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Can we successfully deliver and evaluate a physiotherapist-led behaviour-change programme to support walking in people with intermittent claudication? A feasibility and acceptability study

Submission date
05/06/2014

Recruitment status
No longer recruiting

Registration date
05/06/2014

Overall study status
Completed

Last Edited
22/11/2019

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Intermittent claudication (IC) is a symptom of leg pain that occurs during walking as a result of restricted blood supply in the arteries of the legs, called peripheral arterial disease (PAD). Despite the discomfort it causes, walking exercise can improve the distance and speed of walking. Uptake and maintenance of walking exercise is poor, and people with IC could benefit from interventions aimed at increasing motivation. A recent small-scale study showed that a psychological intervention was successful in increasing walking compared with usual care. This study aims to determine whether delivery of the intervention by a trained physiotherapist is feasible, check whether this intervention can be given to a wider group of patients at various stages of their disease, and find out about the effect on functional walking test performance.

Who can participate?
Patients with peripheral arterial disease who have symptoms of intermittent claudication.

What does the study involve?
First, you will be asked to visit Kings College London (Guys Campus, London Bridge) for a 90-minute appointment. You will be asked to complete a 6-minute walking test along a flat indoor surface. During the walk, you will be able to stop and rest at any point, to relieve any leg pain or if you are tired. You will then be able to sit and recover while you complete a set of questionnaires that ask about your beliefs about PAD, walking as a treatment, and your diet. Then, you will be given a pedometer, which is a small device you can wear on your waistband and which counts the steps you take. You will be asked to take the pedometer home with you and wear this during the day for the next 6 days. Over the next 2 weeks a physiotherapist will visit you in your home on two separate occasions, to pick up the pedometer and to discuss your beliefs about PAD and to set goals and plans for healthy lifestyle changes. These visits will last 60 minutes and will take place at a time that is convenient for you. The physiotherapist will

telephone you after 4 and 8 weeks to see how you are getting on with your goals and to help you address any problems or challenges in achieving your goals. At the end of the study, you will be asked to visit Kings College London for a second appointment where you will repeat the 6-minute walk test, fill out a set of questionnaires and be given a pedometer to take home once again. You will also be given a postage paid envelope that you can return the pedometer in once you are finished wearing it. You may be invited to volunteer and provide feedback on your experience of the intervention by telephone or a face-to-face interview which will take place at Kings College London or your home. The interview will last up to 45 minutes. The audio tapes will be transcribed then destroyed. Direct quotes from the interviews may be used in the write up of the study but these will be anonymised and not able to be traced back to the participant.

What are the possible benefits and risks of participating?
A 6-minute walking test might cause leg pain, tiredness or discomfort. You will be asked to walk at a brisk pace, but will be able to stop and rest at any point during the 6 minutes. Completing questionnaires about your beliefs and health behaviours may be tiring, and may cause you to feel worried or anxious. However, you can choose not to respond to any questions you feel are inappropriate. If you have concerns about any aspect of this study, you may contact the researchers, who will do their best to answer your questions. The physiotherapist visits will provide you with information about PAD and leg pain, and will help you build goals and plans to begin healthy lifestyle changes. By completing the questionnaires, you may learn about your own thoughts and beliefs about PAD and walking as a treatment. The 6-minute walk test will provide information on your walking ability in a safe and secure environment. The information we get from this study will help us to develop a programme that aims to help people with PAD make healthy lifestyle changes.

Where is the study run from?
1. Guys & St Thomas NHS Foundation Trust, UK
2. Kings College Hospital NHS Foundation Trust UK

When is the study starting and how long is it expected to run for?
The study starts in April 2014 and runs until October 2014.

Who is funding the study?
The Dunill Medical Trust (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16709

Study information

Scientific Title
A randomised controlled trial of a physiotherapist-led behaviour-change intervention targeting walking in people with intermittent claudication: a feasibility and acceptability study

Study objectives
This feasibility study evaluates 6 criteria:
1. Study retention
2. Compliance with treatment and attention-control protocols
3. Suitability of the proposed outcome measures
4. Variability of primary outcomes for sample size calculation
5. Suitability of proposed methods for evaluating treatment integrity
6. Acceptability and feasibility based on participant experiences of the trial

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West Greater Manchester West, 18/02/2014, ref: 14/NW/0089

Study design
Feasibility study of a randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Home

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Intermittent claudication due to peripheral vascular disease.

Interventions
1. Treatment: Brief home-based physiotherapist-led behaviour-change intervention targeting walking activity and using the following behaviour change techniques: social support, information about health consequences, goal setting, problem solving, action planning, self-monitoring, review of goals. Treatment will be delivered in two 60-minute face-to-face sessions by a physiotherapist at participants' home, and two 20 minute telephone follow-up calls.
2. Attention-Control: Two 60-minute home-based face-to-face sessions delivered by a physiotherapist and two 20-minute follow-up calls to match the intervention group. Content will address risk factors for peripheral arterial disease and dietary behaviour.

Intervention Type
Behavioural

Primary outcome measure
1. Change in 6-Minute Walk Distance (metres) at 16-week follow-up, measured by a 6-Minute Walk Test;
2. Change in pedometer Step Count (average steps/day) at 16-week follow-up, measured using an Omron Walking Style Pro.

Secondary outcome measures
1. Change in treatment cognitions measured by a Theory of Planned Behaviour Questionnaire at 16-week follow-up
2. Change in illness cognitions measured by the Revised Illness Perceptions Questionnaire at 16-week follow-up
3. Change in self-regulatory processes measured by a modified questionnaire on Action Planning and Action Control at 16-week follow-up

Overall study start date
01/02/2014

Completion date
01/04/2014

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Peripheral arterial disease and intermittent claudication as established by a vascular clinician,

and based on arterial palpitation, or results of angiography, computed tomography, or MRI scanning.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 24; UK Sample Size: 24

Total final enrolment
24

Key exclusion criteria
1. Presence of a condition for which it is unadvisable to increase walking (e.g., unstable angina)
2. Endovascular treatment or bypass surgery scheduled in the upcoming 4 months
3. Comorbidity which limits walking to a greater extent than intermittent claudication
4. Inability or refusal to provide informed consent
5. Inability to comprehend English

Date of first enrolment
03/04/2014

Date of final enrolment
01/10/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's & St Thomas' NHS Foundation Trust
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
King’s College Hospital NHS Foundation Trust
Denmark Hill
London
United Kingdom
SE5 9RS

Sponsor information

Organisation
King's College London

Sponsor details
Guy's Campus
London
England
United Kingdom
SE1 1UL

Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
The Dunill Medical Trust (UK); Grant Codes: RTF09/0110

Results and Publications

Publication and dissemination plan
Not provided at time of registration

2016 results published in thesis: https://kclpure.kcl.ac.uk/portal/files/51618152/2016_Galea_Holmes_Melissa_N_0934448_ethesis.pdf

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	01/06/2019	22/11/2019	Yes	No
HRA research summary			28/06/2023	No	No