Effects of a 12-week supervised or home-based multicomponent training program on Psychological, and Physical variables in Fibromyalgia patients.

LABORATORY/DEPARTMENT

Laboratory of Exercise Science and Sport, Degree Program in Sports Science and Techniques, Department of Translational Biomedicine and Neurosciences (DiBraiN), University of Bari – Aldo Moro

EXPERIMENTAL DESIGN

Interventional

EXPECTED START AND END DATE OF THE PROJECT

March 2025 – May 2025

FUNDS USED FOR THE PROJECT

No

DATE OF THE DOCUMENT

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SCIENTIFIC RATIONALE

Fibromyalgia (FM) is a chronic syndrome characterized by widespread musculoskeletal pain, fatigue, sleep disturbances, cognitive difficulties, and psychological distress. It predominantly affects women and has a significant impact on quality of life, daily functioning, and overall well-being. Despite its high prevalence and burden, the pathophysiology of FM remains complex and not fully understood, and current treatment strategies often require a multifaceted approach. Among non-pharmacological interventions, physical exercise is widely recognized as a cornerstone of FM management, with growing evidence supporting its efficacy in reducing symptoms and improving both physical and psychological outcomes.

A substantial body of research indicates that regular physical activity can help modulate pain perception, improve physical function, and alleviate emotional distress in individuals with FM (McLoughlin et al., 2011). Traditionally, aerobic training has been the most investigated form of exercise in this context, with several randomized controlled trials showing moderate benefits in pain reduction, fatigue, and depression (Tan et al., 2022). However, more recent studies suggest that multicomponent exercise programs—which combine aerobic, resistance, and flexibility training—may produce superior outcomes compared to aerobic training alone (Albuquerque et al., 2022; Bidonde et al., 2019). These findings point to the importance of integrating different types of exercise to address the heterogeneous symptom profile associated with FM.

In parallel, the mode of delivering exercise interventions has also evolved. Remote or home-based exercise programs, especially those delivered via video or telehealth platforms, have demonstrated potential for improving accessibility and reducing barriers such as transportation, scheduling, and physical limitations (Serrat et al., 2022). Nonetheless, there is still limited evidence regarding the effectiveness and adherence to such programs when compared to traditional supervised training. Specifically, it remains unclear whether a structured, supervised multicomponent training program, compared to home-based sessions, can provide additional benefits in terms of clinical outcomes, psychological health, and program adherence.

The program is grounded in the guidelines provided by the American College of Sports Medicine (2018) and tailored to accommodate the specific needs and tolerances of patients with FM.

AIMS AND HYPOTHESES OF THE PROJECT

Primary outcome:

The purpose of this study is to evaluate the effectiveness of supervised MCT on physiological parameters, physical fitness, mental well-being, and quality of life in subjects with a history of FM, compared to a non-supervised home-based MCT protocol and a waitlist control group (WLCG).

Secondary outcome:

Assess the adherence through analysis of dropout rates and the number of completed sessions.

Hypothesis:

We hypothesize that both groups will report improvements in physiological parameters, physical fitness, mental well-being, and overall quality of life compared to the WLCG. Additionally, the supervised MCT group will show superior improvements in physiological parameters and adherence compared to the non-supervised home-based MCT group.

CHARACTERISTICS OF PARTICIPANTS

The study aims to recruit at least 30 individuals with a history of FM, aged between 30 and 75 years.

Inclusion Criteria

- Women/Men
- Diagnosis of fibromyalgia
- Age between 30 and 75 years at the time of initial treatment;
- Signature of a written informed consent form (or their legally recognized representatives must sign) indicating that the patient understood the purpose and procedures required for the study and is willing to participate in the study;
- Sedentary lifestyle (subjects who have not followed WHO guidelines for aerobic and resistance exercise in the past 3 months);
- Positive medical specialist assessment of noncompetitive physical activity practice;

Exclusion Criteria

- Expected absence for more than one week during the intervention period
- Absence of a medical certificate of suitability for non-competitive sports
- Severe musculoskeletal or joint disorders with significant mobility limitations
- Uncontrolled hypertension or untreated heart disease;
- Pshychiatric disorders;

SAMPLE SIZE

A priori power analysis (Kang, 2021) with a Type I error of 0.05 and Type II error rate of 0.10 (90% statistical power) calculated that 9 participants per group would be sufficient to observe moderate interaction effects between "Time x Group."

RECRUITMENT METHOD

Participants will be recruited through the Neurophysiopathology Unit, Polyclinic General Hospital, Bari; located at Piazza Giulio Cesare, 11, 70124 Bari, and will be randomly assigned to one of three groups:

- Supervised MCT
- Non-supervised home-based IMCT
- WLCG

data collection

Before the intervention, all participants, with prior approval from their primary care physician, will sign an informed consent form. All participants will undergo physiological evaluations and functional tests before (T0) and at the end of the intervention (T1). Data will be collected anonymously, assigning each participant a random identification number.

Measurements:

Anthropometric Parameters:

- Height
- Weight
- BMI

Physical Parameters:

- Timed Up and Go (TUG)
- 30 Seconds Chair Stand Test (30"CST)
- 2 Minutes Step Test (TMST)
- Handgrip Strength Test (HGS)
- Back scratch test (BST)
- Arm Curl Test (ACT)
- Chair Sit&Reach Test (CSRT)

Psychological Parameters:

- Tampa Scale of Kinesiophobia (TSK)
- Pain Catastrophizing Scale (PCS)
- Toronto Alexithymia Scale (TAS – 20)
- State Trait Anxiety Inventory (S.T.A.I.1-2)
- Physical Activity Enjoyment Scale (PACES)
- Beck Depression Inventory (BDI)
- Global Physical Activity Questionnaire (GPAQ)
- Brief Pain Inventory (BPI)
- Numeric Pain Rating Scale (NRS)
- Multidimensional Assessment of Fatigue Scale (MAF)
- Medical Outcomes Study Sleep Scale (MOS)
- Short Form Health Survey 36 (SF-36)
- Fibromyalgia Impact Questionnaire (FIQ)

Experimental Design

After initial evaluations, participants will be randomly assigned to one of the three groups. All protocols will last 12 weeks and take place at the Angiulli Artistic Gymnastics Society (Bari).

Sessions will be conducted in small groups. These groups will be closely supervised by exercise professionals, specialists in adapted physical activity (AFA), to ensure participant safety, maintain proper intensity, and correct execution technique. To monitor and regulate training intensity (internal load) during sessions, the Borg Perceived Exertion Scale (RPE) (6-20) will be used at the end of each exercise set to regulate the load to Borg = 13-15 points (Gary Liguori & ACSM, 2021). Participants will be familiarized with the scale beforehand.

Participants in the WLCG will not perform any structured physical activity during the entire intervention period, maintaining their usual lifestyle and placed on a waiting list to receive adapted physical activity after the 24-week intervention period.

Supervised MCT protocol:

Each training session will include an initial muscle activation phase lasting 10 minutes (low-intensity walking, Borg = 10-11) to increase heart rate, improve muscle blood flow, and prepare the main joints for the subsequent work phase. This will be followed by a main 40-minute exercise period (aerobic exercise, mobility exercises, and resistance training) and a 10-minute cool-down period (breathing exercises and stretching).

The cardiorespiratory training will consist of progressive aerobic exercises: controlled and rhythmic jumping jacks, step-ups on a stable platform (such as a low step or a stable surface), alternating knee lifts, rapid lateral steps, or lateral leg raises. Finally, 3 minutes of low-intensity walking will facilitate recovery for the next training phase.

The mobility training will consist of specific exercises (thoracic extensions, cat-cow, overhead stretching with a stick, and active internal hip rotations) targeting the main joints. These will be performed to the maximum (1 to 3 sets) but avoiding pain. The duration will gradually increase from 30 to 60 seconds per repetition, repeating from one to three times. Rest intervals of 30 to 60 seconds will be provided between sets and exercises.

The resistance training will consist of exercises targeting different muscle groups (8 exercises): quadriceps (leg extension with ankle weights/half squat with a chair), biceps (unilateral dumbbell curl), shoulders (dumbbell shoulder press), triceps (dumbbell French press), chest (dumbbell chest press/dumbbell flyes), and back (dumbbell rows). The resistance training program will follow the principle of gradual progressive load. Initially, participants will perform one set of 10-15 repetitions, which will increase to three sets of 10-15 repetitions during the intervention. Load adjustments will

be made to ensure that the perceived effort (RPE) remains between 13 and 15 on the Borg Scale (6-20). During the protocol, participants will be given rest intervals of 60 to 120 seconds between sets and exercises. To prevent early muscle fatigue, exercises will be performed using an alternating training method based on muscle group division (upper body exercises will be performed in the first session and lower body exercises in the second).

The cool-down period will consist of breathing exercises and stretching. Stretching will be performed by seeking the maximum stretch on all the main muscle groups (1 to 3 sets per muscle group) while avoiding joint pain. The duration will gradually increase from 10 to 30 seconds per stretch, repeating from one to three times for a total of 60 seconds per exercise.

Non-supervised home-based MCT protocl:

Each will receive a personalized form via email, with exercises adapted to their level and progressively modulated in terms of intensity and duration consistent with what is proposed in the project, adapted to the individual physical capabilities detected in the initial phase. The protocol will be structured with the integration of joint mobility exercises, aerobic activity and resistance training at natural load or with small. Each session will be supported by video material that can be accessed through a dedicated link: by logging on, the participant would view a comprehensive guide with a detailed explanation of the exercises, accompanied by practical demonstrations, postural cues and suggestions for correct execution. After viewing the video, participants were invited to independently repeat the proposed exercises, respecting the directions regarding the number of repetitions (from 6-8 up to 10-12) and sets (2 or 3), depending on their fitness level and type of exercise.

Each training session, lasting about 60 minutes, was divided into three phases:

1. Initial phase (warm-up and general activation ~10 minutes), light activity such as walking at a gentle pace will be proposed, aiming to activate muscles, gradually increase heart rate and mobilize major joints. The perceived intensity will be at a low level on the Borg scale (10-11).
2. Central phase (main work ~ 40 minutes) exercises with differentiated objectives such as Joint mobility: active and controlled movements aimed at improving range of motion in specific joints (e.g., thoracic spine, hips, shoulders), with progressive number of sets and duration o Aerobic activity: dynamic exercises performed free-body or with simple supports (e.g., step, stable chairs), such as alternating knee lifts, side steps or rhythmic movements involving upper and lower limbs, to stimulate cardiorespiratory capacity o Isometric exercises: muscle toning activities performed in static hold, targeting the major muscle groups (upper and lower limbs, trunk), with progression in the number of sets and duration of contraction. The resistance

training program will follow the principle of gradual and progressive loading. Initially, participants will perform one set of 10-15 repetitions, which will increase to three sets of 10-15 repetitions during the intervention. Load adjustments will be made to ensure that the perceived exertion (RPE) remains between 13 and 15 on the Borg scale (6-20). During the protocol, participants will have rest intervals of 60 to 120 seconds between sets and exercises. Intensity will be adjusted to maintain moderate perceived exertion, alternating between upper and lower body days to avoid overload. Final phase (cool-down ~10 minutes) the session will be concluded with a relaxation phase through video-guided breathing exercises and static stretching. Stretching exercises were performed for all major muscle groups, with progression in time of maintaining positions and attention to respecting individual limits (absence of pain or joint discomfort). The duration will gradually increase from 10 to 30 seconds per stretch, repeating from one to three times for a total of 60 seconds per exercise.

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