ISRCTN72155978 https://doi.org/10.1186/ISRCTN72155978

Could smart insoles help monitor and improve diabetic foot health?

Submission date
13/04/2023

Recruitment status
Recruiting

Registration date
17/04/2023

Overall study status
Ongoing

Last Edited
18/03/2025

Condition category
Nutritional, Metabolic, Endocrine

[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
More than 120 amputations occur every week because of diabetes-related foot ulcers, a huge burden for those losing limbs and their families and costing the NHS £1 billion/year. Foot ulcers occur in areas of high pressure under people's feet. If we can stop these areas of high pressure, we can stop foot ulcers and amputations too. Smart insoles that measure pressure can help by sending "high-pressure alerts" to people, but only if people wear the smart insoles often enough and if they can respond to the alerts. Our previous study told us that people need a choice of smart insoles to be able to use them more often and they want help responding to the pressure alerts.
Smart insoles are already CE-marked and potentially available to the NHS, but they will not be provided to patients without more evidence. This project will help provide part of the evidence required and could impact the provision of smart insoles within 12 months of this project. Longer-term, the researchers plan for a national trial of more than 900 people that would impact nationally (e.g. through national guidelines) and globally (e.g. through the World Health Organisation) in the fight against foot ulcers and amputation.
It has recently been proven in a previous Diabetes UK-funded study that smart insoles can be used to help people reduce pressure under their feet by making simple adjustments to their foot position and walking/standing activities. The researchers made this happen using a smart insole technology that measures pressure under the feet and sends an alert (on a smartwatch) to the wearer when pressure is too high. This technology works: the number of ulcers reduced by 71% compared to current NHS care and reduced by 86% in those that used the smart insoles more often. This is a really important point: when patients use the smart insoles more often they get better results. The aim of this study is to develop methods that help people use smart insoles more, to get the best results and compare the effectiveness of different foot pressure monitoring/alert technologies (smart insoles) for offloading the foot.

Who can participate?
Patients aged 18 years or over with diabetes and peripheral neuropathy

What does the study involve?
The study involves two separate phases with user interviews and questionnaires on device use at key intervals throughout both studies. In phase 1 participants use one of three different smart

insoles over a period of 3 weeks to assess how they respond to pressure alerts from the device. Phase 2 participants each trialling all three devices for a period of 3 weeks each to assess how they respond to pressure alerts and device use.

What are the possible benefits and risks of participating?
The benefits of taking part include participants becoming aware of this smart insole technology and understanding its potential benefits. People with diabetes have commented that even just knowing that there is work going on like this gives them hope for a better quality of life in the future.
There is always a small risk of discomfort or rubbing when changing footwear, this can include the development of foot ulcers if not monitored. However, the devices being tested are fully certified, and to further minimise this risk, the footwear and insoles will be assessed in consultation with an experienced podiatrist (foot specialist) and if necessary, a new pair of shoes will be offered. Also, participants will be asked to check their feet regularly, including 1-2 phone calls during the wear period to check they are not experiencing any issues. If there are any potential concerns, participants will be offered a foot check by a podiatrist.

Where is the study run from?
Manchester Metropolitan University (UK)

When is the study starting and how long is it expected to run for?
June 2022 to February 2026

Who is funding the study?
Diabetes 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 and Medicine, Lancaster University, Health Innovation One Building
Lancaster
United Kingdom
LA1 4YW
-
n.d.reeves1@lancaster.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
320642

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 55606, IRAS 320642

Study information

Scientific Title
REAL PRETECTION - Preventing diabetic foot ulcers using real-time foot pressure monitoring and alert technologies

Acronym
REAL PRETECTION

Study objectives
The aim of the study is to develop a new health behavioural intervention for the use of pressure monitoring technology in diabetic foot health and compare the efficacy of multiple devices.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/04/2023, NHS Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)2071048083; bradfordleeds.rec@hra.nhs.uk), ref: 23/YH/0066

Study design
Randomized; Both; Design type: Process of Care, Device, Active Monitoring, Cohort study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diabetes

Interventions
In phase one of the project, 30 people with diabetes will use one of three smart insole technologies for 3 weeks (using it for as long as they can each day). Their experiences will be

captured through interviews and questionnaires and combined with psychological methods that help people adjust the decisions they make, such as whether to respond to a high-pressure alert or not.

During the inter-linked second phase of the study, 60 people with diabetes will use each of the three different smart insole technologies, including the new method to help them respond to pressure alerts, for 3 weeks (so they participate in the project for 9 weeks). The researchers want to see whether people are better able to respond to high-pressure alerts when they have a choice of systems, the new method to help them respond to alerts, and whether the reductions in high-pressure under the foot are the same with each of the three different types of smart insole systems.

Phase 1:
Device types will be allocated to each participant randomly using a random number generator. Each participant ID will be provided with a random number, and separated into three groups (sized according to availability).

Phase 2:
During phase 2 each participant will use each of the three technologies. These use periods will take place in separate interventional periods for which the order will be allocated randomly before the start of the study to each participant ID.
Orders will be generated by:
1. Generating a list of orders for the number of participants (n=60) where each possible order of interventions is used 10 times (6 possible orders) giving 60 intervention orders
2. Each row of the 60 orders will then be assigned a random number, and the list reordered using the random numbers (sorted from low to high)
3. Each row will then be assigned to the corresponding study ID (e.g. participant 1 will use the order from row 1)
This will ensure each participant is randomly assigned an order for the interventions, but each possible order occurs the same number of times

Insole Descriptions:
1. Walk With Path - Path Feel Insole: Smart insole with embedded plantar pressure sensor and central computer with Bluetooth data transfer to associated apps.
2. Sensoria Smart Socks: Instrumented socks with embedded plantar pressure sensors and connected sensing core for data recording and Bluetooth transfer to associated apps.
3. FeetMe Insoles: Smart insole with embedded plantar pressure sensor and central computer with Bluetooth data transfer to associated apps.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome(s)
Level of pressure offloading is measured using pressure metrics obtained from the devices used following high-pressure alerts across the 3-week study period

Key secondary outcome(s))
1. Device wear time is measured using time-in-use data metrics obtained from the devices used following the 3-week study period
2. Ease of use and user experience is measured using an adapted M-Health app usability questionnaire following each device intervention period
3. Technological capabilities are measured using a digital skills questionnaire following each device intervention period
4. Cognitive and emotional factors are measured using a patient interpretation of neuropathy questionnaire following each device intervention period
5. Adherence factors are measured using a Unified Theory of Acceptance and Use of Technology (UTAUT) questionnaire following each device intervention period
6. User skill is measured using the patient activation measure following each device intervention period

Completion date
28/02/2026

Eligibility

Key inclusion criteria
1. Diagnosis of diabetes
2. Diabetic peripheral neuropathy (VPT ≥25 Volts and/or neuropathy disability score ≥6)
3. Capable of walking independently (30 steps, aids permitted)
4. Aged >18 years
5. Able to understand all of the study requirements

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Active/healed DFU within the last 3 months
2. Active Charcot neuroarthropathy
3. Absent pedal pulses
4. Limb/foot amputation (except toe amputations)
5. Cognitive impairment (Mini-Mental State Examination [Tombaugh & MacIntyre, 1992])
6. Glomerular Filtration Rate (eGFR) <30
7. NHS prescription footwear unsuitable for smart device use (as assessed by a podiatrist)

Date of first enrolment
01/05/2023

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Manchester Royal Infirmary
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
Manchester Metropolitan University

ROR
https://ror.org/02hstj355

Funder(s)

Funder type
Charity

Funder Name
Diabetes UK; Grant Codes: 22/0006420

Alternative Name(s)
The British Diabetic Association, DIABETES UK LIMITED, British Diabetic Association

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No
Participant information sheet	Phase 1 version 2	04/04/2023	17/04/2023	No	Yes
Participant information sheet	Phase 2 version 2	04/04/2023	17/04/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes