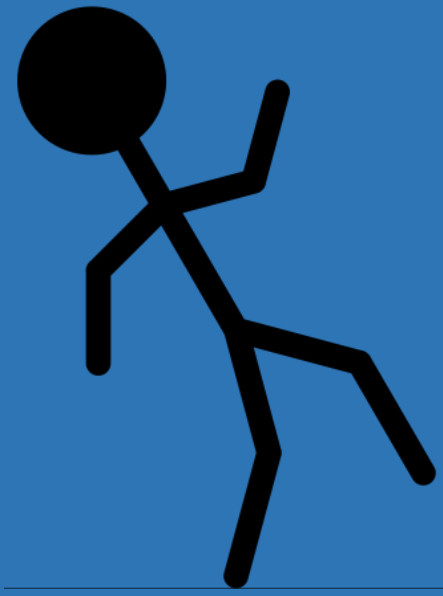
Manchester Metropolitan University

DO YOU HAVE DIABETES?

Are you interested in your balance?

We are investigating a way to improve balance in people with diabetes.

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.

PLESE CONTACT THE RESEARCH TEAM AND WE WILL SEND YOU ONE.

Contact Giorgio Orlando using either of the following methods:

Phone: 07846 135 362

Email: g.orlando@mmu.ac.uk

Manchester Metropolitan University

Manchester Metropolitan University

Participant information sheet

Title of Project: An investigation of a smart insole, for the purpose of improving sensory response in people with Diabetic Peripheral Neuropathy - SMARTSOLE

Version: 1.3

Version date: 15/10/20

IRAS Project ID: 273101

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.

Manchester Metropolitan University

Why have you been selected?

You qualify to participate in this study as you have been diagnosed with diabetes, and have been identified as having some level of loss of sensation in your feet.

What is the purpose of the study?

Vibrating insoles have been shown to improve balance. People with diabetes are known to experience difficulties balancing, so an insole to improve balance control may help prevent falls. This study is investigating a range of types of vibration to establish which type of vibration gives the best improvement in balance.

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 decide to take part, you can choose to withdraw from the study at any time without giving a reason. This will not affect the care you receive now or in the future.

What will I have to do if I take part?

If you are happy to take part in the study you will be invited to visit the Gait and Biomechanics Laboratory at Manchester Metropolitan University in Manchester. The research team can aid with travel requirements, which will be discussed when making an appointment to visit the university.

As we are investigating an insole device, we will screen you for any foot conditions that make it unsuitable for you to wear standard shoes. Therefore, your feet may be assessed either in person or by photograph, by a podiatrist. In order to speed this process, you are also welcome to send a photograph of your feet to the research team in advance of your visit.

During your visit to the university you will undergo a variety of tests related to movement and diabetes. These are:

Sensory assessment: The level of sensation you can feel on the soles of your feet will be assessed by asking if you can feel applied stimuli including: a light touch, vibrations of different levels, temperature differences and a reflex test.

Questionnaire: You will be asked to complete a short questionnaire relating to fear of falling during daily activities.

Gait and balance analysis: This will comprise the majority of the test procedures during the session. You will be asked to complete a gait assessment where we will monitor your balance during walking along an 8m walkway, stair walking on a 7-step staircase (whilst wearing a safety harness) and 3 standing tasks including: quiet standing and standing whilst performing a task speaking out loud (e.g. counting backwards). During these tests, you will be asked to wear a pair of close-fitting shorts and a close-fitting t-shirt. You will also have reflective markers placed on your body to allow us to track your movements. Finally, we will assess your muscle activities using small sensors placed on your legs (these may require shaving small patches of hair in order to get good signals). During these tests you will be provided with a standard pair of shoes

and socks, with an insole placed within the soles that can provide the vibrations to the sole of your foot which we are interested in investigating.

You will be asked to repeat the gait and balance analysis 8 times in order to assess the impact of multiple different types of vibrations. As such this will be the most time consuming part of the testing, however there will be a break between each type of vibration, and you will be able to **request** additional breaks should you desire. Should you wish to take additional breaks, you will be offered the option of splitting the tests into a second visit in order to avoid you being at the university longer on a single day than you might wish.

How long will it take?

Whilst we will endeavour to complete all the tests as quickly as possible, the gait and balance analysis needs to be performed for each type of vibration. As such the entire visit to the university may take approximately 6 hours.

During this time you will be able to take breaks, and drinks (tea, coffee, cold drinks) will be available for you. Additionally, a cold lunch will be provided for you.

Are there any possible benefits?

There are no direct benefits from taking part in the current study. However, we will provide you with the option of receiving a summary of the study's findings.

Further, this study has been developed to inform a clinical trial where we will invite people to test a vibrating insole device in their daily life, in order to establish how well it benefit people by improving balance during daily activities.

You have the opportunity to provide your name during this study to be contacted and invited to also take part in the clinical trial.

Are there any risks of taking part?

The activities performed during the tests are designed to replicate daily activities, with similar risks of falling to everyday life. Activities will be interspersed with breaks to ensure you have time to rest and avoid fatigue.

You will be asked to wear a pair of unfamiliar shoes with the insole device, so there is a minor risk (similar to wearing a new pair of shoes) of discomfort, rubbing, blistering and skin breakage due to the unfamiliar footwear. To minimise this risk, you will be asked to wear soft shoes and seamless socks. Additionally, you will have your feet checked visually throughout the session by the research staff. We will also collect photos of your feet at the start and end of the study as well as during the study in case you develop any relevant skin concerns. If an issue develops these images will then be sent in real time to a podiatrist for clinical advice. If you show any skin breaks or blisters, you will be removed from doing any tests and we will refer you to a podiatrist who will assess you for further care. The photographs taken of your feet will be kept until a month after the study data collection is finalised, then deleted.

If no issues occur, we will still ask you to monitor the health of your feet for a week after your visit, or ask a friend or family member to. The research team will contact you a week after your visit to ensure there have been no issues of rubbing/blister/etc.

Participation and Covid-19

In order to ensure the safety of yourself as a participant, and of the research team your visit to the University will be conducted in accordance to up-to-date governmental guidance and University protocols regarding operating as Covid-Secure. This will include measures such as: frequent cleaning of equipment and seating areas, physical distancing within the laboratory environment, frequent hand washing. Additionally, you may be asked to wear a face covering for short periods during the visit. You should also be aware that should you develop symptoms before your scheduled visit, or if you are advised to self-isolate, you should contact the research team to cancel or reschedule your appointment. Similarly, if the research team member leading your visit develops symptoms, it may be necessary to reschedule your visit at short notice.

In order to reduce the need for public transport, we would encourage participants to use their own cars or taxis wherever possible. If you are travelling by car the research team can arrange free-parking for you. If you would like to travel by taxi, you can discuss this with the research team when you schedule your appointment. We can provide paid-taxi transport within most 'reasonable' distances of the university.

You will be provided with full up-to-date details of the precautions that apply to your visit when you arrange a date with the research team, this is to ensure that our procedures remain up-to-date and maximise the safety of yourself and our team.

GP Contact

We will send a letter to your GP to inform them that you are taking part in the study. This will include a copy of the study protocol and participant information sheet.

Reimbursement of travel expenses

We can reimburse reasonable travel expenses. Wherever possible, this will be discussed with you when you make your appointment, as if possible we will pay for train tickets/parking in advance in order to make things as easy as possible for you.

Who has reviewed the study?

The study has been reviewed by the following research ethics committee:
North West – Greater Manchester (GM) East
Phone: 0207 104 8009
Email: gmeast.rec@hra.nhs.uk
Address: 3rd Floor, Barlow House, 4 Minshull Street, M1 3DZ

How will we use information about you?

We will need to use information from you for this research project.

During this use, we will follow ethical and legal practice, including GDPR requirements.

All information that is collected about you during the course of the study will be kept strictly confidential, and any reference about you (e.g., name, address) will be removed from research data so that you cannot be identified.

Research staff at Manchester Metropolitan University will handle your records. Electronic data will be stored in a password-protected and encrypted device; any hard copies will be stored in a locket cabinet in a access controlled room.

Your, identifiable data will only be accessed by the research staff for the purposes of contacting you to organise study visits or send you the results of the study.

Some of the research data collected from your involvement will be sent to Walk With Path (Denmark), who designed the insole device being used in the study. **No** identifiable information will be given to the company. Walk With Path developed and manufactured the vibrating insole for the study, so they will be provided with anonymised copies of the study data in order to continue their product development. They must adhere to GDPR when protecting your information. 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 such a way that no one can determine your identity.

How long will your data be kept:

At the end of data collection of the study all your identifiable data will be deleted. With the exception of:

- any contact details if you have provided separate consent for these to be retained until the end of the study for the purpose of sending you the study results.

- Your consent form: which contains your name, and will be kept for 3 years after the end of the study in case of any review by ethical or administrative bodies.

However, neither of these items will contain any link between yourself and the research data that was collected.

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 all 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 0161 247 2836

After the Study

You will have the option to be sent a summary of the results found from the study once it is complete. You will be asked whether you prefer to receive the summary by post or email. If you consent to this, your contact details will be kept for this purpose until the summary has been sent to you.

The study is intended to refine the design of the insole devices, therefore as a prototype the devices will not be available to take home from the study. However, the research team are planning a further clinical trial where the devices will be used for a month to assess home-based improvements in balance. If you are interested in taking part in this study as well you will be given the opportunity to leave your contact details to be invited, when the second study takes place.

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: Giorgio Orlando [g.orlando@mmu.ac.uk, 07846 135 362]; Co-Investigator: Dr. Steven Brown: 0161 247 5952, Chief Investigator: Prof. Neil Reeves: 0161 247 5429). If you remain unhappy and wish to complain formally, you can do this by contacting the Manchester Metropolitan University Research Ethics and Governance team via ethics@mmu.ac.uk. , telephone no. 0161 247 2836

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.

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. 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.

Who should I contact if I am interested in taking part?

Giorgio Orlando

Phone: **07846 135 362**

Email: **g.orlando@mmu.ac.uk**

By post: Giorgio Orlando, Research Associates, John Dalton Building, Manchester Metropolitan University, Chester Street, M1 5GD