



Official Title:

Exer-WAPA Project: Physical Exercise on Women's Affective and Physical HeAlth

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Junta
de Andalucía



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PARTICIPANT ID: _____

PATIENT INFORMATION SHEET AND INFORMED CONSENT FORM

STUDY TITLE: Physical Exercise on Women's Affective and Physical Health (Exer-WAPA Project)

STUDY CODE: Reference: C-SEJ-304-UGR23

PRINCIPAL INVESTIGATOR: Yaira Barranco Ruiz

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INSTITUTION: Department of Physical Education and Sport, Faculty of Sport Sciences, Institute for Sport and Health Research (iMUDS), University of Granada, Granada, Spain.

Introduction

You are being invited to participate in a research study. This study has been approved by the Research Ethics Committee of the University of Granada (No. 3778/CEIH/2023) and the Provincial Research Ethics Committee of Granada (SICEIA-2024-003463) in accordance with current legislation ([Declaration of Helsinki – Fortaleza](#), Brazil, October 2013; [Oviedo Convention](#) on Human Rights and Biomedicine, April 4, 1997, ratified in the Spanish Official Gazette on October 20, 1999; [Nuremberg Code](#) (1946); [Spanish Biomedical Research Law 14/2007](#); [Organic Law 3/2018 on Personal Data Protection and Guarantee of Digital Rights](#)).

The purpose of this document is to provide you with the necessary information so that you can decide whether or not you wish to participate in this study. Please read this information sheet carefully. If you have any questions, the research team will be happy to clarify them. You may also consult with anyone you consider appropriate before making your decision.

Voluntary Participation

Your participation in this study is voluntary. You may decide not to participate without any consequences or impact on your healthcare. If you decide to participate, you may withdraw your consent at any time without providing any explanation and without affecting your relationship with your healthcare providers or the care you receive.

Study Objective

The aim of the Exer-WAPA Project is to evaluate the effects of a supervised group-based physical exercise program on emotional well-being and physical health in women presenting mild-to-moderate symptoms of anxiety and/or depression.

Study Description and Activities



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The Exer-WAPA study is aimed at physically inactive adult women experiencing psychological distress with symptoms of anxiety and/or depression (dysthymia) that affect their daily life. The purpose of this study is to evaluate the effectiveness of a supervised group-based exercise program specifically designed for this population, focusing on improving the symptoms mentioned above as well as physical health.

This study plans to include a sample of approximately 80–90 participants. Participation involves attending baseline assessments, taking part in a supervised physical exercise program, and receiving recommendations to promote healthy lifestyle habits aimed at improving physical health and emotional well-being. Participants will also complete follow-up assessments after finishing the exercise program. Assessments may be conducted over one or two days, and participants will be contacted in advance to schedule the assessment appointments and receive instructions prior to the evaluations.

The project is expected to conclude at the end of 2026, and the duration of participation for each participant is approximately 4–5 months. During this period, participants will complete assessments related to their emotional and physical health, take part in a supervised exercise program specifically designed for this study, receive personalized recommendations to support healthy lifestyle habits, and obtain a detailed report of the variables assessed. As this is a clinical study, participants may be randomly assigned to either the intervention group or the control group. Participants assigned to the intervention group will complete the assessments and participate in the exercise program. Participants assigned to the control group will complete the assessments and continue with their usual lifestyle habits and healthcare as needed, while also attending educational sessions providing guidance on physically active and healthy lifestyle habits.

Assessments and Intervention Program

Participants will be evaluated regarding emotional health and lifestyle factors (physical activity, sedentary behaviour, sleep, nutrition, and quality of life) through a series of questionnaires that are easy to understand and complete. Most of these questionnaires consist of short scales. Physical activity and sedentary behaviour will also be measured using accelerometry, which involves wearing a comfortable wrist device for one week that records daily activity levels.

Physical health will be assessed through a battery of simple and validated physical fitness tests adapted to the participants' fitness levels (handgrip strength, lower limb strength, upper and lower limb flexibility and mobility, cardiorespiratory fitness using the 6-minute walk test, postural hygiene assessment). In addition, the following measurements will be assessed: blood pressure, resting heart rate and heart rate variability, and body composition. Blood and urine samples may also be collected to analyse basic biomarkers related to cardiometabolic health and stress (cortisol). If these samples are required, participants will be informed beforehand.

During the intervention, the exercise program will be supervised by professionals in physical education and sport sciences, ensuring safe, individualized, and motivating exercise sessions. In this physical exercise program, you will train your cardiorespiratory fitness, muscular strength, flexibility, and mobility, as well as improve your posture and practice

relaxation techniques. All training sessions will be accompanied by music delivered through an integrated sound system using wireless headphones (Silent System brand) with adjustable volume. This system will help ensure a high level of concentration and body awareness while allowing you to receive clear and direct instructions from the instructor.

Participants may continue attending medical appointments during the study if needed.

Unlike standard clinical practice, where individuals typically receive general recommendations to engage in physical exercise as a preventive and supportive strategy for managing their symptoms, participation in this study will provide you with the opportunity to receive, free of charge, a supervised exercise program specifically designed to improve your symptoms and physical health. This program will be delivered and supervised by qualified exercise professionals. Alternatively, you may attend educational sessions aimed at promoting physically active and healthy lifestyle habits. In addition, you will receive a detailed report of your emotional and physical health status. Your lifestyle habits will also be analysed in order to provide personalized recommendations that may help improve your symptoms.

Risks and drawbacks arising from your participation in the study

No significant adverse effects are expected from participation beyond those normally associated with physical exercise or potential difficulties in adhering to the exercise program. Participation in the study does not involve additional risks beyond those associated with the evaluation procedures and physical exercise sessions.

Potential benefits

Participation in this study may provide the following benefits:

- Participation in a free, three-month supervised exercise program conducted on a regular basis and aligned with the World Health Organization recommendations for physical activity and health. Regular physical exercise is associated with improvements in overall well-being, emotional health, general health status, and several dimensions of quality of life, from which you may benefit. As the program is delivered in a group setting, you may also have the opportunity to enhance your social relationships with individuals experiencing similar symptoms. Social relationships are closely associated with good mental and physical health.
- Receiving a comprehensive report of the assessments, which will provide information about your emotional and physical health status.
- Personalized recommendations based on the analysis of your lifestyle and health-related habits to support improvements in your health and well-being.

Additionally, the information obtained in this study may contribute to scientific knowledge on the improvement of anxiety and depression symptoms and may benefit others in the future.

Contact for questions

If you have any questions during the study or require further information, please contact Dr. Yaira Barranco Ruiz. Telephone: 958241000 ext. 20683. Email: ybarranco@ugr.es. WhatsApp +34 684793383.



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Costs and financial compensation

Participation in this study is free of charge. Participants will not receive financial compensation for their participation.

Funding

This project, entitled Physical Exercise on Women's Affective and Physical Health (Exer-WAPA Project), is funded under grant C-SEJ-304-UGR23, co-funded by the Regional Ministry of University, Research and Innovation and the FEDER Andalucía 2021–2027 Programme.

Personal data protection

Data anonymization or pseudonymization processes and security measures will be implemented in accordance with current regulations (GDPR and Spanish Organic Law 3/2018 on Personal Data Protection). Confidentiality, security, and informed consent of participants will be guaranteed, respecting the principles of transparency and data minimization. If the data were to be used in future studies within the same research line, participants will be informed and asked to provide authorization or withdraw permission.

Collection and use of biological samples

All procedures involving biological samples will follow ethical and legal regulations governing biomedical research (Royal Decree 1716/2011). Samples will be coded anonymously to ensure participant confidentiality, preventing personal identification from being linked directly to the analysed data. These samples will be stored and handled according to applicable data protection regulations. After a period exceeding two years, a protocol for their destruction will be implemented.



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PARTICIPANT ID: _____

WRITTEN CONSENT OF THE PARTICIPANT

Study Title:

Physical Exercise on Women's Affective and Physical Health.
The Exer-WAPA Project.

I, (name and last name) _____, with
I.D./NIE/PASSPORT number _____

I have spoken with a member of the research team responsible for the study.

I have read the information sheet provided to me.

I have had the opportunity to ask questions about the study.

I have received sufficient information about the study.

I understand that my participation is voluntary.

The samples and data obtained in this study will only be used for the purposes of this research.

I understand that I may withdraw from the study:

- At any time
- Without providing any explanation
- Without affecting my medical care

In the event of withdrawal from the study:

- I consent to the use of the data provided for research purposes.
- I do not consent to the use of the data provided for research purposes.

Please tick the appropriate boxes if you agree:

- I freely agree to participate in this study.
- I freely consent to the use of my image and its publication on social media or other media exclusively for academic, research, informational, and dissemination purposes related to the project.

Date

Signature of participant

Date

Signature of the study professional and ID number