PROJECT TITLE

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 – June 2025

FUNDS USED FOR THE PROJECT

No

DATE OF THE DOCUMENT

24/04/2025

INFORMED CONSENT FORM
FOR PARTICIPATION IN THE STUDY/RESEARCH PROJECT

Dear Sir/Madam,

You are invited to participate in the research study/project titled " Effects of a 12-week supervised or home-based multicomponent training program on Psychological, and Physical variables in Fibromyalgia patients." In order to make an informed decision, we are providing you with information about the nature of the study, the objectives of the project, and the activities in which you may be involved for the accomplishment of the research goals.
Please read these details carefully before deciding whether to participate in the project. You may ask any questions for clarification and raise any concerns that have not been answered clearly and thoroughly.
If, after reading and understanding all the provided information, you decide to participate in the study, you will be asked to sign and date the attached Informed Consent Form.
Your personal data will be processed as described in the specific privacy notice, in accordance with EU Regulation 2016/679 and Legislative Decree No. 196/2003. This privacy notice and the related request for consent to data processing will be provided to you separately.

Research title: Effects of a 12-week supervised or home-based multicomponent training program on Psychological, and Physical variables in Fibromyalgia patients.
CUP Project: N/D
Sponsor: N/D
implementing organizations: N/D

INFORMATION REGARDING PARTICIPATION IN RESEARCH

OBJECTIVES: The research project aims to evaluate evaluate the effectiveness of supervised multicomponent training (SMCT) 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 (NSMCT) protocol and a waitlist control group (WLCG). To achieve this objective, the researchers involved in the project aim to collect and analyze data on the estimation of these parameters through physical and psychological tests to be performed before and after the intervention.

STUDY/PROJECT ARTICULATION (PHASES AND TIMELINES):

RECRUITMENT PHASE AND COLLECTION OF INFORMED CONSENT (1-3 months)

Presentation to participants: The informed consent will be distributed during the recruitment procedures. The consent will be collected prior to the initial assessments (T0).

RANDOMIZATION PHASE, INITIAL ASSESSMENTS, AND DATA COLLECTION (1-2 weeks)

After recruitment, participants will be randomly assigned to one of the three groups (SMCT, NSMCT, WLCG). Subsequently, initial assessments will be conducted, consisting of motor tests and psychological questionnaires.

INTERVENTION PHASE (3 months)

During this phase, participants previously randomly assigned to one of the three groups (SMCT, NSMCT, WLCG), under the supervision of field experts, will begin their activities, specifically:

- SMCT group: Participants will follow a supervised adapted multicomponent training program, which includes aerobic, resistance, and mobility/flexibility exercises;
- NSMCT group: Participants will follow a non-supervised home-based adapted multicomponent training program, which includes aerobic, resistance, and mobility/flexibility exercises;
- WLCG group: Participants will not perform any structured physical activity but will continue with their usual lifestyle. They will be placed on a waiting list, guaranteeing them future participation in adapted physical activity after the intervention period.

FINAL ASSESSMENT PHASE AND DATA COLLECTION (1-2 weeks)

Within one week after the end of the intervention period, final assessments will be initiated, consisting of motor tests and psychological questionnaires.

Discussion and Consent Signature: The research team will clarify any doubts of the participants. Participants will sign the consent form after understanding the details and potential risks. A minimum of 10-30 minutes must be provided per participant.

Estimated Time: 10-30 minutes per participant.

BENEFITS: Participants will have access to adapted physical activity tailored to their needs, with the aim of improving psychophysical conditions related to mobility, autonomy, and self-efficacy, ultimately enhancing their quality of life, all under the supervision of field experts.

RISKS: Participation does not involve any risk or discomfort, except for the rare possibility of traumatic events that may occur during the course of the study.

I, the undersigned_____born in_____on_____, residing at _____ street _____ hereby

DECLARE

that I have read and understood the information and wish to participate in the proposed study.

□ I confirm □ I do not confirm

SIGNATURE_____

A signed copy of the identity document is attached.
For the purpose of informed participation in the research, we invite you to sign the following form, specifying that by signing it, you do not waive any legal rights you are entitled to.

CONSENT TO PARTICIPATE IN THE RESEARCH

I declare that:

□ I have voluntarily decided to participate in the research;;

□ I have received all the information related to the request to participate in the research, particularly regarding the purpose, procedures, and what is required of me;

□ I have received, read, and understood the document containing the "Information regarding participation in the research," which was provided to me, and I have received all the necessary information for my responsible participation in the research;

□ I have had the opportunity to ask questions and have received clear, complete, and satisfactory answers;

□ I have been informed about potential risks;

□ I am aware that my participation is voluntary;

□ I have been assured that I can withdraw from the research at any time, and that this will have no negative consequences on the treatment and care I will receive.

For any doubts or questions, you can contact the **Dr. Luca Poli**
Phone 3457687096

Full name of the participant_____. _____
Signature of the participant Date

Full name of the person who obtained the consent _____ _____
Signature of the research supervisor Date

Full name of any witnesses present _____ _____

_____ _____
Signature of the witnesses present Date

WITHDRAWAL OF CONSENT

If you wish to withdraw your consent to participate in this research, please indicate with an "X" the desired option among the following:

I withdraw my consent to continue participating in one or more of the following activities (please specify the individual activities for which you wish to exercise the right to withdraw consent):

- _____
- _____
- _____
- _____

Full name of the participant _____. _____
Signature of the participant Date

Full name of the person who obtained the consent _____ _____
Signature of the research supervisor Date

Full name of any witnesses present _____ _____

_____ _____
Signature of the witnesses present Date

In case of incapacitated individuals and minors:

CONSENT DECLARATION FOR THE PROCESSING OF PERSONAL DATA OF THE SUBJECT CONCERNED BY THE PARENT/GUARDIAN/ CURATOR/ SUPPORT ADMINISTRATOR
PURSUANT TO AND FOR THE PURPOSES OF THE EUROPEAN DATA PROTECTION REGULATION

I, the undersigned _____ _____, born on _____ in _____,
in the capacity of

□ guardian □ curator □ support administrator of

(name) _____(surname)_____, born on _____in_____
in accordance with the provisions of Regulation (EU) 2016/679 and Legislative Decree 196/2003 and subsequent amendments and integrations, and having read the "Information on the processing of personal data".

☐ **I consent** ☐ **I do not consent**

to the processing - necessary for participation in the research in question - of the personal data of the person concerned, including health-related data, for scientific and statistical research purposes, in the manner and for the reasons described in the section titled "Purpose and methods of data processing".

☐ **I consent** ☐ **I do no consent**

to the storage and further use – not necessary for participation in the study in question – of the personal data of the person concerned for subsequent research activities and to be possibly contacted for further studies.

Additionally,

☐ **I consent** ☐ **I do not consent**

to the processing of images of the person concerned (video, audio, and photographic recordings or other audiovisual materials) - necessary for participation in the study - for the research purposes described in point (4.A) and in compliance with copyright law.

Date Signature