ISRCTN44928994 https://doi.org/10.1186/ISRCTN44928994

Alternative program of physiotherapy intervention in peripheral arterial disease

Submission date	**Recruitment status**	[X] Prospectively registered
10/03/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
13/04/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/05/2019	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Peripheral arterial disease (PAD) is a common condition in which a build-up of fatty deposits in the arteries restricts the blood supply to the leg muscles, causing pain during exercise. The gold standard for the treatment of patients with PAD is to walk at least three times a week for a minimum of 30 minutes.
The aim of this study is to compare the effects of two types of training in adults with PAD: a conventional walking program, and walking whilst wearing ankle weights.

Who can participate?
Adults with PAD

What does the study involve?
Participants are randomly allocated to one of two groups. One group walks normally, either on the ground or on a treadmill. The other group walks on the ground or treadmill whilst wearing ankle weights. Both groups walk 3 times per week for 12 weeks. Participants are assessed before and after the 12-week training period.

What are the possible benefits and risks of participating?
The benefits are improved symptoms and increased walking distance. Participants may experience fatigue, tiredness and pain in the lower limbs.

Where is the study run from?
Department of Physical Therapy at the Federal University of Minas Gerais (Brazil)

When is the study starting and how long is it expected to run for?
January 2016 to May 2017

Who is funding the study?
Pro-rector of research - Federal University of Minas Gerais (Brazil) (Pró-reitoria de pesquisa da Universidade Federal de Minas Gerais (PRPq-UFMG)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effects of an alternative program of physiotherapy intervention in peripheral arterial disease : a randomised clinical trial

Study objectives
Current hypothesis as of 26/10/2015:
The overall aim of the present study is to evaluate the effects of a training program using the modified walk concurrently with the use of load in patients with peripheral arterial disease (PAD).

Specific research questions are:
1. Is there a difference in the response of the total distance walked and speed in adults with PAD, comparing two types of training: a conventional aerobic program and an aerobic program with progressively increased load?

2. Is there a difference in the response of time to onset of pain, distance walked by initial pain, duration of maximum pain and time of rest after maximal pain in the tests of shuttle walking test and constant speed treadmill test in adults with PAD, comparing two types of training: a conventional aerobic program and an aerobic program with progressively increased load?
3. Is there a difference in the response of number of plantar flexions performed in the HRT (time in seconds) and velocity (plantar flexions per second) when performing plantar flexions up to the point of volunteer fatigue, comparing two types of training: a conventional aerobic program and an aerobic program with progressively increased load?
4. Is there a difference in the response in the Deoxyhemoglobin (Hb), oxyhemoglobin (HbO2) and oxygen saturation (StO2) in the calf muscles during SWT, HRT and constant speed treadmill test, comparing two types of training: a conventional aerobic program and an aerobic program with progressively increased load?
5. Is there a difference in the response of ankle brachial index (ABI), score of the WIQ and SPPB in adults with PAD, comparing two types of training: a conventional aerobic program and an aerobic program with progressively increased load?
6. Is there a difference in the response in the Heart Rate Variability (HRV) during rest and constant speed treadmill test, comparing two types of training: a conventional aerobic program and an aerobic program with progressively increased load?

Previous hypothesis:
The overall aim of the present study is to evaluate the effects of a training program using the modified walk concurrently with the use of load in patients with peripheral arterial disease (PAD).

Specific research questions are:
1. Is there a difference in the response of the total distance walked and speed in adults with PAD, comparing two types of training: a conventional aerobic program and an aerobic program with progressively increased load?
2. Is there a difference in the response of time to onset of pain, distance walked by initial pain, duration of maximum pain and time of rest after maximal pain in the tests of six-minute walk test and shuttle walking test in adults with PAD, comparing two types of training: a conventional aerobic program and an aerobic program with progressively increased load?
3. Is there a difference in the response of ankle brachial index (ABI) and score of the eight domains of the Short-Form 36 (SF-36) in adults with PAD, comparing two types of training: a conventional aerobic program and an aerobic program with progressively increased load?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Research from UFMG, 15/12/2010, ref: registration ETIC 0559.0.203.000-10

Study design
Single-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Peripheral arterial disease with intermittent claudication

Interventions
Current interventions as of 26/10/2015:
The volunteers will participate in aerobic training, three times a week for 12 weeks. After selection, the volunteer will be allocated randomly to one of two groups: conventional aerobic (CG) and modified using aerobic load (MG). Randomisation will be performed in a block (every four volunteers will be done randomly).

The CG group will initially undergo aerobic training on the ground for 30 minutes until maximum pain (respecting limit of 85% of the maximal Heart Rate for his age). If the individual does not reach maximum pain in 30 minutes walking on the ground, he will walk on the treadmill without inclination, with the average speed achieved on the ground. From the moment that the individual does not achieve symptom-limited in 30 minutes on the treadmill will be performed progressive increase in speed.

The MG group undergoes the same training up to maximum intermittent pain including progressive overload of the lower limbs by addition of weight in the legs. Treatment of MG will be first performed with walking on the ground initially with no load on the lower limbs, which will be added gradually. If the individual reaches a minimum of 15 minutes of walking on the ground without reaching the limiting symptom, weights will be added (in the form of ankle weight) at the level of the ankles to increase overload. Overloading will start with 0.5 kg in each leg, progressing to a maximum of 2 kg, considering the described time and the absence of limiting pain. If the individual reaches a minimum of 15 minutes with 2 kg on each limb during walking on the ground without reaching the limiting symptom, the activity will be performed on a treadmill, with the average speed achieved on the ground without overload in the lower limbs. Weights will be added (in the form of ankle weights) at the level of the ankles to increase the overload. It will start with 0.5 kg in each leg, progressing to a maximum of 2 kg, from the time the individual reaches 15-minute walk on the treadmill without presenting maximum pain.

In both groups, when the volunteer needs to stop for maximum leg pain, they will begin a new walk as soon as the symptoms disappear. The total walking time is given by the sum of all walks performed by the individual and should total 30 minutes, not considering interruption. In every session we will record: time to onset of pain, time to onset of maximum pain, rest time required for the symptoms to disappear and the total distance that the volunteer walks in each session.

Two evaluations will be performed: initial and after 12 weeks of supervised training. The assessment will comprise a body mass index (Asimed®, Barcelona, Spain), Walking Impairment Questionnaire (WIQ), ankle-brachial index (ABI), Shuttle Walk Test (SWT); Short Physical Performance Battery (SPPB); Heel-Rise Test (HRT), constant speed treadmill test. The order of

the four tests will be random.
NIRS will be used during the performance of SWT tests, HRT, SPPB and constant speed treadmill test in order to evaluate the behavior of the variables oxyhemoglobin (O2Hb), deoxyhemoglobin (HHb) and tissue oxygenation (StO2). Heart Rate Variability (HRV) will be assessed during rest and constant speed treadmill test.
One questionnaire (SF-36) and one test (6WT) were excluded from protocol, since were included more specific and adequate instruments for evaluation of PAD.

Previous interventions:
The volunteers will participate in aerobic training, three times a week for 12 weeks. After selection, the volunteer will be allocated randomly to one of two groups: conventional aerobic (CG) and modified using aerobic load (MG). Randomisation will be performed in a block (every four volunteers will be done randomly).
Two evaluations will be performed: initial and after 12 weeks of supervised training. The assessment will comprise a body mass index (Asimed®, Barcelona, Spain), ankle-brachial index (ABI), six-minute walk test (6WT), shuttle walk test (SWT); questionnaire Short-Form 36 (SF-36).
The CG will do aerobic training on a treadmill for 30 minutes with intensity up to maximum claudication pain (respecting limit of 85% HR predicted by age). The MG will do the same training to maximum claudication pain including progressive overload in the lower limbs by the addition of ankle weights (0.5 kg to a maximum of 2 kg). The treatment of MG will be held on treadmill, initially with no load on the lower limbs that will be added gradually.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 26/10/2015:
1. Initial claudication time (ICT) and absolute claudication time (ACT), initial claudication distance (ICD) and absolute claudication distance (ACD) and resting time required for the symptoms disappear in SWT and constant speed treadmill test
2. Number of plantar flexions performed in the HRT (time in seconds) and velocity (plantar flexions per second) when performing plantar flexions up to the point of volunteer fatigue
The results will be measured at time 0 (before intervention) and after 12 weeks of intervention

Previous primary outcome measures:
Speed and distance walked during the 6WT and SWT
The results will be measured at time 0 (before intervention) and after 12 weeks of intervention

Secondary outcome measures
Current secondary outcome measures as of 26/10/2015:
1. Walking Impairment Questionnaire (WIQ) score in each domain
2. Deoxyhemoglobin (Hb), oxyhemoglobin (HbO2) and oxygen saturation (StO2) in the calf muscles during SWT, HRT and constant speed treadmill test
3. Short Physical Performance Battery (SPPB) score
4. Heart Rate Variability (HRV) during rest and constant speed treadmill test
The results will be measured at time 0 (before intervention) and after 12 weeks of intervention

Previous secondary outcome measures:
1 Clinical outcomes (time to onset of pain, distance walked by initial pain, duration of maximum pain on SWT and 6WT tests, resting time required for the symptoms disappear)
2. ABI

3. Quality of life (SF-36)
The results will be measured at time 0 (before intervention) and after 12 weeks of intervention

Overall study start date
15/01/2016

Completion date
01/02/2018

Eligibility

Key inclusion criteria
Adults of both sexes who have ABI < 0.9 and > 0.4 or who do not have pain at rest

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
140

Key exclusion criteria
1. Individuals with ABI > 0.9
2. Presence of diseases or complications that preclude training, such as cardiac failure, unstable angina, arrhythmias, decompensated diabetes (random glucose greater than 250 mg / dl) or signs of haemodynamic instability
3. Patients who have supervised exercise done during the last six months

Date of first enrolment
01/03/2016

Date of final enrolment
01/03/2017

Locations

Countries of recruitment
Brazil

Study participating centre

Departamento de Fisioterapia - Universidade Federal de Minas Gerais
Belo Horizonte
Brazil
31270-901

Sponsor information

Organisation
Federal University of Minas Gerais (UFMG-PRPq) (Brazil)

Sponsor details
Pró-reitoria de pesquisa da Universidade Federal de Minas Gerais (PRPq-UFMG)
Avenida Antônio Carlos 6627, Pampulha
Belo Horizonte
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Sponsor type
Government

ROR
https://ror.org/0176yjw32

Funder(s)

Funder type
Government

Funder Name
Pro-rector of research- Federal University of Minas Gerais (Brazil) (Pró-reitoria de pesquisa da Universidade Federal de Minas Gerais (PRPq-UFMG)

Results and Publications

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

Intention to publish date
01/06/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Débora Pantuso Monteiro (deborapantuso@hotmail.com).

IPD sharing plan summary

Available on request