

# Is arm-ergometry exercise training an effective mode of exercise compared with treadmill exercise training?

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<b>Registration date</b> 21/03/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 13/02/2025	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Supervised exercise training is an important treatment among peripheral arterial disease (PAD) patients with intermittent claudication (muscle pain during exercise). Interval treadmill walking to claudication pain is most commonly used. The repeated exercise-induced leg pain impacts negatively on patients' adherence to exercise training programs. This study aims to compare the impact of arm ergometry (arm cycle) versus treadmill supervised exercise training on cardiorespiratory fitness, walking distances, health-related quality of life, anxiety and depression symptoms, cardiovascular risk factors and blood biomarkers.

### Who can participate?

PAD patients aged 18 years and older with intermittent claudication

### What does the study involve?

Patients were randomly allocated either to arm-ergometry supervised exercise training or treadmill walking exercise. Both groups performed exercise sessions consisting of twice-weekly sessions comprising a 10-minute warm-up, 40-minute treadmill intermittent walking or arm ergometry, resistance exercises and a 10-minute cooldown, led by a physiotherapist and under medical supervision, both with experience in cardiovascular rehabilitation.

Treadmill protocol: Intermittent treadmill walking to a moderate claudication pain level then the patient stopped and rested until the claudication pain completely resolved and then resumed walking.

Arm ergometry protocol: The arm ergometry exercise prescription followed the guidelines for this population; exercise intensity was determined using the cardiopulmonary exercise test results.

Additionally, all patients received nutritional and psychological intervention according to international guidelines. All patients were encouraged to exercise at home at least twice a week for 30 minutes.

### What are the possible benefits and risks of participating?

Exercise training is a first-line treatment for patients with intermittent claudication. The benefits

of exercise training in this population include improved walking distance and duration, increased functional capacity, enhanced quality of life, reduced symptoms of intermittent claudication, and potentially lower rates of cardiovascular events. The exercise prescription adhered to international guidelines for this population and all exercise sessions were supervised by a physiotherapist and conducted under medical supervision. Both professionals had experience in cardiovascular rehabilitation. Heart rate was continuously monitored during sessions.

Where is the study run from?

Cardiovascular Rehabilitation Unit of Centro Hospitalar Universitário de Santo António (Portugal)

When is the study starting and how long is it expected to run for?

January 2016 to April 2023

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Sandra Magalhães, mag.sandra@gmail.com

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

2016-053 (047-DEFI/046-CE)

## Study information

## Scientific Title

Effect of arm-ergometry versus treadmill supervised exercise training in patients with peripheral artery disease: the ARMEX randomized clinical trial

## Acronym

ARMEX

## Study objectives

1. Arm-ergometry exercise training induces a more significant enhancement in cardiorespiratory fitness compared to treadmill supervised training in patients with intermittent claudication
2. Arm-ergometry exercise training induces similar improvement in walking distances compared to treadmill supervised training in patients with intermittent claudication
3. Arm-ergometry exercise training induces similar improvement in walking economy compared to treadmill supervised training in patients with intermittent claudication
4. Arm-ergometry exercise training induces similar enhancement in health-related quality of life, depression and anxiety symptoms compared to treadmill supervised training in patients with intermittent claudication
5. Arm-ergometry exercise training induces similar improvement in cardiovascular risk factors compared to treadmill supervised training in patients with intermittent claudication
6. Arm-ergometry exercise training induces similar enhancement in plasmatic biomarkers (inflammatory, endothelial dysfunction and coagulation) compared to treadmill supervised training in patients with intermittent claudication

## Ethics approval required

Ethics approval required

## Ethics approval(s)

approved 18/05/2016, Ethics Committee of Centro Hospitalar Universitário de Santo António (Largo Professor Abel Salazar, Porto, 4099-001, Portugal; +351 (0)222077545; secretariado.etica@chporto.min-saude.pt), ref: 2016-053 (047-DEFI/046-CES)

## Study design

Single-center single-blinded parallel-group non-inferiority randomized clinical trial

## Primary study design

Interventional

## Study type(s)

Quality of life, Treatment, Efficacy

## Health condition(s) or problem(s) studied

Peripheral artery disease

## Interventions

Eligible patients were randomized either to an arm-ergometry supervised exercise training or a treadmill walking exercise protocol. Randomization was performed with a computer-based random number generator using a 1:1 allocation ratio for block sizes of four patients.

Exercise sessions consisted of twice-weekly sessions: 10-minute warm-up, 40-minute treadmill intermittent walking or arm-ergometry, resistance exercises and 10-minute cooldown, led by a

physiotherapist and under medical supervision, both with experience in cardiovascular rehabilitation.

Treadmill protocol: Intermittent treadmill walking to a moderate claudication pain level (3 – 4 of 5 on the claudication scale); then the patient stopped and rested until the claudication pain completely resolved and then resumed walking.

Arm-ergometry protocol: The arm-ergometry exercise prescription followed the guidelines for this population; exercise intensity was determined using the cardiopulmonary exercise test results.

Additionally, all patients received nutritional and psychological intervention according to international guidelines. All patients were encouraged to exercise at home at least twice a week for 30 minutes.

Total duration of the intervention: 12 weeks.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

Cardiorespiratory fitness: Oxygen uptake (VO<sub>2</sub>) peak evaluated on a treadmill cardiopulmonary exercise test (CPET) at baseline and 12 weeks

## **Key secondary outcome(s)**

1. VO<sub>2</sub> at VT-1 (first ventilatory threshold) assessed by CPET at baseline and 12 weeks
2. Ventilatory efficiency: minute ventilation to carbon dioxide production slope (VE/VCO<sub>2</sub> slope) assessed by CPET at baseline and 12 weeks
3. Maximal walking distance (MWD) evaluated on CPET at baseline and 12 weeks
4. Pain-free walking distance (PFWD) evaluated on CPET at baseline and 12 weeks
5. Maximal walking distance (MWD) assessed in a 6-minute walking test at baseline and 12 weeks
6. Pain-free walking distance (PFWD) assessed in CPET at baseline and 12 weeks
7. Self-reported walking limitations, evaluated in the Walking Impairment Questionnaire (WIQ), taking into account: distance (WIQd), speed (WIQs) and stair climbing (WIQ sc) scores; at baseline and 12 weeks
8. Walking economy: Submaximal VO<sub>2</sub> evaluated on CPET at baseline and 12 weeks
9. Health-related quality of life assessed through the Short form 36 health survey version 2 at baseline and 12 weeks
10. Anxiety and depression symptoms assessed using the Hospital Anxiety and Depression Scale at baseline and 12 weeks
11. Resting brachial systolic blood pressure and diastolic blood pressure measured by an automated measurement device at baseline and 12 weeks
12. Hyperlipidemia measured through fasting blood biochemistry including total cholesterol (TC-C), low-density lipoprotein (LDL-C), high-density lipoprotein cholesterol (HDL-C) and triglycerides (TG) at baseline and 12 weeks
13. Diabetes control measured through glycated haemoglobin (%) in fasting state at baseline and 12 weeks
14. Body composition: body mass index (BMI) and waist circumference (WC) at baseline and 12 weeks
15. Self-reported physical activity assessed using the International Physical Activity Questionnaire, classifying the activity into three categories (low activity levels, moderate activity

levels or high activity levels) at baseline and 12 weeks

16. Physical activity: patients utilized a wearable smartwatch to monitor their daily step count at baseline and 12 weeks

17. Smoking cessation: cigarette smoking habits quantified in pack-year and cigarettes per day to measure exposure to tobacco at baseline and 12 weeks

18. Inflammatory markers: high-sensitivity interleukin-6 (hs IL-6); blood samples collected to access plasma levels of hs IL-6 at baseline and 12 weeks

19. Inflammatory markers: C-reactive protein (CRP); blood samples collected to access plasma levels of CRP at baseline and 12 weeks

20. Endothelial dysfunction markers: asymmetric dimethylarginine (ADMA); blood samples collected to access plasma levels of ADMA at baseline and 12 weeks

21. Endothelial dysfunction markers: vascular cell adhesion molecule-1 (VCAM-1); blood samples collected to access plasma levels of VCAM-1 at baseline and 12 weeks

22. Coagulation marker: blood samples collected to access plasma levels of fibrinogen at baseline and 12 weeks

### **Completion date**

28/04/2023

## **Eligibility**

### **Key inclusion criteria**

1. Patients with PAD older than 18 years old referred to the Cardiovascular Rehabilitation Unit
2. PAD was diagnosed through a clinical history and physical examination and confirmed by an ankle-brachial index (ABI)  $\leq 0.90$  and/or an ABI decrease  $\geq 10\%$  after a symptom-limited treadmill stress test
3. Patients able to walk at a speed of at least 3.2 Km/h
4. Able to participate in a supervised exercise program for 12 weeks
5. No change in medication for PAD (cilostazol, pentoxifylline, statin and antiplatelet therapy) at least 3 months prior to study enrollment. Medication remained unchanged during the study intervention period.

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Lower age limit**

18 years

### **Sex**

All

### **Total final enrolment**

56

## **Key exclusion criteria**

1. PAD Leriche-Fontaine stages I, III or IV
2. A revascularization procedure during the previous 12 months
3. Other chronic conditions causing exercise impairment more than PAD
4. Acute cardiovascular event less than 3 months prior to enrollment
5. Clinical contraindications for physical exercise practice, according to current guidelines

## **Date of first enrolment**

02/01/2017

## **Date of final enrolment**

20/01/2023

## **Locations**

### **Countries of recruitment**

Portugal

### **Study participating centre**

**Centro Hospitalar Universitário de Santo António**

Largo Professor Abel Salazar

Porto

Portugal

4099-001

## **Sponsor information**

### **Organisation**

Centro Hospitalar Universitário de Santo António

## **Funder(s)**

### **Funder type**

Other

### **Funder Name**

Investigator initiated and funded

## **Results and Publications**

## Individual participant data (IPD) sharing plan

The data associated with the paper are not publicly available but are available upon request from Sandra Magalhães (mag.sandra@gmail.com).

The type of data that will be shared: anonymized database.

Dates of availability: up to 1 year after publication of results.

Written informed consent was obtained from all participants prior to their involvement in the study.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Other publications</a>	Secondary outcomes from the ARMEX trial	07/02/2025	10/02/2025	Yes	No
<a href="#">Other publications</a>	Secondary analysis	11/02/2025	13/02/2025	Yes	No