Plantar Fasciitis and the Use of Orthotics as Treatment

Participant Information Sheet

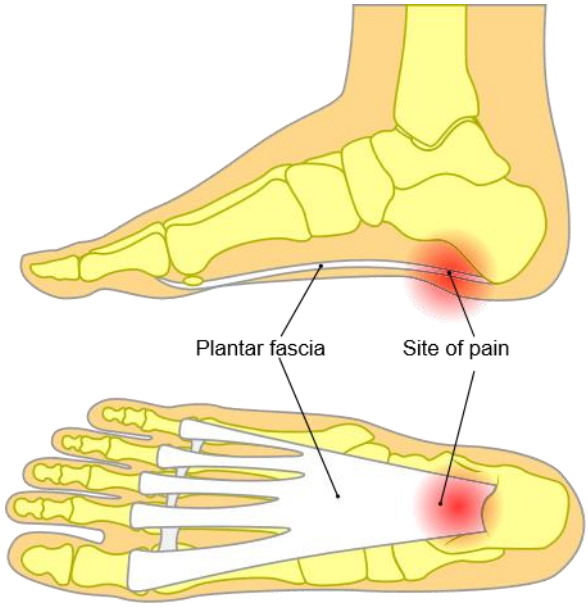
Research team
This research is being undertaken by Dr George Ampat and his research team.

Introduction
Thank you for considering participating in this study. This information sheet outlines the purpose of the study and provides a description of your involvement and rights as a participant should you agree to take part. It is important to understand why this research is being carried out and what it involves before agreeing to take part.

What is the purpose of the study?
Plantar fasciitis is a common condition, causing discomfort to the vast majority of the population. It is therefore important that studies are carried out in order to investigate potential treatments for the condition. This study is to allow us to assess the effects of Orthotics on the symptoms of plantar fasciitis. The study will assess and compare the use of Orthotics (insoles) in combination with the use of Flips (sandals) with built in arch support versus the sole use of insoles. Insoles are inserted into your shoes to be used when outside of the home, whilst Flips are sandal-like devices to be used when inside the home. Therefore, there will be two groups of participants. One group will test the use of both the insoles and Flips together, and the other will test the use of insoles only. This will allow us ascertain which intervention is the most beneficial for plantar fasciitis symptoms.

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

What is Plantar Fasciitis?



The plantar fascia is the band of connective tissue in the sole of the foot which connects the heel to the toes. In plantar fasciitis this band becomes inflamed and irritated. The classic symptom is pain in the heel which is worst when taking the first steps in the morning.

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

1. Are between the ages of 18-75 years old.
2. Have Plantar Fasciitis.
3. Have experienced symptoms for at least 2 months.

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

1. Have ever undergone any surgery on the foot.
2. Suffer from a serious health condition.
3. History of prior treatments for plantar fasciitis besides pain killers.
4. Concurring foot issues unrelated to Plantar Fasciitis which prevent the use of normal footwear.

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-month period. We will be asking you to provide us with data by completing a short questionnaire at 5 points throughout the 6-month period.

Do I have to participate?
It is up to you to decide whether or not to participate. You do not have to take part if you do not want to. If you do decide to take part, we will ask you 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 and without giving a reason. You have 2 weeks from receiving this information sheet to decide if you wish to participate.

I want to participate, what happens next?
We will ask you to have read and understood this information sheet fully before deciding whether to participate or not. A phone call or Zoom call will be arranged with the principal investigator of this study Dr George Ampat 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 like to take part, we will provide you with an informed consent form to sign either by post or online.

On the consent form, we will ask you for some basic information (including your name, date of birth and gender) and contact details (telephone, email, and home address).

Following this:

1. You will be asked to report your pain via a self-reporting Visual Analogue Scale (VAS) using the following scale: 0 to 10, where 0 will indicate no pain and 10 will indicate severe pain.
2. You will be asked to complete a Foot Health Status Questionnaire (FHSQ) to collect data on your foot pain and the impact it has on daily activities.
3. You will be assigned to group A or B by randomly allocated sealed envelopes. At the start of the study, participants in Group A will be provided with both a pair of Orthotics (insoles) and a pair of Flips (sandals) with built in arch support. At this time, participants in Group B will only be provided with a pair of Orthotics (insoles). The study will commence once you have received these Orthotics. All participants in both Groups A and B will be asked to continue with their daily activities, wearing the insoles in their shoes wherever possible. Those in Group A will also be required to wear the Flips wherever possible whilst at home, like they would a slipper or house

shoe. To ensure fairness, participants in Group B who have provided all the required data will also be given a complimentary pair of Flips at the end of the study.

Data will be collected across a 6-month period:

1. Following collection of the data at the onset of the study, you will be asked to report the data through the VAS and FHSQ on the following dates throughout the 6-month study period.
2. You will also be asked to report any changes in your symptoms through the Global Rating Scale of Change (GROC) at these dates, using the scale -5 to +5, where -5 will denote 'very much worse' and +5 will denote completely recovered.
3. Data collection points:
   - After 3 weeks
   - After 6 weeks
   - After 3 months
   - After 6 months
4. Once your data is collected, we will perform analysis of the two groups.

We will ask you to provide data to us via a questionnaire which you can either complete on paper and scan or image it across via email, or complete and return by post. You can also complete the questionnaire online at smartsurvey.co.uk. 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. If you choose to provide data online (via smartsurvey.co.uk), we will provide a link by email.

Instructions on how to use orthotic.

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

Expenses and / or payments

You will receive a £50 voucher at the close of the study on 31/12/2022 if you provide all the 5 sets of data. The minimum required data set will comprise of the personal details and consent on initial enrolment, ongoing consent, and data from all 5 data-collection points within the 6-month study period. We understand that this is only a small token of appreciation for the time and the effort that you have kindly provided. Unfortunately, we are only able to provide this reimbursement to participants who provide the minimum data set as detailed above. If the minimum data set as detailed above is not provided, then the £50 gift voucher will not be given. This is because if the reimbursement is given to participants who have provided less than the minimum required, then it would not be fair on the participants who took the time and effort to provide the entire set of data.

What is the data being used for?

We will use the data you provide to assess the effects of the Orthotics on Plantar Fasciitis. We will use your contact details to provide you with the study materials (Orthotic, information sheets and surveys) and the results of the study after it is completed if you want to be kept updated.

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 below.

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?	Identifiable data will be deleted at the end of this 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?	All 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 to identify you, with all names and other identifiable information removed. This will ensure that you cannot be identified in the published study results. Identifiable data will be kept for the duration of the research and non-identifiable data will be kept for indefinitely for the purpose of other researchers.

What are the possible disadvantages and risks of taking part?
The use of the Orthotics during the study may aggravate your pain. If you experience any new pain 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 during the study, please contact your GP or hospital. You can withdraw from the study at any time if you experience pain and do not wish to continue. Furthermore, you may feel that completing and submitting consent forms and data 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 the knowledge surrounding the effects of the Orthotics on Plantar Fasciitis. Your symptoms of plantar fasciitis may also be reduced.

Furthermore, you will receive a £50 voucher at the close of the study if you provide all the 5 sets of data and you will be able to keep your Orthotics and Flips.

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. These will be completely anonymous, using only your gender and age to identify you, so that the identity of the participants is kept anonymous in the study results.

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 if you request it.

How do I withdraw from the research?
You can withdraw from the study at any point without having to give a reason. If any questions or tasks during the study makes you feel uncomfortable, you do not have to answer them. To withdraw, please email us at research@ampat.co.uk or phone us on 01704 579337 and we will take your details out of the study. You can choose whether you still want any of your collated data to still be used or not. You can also request a copy of the study once we have finished writing it up even if you have withdrawn from the study. You cannot withdraw from the study once the data is made anonymous on 31/12/2022. However, if you withdraw from the study, you will not receive the £50 voucher.

Who has reviewed the research?
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 about the way in which we process your personal data, 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
You do not need to engage in physical activity any more frequently than what 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 pain or injury and do not wish to continue with the study. 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.

Funding
The Orthotics being used for this study are being provided free of charge by Aetrex Inc.

Contact details:
Please do not hesitate to contact us via the following details if you have any questions regarding the study:

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

We thank you for your time and effort.

George and the research team.