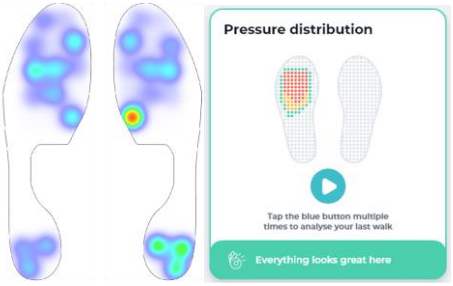
Manchester Metropolitan University

DO YOU HAVE DIABETES?
‘Smart Insoles’ could help look after your feet

If you are interested please take a leaflet to learn more



Manchester Metropolitan University

IF YOU WOULD LIKE A COPY OF THIS LEAFLET IN A LARGER FONT. PLEASE CONTACT THE RESEARCH TEAM AND WE WILL SEND YOU ONE.

Contact [researcher name] using either of the following methods:
Phone: [insert phone number]
Email: [insert email address]

Manchester Metropolitan University

Participant information sheet

Title of Project: REAL PRETECTION - Preventing diabetic foot ulcers using real-time foot pressure monitoring and alert technologies (*Phase 1*)

Version: 2.0

Version date: 04.04.23

IRAS Project ID: 320642

Your participation, your choice
Before you decide whether to take part, it is important to understand the purpose of the study and what it involves. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear, or if you would like more information. Please take your time to decide whether you wish to take part.

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Why have you been invited?

You have been invited to participate in this study because you have been diagnosed with diabetes and may have some loss of sensitivity in your feet (which is quite typical when someone has diabetes).

What is the purpose of the study?

Unfortunately, many people with diabetes develop ulcers under their feet due to areas of high pressure. The loss of normal foot skin sensation due to diabetes means they don't recognise this increase in pressure.

If we can stop these areas of high pressure, we can stop foot ulcers.

Smart insoles that measure foot pressure can help by sending "high pressure alerts" to a watch or app on your phone, but only if people wear the smart insoles often enough and if they act on the alerts.

We have recently shown that smart insoles help people reduce pressure under their feet. Now we want to help people use these smart insoles more often, to get the best results. We also want to test different types of smart insoles in case giving people a choice is useful.

Do I have to take part?

No, your participation is entirely voluntary, and it's up to you to decide whether to take part. If you choose to participate, you can withdraw from the study at any time without giving a reason. This will not affect the care you receive now or in the future.

If your circumstances change during the study, and you would no longer classify as an eligible participant, you will be withdrawn from the study immediately. Data collected up to that point will be reviewed to determine whether it can be included in the study or if it must be disregarded.

What will I have to do if I take part?

We will ask you to use one of three pairs of 'smart insoles' that go inside your shoe (if your shoes are not suitable for the device an alternative footwear can be offered to you) for 3 weeks, using them for as long as you can each day. This smart insole will measure pressure under your feet and send alerts to your mobile phone via an app when pressure is too high. If you do not have a suitable phone, we can provide one for the duration of the study.

We would like to ask you about your experience of using the smart insoles through interviews and questionnaires. We will do these interviews over the phone or video call for your convenience. Questionnaires will be done online if this works best for you (we can also provide paper copies if preferred).

We will ask you to attend the Manchester Metropolitan University three times: once for screening and checking your foot size, a second for smart insole fitting (if the correct size is available immediately fitting may occur at the same time as screening) and a third after your three weeks wearing the insoles. Interview and questionnaires to understand your experience of wearing the insoles will be done before and after your 3-weeks of wearing the smart insoles.

Following your final visit you may receive a phone call interview to ask questions based upon your questionnaire answers.

How long will it take?

Visits to the University in Manchester will take about one and a half hours for your first visit and around an hour for the second and third visits. Interviews will take between half an hour and an hour each. The interviews will help us understand how you experience using the device, the app, and what influences you when responding to an alert. In Phase 1, we are particularly interested in what knowledge or skills you need to help you use the device. This will inform a Health Behaviour Initiative that we will use in Phase 2. In order to really understand your experience while using the device, we would need to record the interviews so that we can become familiar with what you share with us. In any reporting of the results from the research we will never use your real name, instead we will use a pseudonym (a name that is different to your own). We will ask you to fill out five questionnaires – altogether these will take about on 45 minutes to do.

More information about the devices

If you choose to take part in phase 1, you will be asked to try a device for 3 weeks. It could be an insole or a sock. The sock looks like an ordinary sock, but it also has pressure sensors built into it, and a small charging pack. Similarly, the insoles are quite thin, and look like a regular insole with the sensors and battery inbuilt. Examples of what the devices might look like are provided below.

Example insole with the battery charging device:

Example sock:

Are there any possible benefits?

Benefits of taking part in this research include you becoming aware of this smart insole technology and understanding its potential benefits. From the work we have done before, 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 for the future.

What to expect during the consent process

If you are interested in participating you will be invited to a first session at Manchester Metropolitan University. At the start of this visit the research team will confirm you meet the eligibility criteria, give you an overview of the study and what will be involved. You will then be asked if you have any questions, before providing written consent to participate.

Are there any risks of taking part?

As you will be asked to wear a pair of shoes with insoles, 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 that you wear will be assessed in consultation with an experienced podiatrist (foot specialist) and if necessary a new pair of shoes will be offered. Also we will ask you to check your feet regularly, including 1-2 phone calls during the wear period to check you are not experiencing any issues. If there are any potential concerns, we will offer a foot check by our podiatrist.

What happens to the data?

The only information collected from the devices is the pressure information and a time stamp that tells us how long that pressure lasted for. No personal data is shared with the company that manufactures the device. At the end of the study consent forms and interview recordings will be stored on secure, password protected Manchester Metropolitan University servers for 10 years after the study has taken place. Access to these files will be limited to research team staff.

Reimbursement of travel expenses

We will reimburse your travel expenses to come to the University. Wherever possible, this will be discussed with you when you make your appointment and if possible, we will pay for your travel in advance to make things as easy as possible for you. We can also pre-pay a taxi to bring you to the University if you live within the Greater Manchester area.

Who has reviewed the study?
The study has been reviewed by the independent grant review process through Diabetes UK. It has also been reviewed by the study researchers at three Universities: the Manchester Metropolitan University, Keele University and the University of Manchester. The study has also been reviewed by [INSERT NHS REC DETAILS]

How will we use information about you?
We will need to use information from you for this research project. All personal information will be used according to General Data Protection Regulations (GDPR) and the information below.

This information will include your name and contact details. The research team 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.

Some of the data collected from your involvement will be sent to the smart insole technology companies. This will include usage data and pressures collected by the devices. This will **NOT** include any identifiable information (including name, date-of-birth, or contact details). They must follow our rules about keeping your information safe.

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.

Contact details will be disposed of within 3 weeks of the study procedures completing, or 3 weeks of dissemination of the results if you have joined the REAL-pretection register to receive information of the results. Consent forms including your name will be stored for 10 years following the study end date.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep non-identifiable information about you that we already have. If you withdraw, your name and contact details will be deleted from the records to remove any identifiable information related to you.
- 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.

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/
- by asking one of the research team
- by sending an email to ethics@mmu.ac.uk or
- by ringing us on [**insert phone number for research team**].

What happens when the study is finished?
If you would like to know more about the study and find out about the study results, we will invite you when you start the study to register your email to receive updates and an invitation to an end of study engagement event.

This is phase 1 of a 2 phase project, the 2nd phase will use information from phase 1 to run a developed intervention during which all 3 technologies being used during phase 1 will be compared by each participant. If you take part in phase 1, you will be asked if you wish to be contacted regarding participation in phase 2. If you wish to be contacted regarding phase 2 we will retain your preferred contact details for this purpose (this will not oblige you to participate in phase 2 in any way).

We will also publish results from the study as Scientific articles and presentations at conferences.

Hearing about other research opportunities in your area
Participants in the current study may wish to hear about other research opportunities that are available in their local area. This study is working with a local 'consent to contact' database (Research for the Future - https://www.researchforthefuture.org/) which can help patients hear about other research opportunities.
When you complete the consent form for this study, we will ask you if you want to discuss registering with Research for the Future.

If you consent, the Research for the Future team will contact you to discuss registration. There would be no obligation on your part to register or to take part in further research.
If you do not consent, we will not contact you further.

What if I have any concerns?
If you have a concern about any aspect of this study you can speak to the research team in the first instance who will do their best to answer your questions (Researcher: [INSERT RESEARCHER CONTACT NAME EMAIL AND PHONE]; Chief Investigator: Prof. Neil Reeves: 0161 247 5429). Alternatively, you may also speak to the Manchester Metropolitan University Research Ethics and Governance team via ethics@mmu.ac.uk. Telephone no. 0161 247 2836.
The normal National Health Service complaints mechanism is available to you (if appropriate). For independent advice, you may contact either the Research and Development office on 0161 276 4962 or the Patient Advisory and Liaison Service (PALS) on 0161 276 8686.

Indemnity
In the event that something does go wrong and you are harmed during the research study, the Manchester Metropolitan University has made indemnity and insurance arrangements.
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 Manchester Metropolitan University, but you may have to pay your legal costs.

Who has funded the study?
Diabetes UK has funded the study (Grant reference: 22/0006420).

Who should I contact if I am interested in taking part?
Name: [INSERT RESEARCHER NAME]
Phone: [INSERT RESEARCHER PHONE NUMBER]
Email: [INSERT RESEARCHER EMAIL]
Post: [INSERT ADDRESS],