The effects of upper-limb aerobic exercise training on walking performance and lower limb circulatory function in patients with peripheral arterial disease

Submission date 24/08/2006	Recruitment status	Prospectively registered	
24/08/2006	No longer recruiting	[_] Protocol	
Registration date	Overall study status	[] Statistical analysis plan	
27/09/2006	Completed	[X] Results	
Last Edited 04/01/2011	Condition category Circulatory System	Individual participant data	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives

1. Upper-limb aerobic exercise training will evoke a significant improvement in walking performance in comparison to usual patient care.

2. Upper-limb aerobic exerise training will evoke a significant improvement in lower-limb circulatory function in comparison to usual patient care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval granted by the South Sheffield Research Ethics Committee on 23/06/06 (reference number: 05/Q2305/128).

Study design Randomised controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Not specified

Study type(s) Quality of life

Participant information sheet

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

Interventions

Upper-limb aerobic exercise intervention (arm-cranking exercise training, twice per week for 12 weeks) versus usual patient care.

Intervention Type

Other

Phase Not Specified

Primary outcome measure

Walking performance.

Secondary outcome measures

Changes in lower-limb circulatory function.

Overall study start date 01/09/2006

Completion date

31/08/2007

Eligibility

Key inclusion criteria

- 1. Symptoms of intermittent claudication for at least 12 months
- 2. Ankle Brachial Pressure Index (ABPI) more than 0.9
- 3. No interventional procedure in last 12 months
- 4. Ability to undertake exercise
- 5. No exercise-limiting angina
- 6. No shortness of breath
- 7. No severe arthritis

Participant type(s)

Patient

Age group

Not Specified

Sex

Both

Target number of participants

30

Key exclusion criteria

1. Experiencing symptoms of intermittent claudication for less than 12 months

2. Reporting a significant change in walking ability during previous 12 months, denoting unstable claudication

3. Exhibiting features of critical limb ischaemia

4. Re-vascularisation procedure or other surgical intervention to the lower limbs in the previous 12 months

5. Severe arthritis

6. Unstable cardiopulmonary conditions such as shortness of breath or exercise-limiting angina

Date of first enrolment

01/09/2006

Date of final enrolment

31/08/2007

Locations

Countries of recruitment England

United Kingdom

Study participating centre Centre for Sport and Exercise Science Sheffield United Kingdom S10 2BP

Sponsor information

Organisation Sheffield Hallam University (UK)

Sponsor details Centre for Sport and Exercise Science Collegiate Crescent Campus Sheffield England United Kingdom S10 2BP

Sponsor type University/education

ROR https://ror.org/019wt1929

Funder(s)

Funder type University/education

Funder Name Sheffield Hallam University (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/09/2009		Yes	No