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Development and validation of a physical exercise training program for women diagnosed with Fibromyalgia "Pessoas com Fibra" (People with Fiber). A pilot study

Desarrollo y validación de un programa de entrenamiento físico para mujeres diagnosticadas de fibromialgia "Pessoas com Fibra" (Personas con Fibra)

Desenvolvimento e validação de um programa de exercício físico para mulheres diagnosticadas com Fibromialgia "Pessoas com Fibra" (People with Fiber)

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Abstract. Fibromyalgia is a chronic disease that affects patients' quality of life, leading to reduced physical activity levels. This problem can therefore be attenuated by promoting physical exercise training programs (PETP). The aim of this pilot study was to develop and validate a PETP, "Pessoas com Fibra", designed to increase physical activity and improve the quality of life of women diagnosed with Fibromyalgia, aged between 30 and 60. The PETP was designed and validated by physical fitness specialists in accordance with Revised Guidelines for Reporting Criteria on the Development and Evaluation of Complex Health Interventions and the Consensus Guidelines on Physical Exercise Programme Reporting Model. It went through three phases: development, piloting and evaluation. This study presents an intervention proposal based on improving the participants' Fibromyalgia symptoms. "Pessoas com Fibra" program proposal presents suggestions for adaptation to the target population and exercises that can be replicated by professionals in the field of physical exercise and health.

Keywords: Fibromyalgia; Exercise; Health; Complex Intervention; Multicomponent Training; Aerobic Training; Strength Training

Resumen. La Fibromialgia es una enfermedad crónica que afecta a la calidad de vida de los pacientes, haciéndoles menos activos. Por ello, este problema puede atenuarse promoviendo programas de entrenamiento en ejercicio físico (PETP). El objetivo de este estudio piloto fue desarrollar y validar un PETP, "Pessoas com Fibra", diseñado para aumentar la actividad física y mejorar la calidad de vida de las mujeres diagnosticadas de fibromialgia, con edades comprendidas entre 30 y 60 años. El PETP fue diseñado y validado por expertos en ejercicio físico de acuerdo con la *Revised Guidelines for Reporting Criteria on the Development and Evaluation of Complex Health Interventions and the Consensus Guidelines on Physical Exercise Programme Reporting Model*, y pasó por tres fases: desarrollo, pilotaje y evaluación. Este estudio presenta una propuesta de intervención basada en la mejora de los síntomas de fibromialgia de los participantes. La propuesta del programa "Pessoas com Fibra" presenta sugerencias de adaptación a la población diana y ejercicios que pueden ser replicados por profesionales del ámbito del ejercicio físico y la salud.

Palabras clave: Fibromialgia; Ejercicio; Salud; Intervención Compleja; Entrenamiento Multicomponente; Entrenamiento Aeróbico; Entrenamiento de Fuerza.

Resumo. A Fibromialgia é uma doença crónica que afeta a qualidade de vida dos doentes, tornando-os menos ativos. Este problema pode assim ser atenuado através da promoção de programas de exercício físico (PETP). O objetivo deste estudo piloto foi desenvolver e validar um PETP, "Pessoas com Fibra", concebido para aumentar a atividade física e melhorar a qualidade de vida de mulheres com diagnóstico de Fibromialgia, com idades compreendidas entre os 30 e os 60 anos. O PETP foi concebido e validado por especialistas em aptidão física, de acordo com as *Revised Guidelines for Reporting Criteria on the Development and Evaluation of Complex Health Interventions* e o *Consensus Guidelines on Physical Exercise Programme Reporting Model*, tendo passado por três fases: desenvolvimento, pilotagem e avaliação. Este estudo apresenta uma proposta de intervenção baseada na melhoria dos sintomas da doença das participantes. A proposta do programa "Pessoas com Fibra" apresenta sugestões de adaptação à população-alvo e exercícios que podem ser replicados por profissionais da área do exercício físico e da saúde.

Palavras-chave: Fibromialgia; Exercício; Saúde; Intervenção Complexa; Treino Multicomponente; Treino aeróbio; Treino de Força.

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Introduction

Fibromyalgia (FM) is classified as a chronic rheumatic disease and is characterized by chronic widespread pain, muscle stiffness, sleep disturbances and cognitive problems (Atan & Karavelioğlu, 2020a; Chica et al., 2019; Norouzi et al., 2020; O'Dwyer et al., 2019). In addition to these, the following symptoms are also observed: a feeling of fatigue and changes in the psychological state (Chafer & Hamilton, 2015a). Moreover, FM can include muscle pain in the tender points, excessive fatigue, muscle strength loss and some psychological problems as mentioned before (i.e., sleep issues, anxiety, depression and reduced levels of satisfaction with life and self-esteem) (Busch et al., 2011; Chang et al., 2020). Most of the time, the diagnosis is quite difficult to perform because there is no accurate (i.e., validated) diagnostic test to identify the disease. Thus, the diagnosis of this disease is carried out through palpation from tender points specific for FM (Atan & Karavelioğlu, 2020).

Wolfe et al. (1995) stated that the heterogeneous nature of Fibromyalgia symptoms, combined with a lack of a single identifiable cause, makes diagnosis and treatment

challenging. In addition, the heterogeneous symptoms of Fibromyalgia, such as morning stiffness, diffuse pain, sleep disorders, chronic fatigue, headaches, anxiety, depression, behavioral disorders and cognitive alterations. These include memory, attention, language, orientation in space and time (Bazzichi et al., 2011), difficulty concentrating, paresthesias/dysesthesias and irritability (Cardoso et al., 2005; Bazzichi et al., 2011), makes its diagnosis and consequently its treatment difficult, making the pathology a challenge for science (Williams & Clauw, 2009; Wallace, 2014). However, its important to refer that *American College of Rheumatology* (ACR) change the tender point count as a diagnose for FM (Wolfe, 2010). The tender point count was rarely performed in primary care where most fibromyalgia diagnoses occurred, and when performed, was performed incorrectly (Fitzcharles, 2003). Many physicians did not know how to examine for tender points and some simply refused to do (Buskila et al., 1997).The diversity of symptoms associated with Fibromyalgia and the positive impact that regular physical exercise has been shown to have as a form of treatment, among non-pharmacological therapies, for this condition (Chafer & Hamilton, 2015b; Sousa et al., 2023a; Toprak Celenay et al., 2017). However, the lack of physical exercise training programs (PETP) that allow for adequate, effective and safe intervention in accordance with Consensus Guidelineson Physical Exercise Programme Reporting Model (CERT) and Revised Guidelines for Reporting Criteria on the Development and Evaluation of Complex Health Interventions (CReDECI2) guidelines appears to be a gap that needs to be addressed. In addition, the lack of guidelines/intervention protocols at national level (Portugal) in relation to exercise prescription could be an obstacle to its implementation by exercise professionals. Apart from the previous study (Sousa et al., 2024), no other research with Portuguese population was found.

Consequently, there is a pressing need to develop and validate well-defined physical exercise programs that can be replicated by other professionals, thus filling a gap identified in this pathology. The development of exercise programs for Fibromyalgia patients are important for the treatment of the disease and to encourage adherence to these programs. Therefore, the aim of this study is to develop and validate a structured physical exercise program to promote the health and physical fitness of female individuals diagnosed with Fibromyalgia.

Materials and Methods

The present pilot study constitutes in the validation of the specific physical exercise program for women diagnosed with Fibromyalgia adhered to the Revised Guidelines for Reporting Criteria on the Development and Evaluation of Complex Health Interventions (CReDECI2) (Mohler et al., 2015), as well as the Consensus on Reporting Template for Physical Exercise Programs (CERT) Guidelines (Slade et al., 2016) for the detailed description of the program. In addition, the methodologies of other published studies were important for the construction of this exercise program (Bernardino et al., 2024; Santos-Rocha et al., 2020).

Study Design

The exercise program aimed at women diagnosed with Fibromyalgia was designed by specialists in the field of physical exercise, so that it could be implemented or replicated by professionals working in the same field with this population. The literature also points out that FM is more prevalent in women with values between 2.4% and 6.8% and in urban areas between 0.7% and 11.4%. (Marques et al., 2017). In Portugal, the prevalence is estimated at 1.7% (1.1% to 2.1%) (Branco et al., 2016)

Therefore, a set of exercises was planned and developed to promote an increase in the participants' strength, functional capacity, and mobility. The validation process took place over 8 months, from October 2020 to June 2021.

Participants

The validation process involved two distinct groups of participants (n=11):

Expert Panel (n=4):

- Two exercise specialists (PhD in Sports Science) with over 20 years of teaching experience in Physical Activity and Health in higher education;
- One physical exercise professional with a degree in Sports Sciences and three years of experience in Physical Activity and Lifestyle;
- One physiotherapist with MSc degree and over 20 years of clinical experience.

Pilot Study Participants (n=7):

Seven women diagnosed with fibromyalgia for at least three years, without other associated pathologies (i.e., diabetes, cardiovascular diseases, respiratory diseases), who were not regularly participating in supervised physical exercise programs were enrolled and followed up at the Health Center of Rio Maior in Santarém, Portugal.

Instruments and Protocols

For the validation of the exercise program, the revised Criteria for Reporting the Development and Evaluation of Complex Interventions in Health-Care (CReDECI2) guideline developed and validated by Möhler et al. (2015) was used, consisting of 13 items identified for the stages: development, piloting and evaluation (Möhler et al., 2015a). The CReDECI2 model aims to improve the quality of reporting of the development and evaluation stages of complex health interventions. It should be noted that item 2 of the development stage of the CReDECI2 model (Möhler et al., 2015) included the 16 items corresponding to the CERT model.

For the program description, the Consensus on Exercise Reporting Template (CERT) guideline validated by Slade et al. (2016) was used, which aims to provide additional guidance for reporting exercise interventions. The CERT template consists of a 16-item checklist, considered essential for reporting replicable exercise programs. The main aim of

this model is to facilitate understanding, adoption, and dissemination to improve the reporting of essential components of exercise in all possible evaluative study designs for exercise research. CERT also has the potential to increase clinical acceptance of effective exercise programs, enable replication of research, saving time and improving patient outcomes (Slade et al., 2016).

The female participants with Fibromyalgia were recruited through purposive sampling at the Health Center of Rio Maior in Santarém, Portugal. The inclusion criteria were: 1) clinically confirmed diagnosis of Fibromyalgia for at least 3 years because of the quite difficult to perform the diagnosis to identify the disease (Atan & Karavelioğlu, 2020b); 2) age between 30 and 60 years according to the ages of diagnosis (Atan & Karavelioğlu, 2020b; Sousa et al., 2023a; Toprak Celenay et al., 2017). 3) absence of comorbidities such as diabetes, cardiovascular diseases, or respiratory diseases; and 4) not currently engaged in any supervised physical exercise program. Potential participants were identified from the Health Center's patient records and invited to participate in the study. Those who expressed interest were provided with detailed information about the study objectives, procedures, and requirements. Written informed consent was obtained from all participants prior to enrolment.

Ethical Considerations

All the procedures carried out complied with the 1964 Helsinki declaration for studies involving human participants. Informed consent was obtained from all participants. The study received ethical approval. However, there was no ethical approval reference/number to add. The methodological procedures applied fully complied with the code of conduct of the Declaration of Helsinki. The data was collected after the participants had signed an informed consent form authorizing their participation and agreeing to the dissemination of the results, and the confidentiality of their identities was guaranteed. All the assessments of quality of life and physical condition parameters and the exercise sessions were given and supervised by duly qualified exercise professionals who had undergone specific training. During the implementation of the program, no adverse events were reported in the group of participants diagnosed with Fibromyalgia.

Results

The pilot study application proved its applicability and the benefits of the exercise program in women with Fibromyalgia (Sousa et al., 2024). The construction and validation of the physical exercise program to promote health and functional capacity for individuals with Fibromyalgia went through the three stages proposed by Mohler et al. (2015), namely development, piloting and evaluation, which are described below.

First Stage: Development

Item 1: Description of the Theoretical Basis Underpinning the Intervention

Physical exercise in the daily life of individuals diagnosed with Fibromyalgia works as an important mechanism that can positively influence effects such as fatigue, directly or indirectly, through changes in the HPA axis - hypothalamus, pituitary, adrenal axis (Doerr et al., 2017). Physical exercise programs have physical benefits, such as: improved cardiovascular and respiratory condition; increased muscle strength; effects on metabolism, regulating blood pressure and reducing the onset of cardiovascular diseases, diabetes and osteoporosis (DGS, 2016). In terms of social benefits, physical exercise favours interpersonal relationships, promoting interaction through the activities carried out, reduces isolation, but also anxiety and depression in subjects diagnosed with Fibromyalgia (Atan & Karavelioğlu, 2020b; Sousa et al., 2023a). Physical fitness and the ability to generate muscle strength are essential for carrying out daily tasks that influence functionality. A decrease in these factors can lead to disability and a reduction in quality of life in patients diagnosed with Fibromyalgia. Physical exercise is defined as a tool for improving physical fitness, health and quality of life (e.g. (Albuquerque et al., 2022; Sosa-Reina et al., 2017; Sousa et al., 2023b).

For the structure of the program's exercise prescription, regarding the exercises and the structure of the session, the guidelines of the American College of Sports Medicine (ACSM, 2021)) were used as a reference. Considering the recommendation of combined training (which includes aerobic, strength and stretching exercises), the suggestions of the recent systematic review were also adopted (Albuquerque et al., 2022; Sosa-Reina et al., 2017; Sousa et al., 2023b). Aerobic exercise induces adaptations in various functional capacities such as oxygen transport and utilization (Gowans et al., 2001) while strength training is essential for generating muscle strength (Hakkinen, 2001; Larsson et al., 2015) and stretching exercises are beneficial for reducing the loss of mobility due to constant immobilization associated with pain (Triñanes et al., 2014).

Item 2: Description of all the components of the intervention, including the reasons for its selection, as well as its objectives/essential functions

The PETP includes several components that can be adjusted to the context and characteristics of a population diagnosed with Fibromyalgia at least three years ago and recruited by the Health Center of Rio Maior in Santarém, Portugal. Therefore, the CERT was followed to develop the program (Slade et al., 2016) in which the 16 items were as follow:

CERT Item 1: Detailed description of the type of equipment for the exercises.

To carry out the exercise program, some of the following materials were needed to support the sessions: i) Sound system, portable speaker or radio; ii) Mattresses; iii) Cones; iv) Medicine Balls; v) Dumbbells (1kg to 2kg); vi) Shin guards (1kg); vii) Steps. Participants must wear suitable and

comfortable sports equipment (i.e., clothing and footwear). The sessions should take place in a large room (e.g., 50 m^2) with a suitable sports floor and good ventilation and acoustic conditions.

CERT Item 2: Detailed description of the qualifications, teaching/supervisory expertise and/or training carried out by the exercise professional.

The "Pessoas com Fibra" PETP was supervised by the program coordinator and led by the exercise professional. The program coordinator has PhD in Sports Science, specialization in exercise and health and professional experience in the field. The exercise professional has a Master Degree in Physical Activity and Health and two years experience in conducting classes in women diagnosed with FM, has also undergone internal training for the "Pessoas com Fibra" PETP team, which is made up of a multidisciplinary team, namely Physical Exercise Professionals, Physiotherapists and Doctors specializing in General and Family Medicine, on assessment recommendations, exercise prescription in clinical populations and on the care to be taken during the sessions.

CERT Item 3: Description of how the exercises were carried out (individually or in groups)

The "Pessoas com Fibra" PETP for individuals with Fibromyalgia was planned to be carried out in small groups (5 to 10 practitioners) so that there is closer and more individualized monitoring, in face-to-face sessions lasting around 60 minutes of effective exercise, with two weekly sessions, with the aim of promoting improved health and functional capacity.

The PETP sessions consisted of: i) initial instruction, lasting 2-3 minutes to have a brief communication with the participants of the program and reminder to have the bottle of water and also their towel; ii) warm-up consisting of aerobic exercises mainly walking at least 20 minutes; iii) mobility exercises based on the 3D Maps of Gray Institute, for all tender points to prepare and adapt the body for the next phase, maximum 10 minutes; iii) strength training for the major muscle groups with the aim of generating muscle strength for everyday tasks, during 20 minutes; and finally, iv) stretching exercises for all muscle groups, lasting 5-8 minutes. It should also be noted that all the participants underwent individual tests and evaluations at two points in time (i.e., the initial and final points), where functional physical fitness was assessed using the Rikli & Jones Test Battery (1999); i) 30 seconds chair stand; ii) arm curl; iii) sit and reach; 8-foot up and go; iv) back scratch; and vi) 2 minute step, body mass index, the impact of Fibromyalgia on the participants' daily lives using the FIQ-Portuguese Version questionnaire (Rosado et al., 2006), health status using the SF-36v2 (Ferreira et al., 2012) and a visual analog scale for recording pain and sleep.

CERT Item 4: Description of the exercises (supervised or not) and how they are presented

The sessions were held in an exercise room, and when the weather conditions were favourable, the aerobic exercise was carried outdoors, always led by the exercise professional and occasionally supervised by the program's technical coordinator. During the program sessions, all the exercises were explained and exemplified/demonstrated by the physical exercise professional. Special attention was always paid to how the exercises were performed by the participants, by observing how the exercises were carried out and giving feedback to ensure that the technical execution was optimized. This pedagogical intervention aims to improve the participants' performance, control intensity, minimize the risk of injury and promote a sense of competence in the task. Whenever the need to adapt the exercises to the physical and/or health condition was identified, they were modified to respect the principle of individuality (ACSM, 2021).

CERT Item 5: Detailed description of how adherence to exercise is monitored

The adherence to the program was done by recording the participants attendance on an attendance form during the eight months of the PETP. It should be noted that it was made clear to the participants who joined the program free of charge that they could quit at any time. To facilitate communication between the group of participants and the program's exercise professionals, a WhatsApp group was created to provide information and obtain feedback.

CERT Item 6: Detailed Description of Motivation Strategies

The PETP was promoted and publicised through posters delivered to partner organizations. In addition, the posters also presented all the benefits that physical exercise promotes to draw the attention not only of the people with Fibromyalgia, but also the general population as tool to spread the word about the PETP. As mentioned in the previous Item, to ensure greater interaction between the participants and the exercise professionals, a WhatsApp group was created. In person, feedback was given during the sessions about the participants progress. An important strategy was also implemented to promote a feeling of belonging to the group by giving a t-shirt that says "# SOU PESSOA COM FIBRA" (which means "I'm a person with Fibromyalgia") (Bompa & Buzzichelli, 2019).

CERT Item 7 (a): Detailed Description of the Decision Rules for Determining Exercise Progression

The progression of the exercise intensity across the sessions was monitored through the reserve heart rate (HRR), using physical activity meters (Polar® M200, Polar Electro OY, Finland), and the Rating of Perceived Exertion (category ratio of 20 arbitrary units (AU)) (Borg, 1982). Heart rate is a physiological variable that allows you to measure an individual's degree of physical while the rating of perceived exertion is a psychophysiological measure. Together, they can provide a better confirmation of the intensity applied (Achten & Jeukendrup, 2003).

The progression of cardiorespiratory training was carried out in three mesocycles (ACSM, 2021):

- 1st Mesocycles (12 weeks) - 9 AU (Very Light); < 30% of HRR gradually increased;

- 2nd Mesocycles (11 weeks) - 9-11 AU (Very Light to Fairly Light); 30% to 39% of the HRR, gradually increased;
- 3rd Mesocycles (12 weeks) - 12-13 AU (Somewhat Hard); 40% to 59% HRR;

The strength training progression was also carried out in three mesocycles:

- 1st Mesocycles (12 weeks) - < 9 AU (Very Light); 2 sets of 5-8 repetitions and gradually increase to 8-12 repetitions;
- 2nd Mesocycles (11 weeks) - 9-11 AU (Very Light to Fairly Light); 2 sets of 6-9 repetitions and gradually increase to 12-15 repetitions;
- 3rd Mesocycles (12 weeks) - 12-13 AU (Somewhat Hard); 2 sets of 12-15 repetitions and gradually increase to 15-25 repetitions.

CERT Item 7 (b): Detailed Description of How the Exercise Program Progresses (number of repetitions, resistance, load, speed, etc…)

The program was based on the exercise recommendations of the (ACSM, 2021)and a recent systematic review (Sousa et al., 2023b). With regard to the intensity of exercise programs for patients with Fibromyalgia, it is recommended a low to moderate intensity, and individualizing it is crucial to ensure the subjects' adherence to the program and to promote an improvement in health and the impact of the disease and, consequently, an improvement in quality of life. In other words, the progression was made according to the adaptation and evolution of each participant, thus progressively increasing the number of sets and repetitions of each exercise following the previous characteristics described in the previous Item.

CERT Item 8: Detailed description of each exercise to enable replication

The detailed description of each exercise is presented in an exercise manual for the "Pessoas com Fibra" PETP. This manual provides all training plans for eight months, including a detailed description of the exercises and figures of the execution of the exercises.

CERT Item 9: Detailed description of any component of the program carried out at home

In addition to the exercises proposed in the sessions, the participants were also advised to carry out mobility and flexibility exercises proposed by physical exercise professionals. For these tasks, a monitoring grid was created with photos of the exercises to help the participants practice them at home, with the aim of them keeping a weekly record of their practice. They were also encouraged to adopt a more active and healthier lifestyle to improve their health and alleviate symptoms of the disease. To this end, challenges related to physical exercise were proposed every Wednesday. The challenges were explained on a flyer and videos were sent to the WhatsApp group explaining the exercises. The aim was for participants to send their own videos to the WhatsApp group, thus sharing the challenges and increasing their levels of physical activity.

CERT Item 10: Description of the existence of non-exercise components

Other activities were also carried out to promote the adoption of a more active and healthier lifestyle, to improve their general health and alleviate symptoms of the disease, through the production of flyers where advice was given to increase levels of daily physical activity and also healthy eating tips/recipes (flyers). In order to obtain support for the "Pessoas com Fibra" PETP, an application was made to the Sports Government of Portugal (IPDJ) where funding was obtained for the purchase of materials (e.g., elastic bands, agility ladders, etc.), equipment (e.g., Polar M200 physical activity meters) and services (i.e., "Polar Club®" license). As of March 23, 2020, the "Pessoas com Fibra" program was held online in the Skype group, due to the COVID-19 pandemic, to maintain the program and the safety of the participants.

CERT Item 11: Description of the type and number of adverse events occurring during exercise

Not applicable as there were no adverse events during the PETP. It should be noted that the PETP did not add any physical risk or other injury risk to the participants.

CERT Item 12: Description of where the exercises were carried out

The PETP of the "Pessoas com Fibra" was held in one of the exercise rooms of the Sports Science School of Santarém Polytechnic University. The room had ideal conditions in terms of flooring, materials (e.g., dumbbells, shin guards, steps, etc.), equipment (e.g., sound system), ventilation and complied with all hygiene and safety regulations.

CERT Item 13: Detailed description of the exercise intervention, including, but not limited to, number of repetitions/series/sessions, duration of session and program

The sessions were conducted twice weekly, each lasting ninety minutes to ensure sixty minutes of effective exercise time. The sessions were divided into four parts:

i) Initial instruction (2-3 minutes) to carry out a brief communication with the participants in order to greet and remind them using and water bottle during the session and finally, the recording of attendance;

ii) Warm-up consisting of aerobic exercises, namely walking (20 minutes) with the aim of increasing heart rate and body temperature and mobility exercises (10 minutes) to prepare and adapt the body for the next phase;

iii) Fundamental part consisting of strength training exercises (20 minutes) for the major muscle groups with the aim of generating muscle strength for everyday tasks;

iv) Return to calm through flexibility exercises (5-8 minutes) to recover and maintain joint mobility and finally, the final instruction (2-5 minutes) where the aim is to share experiences between the participants and put away the material used during the session.

Aerobic exercise in the initial phase was carried out 1 to 3 times a week at a light intensity of ≤30% for a maximum of 30 minutes a day, and its progression should be carried out 2 to 3 times a week at a moderate intensity of between

40 and 59% for 30 to 60 minutes a day. Mobility exercises should be performed twice a week for a maximum of 10 minutes. As for the fundamental part, namely strength training, this should initially be done 1 to 2 times a week, at a low intensity, 1 set of 4 to 5 repetitions with a rest between sets of 2-3 minutes. The progression of strength exercises should be carried out 2 to 3 times a week at moderate intensity, 2 to 3 sets of each exercise, 8 to 12 repetitions with the same rest time between sets (2-3 minutes) (Medicine, 2014).

CERT Item 14 (a): Describe whether the exercises are generic (applicable to anyone) or personalized

The exercise program was composed of combined exercises (aerobic, mobility, strength and stretching exercise) in order to contribute to an improvement in health and an improvement in functional capacity (Sousa et al., 2023b).

All the components were carried out collectively, always led and supervised by the physical exercise professional in charge of the program. Occasionally, the sessions were also supervised by the program coordinator. The aerobic exercises consisted of walking and the strength training exercises consisted of structured sessions made up of strength exercises with the aim of improving the participants' functional capacity. Mobility exercises based on the 3D Maps of Gray Institute are designed for the participants' daily lives, using the three planes of movement, and stretching exercises are carried out with the aim of improving the range of movement for their daily activities. Exercise professionals can modify or adapt the prescription and progression of the exercises based on the participants' response to the exercise which means that they can also be applied in a personalized manner.

CERT Item 14 (b): Detailed description of how the exercises are adapted to the individuals

The PETP Manual shows an illustration and description of the basic version of each exercise technique, as well as its progression and the ways in which it can be varied in terms of intensity and complexity. The variations in intensity and complexity of each exercise allow it to be adapted to each woman, according to her level of fitness, her ability and level of technical execution, her limitations, even when included in a group activity. Progression was made gradually, depending on the practitioner's adaptation to the exercise. To this end, it is essential that the physical exercise professional maintains eye contact with the whole group throughout the session and provides appropriate demonstrations, information and feedback during the teaching intervention process, motivating the group and ensuring the effectiveness and safety of the exercise. The use of music during the sessions is optional, but it is an important element in controlling the speed and intensity of the exercise as well as a motivational element.

CERT Item 15: Describe the decision rule for determining the starting level at which people begin an exercise program (e.g., beginner, intermediate, advanced)

"Pessoas com Fibra" PETP was structured with a focus on the principle of individuality. However, to control the experience with exercise and the participants initial level of physical activity, the recruitment criterion was the absence of regular participation in supervised physical exercise sessions. After recruitment, to assess the initial physical fitness of the women diagnosed with Fibromyalgia, physical fitness assessments were carried out using the Functional Physical Fitness Test Protocol from the Rikli & Jones Test Battery (1999). This test protocol is commonly used in research carried out with individuals with Fibromyalgia because it is considered to be more appropriate to the pathology, more comfortable, low-cost and safe to administer in this type of population, and also taking into account the age of the participants (Maestre-Cascales et al., 2019). These tests (Rikli & Jones, 1999) assess the parameters defined by the American College of Sports Medicine (2018):

i) 30-sec chair stand: to assess the strength and endurance of the lower limbs;

ii) arm curl: to assess the strength and endurance of the upper limbs;

iii) Sit and reach: to assess the flexibility of the lower limbs;

iv) 8-foot up and go: to assess physical mobility/agility (dynamic balance, speed and agility);

v) back scratch: to assess the flexibility of the upper limbs;

vi) 2-minute step: to assess the aerobic capacity.

CERT Item 16 (a): Describe how adherence to or fidelity of exercise intervention is assessed/measured

With regard to monitoring adherence to the "Pessoas com Fibra" PETP, a field was added to the attendance record for each session to record the reason for the absence in order to check whether it was associated with the practitioner's health condition and related to the symptoms of the disease (e.g., pain, fatigue, poor quality of sleep, etc.). A monthly report was produced calculating the percentage of sessions attended per practitioner and reflecting on the reasons identified. Regarding the fidelity of the intervention, monthly meetings were held to assess the implementation of the training plans, reflect on adaptations to the exercises, leadership and communication in the sessions and, if necessary, define strategies to be implemented individually and/or in groups.

In order to guarantee the reliability of the intervention over time, all the exercise professionals recruited to work in the "Pessoas com Fibra" PETP will have to take part in internal/specific training with the aim of understanding the clinical condition of this population, getting to know the program's methodology, getting to know and train in the application of the program's physical tests and questionnaires, getting to know and train in the instruction and communication to be adopted in the sessions, as well as learning the precautions to be taken with this population. In addition, the exercise manual for the "Pessoas com Fibra" program will be made available to all professionals.

- CERT Item 16 (b): Describe the extent to which the intervention was carried out as planned.

The PETP was planned and periodized taking into account the 8-month intervention period. The program ran smoothly and the participants adherence to the program was high (90%), and their absences were always justified by issues related to the disease, such as rheumatology appointments or intense pain associated with the disease. It should be noted that with the onset of the COVID-19 pandemic, it became necessary to make some adjustments to the sessions, so that the intervention could take place as usual, due to the social distance imposed by the pandemic. In this way, the participants adapted the face-to-face sessions to an online format, via the Skype group. Despite this challenge, this change also turned out to be productive and beneficial, and it was possible to continue the program.

Item 3: Illustration of any intended interaction between different components

Not applicable to the physical exercise program described.

Item 4: Description and consideration of the characteristics of the intervention context

The PETP was developed through a partnership between the Santarém Polytechnic University, School of Sport and Health Center of Rio Maior. In this way, the Physical Exercise Professional takes responsibility for planning the sessions, as well as guiding them (correcting postures, appropriate feedback, instruction). The physical spaces must have the appropriate safety conditions for physical exercise, as well as the necessary materials. The group classes were conducted in an outdoor space or a spacious room, covering approximately 50 m^2, allowing for the execution of all exercises without spatial limitations. All hygiene, cleanliness, and safety standards regarding the type of flooring and ventilation were adhered to. Exercise professionals maintained visual contact with the group throughout the session and provided positive reinforcement feedback, motivating the group to continue with the practice (Bernardino et al., 2024; Santos-Rocha et al., 2020b).

Second stage: Feasibility and piloting

Item 5: Description of the pilot test and its impact on the definitive intervention

The pilot project began at January 2019 and ended in June 2019. Pessoas com Fibra" ("People with Fiber") program was developed by two doctorate in Sports Science and specialist in Physical Exercise and Health who are higher education teachers in the field of Physical Activity and Health and have professional experience (> 20 years), a physical exercise professional specialist with a Master's Degree in Physical Activity and Health with three years experience in planning and conducting sessions of physical exercise for women with FM. Two doctors, 3 nurses and one physiotherapist specialized in community care and pain management (>20 years of experience) of Health Center of Rio Maior (Santarém, Portugal) The sessions were tested in January 2019 and June 2019 with a group of seven females diagnosed with Fibromyalgia, for at least 3 years, without other associated pathologies (i.e. diabetes, cardiovascular diseases, respiratory diseases), without regular participation in supervised physical exercise sessions and enrolled and followed up at the Health Center of Rio Maior in Santarém, Portugal. It should also be noted that no incidents of any kind were reported during the interventions. After the intervention, the participants were asked for feedback on the program, the training sessions and whether the program had improved their quality of life, stress and anxiety, and reported significant improvements in pain points as well as sleep and upper and lower limb strength.

In October 2020, the program began with the seven participants from the pilot project and two new participants were added to the program. On March 23, 2021, the program was implemented in an online format, in the Skype group, due to the COVID-19 pandemic.

Third step: Evaluation

Item 6: Description of the comparator condition and reasons for selection

The combined exercise program was applied to a female intervention group of seven participants. The participants were selected through recruitment by the Health Center, based on the inclusion criteria already mentioned. Before starting the program, an initial assessment was carried out, to be compared in the future with a final assessment, which made it possible to evaluate physical fitness and functional capacity, pain points, stress and anxiety.

Taking into account the benefits of combined exercise ACSM (2021) and a recent systematic review (Sousa et al., 2023b) the following hypotheses were defined: the application of the "Pessoas com Fibra" PETP will result in improvements in: i) functional capacity; ii) body mass index; iii) impact of Fibromyalgia on the participants' daily lives; and iv) health status.

Item 7: Description of the strategy for carrying out the intervention in the context of the study

The PETP was created as part of the internship for the degree in Physical Activity and Lifestyle. In this pilot study, the exercise program was applied by a Physical Exercise Professional and with support of a finalist in the Physical Activity and Lifestyle degree course (trainee), and simultaneously supervised by the program coordinator. In the future, the aim is to expand the program across the country, with the help of Health Centers, the Portuguese Institute of Rheumatology and to implement it in certified spaces for physical exercise (gyms/health clubs), always supervised by professionals and specialists in physical exercise, as an active participation in health and in a more active and healthier lifestyle.

Item 8: Description of all the materials or tools used in the intervention

The PETP was planned to be applied in an exercise room using some materials to support the sessions, such as: i) a sound system, portable speaker or radio; ii) mattresses;

iii) cones or balls; iv) dumbbells (1kg to 2kg) and shin guards (1kg); and v) steps. During the sessions, music is used as a means of controlling intensity, motivation and/or relaxation. The exercise program manual was produced as support material for the exercise professionals participating in the program.

Item 9: Description of the fidelity or delivery process compared to the study protocol

The exercise program presented includes an exercise manual with illustrations and descriptions of the exercises. The progression of the sessions is carried out by increasing external loads/external resistance and the RPE (Borg, 1982) is applied. It should be noted that as well as the progression being made using the Borg Scale, The principle of individuality is one of the main requirements of training and requires that the professional exercise consider the abilities, potential and learning characteristics and the demands of the participants, regardless of the performance level (Bompa & Buzzichelli, 2019). This principle was also applied, considering the adaptation and evolution of the participants. Each participant has physiological and psychological attributes that need to be considered when developing a training program (Bompa & Buzzichelli, 2019). With this assessment, it becomes possible providing the necessary information to the exercise technician responsible for the intervention, in order to adapt each session and exercise to the physical capacity, but also the limitations related to the symptomatology presented by the participant.

Item 10: Description of a process evaluation and its underlying theoretical basis

The program evaluation was designed to determine the outcomes and benefits of the exercise program. The evaluation of the effectiveness of the exercise program was planned to take place through a battery of tests to assess physical fitness as well as improvements in functional capacity and health status. The participants weight, height and Body Mass Index (BMI) were used to assess body composition.

After the recruitment phase for the exercise program, all participants must complete a set of initial assessments in relation to the following parameters and instruments:

Functional Physical Fitness Test Protocol from the Rikli & Jones Test Battery (1999):

- 30-sec chair stand

Objective: To assess the strength and endurance of the lower limbs (number of executions in 30" without using the upper limbs).

Equipment: Stopwatch, chair with backrest (no arms), seat height approximately 43 cm. For safety reasons, the chair should be placed against a wall or otherwise stabilized to prevent it from moving during the test.

Protocol: The test begins with the participant sitting in the middle of the chair, with their back straight and their feet shoulder-width apart and fully flat on the floor. One foot should be slightly advanced in relation to the other to help maintain balance. The upper limbs are crossed at wrist level and against the chest. At the "start" signal, the participant rises to maximum extension (upright position) and returns to the starting seated position. The participant is encouraged to complete as many repetitions as possible in a 30" time interval. While monitoring the participant's performance to ensure accuracy, the assessor counts the correct lifts. Verbal and/or non-verbal instructions can be given to correct the execution.

Score: The score obtained by the total number of correct executions in a 30" interval. If the participant is halfway through the lift at the end of the 30", it should count as one lift.

- Arm curl

Objective: To assess upper limb strength and endurance (number of executions in 30").

Equipment: Stopwatch, chair with backrest (no arms) and dumbbells (2.27 kg for women and 3.36 kg for men). Due to the lack of dumbbells with the right weight, an approximate weight of 2 kg was used for women.

Protocol: The participant sits on a chair, with their back straight, their feet fully flat on the floor and their torso fully leaning back. The dumbbell is held in the dominant hand. The test begins with the forearm in the lower position, next to the chair, perpendicular to the ground. At the "start" signal, the participant gradually rotates the palm of the hand upwards, while flexing the forearm in the full direction of the movement and then returning to the initial forearm extension position. The participant is encouraged to perform as many flexions as possible within a time limit of 30", but always with controlled movements in both the flexion and extension phases. The evaluator should monitor the executions to ensure that the weight is carried throughout the entire range of motion - from full extension to full flexion. Each correct flexion is counted with verbal and/or non-verbal reminders whenever there is an incorrect execution.

Scoring: The score is obtained by the total number of correct flexions performed in a 30" interval. If at the end of the 30" the forearm is in half-flexion, it should be counted as full flexion.

- 8-foot up and go:

Objective: To assess physical mobility - speed, agility and dynamic balance.

Equipment: Stopwatch, tape measure, cone (or other marker) and chair with backrest (approximately 43 cm high). The chair should be positioned against the wall or in another way that ensures a static position during the test. The chair should also be in an unobstructed area, in front of a cone at a distance of 2.44 m (measured from the tip of the chair to the front of the marker). There should be at least 1.22 m of free distance around the cone, allowing the participant to freely go around the cone.

Protocol: The test is started with the participant fully seated on the chair, hands on thighs, and feet fully on the ground (one foot slightly advanced in relation to the other). At the "start" signal, the participant rises from the chair,

walks as quickly as possible around the cone (on either side) and returns to the chair. The participant should be informed that this is a "time" test, the aim being to walk as fast as possible (without running) around the cone and back to the chair. The assessor should act as an assistant, standing halfway between the chair and the cone so as to be able to assist in the event of imbalance. The assessor must start the stopwatch at the "start" signal, whether or not the person has started the movement, and stop it at the exact moment the person sits down.

Score: The result corresponds to the time elapsed between the "start" signal and the moment the participant is seated in the chair. Both values are recorded to the nearest 0.01'. The best result is used to measure performance.

- Back scratch:

Equipment: 45 cm ruler

Protocol: In a standing position, the participant places their dominant hand on top of it and reaches as low as possible towards the middle of their back, palm down and fingers extended (elbow pointing upwards). The hand of the other arm is placed underneath and behind, palm facing up, trying to reach as far as possible in an attempt to touch (or overlap) the middle fingers of both hands.

Scoring: The distance of overlap, or the distance between the middle fingers, is measured to the nearest cm. Negative results (-) represent the shortest distance between the middle fingers; positive results (+) represent the measure of overlap between the middle fingers. Two measurements are recorded. The "best" value is used to measure performance. Make sure you mark the - and + signs on the score sheet.

- 2-minute step test:

Aims: To assess aerobic endurance.

Protocol: Measure the number of knee lifts with the knee as a reference. In the standing position, the maximum number of knee lifts that the individual can perform in 2 minutes is counted. At the signal, the participant begins the stationary gait (without running). The minimum knee height appropriate for the stride must be level at a midpoint between the patella and the anterior superior iliac spine.

Score: The maximum number of knees lifts the individual can perform in 2 minutes is counted.

SF-36 Quality of Life Questionnaire

This is a generic instrument for assessing quality of life, which is easy to administer and understand. It consists of a multidimensional questionnaire made up of 36 items, encompassed in 8 scales or domains: functional capacity, physical aspects, pain, general state of health, vitality, social aspects, emotional aspects and mental health. It has a score ranging from 0 (zero) to 100 (obtained by calculating the Raw Scale), where zero corresponds to the worst general state of health and 100 corresponds to the best state of health. It is a validated questionnaire whose measurement properties, such as reproducibility, validity and susceptibility to alterations (Ferreira & Nunes, 2012).

Fibromyalgia Impact Questionnaire (FIQ-V2)

The FIQ-V2 (Lapa Rosado et al., 2006) is an instrument that was developed to measure the health status and functional capacity of Fibromyalgia patients, and to assess their clinical progression and therapeutic results. It contains 20 questions grouped into 10 items. The first item contains 11 sub-items and focuses on the ability to perform daily tasks (cooking, cleaning, walking, mobility, among others). The answers are distributed on a Likert-type scale from 0 (always able to do) to 3 (unable to do). The 11 sub-items are added together and divided by the number of scores obtained to obtain the functional capacity score.

These outcome measures were planned to be assessed at baseline and re-evaluated after 12 weeks and 32 weeks of intervention (follow-up).

Item 11: Description of the internal facilitators and barriers that potentially influence the intervention, as revealed by the process evaluation

The professionals at the Health Center of Rio Maior in Santarém (Portugal) (doctors and physiotherapist) are facilitators in the process of communicating and recruiting participants, as they are primarily responsible for making this happen. The General Practitioners become fundamental in this recruitment process. The “Plano Nacional de Desporto para Todos (PNDpT)” was fundamental to the implementation of the program in terms of financial support. It should also be noted that the application to the funding program allowed for the purchase of new materials and the payment of the physical exercise professional. The Portuguese Fibromyalgia Association and the Portuguese Institute of Rheumatology (IPR) are important in disseminating and promoting the benefits of physical exercise through this program. The Santarém Polytechnic University, School of Sport, provided the sports space and material resources, such as mattresses, dumbbells, steps, shin pads, among others.

Item 12: Description of external conditions or factors occurring during the study that may have influenced the implementation of the intervention or mode of action (how it works)

With the outbreak of the COVID-19 pandemic, the sessions had to stop being presential face-to-face, thus avoiding the spread of the virus and ensuring the safety and well-being of everyone (participants and exercise professionals). We have therefore resorted to the technologies that we currently have at our disposal, namely Skype, to continue the Program's sessions. The measures taken to continue the program due to the COVID-19 pandemic have been effective, so there have been no changes to its periodization. It became necessary to adapt only the aerobic exercise, consisting of walking, to aerobic exercises.

Item 13: Description of the costs or resources required for the intervention

The program was designed to be applied in an exercise room, requiring little equipment to be applied by any exercise professional who deals with clinical populations daily.

The facilities and materials were provided by the Santarém Polytechnic University, School of Sport. The exercise professional applied for funding to cover remuneration to ensure services and purchase equipment to monitor intensity (e.g., heart rate monitors) during the sessions.

Discussion

From the studies analysed, it is possible to affirm that physical exercise is more effective in controlling the symptoms of Fibromyalgia (Albuquerque et al., 2022; Exercise, 2024; Sosa-Reina et al., 2017; Sousa et al., 2023) than using only pharmacological treatments (Bonnabesse et al., 2019). Women diagnosed with this disease and who have participated in specific physical exercise programs for this disease have reported various physical and mental benefits, reducing muscle stiffness and localized pain as well as levels of anxiety and depression (Busch et al., 2011; Santos et al., 2019). This evidence justifies the continued development of further validation studies of specific physical exercise programs that respect the principle of individuality (Bompa & Buzzichelli, 2019) with the aim of promoting better health and quality of life in subjects with Fibromyalgia. This answered to this need by analysing physical exercise intervention programs for women diagnosed with Fibromyalgia, as well as national guidelines, with a view to developing and validating a physical exercise program. The reason for applying the program to women is because the literature points out that FM is more prevalent in women with values between 2.4% and 6.8% and in urban areas between 0.7% and 11.4% (Marques et al., 2017). In Portugal, the prevalence is estimated at 1.7% (1.1% to 2.1%) (Branco et al., 2016). However, a systematic review already published show that the age ranges between 30 and 59 years old (Sousa et al., 2023) and the physical interventions that was made with this disease are within this range (Bidonde et al., 2019; Britto et al., 2020). Also, the fact that these interventions are made with low intensity makes it suitable for all ages and the results of physical exercise on Fibromyalgia will be seen in a long term (Maestre-Cascales et al., 2019).

This validation study of a physical exercise program for women diagnosed with Fibromyalgia followed the criteria for reporting on the development and evaluation of complex health interventions (CReDECI2) (Möhler et al., 2015a), taking into account that a physical exercise program can be considered a complex intervention, as it is adapted to a specific population and environment and depends on several components for its effectiveness and safety. In line with these criteria, the exercise program was developed in three stages: development, piloting and evaluation (Möhler et al., 2015a).

The results obtained in the program's pilot intervention show that the proposed objectives were achieved, with a reduction in pain points and an improvement in functional physical fitness. The pilot study showed improvements int the majority of the variables of both questionnaires: Fibromyalgia Impact Questionnaire - Portuguese version (FIQ-P) by Lapa Rosado et al., (2006) and the Short Form Health Survey Questionnaire (SF-36v2) - Portuguese version 2 by Ferreira et al. (2012) which seems to be according with previous study that showed a clinical impact of a combined exercise program in the same measures (Sañudo et al., 2012). The physical tests used (Rikli & Jones Test Battery, 1999) show nonsignificant results in most of the tests, although the 2-min step test ($p = .21$) improved from baseline to the final assessment (J. of H. S. and Exercise, 2024). It is also important to mention the positive feedback obtained from the program participants and exercise professionals, which shows the relevance of this intervention program for similar clinical populations, in the context of community programs and access for all.

Strengths and limitations

As a strength of this study is the fact that it's a first similar initiatives carried out in Portugal and the results are really beneficial for this population. The pilot study application proved its applicability and the benefits of the exercise program in women with Fibromyalgia (Sousa et al., 2024). The main limitation of the study was the small sample size and the appearance of the COVID-19 pandemic during the course of the intervention. Due to the pandemic, some changes were made to the program's methodology, although the problem was easily solved. The greatest difficulty experienced was the difference in the intervention as it changed from face-to-face to online, making it less easy to interact and/or correct the exercises, and also on a social level for the participants as the first five minutes of the face-to-face sessions were always dedicated to sharing moments related to each other's pain, consultations and daily lives. Nonetheless, this seems to be a pioneer to validate a PETP for people with Fibromyalgia following the CReDECI 2 guideline by Möhler et al. (2015b). This article is a pilot study and that it is therefore a limitation that we have a small number of experts, consequently, more validation research in people with identical characteristics is needed. In addition, it is also noteworthy that the positive feedback received from the people who participated in the pilot intervention. The fact that there are few professionals running the exercise sessions can also be a limitation.

Conclusion

The CReDECI2 and CERT guidelines proved to be valuable tools in assisting exercise professionals with the development and planning of complex interventions like the "Pessoas com Fibra" exercise program. The pilot study demonstrated the program's applicability and potential benefits for women with fibromyalgia, showing promising improvements in pain, sleep quality, and physical function. This validation process, involving both exercise professionals and the target population, addresses an important gap in fibromyalgia management. The program's structure and outcomes provide a useful framework for planning future training sessions and research initiatives focused on individuals with fibromyalgia. However, it is important to note

that this study represents an initial validation step. Further research is needed to confirm these findings in larger, more diverse samples of individuals with fibromyalgia. Additionally, long-term studies would be beneficial to assess the program's sustained effects and potential modifications needed for different subgroups within the fibromyalgia population. As research in this area continues to evolve, the "Pessoas com Fibra" program offers a promising foundation for improving the quality of life and functional capacity of women living with fibromyalgia through tailored, evidence-based exercise interventions

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Conflicts of Interest

The authors declare no conflicts of interest.

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