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SEDRIC Structured EDucation for Rehabilitation in Intermittent Claudication

Submission date	Recruitment status	[X] Prospectively registered
28/02/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/02/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/05/2016	Circulatory System	

Plain English summary of protocol

Background and study aims
Some people experience a cramp-like leg pain during walking that is relieved only by rest. This is called intermittent claudication and it is a common symptom of peripheral arterial disease. Patients with intermittent claudication struggle to walk, which in turn lowers their quality of life. Medically supervised walking programmes have been shown to improve walking ability and quality of life, but more patients could potentially benefit from physical activity that is self-managed and performed in the community setting. However, little is known about the usefulness of education programmes that promote self-managed physical activity in these patients. This research project aims to develop and test a practical education programme for promoting walking activity in patients with intermittent claudication. We will collect scientific data on the programme's usefulness.

Who can participate?
Men and women aged 18-90 years with intermittent claudication.

What does the study involve?
Twenty five patients with intermittent claudication will be interviewed to inform the development of the education programme. At least 12 patients will test the programme to see if any changes are needed. Once we are satisfied with the design of the programme, we will assess the usefulness of the programme in a further 30 patients, who will be randomly assigned to receive either the education programme or usual care.

What are the possible benefits and risks of participating?
Possible benefits of the programme include an increased understanding about peripheral arterial disease. They will also receive support in developing goals and action plans for walking more often, which if adhered to, may result in improved walking capacity and quality of life. All participants will also receive a medical "check-up" from a Consultant Vascular Surgeon during the eligibility screening. Results from this research will help us plan a much larger trial across several UK institutions. During exertion, there is an increased risk of untoward cardiovascular events such as heart attack. The likelihood of this happening, however, is small. We will minimise the risk of this by only recruiting patients who do not have unstable cardiovascular conditions, by using 12-lead ECG monitoring before, during and after the test, and by ensuring that all tests

are supervised by a clinician and a clinical exercise physiologist. We will make it possible for patients to see a Consultant Vascular Surgeon at any point during the trial, if they or the study team have any medical concerns.

Where is the study run from?
Sheffield Hallam University (UK)

When is the study starting and how long is it expected to run for?
March 2013 to August 2013

Who is funding the study?
Bupa Foundation

Who is the main contact?
Dr Garry Tew
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Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01776710

Protocol serial number
13928

Study information

Scientific Title
Development and piloting of a pragmatic structured education programme that promotes walking in patients with intermittent claudication

Acronym
SEDRIC

Study objectives
Some people experience a cramp-like leg pain during walking that is relieved only by rest. This is called intermittent claudication and it is a common symptom of peripheral arterial disease. Patients with intermittent claudication struggle to walk, which in turn lowers their quality of life. Medically supervised walking programmes have been shown to improve walking ability and quality of life, but more patients could potentially benefit from physical activity that is self-managed and performed in the community setting. However, little is known about the usefulness of education programmes that promote self-managed physical activity in these patients. This research project aims to develop and test a practical education programme for promoting walking activity in patients with intermittent claudication. We will collect scientific data on the programme's usefulness.

Twenty five patients with intermittent claudication will be interviewed to inform the development of the education programme. At least 12 patients will test the programme to see if any changes are needed. Once we are satisfied with the design of the programme, we will assess the usefulness of the programme in 18 patients. In total, 30 patient volunteers will be randomly assigned to receive either the education programme or usual care.

Possible benefits of the programme to be explored include increased daily steps/physical activity, and improved walking capacity and quality of life. Patients will be followed up until 6 weeks after being allocated to intervention or control groups. Encouraging results from this research will help us plan a much larger trial across several UK institutions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & The Humber Sheffield, 25/01/2013, ref: 13/YH/0004

Study design
Interventional and Observational; Design type: Treatment, Qualitative

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions
Structured education programme, The structured education intervention will comprise a 3-hour education workshop delivered by two trained facilitators and a follow-up telephone call 2 weeks later. The aims of the education programme are to enhance patients' understanding of peripheral arterial disease and intermittent claudication, and to support patients in increasing their daily walking activity. Key behaviour change techniques that will be incorporated will include goal setting, action planning, barrier identification/problem.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Feasibility (recruitment, retention, compliance, acceptability) Timepoint(s): Baseline and 6 weeks

Key secondary outcome(s))
1. Claudication onset and maximum walking distances on 6-minute corridor walk test; Timepoint (s): Baseline and 6 weeks
2. Claudication onset and maximum walking distances on incremental treadmill walking test; Timepoint(s): Baseline and 6 weeks
3. Daily steps and physical activity; Timepoint(s): Baseline and 6 weeks
4. Health-related quality of life; Timepoint(s): Baseline and 6 weeks
5. Psychological constructs representing the key mediators of behaviour change; Timepoint(s): Baseline and 6 weeks 6. Self-reported ambulatory ability; Timepoint(s): Baseline and 6 weeks

Completion date
25/04/2014

Eligibility

Key inclusion criteria
1. Men and women aged 18-90 years with intermittent claudication due to peripheral arterial disease
2. Stable disease for >3 months
3. Able to provide consent
4. Able to read and speak English to a level allowing satisfactory completion of written questionnaires and to participate in the education intervention

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
90 years

Sex
All

Key exclusion criteria
1. Previous endovascular/surgical interventions
2. Scheduled endovascular/surgical intervention
3. Critical limb ischaemia
4. Those whose function is uniquely impaired, e.g. wheelchair-bound patients and patients with lower-extremity amputation(s).
5. Presence of contraindications to exercise or co-morbidities that limit exercise performance to a greater extent than the intermittent claudication (e.g. severe arthritis)
6. Major surgery, myocardial infarction or stroke/TIA in the previous 6 months
7. Patients who already perform greater than 30 min of structured exercise three times weekly (self-reported)

Date of first enrolment
25/04/2013

Date of final enrolment
25/04/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sheffield Hallam University
Sheffield
United Kingdom
S10 2BP

Sponsor information

Organisation
Sheffield Hallam University (UK)

ROR
https://ror.org/019wt1929

Funder(s)

Funder type
Charity

Funder Name
Bupa Foundation (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

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	01/08/2015		Yes	No
HRA research summary			28/06/2023	No	No