

# Effects of exercise on health and quality of life in peripheral arterial disease

<b>Submission date</b> 06/07/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 11/09/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 11/09/2009	<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**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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2

## Additional identifiers

## Study information

**Scientific Title**  
Exercise and intermittent claudication: health outcomes and cost effectiveness in a single centre randomised controlled trial

**Study objectives**  
Peripheral arterial disease (PAD) is a manifestation of generalised atherosclerotic disease in which the arterial lumen becomes progressively narrowed by atherosclerotic plaques. This gradual narrowing of the lumen results in reduced blood flow to the tissues causing pain on exercise, relieved by rest (intermittent claudication). PAD is a marker for significant

cardiovascular and cerebrovascular events (e.g., myocardial infarction [MI], stroke). Despite its prevalence and associated cardiovascular risk factors, patients with PAD are treated less intensively than patients with coronary artery disease. Several studies have demonstrated that exercise programmes result in significant improvements in walking distances but the long-term benefits and effects on subsequent cardiovascular morbidity and mortality are unknown. The aim of this study is:

1. To assess the long-term effects on risk factor modification
2. To assess the long-term effects on quality of life
3. To assess the long-term effects on fatal and non-fatal events
4. To compare the cost effectiveness over time between the current management strategy and exercise intervention

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Beaumont Hospital Ethics Committee approved in November 2005

### **Study design**

Single centre randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

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

Intermittent claudication

### **Interventions**

Intervention Group:

Participants participate in a twice-weekly supervised exercise programme for 12 weeks. The total duration of the programme is one hour, including warm-up and cool down periods.

Participants undertake a 10 minute warm-up consisting of gentle walking, stepping and stretching exercises (upper limb, lower limb and trunk). Participants then exercise for 30 - 40 minutes using a range of exercise equipment: treadmill, stepper, elliptical trainer, recumbent cycle ergometer and upper/lower limb cycle ergometer. Participants are encouraged to exercise at an intensity of 70 - 80% heart rate maximum or 70 - 80% of their exercise stress test maximum. On the treadmill participants are encouraged to continue exercising until they are unable to continue due to leg pain (generally a maximum of 10 minutes). Participants are then permitted to rest until the pain subsided and then encouraged to recommence exercising. The exercise level is set at an intensity that produced moderate claudication pain within 5 minutes. Exercise is progressed by increasing resistance and/or time.

Control Group:

Usual care.

### **Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Recorded at baseline, 12 weeks and 1 year:

1. Risk factors:
  - 1.1. Diastolic and systolic blood pressure
  - 1.2. Height
  - 1.3. Weight
  - 1.4. Waist circumference
  - 1.5. Ankle/brachial index (ABI) at rest and exercise
  - 1.6. Laboratory test results: fasting blood glucose, triglycerides, cholesterol, plasma fibrinogen, high-sensitivity C-reactive protein (hs-CRP), glycosylated haemoglobin (HbA1C)
2. Generic health status: 36-item short form health survey questionnaire (SF36)
3. Disease-specific health status: Intermittent Claudication Questionnaire (ICQ)
4. Functional capacity: Walking Impairment Questionnaire (WIQ)
5. Physical activity: peripheral Arterial Disease Physical Activity Recall Questionnaire (PAD-PAR)

**Key secondary outcome(s)**

Recorded at baseline, 12 weeks and 1 year:

1. Health status valuation - EQ5D
2. Morbidity and mortality data from hospital paper and computer records

**Completion date**

01/06/2010

**Eligibility****Key inclusion criteria**

1. Fontaine Stage II: intermittent claudication diagnosed by history of leg pain on exercise relieved by rest, classified by presence/absence of pulse/s, site of pain, ankle/brachial index (ABI) less than 0.9 at rest and/or decrease in ankle pressure by 15 mmHg or more after standard treadmill test (standard incline and constant speed)
2. Stable disease x 3 months
3. Residing within the geographical catchment area of the hospital
4. Aged 48 - 83 years, either sex

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Fontaine Stage I (ambulation not limited by claudication)
2. Fontaine Stage III (rest pain)
3. Fontaine Stage IV (focal necrosis)
4. Co-existing clinical condition, which precluded participation in exercise programme including:
  - 4.1. Unstable cardiorespiratory disease
  - 4.2. Neurological/orthopaedic limitation to exercise
  - 4.3. Poorly controlled hypertension
  - 4.4. Active major medical problem including but not limited to cancer, renal/liver disease
  - 4.5. Dementia
  - 4.6. Poorly controlled diabetes mellitus
  - 4.7. Abdominal aortic aneurysm
  - 4.8. Myocardial infarction within the previous 6 months
5. Participants with acute onset or within the first months of onset of claudication (due to fluctuation in symptoms)
6. Revascularisation procedure/surgery within previous 6 months

**Date of first enrolment**

01/12/2006

**Date of final enrolment**

01/06/2010

## **Locations**

**Countries of recruitment**

Ireland

**Study participating centre**

**Royal College of Surgeons in Ireland**

Dublin

Ireland

2

## **Sponsor information**

**Organisation**

Royal College of Surgeons in Ireland (Ireland)

**ROR**

<https://ror.org/01hxy9878>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Royal College of Surgeons in Ireland (Ireland) - Research Committee

**Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration