ISRCTN87061146 https://doi.org/10.1186/ISRCTN87061146

Development of a new technology for the prevention of ulceration in the diabetic foot

Submission date	Recruitment status	[ ] Prospectively registered
29/03/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/10/2022	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/02/2024	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

This study will test a new load monitoring system (LOMIS) to monitor pressure and shear forces under the foot during different physical activities at home and in daily life. Loads will be measured using novel sensors incorporated into a standard insole worn in the participant's own footwear or footwear provided by the podiatrist. Movement of the foot is also measured using a small hub which will be attached to the shoelaces or Velcro fastening of the footwear. This will help the researchers to understand which physical activities are most responsible for the excessive foot loading.

The LOMIS device is to be used to inform the wearer of increased pressure and highlight the risk of a blister on the bottom surface of the foot. The intended user will be a patient under the care of an NHS podiatry or orthotics team who has diabetes and has been identified by their clinician as at risk of foot ulceration. LOMIS is intended for use independently by the user at home, as well as carrying out research activity in laboratory and clinical settings.

The LOMIS orthotic insole will intend to offload at-risk regions of the foot by providing wider contact and support across the bottom surface of the foot. LOMIS will provide additional monitoring and record data to a mobile application. Notification of high-loading activities can be shown as lights on the device itself.

Who can participate?

Patients aged between 18-85 years who have diabetes and who have regular podiatry and orthotics care within the NHS

What does the study involve?

The study involves using a new insole device which measures the forces produced as you walk. This will include wearing the device during a daily routine and providing feedback on its use. The study will run for 3 months with an option to extend the use of the LOMIS device for up to 12 months. Participants will be provided with a LOMIS device for use in their own footwear and trained to use this. Participants will attend monthly review appointments over the first 3 months and then at 3 monthly intervals thereafter. Review appointments will include a foot assessment, a device use assessment and questionnaires about health and health service use.

What are the possible benefits and risks of participating?
Participants will receive an in-depth foot health check by a trained podiatrist/orthotist. There will be no additional direct benefit from taking part in this study; however, the results of this study aim to inform and improve the technology we use to help clinicians and people with diabetes prevent ulcers.
The systems used in this study are new which may mean some risks are unknown, although the systems used in this study have been tested previously in different studies without problems. Possible side effects associated with foot orthotics are pain, discomfort, blisters, calluses and skin irritation. These effects are more common when first starting to use foot orthotics and can be managed by gradually increasing the amount of time you use the orthotics for. A registered podiatrist/orthotist will perform a foot health check before and after the end of testing to ensure no harm occurs while using the LOMIS. Throughout the study, participants will receive standard clinical care, including podiatry assessment and treatment.
Participants' feet will be closely monitored throughout this trial. The incidence of at-risk episodes based on LOMIS data will be reviewed by researchers at regular intervals. If participants experience an unusual amount of notifications, they will be asked to visit a clinical team member, and after clinical assessment, they will be referred to potential intervention if the high-risk activity is identified.

Where is the study run from?
The study will be run in the Northwest of England at the North Manchester Diabetes Centre and at the University of Salford (UK)

When is the study starting and how long is it expected to run for?
January 2021 to December 2024

Who is funding the study?
The National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Daniel Parker, d.j.parker1@salford.ac.uk

Study website
http://www.lomis.co.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
298091

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 50744, IRAS 298091

Study information

Scientific Title
Development of a 5 dimensions Load Monitoring and Intervention System (LOMIS) to monitor forces under the foot and physical activity profiles over time in a real-world setting which is capable of notifying service users of potentially high-risk activities

Acronym
LOMIS

Study objectives
To investigate the functionality of LOMIS for application in a daily living environment for the intended purpose of capturing pressure and shear in a range of activities akin to normal and expected use.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/12/2021, West Midlands - Edgbaston Research Ethics Committee (3rd Floor Barlow House, Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8070; edgbaston.rec@hra.nhs.uk), ref: 21/WM/0239

Study design
Non-randomized; Interventional; Design type: Treatment, Prevention, Device, Active Monitoring

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home, Hospital, University/medical school/dental school, Other

Study type(s)
Treatment, Safety, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
The LOMIS study is divided into three parts to allow safe and controlled development of a novel device to measure forces under the foot during footwear use in routine daily activities. Participants are recruited from within the podiatry and orthotics department and must have ongoing podiatry care in place. To ensure safe management of participants during the study their local podiatry team will be informed of their involvement and use of the LOMIS device. In all cases a baseline assessment will occur which will include a diabetic foot health screening by a podiatrist and a review of relevant medical records associated with podiatry appointments and diabetes care to build up a picture of each participants risk of ulceration.

LOMIS Study 1 is a gait laboratory study and will include 30 participants. The LOMIS System will be assessed during a range of activities typical of daily living (walking, standing, stair climbing) at different speeds (slow, normal, fast). This assessment will take approximately 3 hours. This will allow us to understand how well the device works or if there are any faults/issues during these activities.

LOMIS Study 2 is a 5 day wear trial and will include 5 participants. The participants will be trained on safe use of the LOMIS device and asked to wear the device during their daily activities over a week. Participants will return for foot health and device usability assessments at day 1, 3 and 5. Following the completion of day 5 the device will be returned to the LOMIS Study team. This study will allow us to understand how well the device functions over this extended period of use and also allow us to identify challenges with the use of the device prior to longer duration trials.

LOMIS Study 3 is a longitudinal study lasting between three months and one year, this will recruit 50 participants. Participants will receive training and a LOMIS device to take home and use throughout the trial, the device can be replaced during the study if needed but will be returned to the LOMIS Study team at the end. Over the first 3 months participants will return for follow up assessments on a monthly basis with short telephone check ins on a weekly basis. If participants choose to continue using the device further follow ups will take place at months 6, 9 and 12 with monthly telephone check ins. Follow up assessments will include a foot health screening, questionnaires about health and wellbeing, questionnaires about the device and usability. Further to this data will be exported from the device to allow assessment of the forces generated under the foot during daily activities and to identify any faults in the device during use.

For all studies we will also invite participants to take part in an optional 30minute recorded follow-up interview about the device to explore how easy it is to use and identify any thing which could be improved.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
LOMIS - Load Monitoring and Intervention System

Primary outcome measure
Device functionality for application in a daily living environment for the intended purpose of capturing pressure and shear in a range of activities akin to normal and expected use will be assessed through gait lab assessment, and controlled dynamic activity at baseline. This will be further assessed through physical activity logs and device fault at 1, 2, 3, 6, 9 and 12 months

Secondary outcome measures
1. Device functionality for real-time feedback is measured through a digital fault log captured by the LOMIS system and a fault log captured in assessment appointments at 1, 2, 3, 6, 9 and 12 months
2. Functionality for footwear fit is assessed through a footwear record, physical activity log, and device fault log at 1, 2, 3, 6, 9 and 12 months. Additionally, this will be assessed within an optional qualitative feedback interview
3. Safety of the LOMIS device is assessed through adverse event logs, device fault logs, clinical assessment at 1, 2, 3, 6, 9 and 12 months. Additional telephone reviews will occur at weeks 1, 2, 3, 5, 6, 7, 9, 10 and 11 and then monthly at months 4, 5, 7, 8, 10 and 11
4. Data validity will be assessed against force plate data within a gait lab assessment at baseline and by comparison of physical activity log and device data at 1, 2, 3, 6, 9 and 12 months
5. Feasibility of LOMIS device for application in daily living will be assessed by study recruitment /retention, device fault logs, physical activity logs, device usability questionnaire (QUEST) and mobility questionnaire at 1, 2, 3, 6, 9 and 12 months. Additionally, this will be assessed within an optional qualitative feedback interview
6. Usability of the LOMIS Device for application in daily living will be assessed by the device usability questionnaire (QUEST), mobility questionnaire, and device fault log at 1, 2, 3, 6, 9 and 12 months. Additionally, this will be assessed within an optional qualitative feedback interview

Overall study start date
01/01/2021

Completion date
31/12/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 20/02/2024:
1. Have diabetes diagnosed by a medical practitioner
2. Are capable of providing informed consent to participate
3. Are aged between 18-85 years
4. Feet classified as a "low, moderate or high risk" by IWGDF Risk Stratification System
5. Have the self-reported capability to walk unaided and without stopping for 25 m

Previous inclusion criteria:
1. Have diabetes diagnosed by a medical practitioner
2. Are capable of providing informed consent to participate
3. Are aged between 18-85 years
4. Have the self-reported capability to walk unaided and without stopping for 100 m
5. Have the self-reported capability to be physically active (either aided or unaided with breaks) for 2.5 hours per day
6. Can use a smartphone and its applications.
7. Have received two COVID-19 vaccinations

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
Planned Sample Size: 80; UK Sample Size: 80

Key exclusion criteria
Current exclusion criteria as of 20/02/2024:
1. Are pregnant
2. Have active foot or leg ulceration
3. Have foot infection
4. Have active Charcot joint
5. Have prior major injuries to lower limb (e.g. fractures requiring internal fixation, skin grafts)
6. Have clinically relevant foot deformity which prevents orthotic provision (eg. Rigid plantarflexed heel)
7. Have major amputation of the lower limbs and foot, this does not include minor amputation of lesser toes
8. Have severe lower extremity artery disease (Peripheral Arterial Disease or Critical Limb Ischaemia)
9. Have any pathologic conditions limiting the participant's ability to walk unaided and without stopping for 25m (eg, cerebrovascular diseases, cardiopulmonary, or other systemic diseases).
10. Have major vascular complications (e.g. Critical Limb Ischaemia)
11. Have severe retinopathy
12. Use walking aids that offload the foot (e.g. Aircast Boot)
13. Use lower limb orthosis during the intervention period which limit ankle movement (e.g. Ankle Foot Orthoses)
14. Have visual impairment that limits normal use of smartphones
15. Have dementia
16. Have uncorrected psychological impairment; psychiatric illnesses or social situations limiting

compliance with the study
17. Have inner ear pathology or other serious underlying balance dysfunction
18. Have current participation in another clinical investigation of a medical device or a drug
19. Have a Body-mass index (BMI) of more than 50 kg/m²

Previous exclusion criteria:
1. Have any of the symptoms related to COVID-19
2. Are pregnant
3. Have active foot or leg ulceration
4. Have foot infection
5. Have active Charcot joint
6. Have prior major injuries to lower limb (e.g., fractures requiring internal fixation, skin grafts)
7. Have clinically relevant foot deformity which prevents orthotic provision (e.g. rigid plantarflexed heel)
8. Have amputation of the lower limbs
9. Have severe lower extremity artery disease (Intermittent claudication or rest pain)
10. Have any pathologic conditions limiting the participant's ability to walk unaided and without stopping for 100 m (e.g., cerebrovascular diseases, cardiopulmonary, or other systemic diseases)
11. Have major vascular complications
12. Have severe retinopathy
13. Use walking aids that offload the foot
14. Use lower limb orthosis during the intervention period
15. Have visual impairment that limits normal use of smartphones
16. Have dementia
17. Have uncorrected psychological impairment; psychiatric illnesses or social situations limiting compliance with the study
18. Have inner ear pathology or other serious underlying balance dysfunction
19. Have current participation in another clinical investigation of a medical device or a drug
20. Have a body mass index (BMI) of more than 40 kg/m²

Date of first enrolment
01/05/2022

Date of final enrolment
31/07/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The University of Salford
School of Health and Society
Fredrick Road Campus

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M6 6PU

Study participating centre
North Manchester Healthcare NHS Trust
North Manchester General Hospital
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Study participating centre
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Sponsor type
University/education

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ROR

https://ror.org/01tmqtf75

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR201315

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal with an intention to publish findings by December 2024

Intention to publish date

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			26/07/2023	No	No