PROJECT TITLE

Adapted Multicomponent Training (Adapted Physical and Sports Activity - AFA) for promoting well-being in individuals already affected by cardiovascular diseases in currently stable or chronic conditions.

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

January 2025 – June 2025

FUNDS USED FOR THE PROJECT

No

DATE OF THE DOCUMENT

28/01/2025

SCIENTIFIC RATIONALE

Cardiovascular diseases (CVDs) remain a significant concern for global health, representing a considerable burden in terms of morbidity and mortality. The prevalence of CVDs is continuously increasing, and their impact on physical health and quality of life (QoL) is profound (Saglietto et al., 2021; Townsend et al., 2022). Risk factors such as obesity, hypertension, hypercholesterolemia, aging, and insufficient physical activity contribute to CVDs (Kraus et al., 2019; Tian & Meng, 2019). Physical activity (PA) has emerged as a crucial therapeutic strategy in the management and prevention of CVDs, helping to improve cardiovascular function, fitness, and overall QoL (Franklin et al., 2022). Physical training, especially aerobic training (AT) and resistance training (RT), has drawn attention as a non-pharmacological approach to managing CVDs. RT has shown potential benefits in improving muscle function, skeletal muscle mass, insulin sensitivity, blood pressure regulation, and endothelial function (Oliveira et al., 2018; Trevizani et al., 2018). Recently, isometric exercises, once considered to be contraindicated for treating cardiovascular diseases, have been shown to be the most effective in managing conditions like hypertension (Edwards et al., 2024). The complexity of CVDs requires a holistic approach to exercise prescription. Multicomponent training (MCT) protocols aim to address various aspects of fitness, targeting not only cardiovascular endurance but also muscle strength, mobility, and balance (Bouaziz et al., 2016). These components can collectively contribute to improved functional capacity and enhanced QoL (Bouaziz et al., 2016). The impact of integrating multiple exercise modalities into an MCT for CVDs remains underexplored. It is not yet entirely clear which protocol may be the most efficient for improving physiological and psychological parameters in individuals with a history of cardiovascular problems that are currently stable.

AIMS AND HYPOTHESES OF THE PROJECT

Primary outcome:

The purpose of this study is to evaluate the effectiveness of MCT on physiological parameters, physical fitness, mental well-being, and quality of life in individuals with a history of cardiovascular problems that are currently stable, compared to an integrated multicomponent training protocol with isometric exercises (IMCT) and a waitlist control group (WLCG).

Secondary outcome:

Assess the enjoyment/motivation in performing the different training protocols, as well as 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 IMCT group will show superior improvements in physiological parameters compared to the MCT group.

CHARACTERISTICS OF PARTICIPANTS

The study aims to recruit at least 30 individuals with a history of cardiovascular problems, currently stable, aged between 45–80 years.

Inclusion Criteria

- Women/Men
- 45–80 years old
- Absence of severe medical conditions (unstable coronary artery disease, decompensated heart failure, severe pulmonary hypertension) or acute conditions that would prevent safe participation in physical activity according to the guidelines of the American College of Sports Medicine (ACSM), American Heart Association (AHA), and the European Society of Cardiology (ESC) (Billinger et al., 2014; Gary Liguori & ACSM, 2021; Pelliccia et al., 2021; Williams et al., 2007)
- History of cardiovascular dysfunctions currently stabilized
- Sedentary lifestyle (individuals not having followed WHO guidelines for aerobic and resistance exercise in the last 3 months)

Exclusion Criteria

- Smokers
- 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

- Presence of joint pain, dizziness, chest pain, or angina during physical activity
- High blood pressure: PBP ≥ 160/100 (untreated))

SAMPLE SIZE

A priori power analysis (Kang, 2021) with a Type I error of 0.05 and Type II error rate of 0.05 (95% statistical power) calculated that 10 participants per group would be sufficient to observe moderate interaction effects between "Time x Group."

RECRUITMENT METHOD

Participants will be recruited through the "Amici di Cuore" association located at Piazza G. Cesare No. 11, c/o Istituto Morgagni Policlinico, 70124 Bari, and will be randomly assigned to one of three groups:

- MCT
- 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

Hemodynamic Parameters:

- Resting Heart rate (RHR)
- Peripheral Systolic Blood Pressure (P-SBP)
- Peripheral Dyastolic Blood Pressure (P-DBP)

Physical Parameters:

- Timed Up and GO (TUG)
- 30 Seconds Chair Stand Test (30"CST)
- 2 Minutes Step Test (TMST)
- Handgrip Strength Test (HGS)

Psychological Parameters:

- SF-36
- BREQ-3

Experimental Design

After initial evaluations, participants will be randomly assigned to one of the three groups. All protocols will last 24 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.

Multi-component Training:

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.

Isometric Multi-component Training:

Each training session will include an initial phase of muscle activation lasting 10 minutes (low-intensity walking, Borg = 10-11) to increase heart rate, improve blood flow to muscles, 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 isometric 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, quick lateral steps, or lateral leg raises. Finally, 3 minutes of low-intensity walking will facilitate recovery for the subsequent phase of training.

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

The isometric training will focus on exercises targeting different muscle groups (8 exercises): quadriceps (isometric leg extension/wall squat), biceps brachii (isometric dumbbell curl), shoulders (isometric lateral raises with dumbbells), triceps brachii (isometric French press with dumbbells), pectoralis major (isometric dumbbell chest press/dumbbell flyes), latissimus dorsi (isometric dumbbell rows). The isometric training program will follow the principle of gradual progressive loading. Initially, participants will perform one set of 30 seconds, which will increase to three sets of 30 seconds over the course of the intervention. Load adjustments will be made to ensure that the perceived effort (RPE) stays between 13 and 15 on the Borg Scale (6-20). During the protocol, participants will be given recovery 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 splitting muscle groups (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 seeking maximum elongation of all major muscle groups (from 1 to 3 sets per muscle group), 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.

EXPECTED RESULTS AND RELEVANCE

Although the positive effect of physical activity in individuals with a history of cardiovascular problems, even in stable conditions, has already been demonstrated, the impact of integrating multiple exercise modalities in a MCT or IMCT in the field of cardiovascular diseases (CVDs) remains underexplored. It is still not entirely clear what the most efficient protocol might be for improving physiological and psychological parameters in individuals with a history of cardiovascular issues, currently stabilized. At the end of this exercise program, we expect to observe a general improvement in physiological, motor, and psychological parameters, with a greater increase in the IMCT group, particularly in relation to physiological parameters. Furthermore, we believe that this new research modality could offer a novel approach to proposing a physical activity that is particularly engaging, motivating, and designed to improve the quality of life (both physiologically and psychologically).

To date, physical exercise remains a crucial factor for promoting psychological and biological improvements with profound implications for public health. Indeed, physical activity promises to be an important tool to be used alone or in combination with traditional therapies (such as drugs or medications), to enhance the effectiveness of prevention and treatment strategies for various chronic non-communicable diseases.

Critical Situations and Potential Negative Effects

The main risks, though rare, but considered, may include:

- Acute cardiovascular events: participants with a history of pre-existing cardiovascular conditions, currently stabilized, may, in rare cases, experience episodes of angina, arrhythmias, or increased blood pressure during the training sessions.

- Falls or injuries: the exercises proposed, if performed incorrectly or without supervision, could pose a risk of falls or musculoskeletal injuries.

Risk Management Strategies

- Continuous monitoring during sessions: each training group will be supervised by professionals specialized in adapted physical activity (APA). The Borg scale will be used to monitor the perceived effort during the exercise, keeping it within a moderate range (13-15 points).

- Emergency procedures: to ensure safety, an emergency plan will be in place. APA operators are adequately trained to recognize any symptoms of fatigue or cardiovascular discomfort and to intervene promptly if necessary.

- Medical support: before starting, participants will provide an exercise clearance evaluation signed by the attending doctor/cardiologist, ensuring they are fit to participate. Additionally, the proximity (about 3 minutes by car, 1.4 km) to the main local medical facility (Policlinico di Bari – University Hospital Consortium, Piazza Giulio Cesare, 11, 70124, Bari) has been

considered to allow for quick access to emergency services.

Documentation in the Research Protocol

All preventive measures and management strategies are included in the protocol:

- In the "intervention" section, the structure of the training sessions, the control of exercise intensity, and supervision by qualified personnel are provided.

- The management of cardiovascular and musculoskeletal risks is addressed in the inclusion/exclusion criteria, which exclude participants with acute or unstable conditions to ensure the safety of the study sample.

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