

# Motivating structured walking activity in intermittent claudication

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<b>Registration date</b> 02/08/2017	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/09/2023	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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](mailto:Lindsay.bearne@kcl.ac.uk)  
(updated 18/11/2020, previously: Dr Julie Bieles, [julie.bieles@kcl.ac.uk](mailto:julie.bieles@kcl.ac.uk))

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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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.  $\geq 50$  years of age
2. Established PAD (Ankle Brachial Pressure Index  $\leq 0.90$  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

United Kingdom

SE1 9RT

## **Sponsor information**

**Organisation**

King's College London

**Sponsor details**

Research Management & Innovation Directorate

K0.58 King's Building

Strand Campus

London

England

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**Sponsor type**

University/education

**Organisation**

Guy's & St Thomas' NHS Foundation Trust

**Sponsor details**

R&D Department  
16th Floor  
Tower Wing  
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Great Maze Pond  
London  
England  
United Kingdom  
SE1 9RT

**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](mailto: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?
<a href="#">Protocol article</a>	protocol	24/08/2019	22/11/2019	Yes	No
<a href="#">Results article</a>		12/04/2022	13/04/2022	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol file</a>	version 6	28/08/2018	19/09/2023	No	No
<a href="#">Statistical Analysis Plan</a>	version 1	08/01/2019	19/09/2023	No	No