

Participant Information Sheet for Part 1 Study

Study Title: Development and evaluation of a load and activity monitoring system in daily living environment

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ERGO number: 63303.A3

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

What is the research about?

NHS England spends £1.13 Billion annually on diabetic foot care and 80% of foot ulcer related lower-limb amputations are preventable. Yet currently there is no practical solution that enables patients to prevent diabetic foot ulceration (DFU) by changing physical activity during everyday living. This study is part of the research project - Loading Monitoring and Intervention Systems (LOMIS), which is a 3-year project funded by NIHR Invention for Innovation (i4i).

This study will test a new sensor device which can measure the loads on the bottom of your foot during walking. The sensor will be used in a standard foot movement and will help us to understand if the loads on your feet change while walking.

The purpose of this study is to know to be a key parameter in determining the likelihood of foot health problem. This information would be useful in foot health diagnostics, rehabilitation and sports medicine. The potential benefit from the outcomes of this study is to develop a system which can achieve this in a clinically practical manner.

The outcome of the whole project will be a LOMIS trial prototype ready for use in clinical trials to test its effectiveness in foot ulcer prevention, and ready to be commercialised into products that can be adopted by the NHS for real patient benefit.

Why have I been asked to participate?

You

- are aged between 18 and 85
- have all normal foot structures present
- had no lower limb fracture nor surgeries
- do not have diabetes
- are able to walk 50 metres without stopping
- are not pregnant

What will happen to me if I take part?

1. We will email you a consent form. We require your electronic signature if you are willing to participate in the study and send the form back to us by replying the email. However, you are free to withdraw from the study at anytime without giving a reason.
2. We will then arrange a training session with you and in this training session:
 - a. We will ask you a few questions as part of our screening process, checking if you or your household are currently having COVID-19 or have symptoms of COVID-19. We will not be able to enrol you if you or your household are infected by coronavirus or having symptoms.
 - b. We will introduce B5, 7 and 9 floor plans and flow system to reduce virus transmission.
 - c. We will let you know what is going to happen on the day and schedule a time with you
3. On the test day
 - a. You will be asked to complete a short questionnaire which includes information about general health, height and weight, lifestyle, activity levels, types of footwear worn regularly, ethnicity, gender and previous medical history.
 - b. A load measuring sensor will then be placed on top of an insole we are testing. These will fit comfortably into the shoes.
 - c. You will be asked to conduct normal daily living activities
4. After the test, you will be asked for complete a short interview either on the scene or online

The whole test lasts approximately 2 hours.

Are there any benefits in my taking part?

There will be no direct benefit to you from taking part in this study however the results of this study will inform and improve the design of foot orthotics used in practice.

Are there any risks involved?

The measurement sessions involve a short period of walking, but this can become tiring. To reduce this risk you will be offered a short rest break between each insole test. The sensors used in this study are new, although these have been tested previously in different studies without problems.

What data will be collected?

As part of this study, your email address and a digitally signed consent form will be collected. These are personal to you and will be kept securely on a University of Southampton, password-protected computer that only the research team can access. Other than that, measurements will be taken during the session. Although personal to you, it will not be possible to identify you from these measurements. The measurements will only be used for the purpose of this study.

Will my participation be confidential?

Your participation and the information we collect about you during the course of the research will be kept strictly confidential.

All data collected from you will be anonymous and you will receive a unique participant code. The electronic consent form and research data will be stored on a protected network drive and access of this folder will be only granted to the researchers. All data transported on laptops and USB memory sticks will be anonymous, identified only by a code, and encrypted to protect against loss.

Only members of the research team and responsible members of the University of Southampton may be given access to data for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities may require access to your data. To be compliant with the collaboration agreement with University of Salford, the project data will be shared with project collaborators at University of Salford, i.e. Prof Christopher Nester under the confidentiality agreement and vice versa. All of these people have a duty to keep your information, as a research participant, strictly confidential.

Consent will include the use of anonymised data for secondary analysis internally and by 3rd parties.

All the personal and research data will be kept in compliance of the Data Protection Policy of the University. In accordance with the University of Southampton Research Data Management Policy, all significant research data should be held for a minimum of ten years.

Do I have to take part?

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part.

If at any time you decide you do not wish to continue, please just let the researcher know.

What happens if I change my mind?

You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights being affected. Your participation is voluntary and you may withdraw consent at any time without your legal rights being affected and without the need for justification.

If you withdraw from the study, we will keep the information about you that we have already obtained for the purposes of achieving the objectives of the study only.

What will happen to the results of the research?

Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent.

Where can I get more information?

Should you require any additional information, please contact Prof Liudi Jiang (L.Jiang@soton.ac.uk), Dr. Jinghua Tang (Jinghua.Tang@soton.ac.uk) and Ms Yudan Zhang (Yudan.Zhang@soton.ac.uk).

What happens if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions.

If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

Data Protection Privacy Notice

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use

personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at

<http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf>

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information – may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).

Thank you.