Official Title:

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

NCT Number:

Pending

Document Date:

19 February 2026

Objective

This randomized controlled trial aims to determine the effects of a 12-week supervised, group-based exercise program incorporating music-synchronized movement on the emotional and physical health of physically inactive, middle-aged women experiencing psychological distress.

Design

The Physical Exercise on Women's Affective and Physical HeAlth (Exer-WAPA) project is a randomised controlled trial (RCT) designed to evaluate the effects of a supervised, group-based exercise program incorporating music-synchronized movement on the emotional and physical health of physically inactive, middle-aged women experiencing psychological distress. A total of 100 participants will be randomized to either the experimental group or a waitlist control group.

Methods

Outcomes

The primary outcome will be emotional well-being, assessed at baseline and post-intervention using the Spanish version of the Positive and Negative Affect Schedule (PANAS). Secondary outcomes will be assessed at baseline and post-intervention and will be grouped into five dimensions: (1) mental health, (2) physical health, (3) lifestyle, (4) gender-related outcomes, and (5) socioeconomic impact. Mental health and self-reported physical activity outcomes will be evaluated at three-month follow-up. Accordingly, the study follows a 2 × 3 statistical design.

(1) Mental Health: In addition to emotional well-being as the primary psychological outcome, the following mental health variables will be assessed: risk of poor mental health, using the General Health Questionnaire (GHQ-12); self-esteem, using the Rosenberg Self-Esteem Scale (RSES); global life satisfaction, using the Satisfaction with Life Scale (SWLS); anxiety symptoms, using the Beck Anxiety Inventory (BAI); depressive symptoms, using the Beck Depression Inventory-II (BDI-II); and general cognitive status, using the Spanish version of the Montreal Cognitive Assessment (MoCA).

(2) Physical Health: Health-related physical fitness will be assessed through health-related body composition (bioimpedance) and anthropometric indicators and physical fitness

components, including cardiorespiratory fitness, using the 6-minute walk test; upper limb muscle strength, using handgrip dynamometry; lower limb muscle strength, using the 30 sit-to-stand test; upper limb flexibility, using the shoulder flexibility test; lower limb flexibility, using the chair sit-and-reach test; and agility, using the T-test. Cardiometabolic risk will be assessed using systolic and diastolic blood pressure measurements. Autonomic cardiovascular function will be assessed using heart rate variability (HRV). Static posture will also be assessed using the Fitness for Work Assessment Tool (OSPAT).

(3) Lifestyle: Sociodemographic variables, including age, sex, educational level, marital status, employment status, and annual income, will be assessed. Prescribed and non-prescribed medication, and exposure to traumatic events will be assessed using a self-reported questionnaire. Physical activity, sedentary behaviour, and sleep quality will be assessed using Axivity triaxial accelerometers (AX3 and AX6). Self-reported physical activity and sedentary behaviour will be assessed using the Spanish version of the International Physical Activity Questionnaire (IPAQ), short version. Self-reported sleep quality will be assessed using the Pittsburgh Sleep Quality Index (PSQI). Commuting behaviour will be assessed using a self-administered questionnaire based on the ALPHA Environmental Questionnaire, including mode of commuting, reasons for the chosen mode of commuting, and whether the trip is made alone or accompanied to different destinations. Dietary habits will be assessed using the Mediterranean Diet Adherence Questionnaire (PREDIMED). Health-related quality of life will be assessed using the Spanish version of the SF-36 questionnaire. In addition, tobacco and alcohol consumption will be assessed using the AUDIT-C questionnaire.

(4) Gender-related outcomes: Gender-related variables that may influence symptoms of anxiety and/or depression will be assessed. Sociodemographic variables, including gender, sexual orientation, relationship status, relationship satisfaction, parenthood, and caregiving responsibilities, will be assessed. Gender norms, including responsibilities at home, at work, and in caregiving, as well as social support and reproductive health, will be assessed using an adapted Spanish version of the Gender-Related Variables for Health Research (GVHR) questionnaire. Quality of life in menopausal women will be assessed using the Spanish version of the Menopause Quality of Life Questionnaire (MENQOL).

(5) Socioeconomic Impact: The socioeconomic impact of the intervention will be evaluated through a cost-effectiveness analysis.

In addition, adherence and compliance variables related to the exercise intervention will be assessed. Attendance and punctuality at sessions will be assessed using session attendance records. Additional physical activity outside the training sessions will be assessed using self-reported questionnaire. Mood before and after each exercise session will be assessed using the Feeling Scale. Perceived exhaustion prior to the start of each session will be assessed using item 8 of the HPHEE Scale. Adverse events will be assessed using standardised incident reporting forms. Subjective session effort will be assessed using the Borg Rating of Perceived Exertion scale (RPE 0–10). Furthermore, immediately after completion of the intervention, participants in the experimental group will complete the Physical Activity Enjoyment Scale (PACES) to assess perceived enjoyment of physical activity during the program. In addition, a focus group will be conducted with a purposive subsample of participants from the experimental group to qualitatively explore their experiences, perceptions, and satisfaction with the intervention program.

Recruitment

A total of 100 middle-aged women (35–60 years) with mild-to-moderate anxiety and/or depression symptoms will be recruited from Granada (Spain) and surrounding areas through local media, university communication channels, and social media platforms. Interested individuals will complete an online screening questionnaire, followed by a telephone screening to confirm eligibility based on inclusion and exclusion criteria.

Table 1. Inclusion and exclusion criteria for Exer-WAPA study.

Inclusion criteria	Exclusion criteria
– Women from Granada and nearby areas aged 35 to 60 years	– Serious acute or terminal illness
– Presence of mild psychological distress or dysthymia symptoms	– Severe psychiatric illness
– Physically inactive (not regularly engaging in physical-sport activities <150 min/week of MVPA)	– Diagnosed chronic cardiac, pulmonary, or metabolic disease
– No previous participation in physical conditioning or sports programs, or no participation within the past six months	– Disabling osteo-muscular pathology (e.g., fracture, sprain) or neuromuscular disorder preventing physical activity

– No disabling or high-risk health condition that contraindicates participation in a supervised exercise program	– Pregnancy
– Provide informed consent to participate	– Taking prescribed medication for dysthymia or sleep disorders, unless on treatment for more than one year with no symptom improvement
– Availability to attend the training program sessions at one of the scheduled times	– Disagreement with the study conditions (e.g., group randomization, attendance at evaluations, etc.)
	– Not signing the informed consent and/or the participation commitment form

Intervention

Participants allocated to the experimental group will undertake a supervised 12-week concurrent exercise intervention combining aerobic and resistance training, delivered through group-based fitness classes with musical and choreographed support. Sessions will be conducted three times per week, lasting 60 minutes each (180 minutes per week), in accordance with World Health Organization recommendations for physical activity in adults. Exercise intensity will be individually prescribed and monitored using heart rate reserve (HRR), targeting intensities ranging from >50% to 85% HRR. Sessions will be conducted in groups and supervised by a graduate in Sports Science or a student enrolled in this degree program with experience in musically choreographed group fitness classes.

Session Structure and Monitoring

Each training session will follow a standardized structure comprising a 5-minute warm-up, a main concurrent training phase combining resistance and endurance exercises, and a 10-minute mindfulness-based cool-down. The main phase will be driven by musical cadence. All sessions will be accompanied by music delivered through an integrated sound system using wireless headphones with zero latency (Silent System), allowing for individual volume control. Musical tempo (beats per minute) will serve as the primary guide for exercise intensity and movement speed, structured as follows: Resistance Component: Each music track will target one or two specific muscle groups. The BPM will dictate the repetition velocity, controlling the cadence of concentric and eccentric phases. Aerobic Component:

This phase will involve global movements and displacements performed as moderate-to-high intensity intervals (HIIT), where whole-body exercise speed is synchronized with the musical rhythm. To ensure protocol adherence and safety, all sessions will be directly supervised by a certified trainer. The trainer's role is to monitor technical execution and ensure that participants strictly maintain the prescribed rhythm and movement velocity dictated by the music track, thereby validating the training intensity. A familiarization phase will be implemented at the beginning of the program to ensure correct exercise technique and execution. Exercise intensity will be progressively increased every three weeks by adjusting both the external load (kg) and the prescribed percentage of HRR.

Waitlist control group

Participants assigned to the waitlist control group will be invited to attend a series of educational sessions aimed at promoting healthy lifestyle and physical activity recommendations. These participants will not receive the exercise intervention during the study period and will be offered the exercise program after completion of the follow-up assessments.