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Smart technology for diabetic foot monitoring

Submission date	Recruitment status	[X] Prospectively registered
18/03/2025	Recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/03/2025	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
15/07/2025	Nutritional, Metabolic, Endocrine	[X] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
338459

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 62619

Study information

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

Acronym

Socksess

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

Secondary study design
Cross sectional study

Study setting(s)
University/medical school/dental school

Study type(s)
Screening, Safety, Efficacy

Participant information sheet
See study outputs table

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

Secondary outcome measures
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

Overall study start date
30/04/2024

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 ≥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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

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
01/08/2025

Date of final enrolment
01/10/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Lancaster Medical School
Medical School, Faculty of Health & Medicine
Lancaster University
Lancaster
United Kingdom
LA1 4YW

Study participating centre
Manchester Metropolitan University
All Saints
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Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
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M13 9WL

Study participating centre

Tameside and Glossop Integrated Care NHS Foundation Trust
Tameside General Hospital
Fountain Street
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Sponsor information

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Lancaster University

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Sponsor type
University/education

Website
https://www.lancaster.ac.uk

ROR
https://ror.org/04f2nsd36

Funder(s)

Funder type
Government

Funder Name
Engineering and Physical Sciences Research Council

Alternative Name(s)
UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, EPSRC

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. Results will be disseminated publicly at scientific conferences, as research articles, via social media and press and participants will not be identifiable in any of these reports.

Intention to publish date

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?
Participant information sheet	version 2	25/07/2024	18/03/2025	No	Yes