**PARTICIPANT INFORMATION SHEET**

**Title of study:** Development of a 5-dimension Load Monitoring and Intervention System (LOMIS)

**LOMIS Study 3 – Use of LOMIS in daily life**

**Name of Researcher: D Parker**

We would like to invite you to take part in a research project. Before you decide to participate, it is essential that you understand why the research is being done and what it would involve. Please read the following information sheet carefully. The Researcher Dr. Dan Parker will be happy to answer any questions you may have about the study before you decide whether to participate or not.

**1. What is the purpose of the study?**

A foot ulcer can occur quickly, even within a day. People with diabetes often cannot feel foot pain and so may fail to recognise the early warning signs like blisters. This means that ulcers often go unnoticed and untreated, and the risk of amputation is increased.

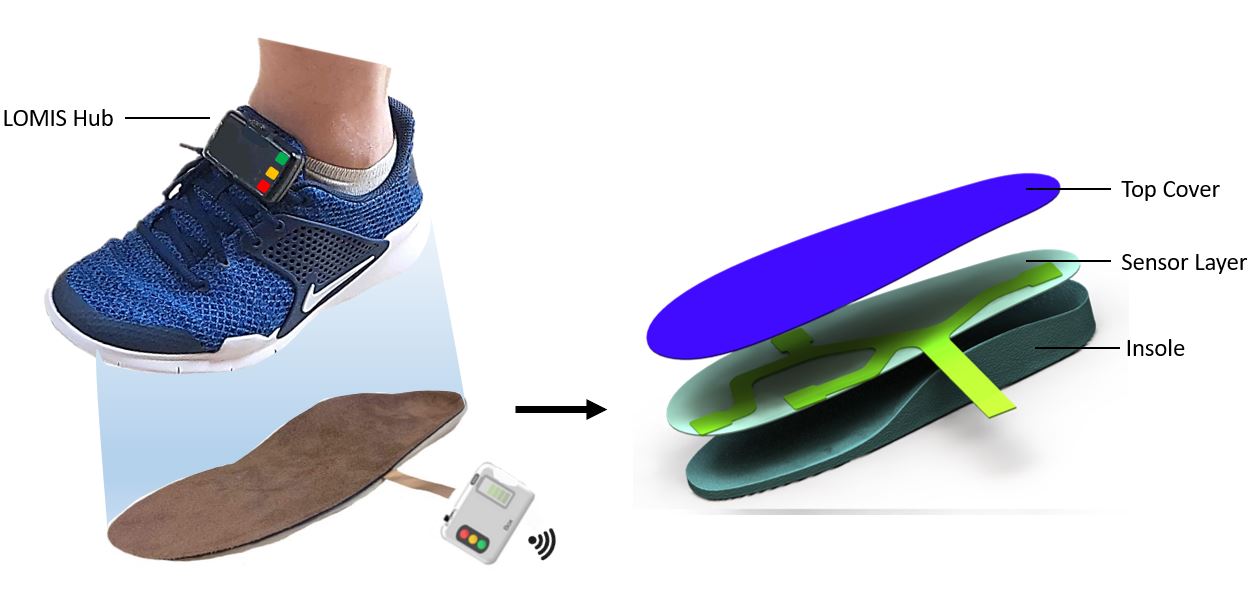
When we walk, we apply load underneath our feet, this load can be described as pressure (compression) and forwards and backwards rubbing forces (shear). When both pressure and shear forces are applied over time this can cause blisters or bruises which can quickly develop into ulcers.

One way to prevent foot ulcers is to alert people with diabetes to excessive loads which are applied to the foot. This requires force sensors underneath the foot that can “feel” the load for someone who has lost their foot sensation. When “damaging” loads are detected, a notification can be provided, helping people to change their behaviour at precisely the right time.

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

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 carry 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.



**2. Why have I been invited to take part?**

You have been asked to take part in this research because a member of your current orthotics or podiatry clinic have been in touch with you about the study and have identified that you:

* Have diabetes diagnosed by a medical practitioner
* Are capable of providing informed consent to participate
* Are aged between 18-85 years

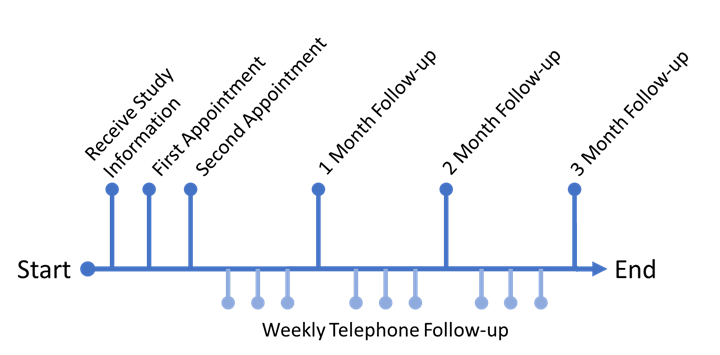
You are able to walk unaided and without stopping for 25 meters

**3. Do I have to take part?**

No, it is entirely up to you to decide if you would like to take part. This information sheet describes what will happen in the study, and you will have one week to consider this before deciding whether you would like to participate in the study. If you agree to attend an appointment, the Investigator will explain the study to you on a one-to-one basis and then ask you to sign a consent form to show you have agreed to participate. You are free to withdraw at any time and without giving a reason. Your current care will not be affected by your decision to participate or not and will not be affected if you decide to withdraw.

**4. What will happen to me if I take part?**

If you decide to participate, the study will run for 3 months with an option to extend use of the LOMIS device for up to 12 months. You will be provided with a LOMIS device for use in your own footwear and trained to use this.



**Initial appointments**

For the first appointment you will be asked to come to the University of Salford or the NHS site for an assessment, during which a registered podiatrist/orthotist will conduct an initial foot assessment to ensure it is safe for you to participate in the study. If you are not eligible, you will not participate in the study, but you will be compensated for your travel expenses (see section 5).

If you are eligible, informed consent will be sought, and the primary study assessment will start. The first visit will take approximately 30 minutes. First, we will ask you to complete a short questionnaire about your age, gender, marital status, ethnicity, education, and occupation. This information allows us to build up a picture of the people we have included in the study and helps us to make sure we have included a group who represent people with diabetes as a whole. Then your height and weight will be measured. After that, a series of clinical assessments which is similar to your annual foot check will be completed by a registered podiatrist/orthotist to investigate the sense of touch within your feet, abnormal feeling sensations at your feet such as pain or prickling, the pulses and blood flow to your feet, the presence of foot deformities, and how much movement is possible at your ankles and great toes.

You will be asked to attend the second study session in one to two weeks’ time. Meanwhile the LOMIS insole will be designed to your shoe size. Details from your medical records relevant to the study will be shared with the University by the NHS, these will include diabetes-related measures such as diabetes type and Fasting blood sugar along with results of previous blood tests confirming the presence of conditions that are linked to diabetes such as kidney disease.

On the second appointment, you will be asked to come to the University of Salford or the NHS site for a 60-minute appointment. A digital photograph of the bottom surface of your foot and a 3D foot scan will be taken for each foot. A registered podiatrist/orthotist will then position the LOMIS device into your own footwear or footwear provided for you by your podiatrist, this should be footwear you currently use with insoles. If you do not currently use insoles please contact the study team to discuss which footwear would be suitable. A registered podiatrist/orthotist will check that the fit and feel is comfortable before you take the LOMIS insole home. We will also collect a short period of walking using a validated in shoe pressure measuring system to ensure no increased pressure is present.

We will show you how to use the LOMIS device and provide you an instruction manual and details to contact in case you have any issues with the device during use. It is important that you report any faults or issues with the device to the research team as soon as possible so these can be resolved for you. You will then take the device home to use whenever you would usually wear your footwear. You are expected to wear the LOMIS device daily between 2 and 8 hours during the trial.

**Tele-reviews**

Each week, over the first three months, a member of the research team from the University of Salford or the NHS site will contact you either by telephone or by video call for a 30-minute review. These reviews will be scheduled at a time convenient for you. If you continue to use the device after three months, then telephone reviews will continue monthly. During the call you will be asked to provide some feedback on your device usage experiences. You will also be asked to fill out a daily activity log and report any LOMIS device issues. You will also be asked to report any new damage or injury to your feet while using LOMIS, such as new ulceration and other critical clinical events.

**Follow-up appointments**

You will also be asked to come to the University of Salford or the NHS site for assessment at months 1, 2, 3 and further in person assessment may be conducted at months 6, 9 and 12. Follow up appointments will take up to 60minutes. During these assessments your feet will be investigated for any new signs of redness, blister, ulceration, or other damages to the bottom surface. Then, your height and weight will be measured, and any new medical appointments (measured since the last session) will be recorded. After that, the same clinical assessments as the first session will be completed by a registered podiatrist/orthotist to investigate the sense of touch of within your feet, abnormal feeling sensations at your feet such as pain or prickling, the pulses and blood flow to your feet, the presence of foot deformities, and how much movement is possible at your ankles and great toes. Finally, a digital photograph of the bottom surface will be taken of each of your feet.

**Feedback Interview**

After three months of device use we will also be asking participants if they would be willing to participate in a 30 minutes one-to-one interview about the system to allow us to get some feedback from you. You will be asked questions about your experiences using the device, how acceptable the device was in addition to your normal insole, how often you used the device and reasons you chose to continue with the device. Questions will also be asked about footwear used with the device and the suitability of each footwear used. You will also be asked to report any new damage or injury to your feet during the use of LOMIS, such as new ulceration and other critical clinical episodes (e,g redness, blister, pain, discomfort, trip and fall). The interview will be conducted at an appropriate social distance, following the guidance provided by both University and the government. You will also have the choice of conducting an online interview via MS Teams and Zoom. The interviewer will take notes, and audio recordings will not be taken.

**5. Expenses and payments?**

For each in-person research session attended, travelling expenses will be reimbursed onstandard class rail fare, bus fares, taxi fares or mileage (when you use your own car). You will also be reimbursed at a rate of £10 per hour to compensate for any costs incurred and for the inconvenience and time commitment. You will not be reimbursed for online interviews, time spent completing tele-reviews or for using the device during daily activities.

**6. What are the possible disadvantages and risks of taking part?**

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 to your feet while using the LOMIS. Throughout the study, you will receive standard clinical care, including podiatry assessment and treatment.

Your feet will be closely monitored throughout this trial. Incidence of at-risk episodes based on LOMIS data will be reviewed by researchers at regular intervals. If we find out that you experienced an unusual amount of notifications, you will be asked to visit a clinical team member, and after clinical assessment, you will be referred to potential intervention if the high-risk activity is identified.

**7. What are the possible benefits of taking part?**

You will receive an in-depth foot health check by a trained podiatrist/orthotist. There will be no additional direct benefit to you 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.

**8. What if there is a problem?**

If you are concerned about any aspect of this study, you should ask to speak to the Investigator (Dr Daniel Parker, Email:d.j.parker1@salford.ac.uk), who will do their best to answer your questions. Should any problems occur with the system during the trial, we will advise you to remove them from your footwear and replace this with the standard orthotic insole supplied. We will then fill in a short form to record this problem, and your LOMIS will be either repaired or replaced. New ulceration and other critical clinical episodes (e,g redness, blister, or damage to the weight-bearing surfaces of the foot) must be reported immediately to a member of the clinical team, and you will receive standard clinical care. If you would rather speak to someone else at the University of Salford, or if you wish to make a formal complaint about this research, please forward your concerns to Professor Andrew Clark, Chair of the School of Health & Society Research Ethical Approval Panel, University of Salford (Email: a.clark@salford.ac.uk or Telephone: 0161 2954109). If you would like to speak to someone else at the NHS, The Patient Advice and Liaison Service (PALS) also offers confidential advice, support and information on health-related matters. You can find your nearest PALS office on the NHS website or phone NHS 111 for details of your nearest PALS.

**9. How will we use information about you?**

We will need to use information from you and from your medical records for this research project. This information will include your [initials/ NHS number/ name/ address/ telephone number and email address]. People will use this information to do the research or to check your records to make sure that 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. This data will be retained for a maximum of 3 years. 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.

**10. What are your choices about how your information is used?**

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. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

**11. 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/](http://www.hra.nhs.uk/information-about-patients/) or by asking one of the research team

**12. What if something goes wrong?**

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against The University of Salford or [NHS Trust] but you may have to pay your legal costs.

**13. Will my taking part in the study be kept confidential?**

Yes. We are responsible for looking after your information and using it properly.

All data collected during this study will be stored in a confidential manner in line with the UK Data Protection Act (2018) and General Data Protection Regulation (GDPR). Your name, address, telephone number and email address will be collected to allow the research team at the University of Salford or within the NHS to contact you and arrange appointments during the study. These details and any other details that could lead to your identification will be kept apart from the other information that we collect about you. This data will be retained for a maximum of 3 years to allow the research team to adequately follow up should any problems or complaints arise during the study. No personal details will be used in analysis or shared with members outside of the research team at the University of Salford. Upon entering the study, you will be given a unique identification number. This will ensure that your research data is anonymous and stored under this code number. All paper records collected about you during the course of the research study will be securely stored and locked away in a fireproof cabinet based at either the NHS Site or the University of Salford. Some data will be recorded digitally and held on a computer with encrypted password storage. Your anonymous information will be used for the purposes of this study. Anonymous data will be retained for 10 years after completing the study and may be used in future studies that we may carry out. For example, when we do other studies with the LOMIS device, we may want to use these results as well. We will share your anonymised data with the University of Southampton as part of this research project, and we may also share your anonymised data with a third party for future research in this area.

**14. What will happen if I don’t carry on with the study?**

You can withdraw from the study at any point without having to give a reason. Upon entering the study, you will be given a unique identification number. This will ensure that your data is anonymous and stored under this code number. Should you wish to withdraw from the study, we ask that you contact the Investigator using the contact details below and quote your identification number. If you withdraw from the study your data will be used unless you specifically request it not to be

**15. What will happen to the results of the research study?**

The study results will be used to evaluate the LOMIS device. You will not be identified in any report of the study results. However, the results of this study will be published in scientific journals and at professional conferences. A summary of the study results will be available from the Investigator by request from 6months after the end of data collection.

**16. Who is organising or sponsoring the research?**

The study is organised by the School of Health Sciences at the University of Salford in partnership with the University of Southampton.

**17. COVID-19 risks control measures**

You will be advised to comply with the following risk control measures to eliminate or control the risks of Covid-19. Any failure could result in cross-contamination leading to significant illness or death. You will be advised to:

* Not to attend for your appointment if you have any of the symptoms related to COVID
* To enter the clinical area no more than 10 minutes before your appointment time
* Wear a face mask or cover to attend the test.
* To attend either alone or only with one other person, if necessary, for their wellbeing.
* To maintain social distancing (Researcher, Staff, Others)
* To use the hand sanitiser available at the main door on entering and exiting the area. All to follow this process each time the site is entered and left during your visit.
* To remain seated until called for your appointment.
* To maintain social distancing when seated in the waiting room, signage, and use assigned seating areas.

**18. Further information and contact details:**

**Principle investigator: [NHS Site Details]**

**Or** [**LOMIS@salford.ac.uk**](mailto:LOMIS@salford.ac.uk)

**Thank you for taking the time to read about this study, if you have any questions please do not hesitate to ask.**