

Participant Information Sheet

Project title: Characterising plantar sole pressure distributions during daily activities

Lead Researcher: Luke Cleland

Principal Investigators: Dr. Hannes Saal, Prof. Claudia Mazzà

You are being invited to take part in a research study funded by the Medical Research Council (MRC). Before you decide whether to participate, it is important for you to understand the purpose of the research and what it will involve. 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. Thank you for reading this.

What is the purpose of the study?

This study aims to the pressure distributions at the foot sole during daily activities, such as walking and climbing stairs.

Why have I been chosen?

This study will use 10-20 healthy participants between the age of 18 and 40 years of age.

Do I have to take part?

No. Taking part in this study is voluntary. If you do decide to participate, you will be given this information sheet to keep and will be asked to sign a consent form. Participants are free to refuse to participate and you may withdraw from the study at any time and do not have to provide a reason.

What will happen to me if I take part?

You will be asked if you have any questions regarding the study. Should you agree to take part, you will be required to complete a consent form.

You will be asked to engage in a series of trials over a period of roughly 2 hours. You will first be asked to lie down while a series of sensory measurements are taken, this will include measuring skin hardness, your sensory perception threshold - these will require you to take your shoes and socks off. We will also take your mass, height, age and sex at birth. All measurements will be taken at a maximum of 13 points on your foot. You will be given a pair of shoes in your size, and will then be fit to a pair of pressure-sensitive insoles before taking part in a series of trials which will include standing, walking, sitting, and climbing stairs. You will be required to wear three inertial movement sensors, which will be attached to your ankles and pelvis. These may need to be attached directly to the skin. We may take videos/photographs of you wearing the equipment or during some trials. Your face and any distinguishing features will be removed so you are not identifiable should these be required for publication or presentations. These will only be collected and saved if specific consent is received by the subject. Data, including photos and videos, will only be used for research and teaching purposes.

Your data will be stored anonymously with no identifying information contained. You will be given a participant ID. Each trial will be saved using the following format:

Study_number/participant_ID/trial_number/YYYY_MM_DD_participant_ID_foot. Your **anonymised** data will be shared on a public repository. All **anonymised** data will be stored for 20 years, in line with MRC requirements. If you choose to withdraw, your data will be destroyed immediately.

What are the possible disadvantages or risks of taking part?

Equipment used in these studies operate on very low power and are non-invasive. You will be asked to stand on a wobble board and walk on gravel, however risk assessments have been carried out to ensure that you will be safe. It is possible that you will feel tired, or the equipment may feel uncomfortable during the experiment. If this is the case, we will give you as much time as you need to rest and will adjust equipment fit accordingly. There will also be a planned 10 minute rest half way through the experiment as standard.

What are the possible benefits of taking part?

There will be no direct benefit to you for participating in this study. If you are a first year undergraduate psychology student recruited through SONA, you will be given 10 research credits. Should you decide to accept, you will be entered into a random draw with the chance of winning a £20 Amazon voucher.

What will happen if I do not want to carry on with the study?

You can withdraw up until data processing has been completed. Therefore you can withdraw during data collection at any point, and a maximum of 5 days after data collection. You cannot withdraw from the experiment after data collection has been completed and your data has been processed, because it will be anonymised and there will be no way of linking you to the data.

Will my taking part in the study be kept confidential?

Yes. Your involvement will be confidential and anonymous. You will be given a participant ID, and this is all that will be associated with your data. Your data will be stored on encrypted storage devices and on the University of Sheffield's protected network. Access to this data will be restricted to the researchers working on the project. After 6-12 months, data may be released to a public repository in line with MRC guidelines.

The 2D video collected will be processed to remove any identifying features from the recordings. These will be used exclusively for the purpose of this research and in the content of scientific presentations and publications. Please do not hesitate to tell us if you feel uncomfortable with this. If you are uncomfortable with this, then you may withdraw from the study if you feel that your concerns are not addressed.

What is the legal basis for processing my personal data?

According to the data protection legislation, we are required to inform you that the legal basis we are applying in order to process your personal data is that 'processing is necessary for the performance of a task carried out in the public interest' (Article 6(1)(e)). Further information can be found in the University's Privacy Notice:

<https://www.sheffield.ac.uk/govern/data-protection/privacy/general>.

What will happen to the data collected, and the results of the research project?

The University of Sheffield will act as the Data Controller for this study. This means that the University is responsible for looking after your information and using it properly. Data must be stored for 20 years post study completion.

We will aim to publish our results in peer reviewed scientific journals. We will also present the findings at national and international meetings. No identifiable information will be included in any written or oral output from the study.

The data collected during the course of the project may be used for additional or subsequent research.

What if there is a problem?

This is observational research and does not involve any interventions like new treatments. If you have a concern about any aspect of this

study, you should ask to speak to the lead researcher who will do their best to answer your questions (contact details at the end of this information sheet). If you feel your concern has not been handled to your satisfaction, you should contact the Head of the Psychology Department, who will then escalate the complaint through the appropriate channels. If you have a complaint relating to how the participants' personal data has been handled, information about how to raise a complaint can be found in the University's Privacy

Notice: <https://www.sheffield.ac.uk/govern/data-protection/privacy/general>.

Is there a COVID-19 protocol?

All researchers involved in data collection are required to return a negative COVID-19 test within 48 hours of collecting data. As a participant, you must display no COVID-19 symptoms (a new or persistent cough, a change in the sense or taste/smell or a high temperature) or must have returned a negative COVID-19 test result within 48 hours of data collection. The University of Sheffield and Department of Mechanical Engineering's COVID-19 risk protocols will be abided by and you can ask to see these at any time.

Who has ethically reviewed the project?

This project has been ethically approved via the University of Sheffield's Ethics Review Procedure, as administered by the Department of Psychology and the Department of Mechanical Engineering.

Thank you for taking the time to read this. You may keep this information sheet.

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