

Participant Information Sheet

Pathstance - Transforming a simple, prescribed NHS wearable into a sensor-rich, at-home rehabilitation device

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Why have I been asked to take part?

You have been asked to take part because we are recruiting healthy adults (18+) who exhibit no lower-limb injury or musculoskeletal disease, and who's UK shoe size ranges between 4 and 13. We are looking to have a total of 160 participants in the study, consisting of 20 participants in each of the following age groups; 18-24, 25-34, 35-44, 45-54, 55-64, 65-69, 70-74, 75+.

What is the purpose of the study?

Falls are the leading cause of non-fatal and fatal injuries among older adults worldwide. Additionally, groups such as post-stroke, diabetes, knee and hip osteoarthritic and multiple sclerosis patients have also been shown to be at increased risk of falling and injury. Measuring and detecting risk factors, such as abnormal spatiotemporal parameters (cadence, step length, stride length), lower-limb joint movement, and postural balance, that contribute to increased falling is imperative to providing timely and effective interventions that aim to reduce the risk of falling.

However, the current gold standard for assessing these risk factors are 3-dimensional motion capture, which requires the participants to come into a gait laboratory and recreate activities of daily living. Wearable technology, which is capable of measuring aspects of human movement outside of a gait laboratory, have shown to be a promising tool for measuring many of the risk factors associated with fall risk. Instrumented insoles, which have a variety of sensors that measure the pressure and position of the feet, allow real-time feedback of foot pressure, and can measure functional performance over time during specific activities. However, the research comparing stability variables derived from instrumented insoles to 3-dimensional gait analysis remains limited and has not been explored within wider populations and during more complex activities.

The primary outcome of this study is to compare the measurements pertaining to stability from the instrumented insoles to the gold-standard of 3-dimensional motion capture. We also aim to develop algorithms to be used on the pressure data from the insoles to identify the activity being performed (i.e. walking, stair ascending/descending, standing up from a chair, etc). Lastly, we'd like to examine how haptic feedback (vibration) to the bottom of the foot influences fall risk during these activities.

What are the insoles that will be used in this study?

The insoles used in this study are the WalkWithPath PathStance instrumented insole (Figure 1). These are fitted with pressure sensors that are able to measure the pressures on the bottom of your feet, accelerometers that measure the position of your feet, and actuators that are capable of providing vibrations to the soles of your feet. These insoles are commercial prototypes.



Figure 1: WalkWithPath Instrumented Insole

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. If you decide to withdraw part-way through the study, any data collected before your withdrawal will be retained and used in the analysis. If you wish to withdraw from the study, please inform the researcher present during data collection.

What will happen if I take part?

You will be invited to the gait laboratory (RA03) in the Miners Block at The University of Sheffield. The assessment will take no longer than 2 hours. Following consenting onto the study, we will record some basic demographic information (age, sex, shoe size and past medical history). This demographic data will be completely anonymous. During the assessment, we will ask you to answer a questionnaire about your physical and mental health. You will be provided with footwear with the insole fitted inside, and tightfitting spandex/lycra shorts and t-shirts. This clothing is needed so that we are able to measure the movement of your body, not the movement of any loose fitting clothing. We will attach 36 reflective markers (Figure 2) onto your body (feet, legs, torso, arms, and head), which allow us to use infrared cameras and a computer to track your movement as you perform activities in the laboratory. You will then be asked to perform a series of functional tasks that mimic activities of daily living, including quiet standing, sit-to-stand, walking (slow/medium/fast), stair ascent/descent. If you are aged 18-24, we will also ask you to perform a load-and-carry activity involving weights of 5kg and 10kg, and we may ask you to perform some of the activities whilst the insole is providing haptic feedback (vibrations) to the bottom of your feet. If you are unable to attend the full assessment due to time-limitations, we may ask you to complete the questionnaire over the phone at a later date.



Figure 2: Full-body marker placement A) anterior view. B) posterior view. (source: vicon.com)

Will I be paid for my participation?

For those who are recruited externally from the University, we will offer a £20 amazon gift voucher for participation in the study.

What are the possible benefits of taking part?

We hope that your help now will give us information that will allow us to measure changes to fall risk during day-to-day activities across a wide population. You will have your gait and movement analysed by biomechanists using gold-standard 3-dimensional motion capture. However, there are no immediate benefits in taking part.

What are the possible disadvantages and risks of taking part?

There are not many disadvantages to taking part in the study. You will be asked to travel to the Mining Block at the University of Sheffield, which may be a burden if you are not local to the University. You will be asked to perform a series of activities, some of which may cause some fatigue. However, these can be performed at your own pace and you will be able to rest at any time during the assessment.

What if there is a problem?

If you have a concern about any aspect of the study please contact Alexander Jakubiec (a.jakubiec@sheffield.ac.uk), Prof. Matt Carre (m.j.carre@sheffield.ac.uk) or Prof. Elizabeth Cross (e.j.cross@sheffield.ac.uk) who will do their best to answer your questions. The normal university complaints mechanisms will still be available to you.

Will my taking part in the study be kept confidential?

All the information that we collect about you during the course of the research will be kept strictly confidential and will only be accessible to members of the research team. The only record of personal data we will collect will be your name when you consent into the study. All of the data we collect after consenting will be completely anonymised. You therefore will not be able to be identified in any of the reports or publications that may follow the study. Nor will you be identifiable if you agree to us sharing the information you provide with other researchers (e.g. by making it available in a data archive).

All paper copies of your personal information (i.e. the consent forms), as well as the hard copies of the questionnaires you answer, will be kept at the University of Sheffield in locked filing cabinets within locked rooms. The anonymous data you provide during data collection will be backed up electronically within the University on encrypted university computers.

How will you use information about me?

According to 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>.

We will need to record information from you for this research project. This information will include your name and signature during the consenting process. We will also collect the following information about you during data collection:

- Age
- Sex
- Shoe Size
- Past medical history

Researchers will use this information to do the research. However, this information will be anonymous, as the data we collect following you consenting into the study will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep the anonymous data so we can check the results, and your personal data (consent forms) will be destroyed. Due to the nature of this research it is very likely that other researchers may find the data collected to be useful in answering future research questions. We will ask for your explicit consent for your data to be shared in this way. We will write out reports and deposit the anonymous data into an archive in a way that no-one can see that you took part in the study.

What are my choices about how my information is used?

You can stop being part of the study at any time, without giving any reason, but we will keep information and data about you that we have already collected.

Following data collection, your data and information will be anonymous. This means that we won't be able to let you see or change the data we hold about you.

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.

What will happen to the results of the study?

The study will be written up as a scientific paper for publication in the public domain, so that other researchers and clinicians can benefit from this knowledge in how to measure fall risk outside of the gait laboratory using instrumented insoles. You will not be identifiable in any published results. If you would like to know the outcome of the study once it has been completed, we will send you a summary of the results once they are available. You can request a summary by contacting a member of the research team.

Who is organising the research?

This study is being organised by the University of Sheffield.

Who is funding the research?

This study is being funded by Innovate UK.

For further information on this study, please contact the Principle Investigator (Prof. Matt Carre) or the Research Associate (Alexander Jakubiec) directly:

Contact for further information

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