MOtivating Structured walking Activity in people with Intermittent Claudication

PATIENT PARTICIPANT INFORMATION SHEET:

MOSAIC2 FEASIBILITY STUDY

Chief Investigator: Prof Lindsay Bearne

You can contact the research team:

<<Insert Principal Investigator name>>

<<Insert local location contact details>>

This information sheet will provide you with information about the study. You do not have to take part. If you do agree to take part, then you are free to withdraw at a later date. You can find information on how to do this later in this information sheet.

Summary

- You are being invited to participate in the MOSAIC2 feasibility study.
- You have been invited because you are aged 50 years old or over and have been diagnosed with peripheral artery disease, which causes leg pain while walking.
- In this study, you will complete a walking test, some health assessments, and questionnaires before and after you complete the MOtivating Structured walking Activity in Intermittent Claudication (MOSAIC2) programme. This will take place as an in-person appointment. You will also be asked to wear a wrist-worn activity tracker at home.
- You will then complete the 3-month MOSAIC2 programme. You will attend a series of sessions with a trained practitioner to help you start and continue to do walking exercise at home. These sessions can be delivered in person, via video call or the telephone.
- After completing the MOSAIC2 programme, you may be invited to be interviewed by a researcher from City St George's, University of London. This interview will discuss your experiences of MOSAIC2 and the study to help us improve these.
- In this study, we will use information from you, your medical records and your GP. We will only collect information that is necessary. We will let very few people know your name or contact details, and only if they really need it for this study.

- Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.
- If you agree to it on the consent form, at the end of the study, we will save some of the data in case we need to check it or for future research.
- We will make sure no-one can work out who you are from the reports we write.
- The end of the study will be when all data is collected from all participants and we can consider that this data is correct as possible.

Invitation to Participate

You have been asked to take part in this study because you have peripheral artery disease, also referred to as PAD. PAD is a common condition where the arteries in your leg(s) become narrowed by a build-up of fatty deposits, meaning that the blood flow to your leg(s) is reduced. It can lead to symptoms such as leg pain, cramping or tiredness when walking, which usually eases with rest. This symptom is called intermittent claudication.

The purpose of this information sheet is to explain the MOSAIC2 feasibility study and to seek your permission to take part in this study.

To help you decide whether to take part, it is important for you to understand why the study is being done, what it will involve and what you will need to do. Please take time to read this information sheet carefully and discuss with others if you wish. It is up to you to decide whether or not to take part. If you decide to take part, you may still change your mind at any time during the study. A decision to withdraw or decline taking part will not affect the medical care you receive.

If there is any part of this information sheet that you do not understand, or if you require further information, please contact us and we will be happy to answer any questions. Our contact details are on the final page.

What is the purpose of this study?

One in five older people have narrowing in their leg arteries due to peripheral artery disease. This causes poor circulation and pain when walking. This leg pain is 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, we have designed a supported, home-based walking exercise programme. This three-month programme aims to help people with intermittent claudication start and continue walking exercise at home. It is called MOtivating Structured walking Activity in Intermittent Claudication (MOSAIC2). In this study we want to see if MOSAIC2 can be

provided in GP practices and local community hospitals and if it is acceptable to participants.

What will happen if I take part?

Event Schedule	Approximate Duration
Consent A member of the study team will talk to you on the telephone to check that you are eligible for the study and answer any questions. If you decide you would like to take part, you will be sent an electronic link to complete and submit a consent form. If it is not possible for you to fill in the consent form on your computer, a member of the study team will talk you through the consent process on the telephone and, with your agreement, sign a consent form on your behalf. You will be provided with a copy of the consent form for your records.	30 minutes
Activity monitoring at home Once you have consented to take part in the study, you will be sent a wrist-worn activity tracker to wear at home for 9 days. The tracker should be worn all the time, except when swimming. You will be sent a log to record when you are asleep each day and a prepaid postage envelope to return the activity tracker and log.	15 minutes
Assessment Information about you and your condition, medical history, medications, health assessments, walking test and study-related questionnaires will be completed with you, in-person at your GP practice or community hospital.	70 minutes
MOtivating Structured walking Activity in Intermittent Claudication (MOSAIC2) programme MOSAIC2 includes up to six meetings with a trained professional from your GP practice or local community hospital over 3 months. In the meetings, the practitioner will talk to you about the causes of your leg pain, how walking can help and how you can overcome walking difficulties. You will agree a walking plan to do at home and will be offered a step counter and a workbook	2-2.5 hours in total

to help you monitor your progress. You will complete your planned walking exercise at home. These meetings can be in-person, via video call or telephone, depending on your preference. We record the meetings and we will download and listen to the audio recording to check the treatment has been delivered well.	
Activity monitoring at home Before the end of the MOSAIC2 programme you will be sent a wrist-worn activity tracker to wear at home (except when swimming) with a paper sleep log and a stamped addressed envelope so you can return the activity tracker. You will wear this for 4 weeks continuously (3 weeks before MOSAIC2 ends and one week after).	15 minutes
Assessment Health assessments, walking test and questionnaires will be completed with you in-person again.	70 minutes
Optional interview If you have consented and been invited to be interviewed, a researcher will contact you and arrange a video call or telephone interview.	Up to 45 minutes

We want you to feel comfortable, so please feel free to bring a friend, family member or carer along to your sessions. While they are there to support you and listen to the discussion, the assessments and interviews are designed to capture your unique thoughts and feelings. For this reason, we will ask that you provide all the answers yourself.

What are the risks?

There are minimal risks associated with this study. During the study you will be supported to start and continue walking exercise at home. As with any exercise, you may experience some muscle or joint discomfort. There may be a small increase in the risk of falls as you are increasing your walking exercise at home.

If you experience any new chest pain, angina, breathlessness, dizziness or collapse, then you should stop the programme and discuss any new symptoms urgently with your GP. If the effects do not dissipate upon stopping, then emergency services should be contacted.

Whilst we do not expect any of the assessments, questionnaires or topics discussed in the optional interviews to be upsetting, if you feel distressed at any time, you can contact a member of the site study team including the site principal investigator. They will talk to you and help you access the relevant resources and forms of support.

What are the benefits?

Because you will be completing a new home-based walking exercise programme, this may improve your walking capacity and your overall health.

Your participation may help improve treatment for others with intermittent claudication in GP practices and community hospitals.

Are there any financial incentives?

We will compensate participants for any travel expenses to research assessment visits outside of the normal standard of care. This includes any parking charges. You will need to provide receipts as evidence of your claim.

As part of the research assessment, you will wear a wrist-worn activity tracker at home (except when swimming). As a thank you for returning the accelerometer, you will be offered a £10 shopping voucher on each occasion.

What if new information becomes available?

Sometimes during a research project, new information becomes available about the treatment that is being studied. If this happens, a researcher will tell you about it and discuss whether you want to or should continue in the study. If you decide not to carry on, a researcher will make arrangements for your care to continue as per normal. If you decide to continue in the study, you will be asked to sign an updated consent form. Also, on receiving new information your researcher might consider it in your best interest to withdraw you from the study. The researcher will explain the reasons and arrange for your care to continue. If the study is stopped for any other reason, you will be told why and your continuing care will be arranged.

What if something goes wrong?

It is very unlikely that you will be harmed by taking part in this type of research study. However, if you wish to complain or have any concerns about the way you have been treated in connection with the study, you should ask to speak to the local study team on <<Insert local site contact details>> who will do their best to answer your questions.

If you remain unhappy and wish to address your concerns or complaints on a formal basis you should contact the Patient Information and Liaison Service (PALS) or local complaints service on <<Insert local details here>>.

If something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against

City St George's, University of London but you may have to pay your legal costs. The normal NHS complaints service will still be available to you.

How will we use information about you?

We will need to use information from you, from your medical records and your GP for this research project.

This information will include your:

- Name
- NHS Number
- Date of birth
- Sex/gender
- Date of death (if applicable)
- Ethnicity
- Address
- Email address
- Telephone number

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a unique code number instead.

City St George's, University of London is the sponsor of this research. They are responsible for looking after your information. They will also use your contact information for study processes such as arranging interviews, sending thank you vouchers, and reviewing recorded treatment sessions to check that the sessions have been delivered well by the professionals.

We will share your information related to this research project with the following organisations:

- Leicester Clinical Trials Unit, who will be collecting and analysing the data on behalf of the sponsor.
- Leicester Lifestyle & Health Research Group, at the University of Leicester, will be sending out wrist-worn activity trackers, as well as collecting and analysing your activity data.
- Kings College London, who will receive only de-identified (pseudonymised) data to analyse the health economics questionnaire data.
- An independent, approved transcription service, if required, for individuals who have participated in the optional interviews.

- If there are any safety concerns about this study, then we may make your data available to an independent committee to ensure that we do not put participants at any risk.

Confidentiality

We will keep all information about you safe and secure by:

- Making sure only those who need it will have your contact information.
- Storing electronic data on secure university servers.
- Deidentifying (pseudonymised) your data by assigning you a unique code.

What Will Happen to the Results?

The results will be shared with healthcare professionals, published in journals, presented at conferences and we will share this information on the MOSAIC2 website. You will not be identified in any publication.

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep all your personal data for up to 1 year after the end of the study.

However, if you have told us on the consent form that you want to receive study communications, then your name and contact details will be held for ten years after the study has finished in a password protected, university networked drive, then deleted.

If you have told us on the consent form that you want to be contacted about future studies, then we will keep your contact details until such time that the sponsor feels it is no longer required.

After this, only select electronic de-identified data will be stored for use in potential future ethically approved research. Other study data will be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

Further information on how data is used in research is available on the NHS Health Research Authority website: www.hra.nhs.uk/patientdataandresearch. If you would like a printed copy, please ask a member of the study team.

You can also find out more about how we use your information:

- by asking one of the research team
- by sending an email to mosaic2@leicester.ac.uk
- by emailing the City St George's, University of London Data Protection Officer - dataprotection@citystgeorges.ac.uk

There is also additional information on the Sponsor's website which can be found here: www.citystgeorges.ac.uk/research/support/data/active-research-data.

Contact for Further Information:

If you have any questions or concerns, please contact the study team at your local site. These can be found on the first page, at the top of the document.