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A study to test a home walking programme for people living with peripheral artery disease

Submission date
04/08/2026

Recruitment status
Recruiting

Registration date
24/08/2026

Overall study status
Ongoing

Last Edited
03/09/2026

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
One in five older people has narrowing in their leg arteries (called peripheral artery disease). This causes poor circulation and pain when walking (called intermittent claudication). Walking frequently is the best way to improve this pain and reduce the risk of other health problems or severe artery disease. Unfortunately, it is hard for people to walk on their own when they are in pain. To help with this, the study team worked with patients and practitioners to design and test a new home walking exercise programme with regular physiotherapist support. It was called MOtivating Structured walking Activity in Intermittent Claudication (MOSAIC1; https://www.isrctn.com/ISRCTN14501418). When delivered in hospitals, it improved people's walking capacity and was acceptable and valued by both patients and providers. This intervention has now been adapted so it can be provided in GP practices and community services by a broader range of providers. This adapted 3-month programme will be called MOSAIC2.
The study team will now see if MOSAIC2 works, whether it is value for money for the NHS and how it can be rolled out. This feasibility study is the first phase of the research that will answer these questions. The feasibility study will assess whether MOSAIC2 can be provided in GP practices and community services well and help us design a larger trial.

Who can participate?
Patients aged at least 50 years with intermittent claudication.

What does the study involve?
Participants will be recruited from GP practices or community trusts over 6 months. The study team will train practitioners to deliver MOSAIC2. They will assess patients' activity at home, do walking and health tests and ask some questionnaires before and after completing the MOSAIC2 programme. They will also invite some patients and practitioners to give feedback on the MOSAIC2 programme and our study processes. The findings will be summarised to see if the MOSAIC2 programme or the trial plans need adapting.

What are the possible benefits and risks of participating?
Participants may benefit from increased motivation, improved walking capacity, and better mobility to support daily activities. The findings will also help research design a larger trial to improve care for people with peripheral artery disease in the NHS. The risks are low. Participants

may experience mild muscle aches, soreness, or cramps as they increase their walking activity, as well as a small risk of falls while exercising at home. To minimise these risks, participants received support from a trained healthcare professional who will tailor the walking plan to their individual ability.

Where is the study run from?
The study is sponsored by City St George's, University of London, and coordinated by the Leicester Clinicals Trials Unit, University of Leicester. This walking programme will take place across six GP practice and community health trusts across England, Scotland and Wales.

When is the study starting and how long is it expected to run for?
September 2026 to June 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Prof. Lindsay Bearne, lbearne@citystgeorges.ac.uk

Contact information

Type(s)
Scientific, Public

Contact name
None Claire Smith

Contact details
Leicester Clinical Trials Unit
College of Life Sciences
University of Leicester
Maurice Shock Building
University Road
Leicester
United Kingdom
LE1 7RH
-
mosaic2@leicester.ac.uk

Type(s)
Principal investigator

Contact name
Prof Lindsay M. Bearne

Contact details
Population Health Research Institute
School of Health and Medical Sciences
Tooting Campus
City St George's, University of London
Cranmer Terrace

London
United Kingdom
SW17 0RE
-
lbearne@citystgeorges.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
364476

Central Portfolio Management System (CPMS)
74827

National Institute for Health and Care Research (NIHR)
208123

Study information

Scientific Title
The MOtivating Structured walking Activity in Intermittent Claudication (MOSAIC2) feasibility study

Acronym
MOSAIC2

Study objectives
The feasibility of recruitment and randomisation were tested in the MOSAIC-1 trial. Therefore, the objectives of this feasibility study are to:
1. Assess MOSAIC-2 fidelity of delivery
2. Assess acceptability of provider training and MOSAIC-2 delivery
3. Identify actual implementation barriers and enablers for MOSAIC-2 adoption in primary care and community services

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/07/2026, West of Scotland Research Ethics Service (West of Scotland Research Ethics Service Admin Building, Level 2, Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow, G12 0XH, United Kingdom; -; ggc.wosres@nhs.scot), ref: 26/WS/0095

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Peripheral artery disease

Interventions
Training: At least two MOSAIC-2 professionals per site will be trained in intervention delivery. This can be any registered Nurse or Allied Health Professional (AHP) including Physicians' Associates.

We will also welcome non-traditional healthcare providers. This may include health and wellbeing practitioners, primary care Healthcare Assistants and NHS band 4 exercise technical instructors as long as they have the appropriate qualifications and area of expertise. We do require that in this instance at least one registered health professional per site will provide oversight to these non-traditional healthcare exercise providers.

Professional training is likely to include training in PAD aetiology, disease progression symptoms and management, evidence based, safe tailored exercise prescription, motivational interviewing and behaviour change principles. Training will emphasise the safety of participants ensuring that participants know to stop exercising if they develop any new symptoms and that these should be reported as an adverse event and to a GP or healthcare professional.

It is envisaged that the training will include at least 12 hours of remote asynchronous and synchronous group and individual training sessions, led by the experienced central training team including patient advisors, health psychologists, physiotherapists and primary care practitioner with physical activity expertise.

Prior to the delivery of MOSAIC-2, all providers will be trained and assessed for fidelity of delivery and proficiency of motivational interviewing using practiced scenarios. Additional training will be provided for those who do not meet the
standards required.

Training resources will be hosted on a dedicated website and monthly remote group support sessions, with the training team, will be offered to problem solve, minimise drift from the intervention, maintain skills and maximise fidelity. Developing a 'community' amongst the practitioners will be encouraged whereby they can meet and reflect on the success and the challenges of implementing MOSAIC-2 throughout the intervention delivery period. A practitioner checklist outlining session components will be provided to support this process.

Potential patient participant identification: people aged at least 50 years old with PAD, will be identified by appropriate healthcare professionals at individual sites, from electronic record searches in primary care, clinical lists in community services and health professional referrals. Patients considered for the study will be recorded on a screening log which will allow us to determine any trends, numbers of eligible patients and where provided, reasons why patients refused to participate. Collecting this information will allow us to determine if there is anything we can do to increase patients access to the larger trial as well as understanding the type of participants taking part in this research. No patient will be identifiable by the data collected on the screening log.

Patient screening: Potentially eligible patients will be approached either via WhatsApp, text, email or in person (depending on usual processes at each site) and provided with a Patient Information Leaflet (PIL) and Patient Information Sheet (PIS) and we will ask them to complete a 'permission to contact' form. We will send up to two reminders if the permission to contact form is not completed. If the 'Permission to contact' form has been submitted an appropriate researcher will contact the potential participant at a time/date that is suitable to the patient as agreed on the form. The patient will be screened against the eligibility criteria. If eligible, the risks and benefits of participating in the study will be explained to the patient and they will be given the opportunity to ask any questions.

Consent: Only once they understand the requirements of the study will the patient be asked if they have read the PIS and if so, asked if they are willing to consent and if agreed they will receive a link to the consent form. This link will also contain a localised PIS as well as the local practice contact details. After reading the consent form, and using the check boxes as evidence they agree with each statement they will submit the form.

Should the participant have any difficulties using the link, or they are unfamiliar with this technology, then they can ask for an appropriately delegated person to help them with the consent process. This person can complete the consent form on the patient's behalf. They will need to read out each point of the consent, ensuring the patient understands and agrees before moving onto the next point. The person taking consent will then need to read the declaration at the bottom of the consent form and provide their details as evidence it was done on behalf of the patient who fully understood what they were consenting to.

If an electronic consent form cannot be completed (i.e., due to internet connectivity issues), a paper consent form can be used and the research can transcribe the data onto the electronic data base as soon as possible. A copy of the consent form will be available to the participant.

Procedure: The consent form will require the participant to provide address details. These address details will be made available to the Leicester Lifestyle & Health Research Group so they can send the participant an accelerometer. This is essential to the study to record a participants step count and usual activity prior to attending their first assessment. Participants will also receive a diary to record wake and sleep duration and a self-addressed envelope so the accelerometer can be returned. The address will also be used by the research team at the City of St George's so the participant is sent a voucher once the accelerometer is returned. The accelerometer is to be worn for at least 7 days prior to the baseline assessment.

At the baseline assessment the participant will be provided questionnaires to complete and the assessor will obtain other details necessary for the study which will be recorded on the database. There will also be a number of tests to complete including; an ankle brachial pressure index, blood pressure and a 6-minute walking distance test.

We will seek consent to notify their General Practitioner of their participation in the trial.

After the baseline assessment participants will receive the 3-month MOSAIC2 programme delivered by a trained practitioner. This is up to 6 sessions, delivered in-person, remote or telephone sessions as per participant preference. Session duration will vary, depending on content included. The content of these sessions will be tailored to each participant and will depend upon each person's own knowledge and current walking exercise behaviour. The practitioner will help participants identify their current abilities and goals and to increase their motivation and commitment to walking exercise. A tailored walking plan that the participant will complete at home will be developed. The challenges of completing the walking exercise programme and how to overcome them will be discussed.

Participants will be offered a step counter and a revised workbook. This will include information to support walking exercise such as information on intermittent claudication, risk factors and walking guidelines. It will include an exercise diary, which has been revised from the original MOSAIC trial (with adaptations included from earlier MOSAIC2 work packages), to document exercise frequency, intensity and time, goal setting, problem-solving and action planning worksheets. All materials will be offered in a variety of formats, so participants can receive these electronically or in paper form. All intervention sessions will be audio recorded and assessed to ensure MOSAIC2 is being delivered well and as this will help determine our progression criteria.

Towards the end of MOSAIC2 participants will be sent another wrist worn activity tracker and attend one more in person
appointment to repeat the health assessments and questionnaires.

As part of the feasibility, we also want to ensure that the design of the study is suitable to both participants and professionals in a primary care setting. These qualitative interviews will be conducted with up to 12 patients (2 participants per site) by one researcher. Focus groups will be conducted with at least 6 providers (one provider per site) and 6 service planners. This will provide rapid feedback on acceptability of training and MOSAIC2 delivery and actual barriers and enablers to implementation. The following will be used to determine the suitability of MOSAIC-2 in primary care:
1. Intervention Acceptability Questionnaire
2. Intervention Feasibility Questionnaire
3. Intervention Appropriateness Questionnaire
4. Intention to adopt the intervention – single item from Theory of Planned Behaviour Questionnaire

Qualitative interviews will be conducted with up to 12 patients (2 participants per site) by one researcher. Focus groups will be conducted with at least 6 providers (one provider per site) and 6 service planners. If anyone is unable to attend then a interview can be arranged at a time to suit them. This will provide rapid feedback on acceptability of training and MOSAIC2 delivery and actual barriers and enablers to implementation. Data will be analysed thematically, as well as drawing on COM-B - a widely used behavioural science framework proposing that for any behavior to occur, an individual must have the Capability, Opportunity, and Motivation.

Public involvement: PPI&E played an instrumental role in the design of the study including the development of the intervention and study materials They will continue to contribute through public advisory groups and dissemination activities.

Two of the co-applicants are public advisors with over a decade of lived experience of PAD. One has been part of the research team since 2016, contributing to the MOSAIC-1 public advisory

group which shaped the intervention design and contributed to research management, oversight and provider training which will be pivotal to the development of MOSAIC-2. A second public advisor joined the team to prepare the MOSAIC2 funding application, sharing patient views on which settings and non-traditional exercise providers would be acceptable and credible for patients.

The co-applicant public advisors will also attend research management meetings and contribute to designing and delivering knowledge mobilisation and dissemination strategies at patient forums and events.

Alongside the public advisory group, wider PPI&E will provide the patient perspective throughout the programme. Representation is included from urban (London) and rural (Leicestershire) areas. Two community engagement officers from underrepresented communities will help us engage with ethnic minority communities and comment on public facing documentation to ensure suitability.

Intervention Type
Behavioural

Primary outcome(s)
1. Fidelity of delivery measured using audio recording and evaluating intervention sessions against a practitioner checklist at 3 months (during/at completion of the 3-month programme)

2. Proficiency of motivational interviewing measured using audio records of practitioner sessions at 3 months (during/at completion of the 3-month programme)

3. Acceptability and implementability measured using the Intervention Acceptability Questionnaire, Intervention Feasibility Questionnaire, Intervention Appropriateness Questionnaire, and Theory of Planned Behaviour Questionnaire at baseline and 4 months

Key secondary outcome(s)
1. Physical activity: daily step count measured using a wrist-worn accelerometer for 7 days at baseline and 4 months
2. Walking capacity measured using the 6-minute walking test (6MWT) at baseline and 4 months
3. Claudication symptoms measured using the self-reported San Diego Claudication Questionnaire at baseline and 4 months
4. Walking impairment and self-efficacy measured using questionnaires assessing walking distance/speed, illness perceptions, self-efficacy, and walking habit strength at baseline and 4 months
5. Quality of life measured using the SF-36 Physical Functioning Scale and EQ-5D-5L Questionnaire at baseline and 4 months
6. Vascular parameters: ankle-brachial pressure index (ABPI) and blood pressure measured using a blood pressure cuff and a handheld Doppler at baseline
7. Resource usage measured using a modified Adult Services Use Schedule and routine medical records at 4 months

Completion date
30/06/2027

Eligibility

Key inclusion criteria
1. Adults aged 50 years or older
2. Established PAD recorded in medical records based on:
2.1. Ankle-brachial pressure index (ABPI) of 0.90 or less
2.2. Radiographic evidence of PAD or
2.3. Clinician-reported diagnosis of PAD
2.4. People with an ABPI >0.90 will be enrolled if there is other evidence of PAD (e.g., clinical diagnosis; radiographic evidence of PAD determined by the consulting clinician, toe pressure <70 mmHg or toe brachial index ratio of <0.60 if asymptomatic or <0.70 if symptomatic)
3. Symptomatic leg pain defined by one of the following:
3.1. Ischaemic leg symptoms identified using the self-reported San Diego Claudication Questionnaire
3.2. Interview with potential participant about presence and nature of leg symptoms during walking activity
4. Sufficient grasp of the English language to participate in a dialogue- based intervention
5. Ability to participate in the trial and provide informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. From Read code search of primary/community care records: Major amputation, wheelchair confinement, having a foot ulcer or critical limb ischaemia
1. From Read code search of primary/community care records: housebound; terminal illness; > 3 falls in previous year; dementia or significant cognitive impairment, psychotic illness; registered blind; new onset chest pain, myocardial infarction, coronary artery bypass graft or angioplasty within the last 3 months
3. From Read code search of primary/community care records: Major surgery including individuals that have had lower extremity revascularisation (and now have normal ABPI) or orthopaedic surgery (that still compromises walking ability) during the prior 3 months or anticipated in the next 6 months
4. Those without self-reported ischaemic leg symptoms during walking or having a walking limitation for a self-reported reason other than PAD or anticipate having major surgery or orthopaedic surgery affecting walking ability in the next 6 months

5. Self-reported completion of any medically prescribed supervised exercise intervention or exercise trial in the previous 3 months or planned participation in prescribed supervised exercise in the next 6 months

Date of first enrolment
01/09/2026

Date of final enrolment
28/02/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Market Harborough Med.ctr
67 Coventry Road
Market Harborough
England
LE16 9BX

Study participating centre
Leeds Community Child and Adolescent Mental Health Services
Kirkstall Health Centre
15 Morris Lane
Leeds
England
LS5 3DB

Study participating centre
The Valleys Medical Partnership
Gosber Road
Eckington
Sheffield
England
S21 4BZ

Study participating centre
Cornwall Partnership NHS Foundation Trust
Carew House

Beacon Technology Park
Dunmere Road
Bodmin
England
PL31 2QN

Sponsor information

Organisation
City St George's, University of London

ROR
https://ror.org/047ybhc09

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Lindsay Bearne (lbearne@citystgeorges.ac.uk).
Type of data: De-identified individual participant data and anonymised data.
Access: Available upon reasonable request for ethically approved research, subject to a formal

data sharing agreement and institutional information governance approval.
Participant consent: Specific consent for potential sharing of anonymised data for future ethically approved research is obtained from participants at consent.
Data anonymisation: All data will be fully anonymised/de-identified prior to sharing to ensure confidentiality in accordance with UK GDPR and the Data Protection Act 2018.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			03/09/2026	No	No
Participant information sheet	version 1.1	02/07/2026	18/08/2026	No	Yes