DO YOU HAVE TYPE 2 DIABETES?

“Are you interested to learn how we might help prevent diabetic foot ulcers in the future?”

IF YOU WOULD LIKE A COPY OF THIS LEAFLET IN A LARGER FONT.

PLEASE CONTACT THE RESEARCH TEAM AND WE WILL SEND YOU ONE.

Contact [researcher name] using either of the following methods:
Phone: [insert phone number]
Email: [insert email address]

Participant information sheet

Title of Project: SOCKSESS - Measurement of Foot Shear Stress for discriminating between patients with and without diabetic peripheral neuropathy

Version: 2.0

Version date: 25/07/2024

IRAS Project ID: 338459

Your participation, your choice

Before you decide whether to take part, it is essential to understand the purpose of the study and what it involves. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that needs to be clarified or if you would like more information. Please take your time to decide whether you wish to take part.

Why have you been selected?

You have been invited to participate in this study because you have been diagnosed with type 2 diabetes. We are looking for people with type 2 diabetes with and without loss of sensitivity in the feet (or with and without diabetic peripheral neuropathy).

What is the purpose of the study?

Diabetes damages nerves in the feet, known as 'neuropathy', affecting up to half the population with diabetes. This complication of diabetes causes loss of sensation and increases the susceptibility to skin breakdown because of high levels of vertical pressure and shear stresses (i.e., a force that acts along an area of skin) to the feet. These factors predispose people with neuropathy to foot ulcers (holes in the skin), which may lead, if they become infected, to foot and leg amputations. There are over 120 amputations in the UK every week because of a diabetic foot ulcer.

Currently, there is no tool to assess shear stress (rubbing on the feet) in people with diabetes. Our project is testing a new way to measure shear stresses, including wearing custom socks in diabetic patients with and without impaired sensation during walking. We want to test if our approach can tell the difference between people with and without loss of sensation and increase the knowledge of the factors (e.g., walking speed, etc.) affecting shear stress during walking.

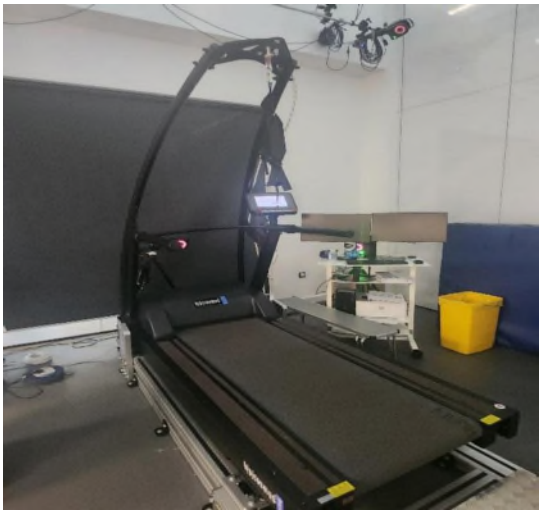
Do I have to take part?

No, your participation is entirely voluntary, and it's up to you to decide whether to take part. If you choose to participate, you can withdraw from the study at any time without giving a reason. This will not affect the care you receive now or in the future.

What will I have to do if I take part?

If you accept the invitation to participate in the study, you will be asked to visit the Gait and Biomechanics Laboratory of Manchester Metropolitan University for only one day, during which you will be asked to walk on a treadmill (Figure 1) while we do a few different assessments, including walking in our socks with and without your shoes for short periods (30 seconds at a time).

Figure 1. Treadmill system with body weight support.



During the visit, we will check whether you meet the details of the people we need to take part (the eligibility criteria) and ask you to sign a consent form. We will explain the details of the study and will give you the opportunity to ask any questions. We will also test your foot sensitivity and ask some questions about your medical history.

If you meet the criteria, you will be asked to wear the custom socks (Figure 2) and photos of your feet with and without the socks will be taken. You will wear a new pair of custom socks to exclude any skin infection. You will then be asked to complete a series of simple tests to assess foot pressure and how you walk wearing socks (with and without your shoes) during level and inclined (slightly uphill) walking on the treadmill. Custom socks will consist of cotton, nylon, elastic and lycra yarns, and stretch sensors printed on different parts of socks (e.g., big toe, metatarsal heads). These sensors will be connected via conductive fibre with a small chip-based amplifier, microcontroller, and Bluetooth unit located at the top of the sock. Socks are produced at the Manchester Fashion Institute of the Manchester Metropolitan University. At the end of the walking tests, you will be asked to complete a questionnaire about the comfort of the custom socks. Finally, we will also ask you to wear two different commercial diabetic socks (new pairs) and complete a questionnaire for each pair of socks to have your feedback on their comfort.

Specifically, we will assess your:

- **Feet sensation and blood circulation:** The level of sensation you can feel on the soles of your feet will be assessed by asking if you can feel light touch, vibrations at different levels, temperature differences and reflex tests. Foot pulses will be checked by touching specific parts of your feet.

- **Medical history**: We will ask a few questions about your medical history to collect information on the type and duration of your diabetes, previous foot complications, the presence of other conditions, and any medications you currently are taking.

- **Gait and balance analysis:** You will be asked to complete level and inclined walking tests on a treadmill wearing socks with and without your shoes. We will only ask you to walk for 30 seconds at a time and ask you to repeat this four times with rest in between. There will be plenty of rest in between each walk. For these assessments, you will be asked to wear close-fitting shorts and reflective balls will be placed onto your legs to allow us to track your movements.
  Before starting any tests, you will be familiarised with the treadmill and if you are not comfortable, you will not continue the study. There is a minimal risk of rubbing or skin damage to the feet during walking; this will be checked by the researcher after each walk, and in case of a skin issue, you will be asked to stop the walking activities. We will also collect some photos of the problem and send them, with your consent, to the research podiatrist for advice on whether you should continue the study and what further treatment you need.
  User feedback: At the end of the walking tests, you will complete a questionnaire about the comfort of the custom socks. You will also be asked to wear two different commercial diabetic socks and complete the same questionnaire you completed for the custom socks, two times.

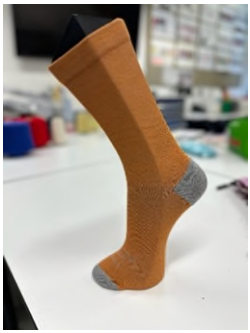


Figure 2. Custom socks with embedded stretch sensors.

How long will it take?
The study will require only one visit, which will last about 2 hours in total (a lot of this will be setup and measurement preparation time). During this time, you can take breaks, and drinks (e.g., tea, coffee, and cold drinks) will be available.

Are there any possible benefits?
There are no direct benefits from taking part in the current study. However, this study has been developed to inform future research, that may contribute towards reducing the occurrence of foot ulcers in people with diabetes.

Are there any risks of taking part?
As you will be asked to walk without shoes, there is a small risk of discomfort or rubbing. However, this risk will be minimised by you only walking for short durations (30 seconds at a time) and we will check your feet carefully after each walking test.

Because you will be asked to walk on a treadmill, you will be asked to wear a harness to prevent any falling in case this happens. Activities will be separated by breaks to ensure you have time to rest and recover, thereby avoiding fatigue.

Reimbursement of travel expenses
We can reimburse reasonable travel expenses. This will be discussed with you when you make your appointment. We will pay for train tickets/parking in advance in order to make things as easy as possible for you.

If you would like to travel by taxi, you can discuss this with the research team when you schedule your appointment. We can provide paid-taxi transport within most 'reasonable' distances from the university.

What happens upon completion of the study?
You will have the opportunity to receive a summary of the results of the study once it is completed. You can let us know whether you prefer to receive the summary via post or email. To appreciate your help and the time you will spend on the study, we will give you a £20 Amazon voucher at the end of the study.

Who has reviewed the study?

The study has been reviewed by members of the research team at Manchester Metropolitan University, the University of Leeds, University of Southampton and East London. It has been reviewed by independent expert reviewers as part of the grant review process for the funder (the Engineering and Physical Sciences Research Council; EPSRC). The sponsor, Lancaster University, has also reviewed the study. The procedures of the study have been reviewed by members of the East Midlands – Nottingham 2 NHS Research Ethics Committee.

How will we use information about you?
We will need to use information from you for this research project. All personal information will be used according to the General Data Protection Regulations (GDPR) and the information below.

This information will include your name and contact details. The research team will use this information to do the research or check your records to ensure 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 code number instead.

We will keep all information about you safe and secure.

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.

All personal information will be kept no longer than two years after the study end date.

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 non-identifiable information about you that we already have. If you withdraw, your name and contact details will be deleted from the records to remove any identifiable information related to you.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

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

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

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to Information Governance Manager: Michael.abbotts@lancaster.ac.uk or
- by ringing us on [**insert phone number for research team**].

What happens upon completion of the study?

You will have the opportunity to receive a summary of the results of the study once it is completed. You can let us know whether you prefer to receive the summary via post or email. If you consent to this, your contact details will be stored for this purpose until the summary has been sent to you. To appreciate your help and the time you will spend on the study, we will give you a £20 Amazon voucher at the end of the study.

What if I have any concerns?

If you have a concern about any aspect of this study you can speak to the research team who will do their best to answer your questions (Researcher: [INSERT RESEARCHER CONTACT NAME EMAIL AND PHONE]; or Chief Investigator: Prof. Neil Reeves: n.d.reeves1@lancaster.ac.uk).

If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to the researcher, you can contact:

Dr Jemma Kerns
Senior Lecturer and Director of Research
Email: j.kerns@lancaster.ac.uk
Lancaster Medical School
Lancaster University
Lancaster
LA1 4YW

If you wish to speak to someone outside of the Medical School, you may also contact:

Professor Steven Jones

Chair of FHM REC Email: s.jones7@lancaster.ac.uk
Faculty of Health and Medicine
Lancaster University
Lancaster
LA1 4YG

Lancaster University holds appropriate indemnity cover which includes but is not limited to Public Liability, Professional Indemnity and Employers Liability Insurance. If you are harmed whilst taking part in this study as a result of negligence by Lancaster University or its staff members, you may have grounds for legal action and should obtain independent legal advice. Non-negligent harm is not covered, and any claims that arise may be referred to the insurance provider for assessment. Should you require more information on the indemnity cover that Lancaster University holds, please contact the researcher. .

The normal National Health Service complaints mechanism is also available to you (if appropriate). For independent advice, you may contact the Patient Advisory and Liaison Service (PALS) on 0161 276 8686.

Who has funded the study?

This study has been funded by EPSRC – Grant agreement ID: EP/X001059/2

Who should I contact if I am interested in taking part?
[INSERT RESEARCHER NAME]
Phone: [INSERT RESEARCHER PHONE NUMBER]

By post: [INSERT RESEARCHER NAME], Health Innovation One, Faculty of Health and Medicine, Lancaster University, Lancaster LA1 4YW.