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Motivating structured walking activity in intermittent claudication

Submission date
31/07/2017

Recruitment status
No longer recruiting

Registration date
02/08/2017

Overall study status
Completed

Last Edited
19/09/2023

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Peripheral arterial disease can cause leg pain or discomfort (called intermittent claudication (IC)), which limits the ability to walk and carry out everyday activities. Lifestyle changes, like increasing walking, can lead to improvements, but can be a challenge to begin and then continue. The aim of this study is to investigate if a physiotherapist-led, behaviour change treatment effects walking in people with IC. The treatment is designed to build an understanding of IC and walking exercise and help individuals develop strategies to increase regular walking.

Who can participate?
Adults aged 50 years or older who have IC

What does the study involve?
Participants attend a study visit to complete two short walking tests and answer questionnaires about their daily activities, beliefs about their symptoms and treatment, quality of life and the costs of having IC. Participants are then randomly allocated to one of two groups. Those in the first group receive the new treatment which involves two 60-minute face-to-face sessions (at the participant's home or local hospital) and two 20-minute telephone calls with a physiotherapist to discuss participants' understanding and beliefs about IC, walking and help participants to set goals and plans to increase walking over 12 weeks. Participants are provided with a step counter (pedometer) and walking record. Those in the second group receive their normal care. After 3 months, all participants attend a second appointment where they will repeat the walking tests and fill out another set of questionnaires. A final set of questionnaires are completed by all participants after 6 months (by post or electronically). Some participants will be invited to provide feedback on their experience of the treatment and trial by telephone or a face-to-face interview with a researcher.

What are the possible benefits and risks of participating?
Participants may benefit from receiving consultations with a physiotherapist, and receiving a step counter and walking diary which can help them increase their walking ability. Participants may benefit from completing a walk test and learning about their own walking ability and walking as a treatment for intermittent claudication. Participants who engage in the walking

activity may experience an increase in pain or discomfort. The treatment involves education and reassurance that these symptoms are unpleasant but do not indicate harm.

Where is the study run from?
Guy's Hospital (UK)

When is the study starting and how long is it expected to run for?
July 2017 to July 2020

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

Who is the main contact?
Dr Lindsay Bearne, Lindsay.bearne@kcl.ac.uk
(updated 18/11/2020, previously: Dr Julie Bieles, julie.bieles@kcl.ac.uk)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
215024

ClinicalTrials.gov number
NCT03238222

Secondary identifying numbers
CPMS 34022, IRAS 215024

Study information

Scientific Title
A brief physiotherapist-led behaviour-change intervention to facilitate walking in older people with peripheral arterial disease: a randomised controlled trial

Acronym
MOSAIC

Study objectives
The aim of this study is to answer the questions:
1. Does MOSAIC improve walking ability (measured by the 6 Minute Walking Distance [6MWD]) at 3 months compared to usual NHS care in older people with intermittent claudication (IC)?
2. Does MOSAIC improve activities of daily living and QoL at 3 months and walking ability, activities of daily living and QoL at 6 months compared to usual NHS care in people with IC?
3. Is it feasible to collect the measures required to estimate cost utility in future phase 3 trials in people with IC?
4. What are the Mean Clinically Important Difference (MCID) thresholds for the assessment measures in this population?

Ethics approval required
Old ethics approval format

Ethics approval(s)
London-Bloomsbury Research Ethics Committee, 27/04/2017, 17/LO/0568

Study design
Randomised; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Physical, Rehabilitation

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Intermittent claudication

Interventions

Participants visit the study site to complete two short walking tests and answer questionnaires about their daily activities, beliefs about their symptoms and treatment, quality of life and the costs of having IC.

Following informed consent and completion of the baseline assessment, the participant is randomised to one of two arms. Participants are randomised at the level of the individual, stratified within recruitment site, to receive either MOSAIC plus usual NHS care or usual NHS care alone in a ratio of 1:1. The King's College London Clinical Trials Unit provides randomisation. The system is online and can be accessed 24 hours a day. The RA logs in, enters key information about the participant, and the randomisation allocation occurs instantly. Confirmation emails are generated automatically and sent to the CI (and delegated members of the research team) and trial physiotherapists delivering MOSAIC. The RA, who is the outcome assessor, is blind to group allocation. Once the participant is randomised they are given a unique trial identifying number.

Arm 1 MOSAIC Treatment: Participants in this group receive two 60-minute individual face-to-face consultations (on weeks one & two) and two 20-minute follow-up telephone calls (weeks six & 12) delivered at a convenient time and location of participant’s choice (local NHS Trust or participant’s home). All sessions are delivered by a trained Band 6/7 physiotherapist. A checklist outlining the components for each session is provided to each physiotherapist. All participants randomized to this arm are provided with a pedometer and a patient manual which include information on intermittent claudication (IC), risk factors, walking guidelines, goal setting, problem solving and action planning worksheets and a walking diary.

Arm 2 Usual Care comparison: Participants randomized to the comparison group continue to receive usual NHS care for intermittent claudication which typically consists of an initial assessment, drug therapy and simple advice to walk provided by a vascular specialist and delivered in the vascular outpatient clinic.

After 3 months, all participants attend a second appointment where they will repeat the walking tests and fill out another set of questionnaires. A final set of questionnaires are completed by all participants after 6 months (by post or electronically). Some participants are invited to provide feedback on their experience of the treatment and trial by telephone or a face-to-face interview with a researcher.

Intervention Type
Behavioural

Primary outcome measure
The 6 Minute Walking Distance (in metres) at 3 months is measured during a self-paced, standardised 6 Minute Walk Test conducted around a level, 100-foot circuit.

Secondary outcome measures
1. Pain-free and maximal walking ability measured during a 6 Minute Walk Test at baseline, 3 and 6 months
2. Self-reported maximal walking distance measured by a global single-item at baseline, 3 and 6 months
3. Self-reported walking ability measured by the Walking Estimated-Limitation Calculated by History [WELCH] questionnaire at baseline, 3 and 6 months
4. Activities of Daily Living measured by the Nottingham Extended Activities of Daily Living

[NEADL] questionnaire at baseline, 3 and 6 months
5. Quality of Life measured by the Vascular Quality of Life Questionnaire-6 [VascuQol-6] at baseline, 3 and 6 months

Process and feasibility outcomes:
1. Treatment cognitions measured by a Theory of Planned Behaviour Questionnaire (TPBQ) at baseline, 3 and 6 months
2. Illness cognitions measured by the Brief Illness Perceptions Questionnaire (BIPQ) at baseline, 3 and 6 months
3. Walking adherence measured by the Exercise Adherence Rating Scale (EARS) at baseline, 3 and 6 months
4. Resource use measured by the Client Services Receipt Inventory at baseline 3 and 6 months
5. Quality of Life measured by the EuroQuol 5D-5L (EQ-5D-5L) at baseline 3 and 6 months

Overall study start date
10/07/2017

Completion date
09/01/2021

Eligibility

Key inclusion criteria
1. ≥50 years of age
2. Established PAD (Ankle Brachial Pressure Index ≤0.90 and/or radiographic evidence [added 21/02/2019: or clinician reported diagnosis]) and IC (presence of symptoms reported on the San Diego Claudication Questionnaire (SDCQ))
3. Able to participate in MOSAIC
4. Able and willing to provide informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 192; UK Sample Size: 192

Total final enrolment
190

Key exclusion criteria
1. Unstable IC (self-reported change in symptoms in previous 3 months)
2. Walking more than 90 minutes per week (reported via Brief International Physical Activity Questionnaire
3. Contraindications to walking exercise (e.g. unstable angina) confirmed by their vascular

specialist
4. Have completed any prescribed exercise sessions in the previous 6 months or been offered prescribed exercise sessions in the next 6 months.

Date of first enrolment
10/10/2017

Date of final enrolment
20/03/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy’s Hospital
Guy’s & St Thomas’ NHS Foundation Trust
Great Maze Pond
London
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Sponsor information

Organisation
King's College London

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Sponsor type
University/education

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Dunhill Medical Trust

Alternative Name(s)
The Dunhill Medical Trust, DMT

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal, anticipated October 2021.

Intention to publish date
09/01/2022

Individual participant data (IPD) sharing plan

Current IPD sharing statement as of 14/04/2022:
Requests for sharing deidentified data should be addressed to Lindsay Bearne at lindsay.bearne@kcl.ac.uk.

Previous IPD sharing statement:
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	24/08/2019	22/11/2019	Yes	No
Results article		12/04/2022	13/04/2022	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version 6	28/08/2018	19/09/2023	No	No
Statistical Analysis Plan	version 1	08/01/2019	19/09/2023	No	No