Carbonell-

Baeza, Ruiz, Aranda, Tercedor, Delgado-Fernandez, y Ortega, 2013; Aparicio, Ortega, Heredia, Carbonell-Baeza, Sjöström, y Delgado-Fernandez, 2011; Aparicio, Segura-Jimenez, Alvarez-Gallardo, Soriano-Maldonado, Castro-Pinero, Delgado-Fernandez, y Carbonell-Baeza, 2015; Castro-Piñero, Aparicio, Estévez-López, Álvarez-Gallardo, Borges-Cosic, Soriano-Maldonado, y Segura-Jiménez, 2017). Actualmente, se considera el test de fuerza de prensión manual como un importante marcador de salud en fibromialgia (Aparicio y col., 2013; Aparicio y col., 2011; Aparicio y col., 2015). Sin embargo, este test de fuerza de prensión manual no ha sido estudiado en relación con el bienestar subjetivo de las personas con fibromialgia.

Por lo tanto, el test de fuerza de prensión manual es un marcador de salud física, pero se desconoce si también lo es de salud psicológica, en general, y del bienestar subjetivo, en particular. Por ello, el objetivo del presente estudio ha sido evaluar la asociación de los niveles de fuerza con el bienestar subjetivo en mujeres con fibromialgia. Por lo tanto, el test de fuerza de prensión manual es un marcador de salud física, pero se desconoce si también lo es de salud psicológica, en general, y del bienestar subjetivo, en particular. Por ello, el objetivo del presente estudio ha sido evaluar la asociación de los niveles de fuerza con el bienestar subjetivo en mujeres con fibromialgia.

Material y método

Participantes

La metodología y el procedimiento de muestreo que se utilizó en este estudio transversal aparece detallado previamente en el proyecto al-Ándalus (Segura-Jimenez, Alvarez-Gallardo, Carbonell- Baeza, Aparicio, Ortega, Casimiro, y Delgado-Fernandez, 2015a). El proceso de reclutamiento de los participantes se llevó a cabo mediante dos vías; la primera, a través de la Federación Andaluza de Fibromialgia, contactando con las correspondientes asociaciones locales de las ocho provincias que abarca la comunidad autónoma de Andalucía y la segunda, vía telefónica, postal, por correo electrónico, prensa digital y a través de universidades.

Un total de 646 pacientes adultos con fibromialgia se ofrecieron como voluntarios para participar en el estudio. Este número de participantes superó el mínimo establecido para obtener una muestra representativa de la población Andaluza con fibromialgia (Segura-Jimenez y col., 2015a). Dada la transcendencia social que este estudio tuvo, el equipo investigador decidió no restringir la participación de ninguna persona que cumpliese los criterios de inclusión. Todos los participantes fueron informados sobre los objetivos y cumplieron con los siguientes criterios de inclusión; a) haber sido previamente diagnosticados de fibromialgia por un reumatólogo, y b) cumplir los criterios de diagnóstico para la fibromialgia según el Colegio Americano de Reumatología (ACR) (Wolfe, Smythe, Yunus, Bennett, Bombardier, Goldenberg, Clark, 1990), lo que fue corroborado por los investigadores del proyecto al-Ándalus. Antes de participar en el estudio, todos ellos firmaron el consentimiento informado por escrito. El protocolo del proyecto X fue aprobado por el Comité de Ética del del Hospital Virgen de las Nieves

(Granada, España); Número de registro: 15/11/2013-N72. Además, se siguieron las pautas éticas de la Declaración de Helsinki (modificada en 2008).

Instrumentos

Datos sociodemográficos

La información sociodemográfica de los participantes fue registrada mediante una entrevista inicial donde se recogieron datos como la fecha de nacimiento, el estado civil y nivel educativo. Para finalizar, debían responder a la siguiente cuestión: “¿Alguna vez le han diagnosticado una enfermedad aguda o terminal?” siendo este un criterio de exclusión.

Consumo de fármacos

Los participantes indicaron de forma dicotómica (si/no) si ingerían fármacos para el dolor, depresión y sueño/relajación.

Índice de Masa Corporal (IMC)

Se midió el peso en kilogramos (InBody R20, Biospace, Seoul, Sur Korea) y altura en centímetros (Seca 22). Para calcular el Índice Masa Corporal (IMC) se utilizó la fórmula matemática kg/m².

Rendimiento cognitivo

El deterioro cognitivo se midió a través de la escala Mini Mental Examination (MMSE) (Lobo, Ezquerra, Gómez, Sala y Seva, 1979), compuesta por siete categorías: orientación espacial, orientación temporal y concentración, recuerdo, lenguaje y construcción visual. La puntuación de MMSE oscila entre 0 a 30, por lo tanto, las puntuaciones más bajas reflejan un mayor deterioro cognitivo. Los participantes con deterioro cognitivo severo (puntuación ≤ 10) fueron excluidos.

Puntos de dolor

Los puntos de dolor fueron evaluados de acuerdo con los criterios del Colegio Americano de Reumatología en 1990 (American College of Rheumatology, ACR-1990; Segura-Jiménez y col., 2014; Wolfe y col., 1990) para el diagnóstico y clasificación de la fibromialgia. Se utilizó un algómetro de presión estándar (FPK 20; Wagner Instruments, Greenwich, CT, USA). Se registró el total de puntos sensibles al dolor para cada participante.

Bienestar subjetivo (PANAS) y satisfacción con la vida (SWLS)

El bienestar subjetivo se midió a través del cuestionario Positive and Negative Affect Scale (PANAS) (Watson, Clark y Tellegen, 1988), diseñado para evaluar el afecto positivo y afecto negativo. Este cuestionario abarca 20 ítems, 10 relacionados con afecto positivo (entusiasmado, etc.) y los otros 10 con afecto negativo (asustado, etc.). Los participantes respondieron para cada ítem en una escala tipo Likert: 1) muy ligeramente o nada, 2) un poco, 3) moderadamente, 4) bastante, y 5) extremadamente. El marco temporal adoptado fue en “general”. Los ítems del PANAS son: Interesado, angustiado, excitado, molesto, fuerte, culpable, asustado, hostil, entusiasta, orgulloso, irritable, alerta,

avergonzado, inspirado, nervioso, determinado, atento, nervioso, activo y asustado. El rango de puntuación es de 10-50 tanto para el afecto positivo como para el afecto negativo. Para la satisfacción con la vida se utilizó la escala SWLS (Satisfaction with Life Scale), la cual abarca una puntuación que varía entre 5-25-

Test de fuerza de prensión manual

El test de prensión manual es válido, fiable y viable (Nordenskiold y Grimby, 1993; Valkeinen y col., 2008) ya que proporciona información útil sobre la fuerza muscular general del participante. Se evaluó mediante el dinamómetro de mano TKK ya que el sesgo sistémico es pequeño y ha demostrado tener los resultados más fiables cuando se utilizan mediciones repetidas con pesos conocidos. El rango de agarre es ajustable, para ello se utilizó la fórmula sugerida por Ruiz y col. (2006) para calcular la distancia óptima de agarre. El sujeto apretó de forma gradual manteniendo al menos 2 segundos, realizando el test con la mano derecha e izquierda a su vez. Cada paciente realizó dos intentos con cada mano, colocando el brazo completamente extendido y formando un ángulo de 30° con respecto al tronco. Se registró la puntuación máxima en kilogramos (kg) de cada mano y se utilizó la puntuación media de la mano izquierda y derecha para los análisis.

Procedimiento

Las pruebas, test y cuestionarios se realizaron en un orden determinado, el cual garantiza que los resultados no se viesen alterados. Estas, se llevaron a cabo en tres días consecutivos, siendo el primer día destinado a la evaluación del rendimiento cognitivo (MMSE), datos sociodemográficos, composición corporal (bioimpedancia eléctrica) y la corroboración del diagnóstico siguiendo los criterios del ACR-1990. En el segundo día, los participantes cumplimentaron de forma autónoma los cuestionarios de PANAS y SWLS. Para finalizar, en el tercer día realizaron las mediciones de fuerza manual.

Análisis estadístico

La frecuencia y el porcentaje o la media y la desviación típica se utilizaron para informar de la estadística descriptiva de las variables categóricas y continuas, respectivamente. Por otro lado, la asociación entre el test de fuerza de prensión manual y las puntuaciones de bienestar subjetivo se analizaron mediante el análisis de regresión lineal. Antes de proceder con este análisis, se comprobó que los supuestos de linealidad, normalidad y homocedasticidad (e independencia de errores) se cumplieron. En los modelos de regresión lineal, la fuerza de presión manual fue la variable independiente. La edad y la medicación para el dolor, depresión, relajación o sueño se introdujeron como variables confusoras (paso 1). Se exploró el posible papel confusor del IMC y el peso, pero ninguno jugó dicho papel por lo que no fueron incluidos en el modelo. Posteriormente en el paso 2, afecto positivo, afecto negativo y satisfacción con la vida entraron como variable dependiente en tres modelos de regresión lineal (uno por variable dependiente). Dichos análisis se llevaron a cabo utilizando el paquete estadístico para Ciencias Sociales (IBM SPSS for Mac, versión 20.0; Armonk, NY, USA). En todos los análisis el nivel de significación estadística fijado fue de $p<0,05$.

Resultados

De 646 posibles participantes, 181 fueron excluidos por diferentes motivos: 39 no estaban diagnosticados por un reumatólogo, 99 no cumplieron los criterios de ACR-1990, 21 eran hombres, 1 mostró un rendimiento cognitivo deteriorado, 2 presentaron alguna enfermedad aguda o severa, 1 no tenía datos de composición corporal y 18 no realizaron el test de prensión manual. La figura 1 muestra el diagrama de flujo del estudio.

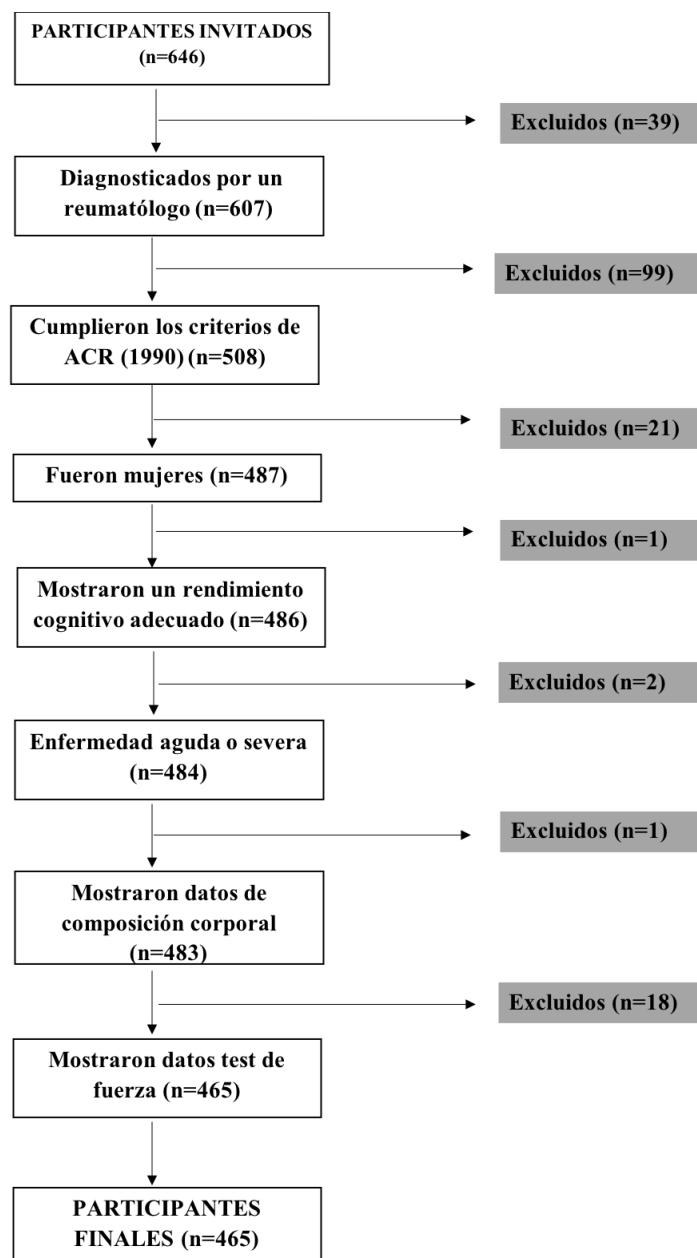


Figura I. Diagrama de flujo del estudio

Las características descriptivas de los 465 que formaron parte finalmente del estudio se presentan en la tabla 1. Las tablas 2, 3 y 4 muestran los resultados procedentes del análisis de regresión lineal entre los niveles de fuerza y el afecto positivo, el afecto negativo y la satisfacción con la vida. Entre ellos encontramos que un mayor nivel de fuerza manual está asociado con mayor afecto positivo ($t=3,26$; $p<0,01$), menor afecto negativo ($t=-3,95$; $p<0,001$) y mayor satisfacción con la vida ($t=2,57$; $p<0,05$). El modelo final explicó entre el 6% y 11% de variabilidad en las dimensiones del bienestar subjetivo [los valores de R^2 ajustados fueron 0,09, $p<0,01$, para el afecto positivo; 0,11, $p=0,001$ para el afecto negativo y 0,06, $p<0,05$ para la satisfacción con la vida].

Tabla 1. Características de las participantes en el estudio (n = 465)

Variables	Media	DT
Edad	52,1	7,9
Altura (cm)	157,83	6,03
Peso (kg)	71,16	13,78
Índice Masa Corporal (kg/m ²)	28,5	5,3
Puntos de dolor: número total	16,7	1,9
Condición física		
Test de prensión manual (kg)	19,06	6,5
Componentes del bienestar subjetivo		
Afecto positivo (PANAS; 10-50)	22,9	6,7
Afecto Negativo (PANAS; 10-50)	24,0	8,4
Satisfacción con la vida (SWLS; 5-25)	14,0	4,6
	Frecuencia	%
Estado civil		
Casada	312	75,7
Soltera	36	7,7
Separada/divorciada	52	11,2
Viuda	25	5,4
Nivel de educación		
Estudios sin finalizar	50	10,8
Primaria	225	40,8
Secundaria y FP	126	27,1
Título universitario	64	13,8

DT: Desviación típica, PANAS: *Positive and Negative Affect Scale Schedule*, SWLS: *Satisfaction with Life Scale*, FP: Formación Profesional.

Tabla 2. Asociación entre fuerza de presión manual y el afecto positivo (n=465)

Pasos	B	95% IC: Límite Inferior	95% IC: Límite Superior	β	Adj R ²
1					0,07***
Edad (años)	0,23	0,17	0,11*		
Medicamentos para la depresión	-3,32	-0,70	-0,14**		
Medicamentos para el dolor	-4,52	-0,45	-0,10*		
Medicamentos para la relajación o el sueño	-3,04	-0,12	0,15*		
2					
Test de presión manual (kg)	0,09**	0,06	0,25	0,15**	0,09**

En el paso 1, se incluyeron las variables confusoras y en el paso 2, la variable independiente de interés.

B y β , Coeficientes de regresión no estandarizados y estandarizados con los niveles de significación basados en el estadístico t, respectivamente; IC, Intervalo de Confianza; Adj.R², R² ajustado con los niveles de significación basados en el cambio de F; PANAS; *Positive and Negative Affect Scale Schedule*.

* p < 0,05; ** p < 0,01; *** p < 0,001

Tabla 3. Asociación entre fuerza de prensión manual y el afecto negativo (n=465)

Pasos	B	95% IC: Límite Inferior	95% IC: Límite Superior	β	Adj R ²
1					0,08***
Edad (años)	-0,22	-0,32	-0,13	-0,21***	
Medicamentos para la depresión	1,78	0,16	3,40	0,10*	
Medicamentos para el dolor	0,68	-1,82	3,19	0,02	
Medicamentos para la relajación o el sueño	2,84	1,04	4,65	0,15**	
2					
Test de prensión manual (kg)	-0,23	-0,35	-0,11	-0,18***	0,11***

En el paso 1, se incluyeron las variables confusoras y en el paso 2, la variable independiente de interés.

B y β , Coeficientes de regresión no estandarizados y estandarizados con los niveles de significación basados en el estadístico t, respectivamente; IC, Intervalo de Confianza; Adj.R², R² ajustado con los niveles de significación basados en el cambio de F; PANAS; *Positive and Negative Affect Scale Schedule*.

* p < 0,05; ** p < 0,01; *** p < 0,001

Tabla 4. Asociación entre fuerza de prensión manual y la satisfacción con la vida (n=465)

Pasos	B	95% IC: Límite Inferior	95% IC: Límite Superior	β	Adj R ²
1					0,05***
Edad (años)	0,58	6·10 ⁻²	0,11	0,10*	
Medicamentos para la depresión	-1,62	-2,53	-0,71	-0,17***	
Medicamentos para el dolor	-0,01	-1,42	1,39	1·10 ⁻²	
Medicamentos para la relajación o el sueño	-0,86	-1,88	0,14	-0,08	
2					
Test de prensión manual (kg)	0,08	0,02	0,15	0,12*	0,06*

En el paso 1, se incluyeron las variables confusoras y en el paso 2, la variable independiente de interés.

B y β , Coeficientes de regresión no estandarizados y estandarizados con los niveles de significación basados en el estadístico t, respectivamente; IC, Intervalo de Confianza; Adj.R², R² ajustado con los niveles de significación basados en el cambio de F; PANAS; *Positive and Negative Affect Scale Schedule*.

* p < 0,05; ** p < 0,01; *** p < 0,001

Discusión

En la fibromialgia, la importancia del bienestar subjetivo, en concreto, el afecto positivo cuya finalidad es alcanzar una mejor salud, ha sido estudiado previamente (Hassett y col., 2008; van Middendorp y col., 2010), insistiendo en la importancia de identificar posibles factores determinantes del bienestar subjetivo. Por lo tanto, el objetivo de este estudio fue analizar la asociación entre la fuerza de prensión manual, considerado como un marcador de salud, con el bienestar subjetivo en mujeres con fibromialgia. Nuestro estudio mostró una asociación entre los mayores niveles de fuerza de prensión manual y puntuaciones más favorables en relación con el bienestar subjetivo (mayor afecto positivo, menor afecto negativo y mayor satisfacción con la vida). Aun siendo significativa, la fuerza de estas asociaciones fue en general débil. Estos hallazgos sugieren que la fuerza podría favorecer al bienestar subjetivo, lo que requiere ser corroborado en estudios longitudinales y experimentales.

La gran mayoría de los estudios previos que han analizado la asociación entre la condición física, en concreto los niveles de fuerza, y los síntomas de la fibromialgia, se han centrado en la sintomatología física (Aparicio y col., 2011; Koklu, Sarigul, Ozisler, Sirzai y Ozel, 2016; Mannerkorpi y col., 2006; Soriano-Maldonado, Henriksen, Segura-Jimenez, Aparicio, Carbonell-Baeza, Delgado-Fernandez y Ruiz, 2015; Tomas-Carus, Gusi, Hakkinen, Hakkinen, Raimundo, y Ortega-Alonso, 2009), demostrando que los niveles de fuerza más altos se asocian con niveles más saludables en relación con el impacto, dolor y funcionamiento físico y vital (Aparicio y col., 2011; Mannerkorpi y col., 2006). Resultados similares se han obtenido para otras variables relacionadas con la calidad de vida como, mayores niveles de fuerza y salud física y mental en estos pacientes (Cordoba-Torrecilla, Aparicio, Soriano-Maldonado, Estevez-Lopez, Segura-Jimenez, Alvarez-Gallardo, y Delgado-Fernandez, 2016; Soriano-Maldonado, Artero, Segura-Jimenez, Aparicio, Estevez-Lopez, y Alvarez-Gallardo, 2016; Soriano-Maldonado, Estévez-López, Segura-Jiménez, Aparicio, Alvarez-Gallardo, Herrador-Colmenero, y Delgado-Fernández, 2015; Tomas-Carus y col., 2009). También hay evidencias que asocian mayores niveles de condición física con menores de fatiga y rigidez muscular, así como mayor densidad mineral ósea (Estévez-López y col., 2015; Aparicio y col., 2015; Castro-Piñero y col., 2017; Soriano-Maldonado, Ruiz y col., 2015). Por lo tanto, nuestros resultados apoyan que alcanzar mayores niveles de fuerza puede tener un efecto beneficioso no solo en la salud física sino también en la salud psicológica en mujeres con fibromialgia.

Centrándonos en síntomas psicológicos, investigaciones previas han observado que niveles más altos de fuerza muscular se asociaron con mejor rendimiento cognitivo en mujeres con fibromialgia (Soriano-Maldonado y col., 2016) y menor depresión en personas diagnosticadas de fibromialgia (Sener, Ucok, Ulasli, Genc, Karabacak, Coban, y Cevik, 2016). Respecto a la ansiedad, un estudio obtuvo asociaciones significativas inversas entre la fuerza muscular y los niveles de ansiedad en las mujeres con fibromialgia (Cordoba-Torrecilla y col., 2016). Por lo tanto, nuestro estudio, extiende el posible papel

beneficioso de tener una mejor condición física, en concreto mayores niveles de fuerza desde los aspectos psicológicos negativos (por ejemplo, ansiedad y depresión) a los positivos, como es el bienestar subjetivo.

Aunque este trabajo no se centra en estudiar los mecanismos de las asociaciones analizadas, estudios previos han indicado que la actividad física puede promover una mejor salud mental a través de, al menos, tres mecanismos distintos (neurobiológicos, psicosociales y comportamentales). Así, se ha sugerido que la actividad física puede promover aumentos en los niveles de norepinefrina, serotonina y dopamina en el cerebro, todos ellos asociados con sentimientos de felicidad (Mathew y Paulose, 2011); i.e., mecanismos neurobiológicos. Además, diversos estudios han mostrado que realizar actividad física promueve sentimientos positivos (por ejemplo, Kanning y Schlicht, 2010) posiblemente relacionados con la capacidad de afrontar satisfactoriamente las actividades de la vida diaria que requieren ciertos niveles de condición física; i.e., mecanismos psicosociales. En concreto, la fuerza muscular puede ayudar a satisfacer estas necesidades y conducir así a un mayor bienestar subjetivo en las mujeres con fibromialgia. Por último, participan regularmente en actividad física puede promover la adquisición de otros hábitos de vida saludables (i.e., mecanismos comportamentales) como, por ejemplo, seguir una dieta saludable o una buena higiene de sueño lo cual puede favorecer mayores niveles de bienestar (Borges-Cosic, Aparicio, Estévez-López, Soriano-Maldonado, Acosta-Manzano, Gavilán-Carrera, y Segura-Jiménez, 2019; Carvalho, Ronca, Michels, Huybrechts, Cuenca-García, Marcos, y Carvalho, 2018; Palagini, Carmassi, Conversano, Gesi, Bazzichi, Giacomelli, y Dell'Osso, 2016; Ruiz-Cabello, Soriano-Maldonado, Delgado-Fernandez, Alvarez-Gallardo, Segura-Jimenez, Estevez-Lopez, y Aparicio, 2017)

Las recomendaciones actuales para el tratamiento de la fibromialgia indican que el primer paso debe ser realizar ejercicio físico (Clauw, 2014). Así, la European League Against Rheumatism (EULAR) recientemente ha indicado que el ejercicio físico es la única terapia que tiene un grado de evidencia fuerte en esta patología (Macfarlane y col., 2017). Si la causalidad de nuestros resultados es corroborada en futuros estudios, nuestros hallazgos podrían tener implicaciones clínicas. En concreto, nuestros resultados sugieren que aquellos programas de ejercicio físico que mejoren los niveles de fuerza podrían no solo aportar beneficios físicos sino también psicológicos (i.e., mayores niveles de bienestar subjetivo) para las mujeres con fibromialgia.

Este estudio presenta algunas limitaciones. En primer lugar, la naturaleza transversal de nuestro estudio impide la interpretación causal de los resultados. Además, los tamaños del efecto (R^2 ajustado) de las asociaciones estudiadas fueron aparentemente pequeños. Sin embargo, dado que en el contexto de la salud mental se desconoce cuáles son los puntos de corte de dichos tamaños del efecto para sugerir relevancia clínica, no se puede interpretar la magnitud del tamaño del efecto (Rodriguez-Ayllón, Acosta-Manzano, Coll-Risco, Romero-Gallardo, Borges-Cosic, Estévez-López, y Aparicio, 2019). En segundo lugar, las mujeres con fibromialgia del sur de España podrían estar más afectadas que las residentes en otros países desarrollados como los Países Bajos (Ruiz-Montero, Van

Wilgen, Segura-Jiménez, Carbonell-Baeza, y Delgado-Fernández, 2015) o Estados Unidos (Toussaint, Vincent, McAllister, Oh, y Hassett, 2014). En tercer lugar, debido al pequeño tamaño muestral de los hombres, en este estudio solo se incluyeron mujeres. Por lo tanto, nuestros resultados no pueden ser extrapolables a otras poblaciones ni a hombres con fibromialgia. Para confirmar el hallazgo principal del presente estudio, sería interesante replicarlo en estudios futuros con muestras independientes. En cambio, como principal fortaleza del presente estudio, destacamos el tamaño muestral con la que se ha trabajado, siendo representativa de la población Andaluza de mujeres con fibromialgia (Segura-Jimenez y col., 2015a). Además, el equipo de investigación corroboró el diagnóstico de fibromialgia de los participantes.

Conclusiones

Nuestros hallazgos sugieren que las mujeres con fibromialgia con mayores niveles de fuerza indicaron tener mayores niveles de bienestar subjetivo, en concreto mayores de afecto positivo y satisfacción con la vida, así como menores de afecto negativo. En general, la fuerza de estas asociaciones fue débil. Si futuros estudios experimentales confirman la causalidad de nuestros hallazgos, los programas de ejercicio que mejoren los niveles de fuerza podrían suponer de forma efectiva el aumento del bienestar subjetivo en las mujeres con fibromialgia. En el caso de producirse dichos aumentos, los futuros estudios deben evaluar la relevancia clínica de sus hallazgos.

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APPENDIX VII

**FULL TITLE: ASSOCIATIONS OF SEDENTARY TIME AND PHYSICAL
ACTIVITY WITH PHYSICAL FITNESS IN WOMEN WITH FIBROMYALGIA:
AN ISOTEMPORAL SUBSTITUTION APPROACH**

**RUNNING HEAD: SEDENTARY TIME, PHYSICAL ACTIVITY, FITNESS
AND FIBROMYALGIA**

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Abstract

Background. Behaviours of people with fibromyalgia may impact their levels of physical fitness, which is a marker of physical and psychological health. However, scarce research has studied the association of sedentary time (ST) and physical activity (PA) with physical fitness. Interestingly, increasing time in one behaviour requires decreasing time in another. Thus, it is also of interest to understand what the theoretical impact is of replacing sedentary time (ST, e.g., sitting) by light or moderate PA (LPA and MPA, respectively) as well as replacing LPA by MPA on physical fitness in fibromyalgia. Objectives. To assess the association of replacing ST for different physical activity levels (i.e., ST by LPA or MPA) as well as of LPA by MPA with physical fitness in women with fibromyalgia.

Methods. A total of 407 women with fibromyalgia (51.87 ± 8.01 years old) participated in this cross-sectional study. ST, LPA and MPA were objectively measured with triaxial accelerometer for 7 consecutive days. Vigorous physical activity was not analysed as this is a very uncommon behaviour in the population. Physical fitness was assessed through the Senior Fitness Test Battery plus the handgrip strength test. The associations between the replacement of 30 min/day of ST with an equivalent time of LPA or MPA were tested by isotemporal substitution analyses. Body mass index and age were included as covariates.

Results: Replacing 30 minutes of ST with LPA was associated with better strength in upper limb ($B=0.19$), handgrip strength ($B=0.02$) and aerobic fitness ($B=2.29$); all $p<0.03$. Replacing 30 minutes of ST with MPA was related to better strength and flexibility in lower and upper limb (B ranging from 0.43 to 1.97; all $p<0.02$). Finally, replacing 30 minutes of LPA with MPA was associated with better strength and flexibility in lower and upper limb, aerobic fitness and balance (B ranging from 0.15 to 8.54; all $p<0.04$).

Conclusions: Replacing short time periods (30 min) of ST by PA (especially of moderate intensity) was related to better physical fitness. Moreover, to replace 30 min of LPA by MPA was related to better physical fitness. Our findings support the implementation of experimental research to better understand the extent to which replacing sedentary time (by LPA or MPA) or replacing LPA (by MPA) might enhance increase different components of physical fitness in fibromyalgia. Such findings would have direct clinical implications.

INTRODUCTION

Fibromyalgia is a common disease [1] characterized by a genetic susceptibility [2,3] to chronic widespread pain and increased sensitivity to painful stimuli [4,5]. Along with chronic pain, the clinical manifestation of the disease often involves an array of physical and psychological symptoms such as, for instance, increased physical fatigue and reduced well-being [6,7]. The overall impact of fibromyalgia is greater on physical health than on psychological health [8]. For instance, in comparison to non-fibromyalgia peers, physical fitness is clearly impaired in people with fibromyalgia [9].

In the general population, lower levels of physical fitness are related to increased risk for death and disability later in life [10–12]. Thus, higher physical fitness is acknowledged as a powerful marker of health [13]. Evidence from the literature also shows a wide range of associations between physical fitness and the cardinal symptoms of fibromyalgia [14–18], which collectively suggests that lower physical fitness is associated with higher fibromyalgia severity [19–27]. Thus, it is of public health interest to identify potentially modifiable risk factors related to physical fitness in fibromyalgia. This identification may be particularly important for those factors that are easy to target and improve and implement clinical through health care systems.

Along with other factors, physical activity and sedentary time determinate one's levels of physical fitness because fitness is composed of genetic factors and physical activity factors, therefore physical activity is the only modifiable factor that could increase fitness [28–30]. In fibromyalgia, a physical activity intervention promoted enhancements on physical function [31], which may be seen as a proxy of improvements on physical fitness [23,32]. Although there is also a paucity of observational research, previous studies have shown mutual associations between physical activity, sedentary time and physical fitness in fibromyalgia population [19,20,25,26,33]. Although valuable, previous literature is based on traditional regression models which ignore that total daily time during a day is fixed. Hence, increasing time in one behaviour requires decreasing the same amount of time in another. In addition, an activity will have different effects on a health outcome depending on the activity that is being displaced. The application of innovative approaches that account for this time substitution effect (i.e., isotemporal substitution analyses) would help to better understand the potential impact of reallocating time through different behaviours on physical fitness. Therefore, the present study aimed at

analysing the associations of allocations of time spent in sedentary and physical activities with physical fitness components in women with fibromyalgia.

MATERIALS AND METHODS

Study sample and design

The sample for this cross-sectional study was mostly recruited from local southern Spanish fibromyalgia associations. After providing detailed information about the aims and study procedures, all interested participants signed a written informed consent. The inclusion criteria for participating were (i) to meet the 1990 American College of Rheumatology (ACR) fibromyalgia criteria [5], (ii) no acute or terminal illness (such as cancer, stroke, recent cardiopathy, severe coronary disease, schizophrenia, or any other disabling injury), and (iii) no severe cognitive impairment (as a proxy of having dementia potentially, Mini Mental State Examination (MMSE) < 10) [34]. The study was approved by the Ethics Committee of the “Hospital Virgen de las Nieves” Granada (Spain).

Procedure

The assessment protocol into place over two appointments and all measurements were performed by the same trained researcher in order to reduce inter-examiner error. At the first appointment, fibromyalgia diagnosis was confirmed, height and weight were measured. Two days later, at a second appointment, physical fitness was assessed through the senior fitness test battery. Then, participants received an accelerometer to be worn for 9 consecutive days and returned it back after that period.

Materials

Fibromyalgia diagnosis

Using a standard pressure algometer (FPK 20; Wagner Instruments, Greenwich, CT, USA) and according to the 1990 ACR criteria for fibromyalgia, we assessed the 18 tender points. A tender point was scored as positive when the patient noted pain at pressure \square 4 kg/cm². The total count of positive tender points (tender points count) was recorded for each participant. The average score of two measurements for each tender point was used in the analysis. The diagnosis of fibromyalgia was corroborated when, at least, 11 out of 18 tender points were positive.

Severe cognitive impairment

Each participant was interviewed by trained researchers in order to complete the MMSE [34]. Five areas of cognitive functioning were assessed: orientation, immediate memory, attention/concentration, delayed recall and language. This test was used for exclusion criteria purpose only.

Body Mass Index (BMI)

We used a portable eight-polar tactile-electrode impedance analyser (Inbody R20, Biospace, Seoul, Korea) to measure body weight (kg). Height (cm) was measured using a stadiometer (Seca 22, Hamburg, Germany). BMI was calculated as weight (kg) divided by squared height (m²).

Age

Age was self-reported in a questionnaire.

Physical activity and sedentary time

Participants wore a triaxial accelerometer GT3X+ (Actigraph, Pensacola, Florida, USA) around the hip, secured with an elastic belt for nine whole days (24 h) except for water-based activities. Using the default mode filter option, data were collected at a rate of 30 Hz and at an epoch length of 60 seconds [35]. Given that patients received the accelerometer at different times throughout the first day and to avoid any possible reactivity to the awareness of being monitored, we excluded this familiarization day from the analysis. The last day (device return) was excluded from the analysis as well. A total of 7 continuous days with a minimum of 10 valid hours/day were required to be included in the analysis. Data download, reduction, cleaning, and analyses were conducted using the manufacturer software (ActilifeTM v.6.11.7 desktop). Accelerometer wearing time was calculated by subtracting sleeping time and non-wear periods. Sleeping time was obtained from a sleep diary, where patients indicated the time they went to bed and time they woke up. According to Choi algorithm [36], non-wear periods were considered as bouts of 90 continuous minutes (30 minutes small window length and 2 minutes skip tolerance) of 0 counts.

Physical activity intensity levels (i.e., light, and moderate-to-vigorous) were calculated based upon recommended physical activity vector magnitude cut points [35,37]: 200-

2689, ≥2690cpm, respectively. Sedentary time was estimated as the time accumulated below 200 counts per minute (cpm) during periods of wear time [36]. All values were initially expressed in min/day but were converted to units of 30 minutes (1 represents 30 minutes) for ease of interpretation of the results. To do this, min/day spent in each behaviour and total wear-time were divided by 30.

Physical fitness testing

The Functional Senior Test battery was used for several reasons (i) the battery has no ceiling and floor effects and we could better capture heterogeneity of this population, (ii) due to the reduced physical capacity of people with fibromyalgia [9,19,20,38], and (iii) it is relatively easy to administer, safe, and requires minimal equipment and space [39]. Therefore, the tests used are feasible to perform in epidemiological research in fibromyalgia. The Functional Senior Test battery is composed by the following tests [40]: the ‘30-s chair-stand test’ (a measurement of lower-body muscular strength), ‘arm curl test’ (upper-body muscular strength), ‘chair sit & reach test’ (lower-body flexibility), ‘back-scratch test’ (lower-body flexibility), ‘8-feet up & go test’ (dynamic balance) and ‘6-min walk test’ (cardiorespiratory fitness). Participants also performed the handgrip strength test (upper-body muscular strength), which is commonly used in fibromyalgia [41]. Online supplementary information presents a detailed description of each tests, including their scoring.

Statistical analyses

Descriptive statistics were used to examine the characteristics of the sample. Age and body mass index were entered as covariates in all the analyses described below.

Preliminary analyses: individual association of behaviours and fitness

As previous literature has widely omitted accounting of the finite nature of one day (i.e., 24 hours), in the present study we decided to report results of traditional linear regression models testing the individual associations of physical activity and sedentary time with physical fitness in order to compare with similar approaches in which previous literature is mainly based.. In separate models, each behavioural variable (e.g., light physical activity) was entered as the independent variable and the performance on each physical fitness test (e.g., the 30-s chair-stand test) was entered as the dependent variable. Thus, a

total of 21 models were conducted to assess the single associations of physical activity and sedentary time with physical fitness.

Main analyses: potential effects of substituting behaviours on fitness

A detailed description, including the rationale, of the isotemporal substitution modelling is provided elsewhere (Mekary, Willett, Hu, & Ding, 2009). Briefly, this statistical approach considers that because the time available to perform activities throughout the day is fixed, increasing time in one behaviour necessarily requires decreasing the same amount of time in others. Through these models we can estimate the effects on a health outcome of substituting different behaviours in an equal time-exchange manner while holding the total time conferred to different activities constant. To build these models the total time and all of the behaviours except the activity that is being replaced are included as independent variables. Consequently, the coefficient from the regression analysis for each of the included behaviours is an estimation of the mean effect on the outcome of substituting a fixed amount of time (in the present study, 30 minutes) of the omitted activity with the same amount of each of the included activities (while holding time spent in other activities constant). For instance, an isotemporal substitution model can be expressed as follows:

Performance on the handgrip strength test (kg) = (β_1) light physical activity + (β_2) moderate physical activity + (β_3) vigorous physical activity + (β_4) total time + (β_5) covariates. Given that sedentary time is omitted from the model, β_1 expresses the change in the performance on the handgrip strength test that would result from reallocating 30 minutes of sedentary time to light physical activity. The β_2 coefficient would provide the same information in relation to moderate physical activity. Finally, all criteria were met for regression analysis

In the present study, for all fitness outcomes we built two types of substitution models: i) substituting sedentary time with light and moderate physical activity, and ii) substituting light physical activity with moderate physical activity.

RESULTS

From 646 potential participants with fibromyalgia, 241 were excluded due to the following reasons: 39 were not previously diagnosed by a rheumatologist, 100 did not fulfil the 1990 criteria, 1 showed severe cognitive impairment, 19 were men, 2 reported

to have an acute or terminal illness, 56 did not satisfy accelerometry criteria and 21 did not complete all functional fitness test. Therefore 407 participants were included in the analysis. Table 1 provides an overview of the participants' characteristics.

Table 1. Characteristics of the participants ($n=407$)

Variables	Mean	SD
Age, years	51.8	8.0
Body mass index (kg/m^2)	28.6	5.4
Total tender points (11-18)	16.7	1.9
Physical activity and sedentary time (accelerometer, min/day)		
Light physical activity	419.6	91.8
Moderate physical activity	43.6	29.0
Vigorous physical activity	0.4	1.9
Sedentary time	460.0	103.0
Physical fitness tests		
30-s arm curl test (repetitions)	14.3	4.8
Handgrip strength test (kg)	19.2	6.2
30-s chair stand test (repetitions)	10.4	3.0
Chair sit and reach test (cm)	-6.6	0.4
Back scratch test (cm)	-11.0	11.4
6-min walk test (m)	489.3	76.0
8-foot up and go test [#] (s)	6.7	1.6

SD, Standard Deviation. [#]Lower scores indicate better performance.

For the sake of comparability with previous and possibly with future studies, the results of the traditional linear regression models examining the individual associations of physical activity intensity levels and sedentary time with physical fitness tests are shown in table 2.

The results of the isotemporal substitution models replacing 30 minutes of sedentary time by 30 minutes of light or moderate physical activity are shown in table 3. The substitution by light physical activity was associated with better performance in the arm curl ($t=2.31$; $p=0.021$), handgrip strength ($t=2.64$; $p=0.008$), and 6-min walk ($t=2.17$; $p=0.030$) tests.

The substitution by moderate physical activity was associated with better performance in the arm curl ($t=3.15$; $p=<0.001$), 30-s chair stand ($t=3.15$; $p=0.002$), chair sit-and-reach ($t=4.09$; $p=<0.001$), back scratch ($t=2.23$; $p=0.026$), 6-min walk ($t=2.63$; $p=<0.001$), and 8-foot up-and-go ($t=-2.84$; $p=0.005$) tests. Finally, replacing 30 minutes of sedentary time with 30 minutes of vigorous physical activity was associated with better 30-s arm curl ($t=5.40$; $p=<0.001$), handgrip strength ($t=3.05$; $p=0.002$), 30-s chair stand ($t=5.17$; $p=<0.001$), chair sit- and- reach ($t=4.09$; $p=<0.001$), back scratch ($t=2.00$; $p=0.046$), 6-min walk ($t=4.98$; $p=<0.001$), and 8- foot up- and- go ($t=-2.00$; $p=0.045$), tests.

The results of the isotemporal substitution models replacing 30 minutes of light physical activity by 30 minutes of moderate physical activity are showed in table 4. This substitution was associated with better performance in the 30-s arm curl ($t=2.71$; $p=0.007$), 30-s chair stand ($t=2.10$; $p=0.035$), chair sit-and-reach ($t=2.99$; $p=0.003$), back scratch test ($t=2.04$; $p=0.041$), 6-min walk test ($t=2.56$; $p=0.011$), and 8- foot up-and-go ($t=-2.02$; $p=0.43$) tests. Finally, the replacement of 30 minutes of light physical activity by 30 minutes of vigorous physical activity was associated with better performance in the arm curl ($t=5.31$; $p=<0.001$), handgrip strength ($t=2.93$; $p=0.004$), 30-s chair stand ($t=5.09$; $p=<0.001$), chair sit- and- reach ($t=4.02$; $p=<0.001$), back scratch ($t=2.01$; $p=0.044$), and 6-min walk ($t=4.90$; $p=<0.001$) tests, respectively.

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Table 2. Individual associations of physical activity (PA) and sedentary time (ST) with physical fitness (*n*=407)

	30-s arm curl test		Handgrip strength test		30-s chair stand test		Chair sit and reach test		Back scratch test		6-min walk test		8- foot up-and-go test#	
	B	95 % (CI)	B	95 % (CI)	B	95 % (CI)	B	95 % (CI)	B	95 % (CI)	B	95 % (CI)	B	95 % (CI)
LPA	0.22**	0.07 to 0.34	0.22*	0.02 to 0.42	0.15**	0.05 to 0.25	0.59**	0.22 to 0.95	0.25	-0.11 to 0.61	4.24***	2.00 to 4.47	-0.07**	-0.12 to -0.02
MPA	0.58*	0.08 to 1.07	-0.24	-0.88 to 0.40	0.42**	0.11 to 0.72	1.73**	0.56 to 2.91	0.79	-0.36 to 1.96	13.31***	6.15 to 20.48	-0.22*	-0.38 to -0.05
VPA	12.46**	5.33 to 19.58	4.19	-5.09 to 13.47	5.59*	1.12 to 10.08	13.98	-3.11 to 31.08	4.89	-11.86 to 21.65	140.65**	36.27 to 245.03	-0.89	-3.29 to 1.49
ST	-0.09	-0.23 to 0.05	-0.14	-0.32 to 0.04	-0.08	-0.17 to 0.01	-0.29	-0.62 to 0.04	0.12	-0.21 to 0.44	-2.32*	-4.35 to -0.29	0.03	-0.02 to 0.07

B, non-standardized regression coefficient. CI, Confidence interval. LPA, Light Physical Activity. MPA, Moderate Physical Activity. VPA, Vigorous Physical Activity. ST, Sedentary Time.

* *p* < 0,05; ** *p* < 0,01; *** *p* < 0,001. All the models included body mass index and age as covariates. #Lower scores indicate better performance.

Table 3. Potential effects of substituting 30 minutes/day of sedentary time (ST) by 30 minutes/day of light or moderate physical activity (PA) on physical fitness (n=407)

	Sedentary Time	Light PA			Moderate PA			Vigorous PA		
		B	95 % CI	p	B	95 % CI	p	B	95 % CI	p
30-s arm curl test	Dropped	0.19	0.03 to 0.35	0.021	0.89	0.46 to 1.34	<0.001	13.14	8.36 to 17.91	<0.001
Handgrip strength test	Dropped	0.02	0.11 to 0.48	0.002	0.17	-0.22 to 0.68	0.501	8.50	3.03 to 12.97	0.002
30-s chair stand test	Dropped	0.09	0.00 to 0.19	0.051	0.43	0.16 to 0.70	0.002	7.72	4.79 to 10.65	<0.001
Chair sit and reach test	Dropped	0.31	-0.04 to 0.65	0.082	1.97	1.03 to 2.94	<0.001	21.67	11.20 to 31.92	<0.001
Back scratch test	Dropped	-0.05	-0.36 to 0.25	0.727	0.95	0.12 to 1.79	0.026	9.27	0.18 to 18.36	0.046
6-min walk test	Dropped	2.29	0.22 to 4.35	0.030	10.87	5.21 to 16.54	<0.001	155.63	94.32 to 216.93	<0.001
8- foot up and go test#	Dropped	-0.03	-0.08 to 0.01	0.167	-0.18	-0.31 to -0.06	0.005	-1.39	-2.76 to -0.03	0.045

B, non-standardized regression coefficient. CI, Confidence interval. All the models included body mass index, age, and total activity time (sedentary time + light PA + moderate PA + vigorous PA). Coefficients of 1 represents reallocating 30 minutes/day. #Lower scores indicate better performance.

Table 4. Potential effects of substituting 30 minutes/day of light physical activity (PA) by moderate physical activity on physical fitness (n=407)

		Light PA		Moderate PA		Vigorous PA			
			B		95 % CI	p	B	95 % CI	p
30-s arm curl test	Dropped		0.71		0.19 to 1.22	0.007	12.92	8.14 to 17.69	<0.001
Handgrip strength test	Dropped		-0.12		-0.70 to 0.46	0.679	8.16	2.69 to 13.63	0.004
30-s chair stand test	Dropped		0.33		0.03 to 0.65	0.035	7.60	4.68 to 10.53	<0.001
Chair sit and reach test	Dropped		1.67		0.58 to 2.77	0.003	21.22	10.87 to 31.56	<0.001
Back scratch test	Dropped		1.00		0.04 to 1.97	0.041	9.33	0.25 to 18.41	0.044
6-min walk test	Dropped		8.54		2.01 to 15.08	0.011	152.98	91.71 to 214.24	<0.001
8- foot up and go test#	Dropped		-0.15		-0.29 to -0.01	0.043	-1.36	-2.72 to 0.01	0.051

B, non-standardized regression coefficient. CI, Confidence interval. All the models included body mass index, age, and total activity time (sedentary time + light PA + moderate PA + vigorous PA). Coefficients of 1 represents reallocating 30 minutes/day. #Lower scores indicate better performance.

DISCUSSION

Our isotemporal models showed that the theoretical replacement of 30 min/day of sedentary time by light physical activity may be associated with improved upper-body muscular strength and aerobic fitness. Furthermore, to substitute 30 min/day of sedentary time or even light physical activity by moderate physical activity may be associated with improved performance in all the physical fitness components. Collectively, the isotemporal models suggest that engaging in physical activity has the potential to counteract negative effects of sedentary time on physical fitness in women with fibromyalgia. This finding is interesting as women with fibromyalgia often spend most of their time in sedentary behaviours [43,44].

It is widely agreed that increasing physical activity levels is advisable in the management of fibromyalgia [45]. Nevertheless, the intensity of physical activity most strongly associated with better health is unknown. Findings from the present isotemporal models, may suggest a key role of moderate physical activity in maintaining or improving all the components of physical fitness, which seems to be in line with the general advice of engaging in moderate physical activity to improve health in fibromyalgia [45]. It is important to keep in mind, however, that people with fibromyalgia often avoid intense activities, which are perceived as frightening [46]. Thus, a gentle progression from light to moderate physical activity ensuring the confidence of people with fibromyalgia to engage in more intense activities gradually seems to be advisable.

In addition, light physical activity has the potential to improve health in people with reduced levels of physical fitness or those who are inactive [47–49]. In fibromyalgia, light physical activity is concurrently associated with diverse symptoms and health-related outcomes [50,51]. Moreover, a previous randomised trial showed that by increasing walking gradually (i.e., up to 25% of steps/day) for people with fibromyalgia may achieve clinically significant improvement in health outcomes including physical function (a proxy of physical fitness) [52].

Clinical applications

In the general population, ageing is related to reductions in physical activity and consequently deteriorated levels of physical fitness [53]. This process may be premature in women with fibromyalgia. There is a clear relationship between daily physical activity

and physical function in fibromyalgia [33], which suggests a connection between lifestyle and physical fitness. The present study provides a theoretical insight into how to replace time spent in one behaviour (e.g., sedentary time) for another behaviour (e.g., light physical activity) might impact on physical fitness, which is acknowledged as a powerful marker of health in fibromyalgia [14–26]. If future research confirms the causality of the present findings, a number of clinical applications might be suggested.

To reduce sedentary time in order to increase time spent on physical activity may be related to better physical fitness. Although in comparison to light physical activity the effects of this replacement on physical fitness might be extensible to more fitness components and larger, women with fibromyalgia often appraise intense activities as scary, which in turn may evoked anxiety and a sense of being pushed beyond one's capability [46]. Thus, a graded approach in which people engage first in light physical activity and, when they feel confident, progress to activities of moderate intensity might be advisable, particularly to those who are sedentary. As the fibromyalgia population is heterogeneous [24], people that experience negative cognitions related to their symptoms or movement might need further support from health professionals (e.g., education or psychological techniques [54–56]). For instance, people with high pain catastrophizing might prevent themselves from engaging in moderate physical activity even if they are capable of doing so [23]. In this context, cognitive management techniques may help to lower pain catastrophizing and consequently to break the vicious circle of increased symptoms and behavioural avoidance [57–59]. To sum up, although our findings suggest that moderate physical activity is theoretically more beneficial for enhancing physical fitness than light physical activity, it does not mean that engaging in moderate physical activity is advisable to everyone with fibromyalgia. Indeed, replacement of sedentary time with light physical activity results in significant improvements in outcomes. Therefore, instead of standard one-size-fits-all physical activity programs, goals and progression of the programs might be better based on personalised approaches and the appropriateness of complementing physical activity with other modalities of therapy may be considered [15,24,60].

Limitations and strengths of the study

This study has some limitations. First, as a cross-sectional study, we are unable to infer a cause-and-effect relationship in our findings. Indeed, behavioural patterns may reflect

functional status. Second, our physical activity assessment did not account for activities involving only upper or lower limbs without trunk movement (e.g., some household work and cycling) and water-based physical activity (e.g., swimming or underwater walking). The objective measurement of physical activity, sedentary time and physical fitness in a large sample size that was representative of the southern Spanish (Andalusian) population of women with fibromyalgia may be seen as strengths of the study.

CONCLUSIONS

In conclusion, the isotemporal models showed that the theoretical replacement of 30 min/day of sedentary time by 30 minutes/day of light physical activity may be associated with improved upper-body muscular strength and aerobic fitness. Moreover, to substitute 30 min/day of sedentary time or light physical activity by 30 minutes/day of moderate physical activity may be associated with further benefits across a range physical fitness component and afford greater effects on physical fitness.

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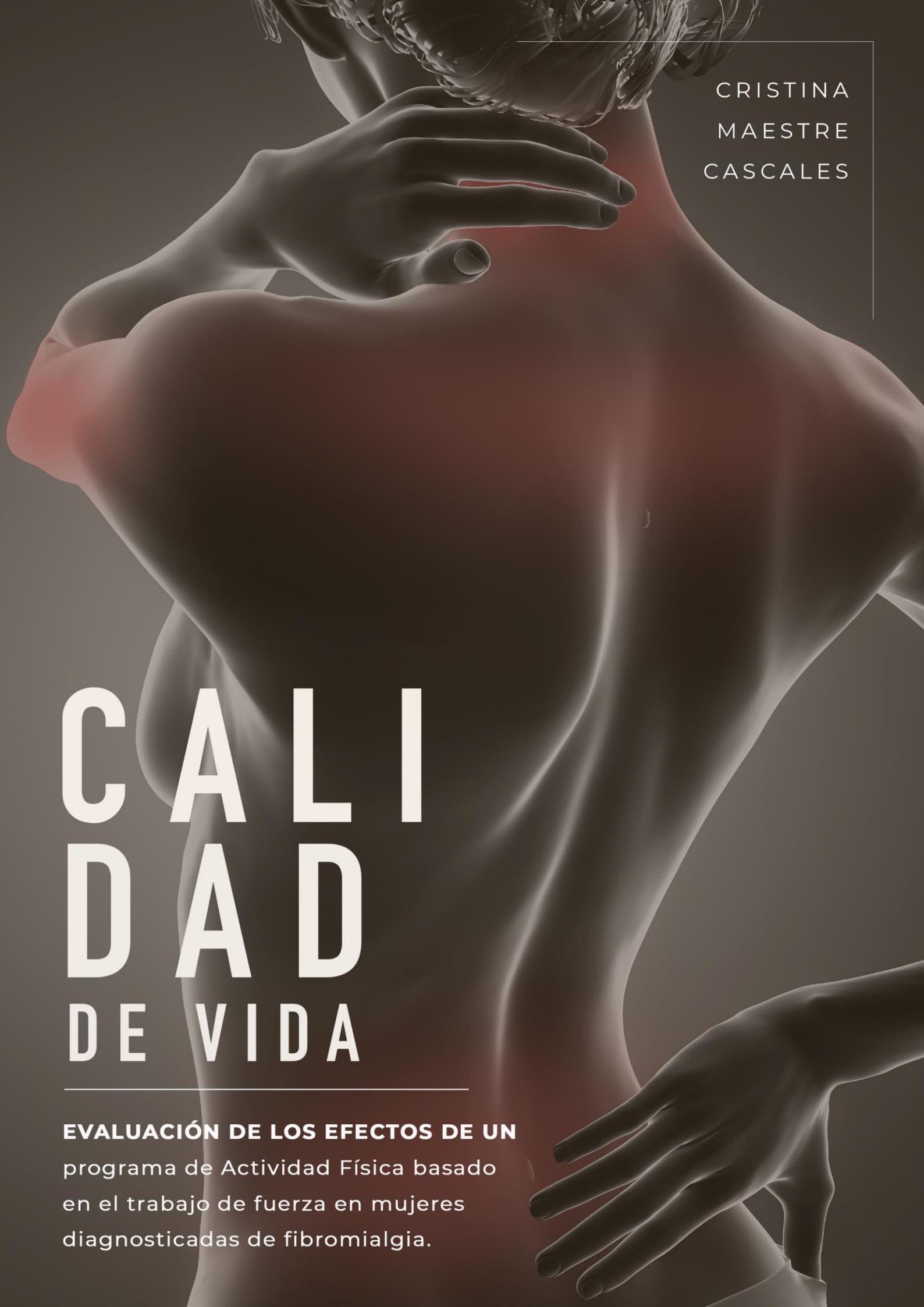
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***Nuestra recompensa se encuentra el en esfuerzo y no en el resultado.
Un esfuerzo total es una victoria completa***

(Mahatma Gandhi)



CRISTINA
MAESTRE
CASCALLES

CALIDAD DE VIDA

EVALUACIÓN DE LOS EFECTOS DE UN
programa de Actividad Física basado
en el trabajo de fuerza en mujeres
diagnosticadas de fibromialgia.

