

PARTICIPANT INFORMATION SHEET

Study title:

“Foot pressure measurements during walking, sitting and standing”

You have been invited to take part in this study, before you decide whether to take part it is important to understand the purpose of the research and what it will involve. Please take time to read the following information and don't hesitate to make contact for more information.

Purpose of the study:

Some people with diabetes experience problems with their feet including the development of ulcers. These ulcers typically develop because of a loss of foot sensation and the development of high pressures on the bottom of the feet that go undetected because of the loss of sensation. Recent indications suggest that it may not only be the pressures on the feet developed during walking that are important but also those while walking and sitting. The purpose of this study is to provide reference values for foot pressures in people without diabetes, that can then be compared against those from people with diabetes.

Why have you been selected?

You have been selected as someone without diabetes, who is over the age of 55, male and able to walk a short distance unaided.

What will happen to me if I take part?

After having the study procedures explained and having had the opportunity to ask any questions, you will be asked to sign a consent form to ensure you understand what is involved. If you agree, basic information about your height, weight and age will be taken. If possible, it is requested you don't eat for at least 30 minutes prior to testing so a blood glucose sample can be taken. This will involve a small prick on the end of your finger to extract a very small amount of blood to be analysed.

Due to using pressure insoles we will require your shoe size, to ensure the insoles we use fit in your own shoes correctly. The insoles will be inserted into each of your shoes and connected via a lead to the laptop which will measure the various pressures over the bottom of your feet. The insoles are very thin and are highly unlikely to cause any discomfort.

A familiarisation task will take place to wear in the insoles and ensure you are aware of the task ahead. A calibration then needs to be performed which involves following some instructions and standing on one leg (with support if required) for a very short period. You will then be asked to complete some simple task that involve – 1) walking at your own comfortable speed, 2) standing and 3) sitting.

You will be asked to wear a small watch-like device for up to 4 weeks and asked to keep it on for as long as possible whilst awake. You will not need to do anything apart from wear the device and this will just track your movement. After the 4 weeks we would ask you to return the device.

The study involves one visit to Manchester Metropolitan University's laboratory and a further short meeting to return the watch-like device.

What are the potential risks involved?

This study is expected to be very low risk with little if any discomfort caused. Taking a small capillary blood sample may cause some people discomfort as we need to pierce the skin with a very small pinprick.

Do I have to take part?

The study is entirely voluntary and no reason has to be given if you feel you don't want to take part. If you want to withdraw from the study you may do so at any time. Any data collected may be used in the study but only with your consent.

Reimbursement of travel expenses?

Unfortunately, we are not able to reimburse travel expenses.

Ethical approval and confidentiality:

The study has gained ethical approval from an expedited ethics committee at the Manchester Metropolitan University. All participants will be identified using a unique code to ensure all research data is stored anonymously and will be kept strictly confidential.

What if I have any concerns or questions?

You can contact the researchers or supervisor (Prof. Neil Reeves: n.reeves@mmu.ac.uk) with any queries or information on how to take part using the details below:

Researchers:

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The Study will take place at:

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