Orthotics, Pain & Fear of Falling

Participant Information Sheet

Research team
This research is being undertaken by Dr George Ampat and his research team.

Introduction
We would like to invite you to take part in a research study. Before you decide whether you would like 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. If you have any questions, please do not hesitate to contact the lead investigator via the details at the bottom of this leaflet.

What is the purpose of the study?
Foot pain is a common problem in people over the age of 60 and may reduce quality of life and physical performance. Additionally, generalised, persistent musculoskeletal pain is highly prevalent in older adults and is recognized as a significant threat to maintaining physical and mental health in older age. Furthermore, falls are also a considerable issue, potentially causing injury and an increased fear of falling. Fear of falling can negatively affect a person's confidence, further reducing their physical activity levels and ability. It is therefore important that research is carried out in order to investigate potential interventions for these issues. This study will allow us to assess the use of the Orthotics (insoles) in reducing foot pain, generalised musculoskeletal pain, and fear of falling.

An Orthotic is an insole which is placed inside your shoe.

Please read the following information carefully. Should you have any questions, please do not hesitate to ask. Contact information is provided at the end of this information sheet.

Do I qualify to participate in this study?
You are qualified to participate if you meet all the following criteria:

1. Aged 60 years and over.
2. Living in a community-based setting.
3. Able to walk without support.
4. Have some form of foot pain which you have personally identified.

You cannot participant in the study if any of the following apply to you:

1. Have compromised skin integrity of the lower limbs (i.e. diabetic foot ulcers).
2. Have peripheral neuropathy and lack of sensation in the feet.
3. Have a previous history of foot surgery.
4. Are unable to follow the instructions and procedures of this study's protocol.

Please let us know if any of these apply to you.

How much of my time will be required?
The study will be conducted over a 6-week period. We will be asking you to provide us with data twice during the 6-weeks, by filling in a short survey once at the beginning and once at the end of the study period.

Do I have to participate?
It is up to you to decide whether or not to take part. You do not have to take part if you do not want to. 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 initially decide to take part, but change your mind later, you are still free to withdraw at any time without giving a reason. You have 2 weeks from receiving this information sheet to decide if you wish to take part.

I want to participate, what happens next?
We will ask you to have read and understood this information sheet fully before deciding whether to take part or not. If you do want to take part, contact us using the details provided. An in-person consultation will then be arranged with the principal investigator of this study Dr George Ampat, at his private clinic in Southport, Merseyside to ensure that you understand the study and meet the eligibility criteria. This will also provide you with the opportunity to ask any questions. If you would still like to take part, we will provide you with an informed consent form to sign.

The consent form will ask you for some basic information (including your name, date of birth, gender, presence of foot pain) and contact details (telephone, email, and home address).

You will then be asked to:

1. Report your pain in the lower back, hips, knees, ankles, and feet using the Visual Analogue Scale (VAS) using the following scale: 0-10, where 0 will indicate no pain and 10 will indicate severe pain.
2. Report your foot pain and functionality, and the impact it has on daily activities, using the Foot Health Status Questionnaire (FHSQ).
3. Report your fear of falling using the Falls Efficacy Scale International (FES-I) short.

If you agree to participate in the study, Dr. Ampat will open a pre-sealed envelope which will randomly assign you to one of two groups, group A or group B. Dr. Ampat will then provide you with Orthotics based on your UK shoe size. Those assigned to group A will receive Orthotics with a built-in metatarsal pad, whilst those in group B will receive Orthotics without a metatarsal pad. These Orthotics (insoles) are to be placed inside your shoes. An instruction sheet on how to use them will be provided along with the Orthotics.

During your consultation, you will also undergo analysis of your feet using the Gaitway scanner. This scanner measures the pressure points of the feet to determine if any foot/gait abnormalities exist. The results of this scan will not be used to determine what group you are placed in, nor will it be used to determine the type of Orthotics you will receive. Rather, the results of the Gaitway scanner will be used to assess the accuracy of the scanner. Such results will be anonymised and shared with the manufacturers of the scanner (Aetrex Inc) but will not be used in the final results of the study.

After you receive the Orthotics, the study will continue for a period of 6 weeks. We will ask you to continue with your daily activities in your normal manner for the 6-week study period, using the Orthotics wherever possible. At the end of the 6-week period, we will ask you again to complete the questionnaires described previously. You will also be asked to report how many hours, on average, you wore the Orthotics throughout the 6-week period.

We will ask you to provide data to us via a survey which you can either fill out online (at smartsurvey.co.uk), or complete on paper and return via post. It is your choice on how you do this, as we want to make this as convenient as possible for you. For participants who select to return completed surveys via post, we will provide a stamped, addressed envelope, to prevent any cost being incurred to participants for postage.

Instructions on how to use the Orthotics.
When we provide the Orthotics, we will also provide instructions explaining how to use the Orthotics. Alternatively, an online video tutorial on how to use the Orthotics will also be available throughout the study. You can also contact us if you require further instruction.

What is the data being used for?
We will use the data you provide to assess the effects of the Orthotics on foot pain and fear of falling. We will only use your contact details to provide you with the study materials (Orthotics, information sheets and surveys) and to provide you with a plain English report of the research once the study is completed. You can also be sent a copy of the final study paper if you request it.

The Principal Investigator / Supervisor acts as the Data Processor for this study, and any queries relating to the handling of your personal data can be sent to Dr. George Ampat (details are listed below). Further information on how your data will be used can be found in the table on the following page.

How will my data be collected?	Through questionnaires sent by post or smarysurvey.co.uk
How will my data be stored?	On Microsoft Excel spreadsheets. The data will be stored on secure computers.
How long will my data be stored for?	Identifiable data will be kept until the study is finished (31/12/2022). Non identifiable data will be kept indefinitely.
What measures are in place to protect the security and confidentiality of my data?	Computer is password protected. No one apart from the research team will have access to the data.
Will my data be anonymised?	Yes, any identifiable data will be deleted at the end of the study.
How will my data be used?	The data will be collated to form the results of the study.
Who will have access to my data?	Dr George Ampat and his research team.

Will my data be archived for use in other research projects in the future?	Yes, only non-identifiable data.
How will my data be destroyed?	Identifiable data will be deleted.

Will my data in this study be kept confidential?
Yes, all information collected about you will be kept strictly confidential. Privacy and anonymity will be ensured in the collection, storage, and publication of research material. Data generated by the study will be retained in accordance with Data Protection guidelines. Your personal information, including any contact details, will be stored securely in an electronic format and will only be accessed by the research team. At no point will this personal information be shared outside of the research team. Any data used in analysis and publication of the study results will be completely anonymised, using only your gender and age, with all names and other identifiable information removed. This will ensure that you cannot be identified in the published study results. Anonymised results will be stored securely by the researchers in an electronic format indefinitely. The results of the Gaitway scanner, which will be shared with the manufacturer Aetrex Inc, will also be anonymised.

What are the possible disadvantages and risks of taking part?
The need to wear Orthotics may aggravate your pain. If you experience any new pain during the study period or feel the Orthotics are not useful, then please contact Dr George Ampat who can offer you advice. If you have any serious health concerns throughout the study, please contact your GP or hospital. As a result of being provided with the Orthotics, you may decide to exercise more during the study than you would do normally. This may increase your risk of falling and so caution should be taken at all times during physical activity. If you experience a fall related injury, please contact your doctor.

During the COVID-19 pandemic, face to face consultations can potentially increase the chance of spreading the virus. All social distancing measures will be adhered to prevent such spread. Furthermore, you may feel that completing and submitting consent and data forms is inconvenient. However, we have designed the forms to be as simple and straight forward as possible, so that the time taken for participants to complete these is kept to a minimum.

What are the possible benefits of taking part?
You could be part of a study which contributes to understanding the effects of Orthotics on foot pain and fear of falling. You will also be able to keep the Orthotics.

What will happen to the results of the research study?
We would like to publish the research in scientific journals and present them in national specialty (orthopaedics, sports-science) conferences. Published data will be completely anonymous, using only gender and age, so that the identities of the participants are kept anonymous in the study results. Again, you will receive a written report of the research as standard and will be provided with the full publication if you request it.

Will I be debriefed at the end of the research?
When the data collection is completed, we will send you a debrief sheet containing further information about the study. We can also send you a copy of the results at your request and will provide you with a written report as standard.

How do I withdraw from the study?
You can withdraw from the study at any point without having to give a reason. You do not have to answer any questions during the study that make you feel uncomfortable. If you wish to withdraw, please email us at research@ampat.co.uk , or phone us on 01704 579337. You can decide whether you still want any of your collated data to be used or not. You can also request a copy of the study once it is complete even if you have withdrawn from the study. You cannot withdraw from the study once the data is made anonymous on 31/12/2022.

Who has reviewed the study?
The research has been approved by RECs within the UK Health Departments' Research *Ethics* Service (NHS/HSC RECs).

Concerns
If you are unhappy, or if there is a problem, please feel free to let us know by contacting Dr George Ampat or his research team using the contact details below, and we will try to help. We strive to maintain the highest standards of rigour in the processing of your data. However, if you have any concerns regarding how your data is processed, it is important that you are aware of your right to lodge a complaint with the Information Commissioner's Office through the following contact details:

Information Commissioners Office
Wycliffe House Water Lane
Wilmslow
Cheshire
SK9 5AF
www.ico.org.uk

Safety notice
During the study, you do not need to engage in physical activity any more frequently than you usually would. If you experience pain, please do not fight or ignore it. You can contact Dr Ampat or withdraw from the study at any time if you experience injury or pain and do not wish to continue. If you have any serious health concerns during the study, please contact your GP or hospital.

Disclaimer
Dr. Ampat has a commercial interest in Ease the Feet which supplies the Orthotics manufactured by Aetrex Inc. He is also employed as Director of the company sponsoring/funding the study (Talita Cumi LTD).

Funding
The study is being privately funded by Talita Cumi LTD. Orthotics / Insoles used in the study are being provided free of charge by Aetrex Inc.

Who can I contact if I want to take part in the study?
If, after reading this participant information sheet, you are still interested in participating in our study, please contact Dr. Ampat or his assistant using the details below. We will then proceed with organising your consultation with Dr. Ampat.

Contact Details:

Dr. George Ampat
Consultant Orthopaedic Surgeon
Free from Pain
681 Liverpool Road
Southport
PR8 3NS
Mobile: 01704 579337
Email: research@ampat.co.uk

We thank you for your time and effort.

George and the research team.