

# Smart technology for diabetic foot monitoring

<b>Submission date</b>	<b>Recruitment status</b>	<input checked="" type="checkbox"/> Prospectively registered
18/03/2025	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
27/03/2025	Completed	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
02/01/2026	Nutritional, Metabolic, Endocrine	<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Diabetes can damage nerves in the feet, leading to loss of sensation and increased risk of foot ulcers and amputations due to high pressure and rubbing forces (shear stress). Currently, there's no reliable way to measure shear stress in diabetic patients. This study aims to test a new method using custom socks to measure shear stress during walking in people with and without diabetic nerve damage, to see if it can differentiate between them and identify factors affecting shear stress.

### Who can participate?

1. Adults with type 2 diabetes, with or without loss of sensation in their feet, who can walk independently.
2. Patients without diabetic peripheral neuropathy - Absence of diabetic peripheral neuropathy
3. Patients with diabetic peripheral neuropathy
4. Capable of walking independently (>50 metres)
5. Aged over 18 years
6. Presence of at least one pedal pulse

### What does the study involve?

Participants will visit the lab for one day and walk on a treadmill while wearing custom socks, with and without shoes, for short periods. Foot sensation, medical history, and walking patterns will be assessed. Participants will also provide feedback on the comfort of the socks.

### What are the possible benefits and risks of participating?

There are no direct benefits, but the study will help develop better ways to prevent foot ulcers in diabetic patients. There's a small risk of discomfort or rubbing during walking, which will be minimized and monitored.

### Where is the study run from?

Gait and Biomechanics Laboratory, Manchester Metropolitan University (UK)

### When is the study starting and how long is it expected to run for?

April 2024 to October 2025.

Who is funding the study?

1. Lancaster University (UK)
2. Engineering and Physical Sciences Research Council (EPSRC) (UK)

Who is the main contact?

Prof. Neil Reeves: n.d.reeves1@lancaster.ac.uk

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Prof Neil Reeves

### ORCID ID

<https://orcid.org/0000-0001-9213-4580>

### Contact details

Medical School, Faculty of Health & Medicine  
Lancaster University  
Health Innovation One, University, Sir John Fisher Dr  
Lancaster  
United Kingdom  
LA1 4AT  
+44 1524522239  
n.d.reeves1@lancaster.ac.uk

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

338459

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

CPMS 62619

## Study information

### Scientific Title

Measurement of Foot Shear Stress for discriminating between patients with and without diabetic peripheral neuropathy

### Acronym

## **Study objectives**

The overall aims of this project are:

1. Investigate the efficacy of using a new approach for measuring foot dorsal and plantar shear stress in discriminating between two groups of diabetes patients with and without moderate to severe diabetic peripheral neuropathy.
2. Compare the shear stress measurement values at the foot to other gait parameters, including spatio-temporal variables, vertical pressure, and vertical and shear ground reaction forces.

**Primary Objective:** This study aims to investigate the efficacy of using a new approach to measuring foot dorsal and plantar shear stress in discriminating between two groups of diabetes patients with and without moderate to severe neuropathy.

**Secondary Objectives:**

1. Compare the shear stress measurement values to other gait parameters including spatio-temporal variables, vertical pressure, vertical and shear ground reaction forces.
2. To obtain patient feedback on the wearability and comfort of socks

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

approved 17/06/2024, East Midlands – Nottingham 2 NHS Research Ethics Committee (The Old Chapel Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 207 104 8009; nottingham2.rec@hra.nhs.uk), ref: 24/EM/0110

## **Study design**

Multi-centre cross-sectional observational study

## **Primary study design**

Observational

## **Study type(s)**

Screening, Safety, Efficacy

## **Health condition(s) or problem(s) studied**

Type 2 Diabetes Mellitus

## **Interventions**

Participants are first screened against all inclusion/exclusion criteria and informed consent obtained. Afterwards, gait analysis will be assessed in different walking trials, and patient experience information will be collected via qualitative measurements.

## **Identification and recruitment**

Participants will be identified and recruited from NHS hospital sites and via other routes, including volunteer databases including the NIHR Clinical Research Network 'Research for the Future',

## **Measurement equipment**

Participants will walk on a treadmill instrumented with force platforms measuring vertical and

two components of shear force. The treadmill can also measure vertical plantar pressure and can be inclined to different degrees. An optoelectronic system (Vicon system) including ten cameras will also be used to collect kinematic data during walking.

#### Custom Socks

Custom socks will be used to measure foot shear stress (also known as shear Strain). Thirty participants with and without diabetic neuropathy who meet the inclusion and exclusion criteria will be tested at the biomechanics lab. They will attend a single one-day session, at the start of which they will provide their informed written consent. Participants will perform four walking trials (after familiarisation with the treadmill), during which gait analysis data (kinetics and kinematics) will be collected. At the end of the walking trials, participants will be asked to complete a questionnaire to collect information about the comfort and performance of the custom socks.

#### Biomechanics analysis

In one laboratory session, the participants will undertake a series of walking trials on an instrumented treadmill while wearing the measurement socks with and without their footwear. During the walking tests, kinematic and kinetic data will be recorded using a combination of an optoelectronic motion capture system and force platforms embedded under the treadmill belt. These tools will allow the measurement of spatio-temporal gait parameters (i.e., step length, step width, stance time, swing time, double support time), ground reaction forces and torques in three directions to estimate shear stresses on the foot during the different walking tasks.

Retroreflective markers (small balls that reflect light, often used for animations in movies and video games) will be placed on the participant's ankle, feet, and legs up to the hip to collect 3D motion data.

#### Medical history and neurological evaluation

Participants will be asked to provide details about long-term complications and a history of previous ulcers. This information will be recorded by a member of the research team to have a detailed characterisation of the clinical condition of the participant.

The presence and extent of diabetic peripheral neuropathy will be evaluated by researchers through a clinical score system, the modified Neuropathy Disability Score (mNDS), and quantitative sensory tests. The mNDS is a composite score representing the functional status of the sensory system (small and large fibres) at the lower extremities, comprising a series of simple clinical tests that examine pain sensitivity, temperature perception, vibratory sensation and tendon reflex responses. Quantitative measurements will include the assessment of the vibration perception threshold (VPT) using a neurothesiometer (Horwell, Nottingham, UK). VPT will be assessed at the halluces of both feet. This measure will allow the quantification of the functional status of the large sensory fibres.

#### Intervention Type

Other

#### Primary outcome(s)

Shear stresses measured using an instrumented treadmill while wearing the measurement socks in a single session

#### Key secondary outcome(s)

Measured in a single session:

1. Vertical forces measured using instrumented treadmill while wearing the measurement socks

2. Spatiotemporal parameters measured using instrumented treadmill while wearing the measurement socks

**Completion date**

31/10/2025

## Eligibility

**Key inclusion criteria**

1. Diagnosis of type 2 diabetes mellitus
2. Patients without diabetic peripheral neuropathy - Absence of diabetic peripheral neuropathy (vibration perception threshold (VPT) <15 Volts and modified neuropathy disability score (mNDS) <3)
3. Patients with diabetic peripheral neuropathy - presence of moderate to severe diabetic peripheral neuropathy according to a VPT  $\geq$ 25 Volts and/or NDS >6.
4. Capable of walking independently (>50 metres)
5. Aged over 18 years
6. Presence of at least one pedal pulse

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

100 years

**Sex**

All

**Total final enrolment**

10

**Key exclusion criteria**

1. Active foot ulcer
2. Presence of Charcot deformity
3. Lower limb amputation (anything more than amputation of two lesser toes)
4. Presence of edema to the extent that it prevents normal wear of a sock
5. Persons unable to understand verbal and written information in English will be excluded from the study.

**Date of first enrolment**

16/08/2025

**Date of final enrolment**

31/10/2025

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Lancaster Medical School**

Medical School, Faculty of Health & Medicine

Lancaster University

Lancaster

England

LA1 4YW

**Study participating centre**

**Manchester Metropolitan University**

All Saints

Grosvenor Square

Manchester

England

M15 6BH

**Study participating centre**

**Manchester University NHS Foundation Trust**

Cobbett House

Oxford Road

Manchester

England

M13 9WL

**Study participating centre**

**Tameside and Glossop Integrated Care NHS Foundation Trust**

Tameside General Hospital

Fountain Street

Ashton-under-lyne

England

OL6 9RW

# Sponsor information

## Organisation

Lancaster University

## ROR

<https://ror.org/04f2nsd36>

# Funder(s)

## Funder type

Government

## Funder Name

Engineering and Physical Sciences Research Council

## Alternative Name(s)

EPSRC Engineering & Physical Sciences Research Council, UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, The Engineering and Physical Sciences Research Council (EPSRC), EPSRC

## 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 will be available upon request.

Contact: Prof Neil Reeves, n.d.reeves1@lancaster.ac.uk or Dr Rachel Mason, r.mason5@lancaster.ac.uk

Type of data: Individual participant data (IPD) including anonymised demographic, clinical, and sensor-derived outcome data.

Availability: Data will be available upon publication of the main findings and for a minimum of 5 years thereafter.

Access criteria: Data will be shared with qualified researchers for the purpose of meta-analyses,

secondary analyses, or validation, subject to data sharing agreements.

**Consent and anonymisation:** Participant consent for data sharing will be obtained, and all shared data will be anonymised in accordance with ethical and legal standards.

**Restrictions:** Data sharing is subject to ethical approval and compliance with data protection regulations.

## IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version 2	25/07/2024	18/03/2025	No	Yes
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes