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

Submission date	**Recruitment status**	[_] Prospectively registered
20/03/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/03/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
13/02/2025	Circulatory System	[X] 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

Study website
Not applicable

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Quality of life, Treatment, Efficacy

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
Cardiorespiratory fitness: Oxygen uptake (VO2) peak evaluated on a treadmill cardiopulmonary exercise test (CPET) at baseline and 12 weeks

Secondary outcome measures
1. VO2 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/VCO2 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 VO2 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

Overall study start date
02/01/2016

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) ≤0.90 and/or an ABI decrease ≥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

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
27 participants per group

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
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Sponsor information

Organisation
Centro Hospitalar Universitário de Santo António

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
https://www.chporto.pt/

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/09/2024

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?
Other publications	Secondary outcomes from the ARMEX trial	07/02/2025	10/02/2025	Yes	No

Other publications	Secondary analysis	11/02/2025	13/02/2025	Yes	No