Orthotics and Running

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 participate in a research study. Before you decide whether you would like to participate, 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 provided at the bottom of this leaflet.

What is the purpose of the study?
Running has become a very popular sport. It provides the moderate physical activity required to keep healthy. Unfortunately running also causes injuries. Injuries are more common among less experienced runners than experienced runners. Research has not clearly shown the effects of Orthotics on running performance and running related injuries. This study hopes to obtain more information on this topic.

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

1. Aged 18 years and over.
2. Used to running 5kms in the last 1 year.

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

1. Are currently using prescription Orthotics.
2. Have any ongoing pain or deformity in the foot.
3. Suffer from a serious health condition which has led to a doctor advising you not to exercise.
4. Have undergone any surgery in the last 6 months.
5. Have ever undergone any surgery on a foot.

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 an 8-week period. We will be asking you to run as often as you would like during weeks 1 & 2 and weeks 7 & 8, whilst providing us with injury report data at least once a week. During weeks 3 – 6, we will ask you to run at least 10 times, providing running data after each run by filling in a short survey. You will also continue to provide injury reports during these 4 weeks. .

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, 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 and 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 want to take part, please contact us using the details at the end of this sheet. A phone call or Zoom call will then be arranged with the principal investigator Dr George Ampat to ensure that you understand the study and meet the eligibility criteria. This will also give you 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, gender) and contact details (telephone, email and home address).

Following this:
We will randomly assign you to one of two groups. One group will be asked to run with the Orthotics inside their running shoes and the other group will be asked to run in their normal shoes without the Orthotics. The study will continue for a period of 8 weeks from when you are put into your group. Please note that those who are placed into the group to run without the Orthotics will still receive a complimentary pair at study completion.

Acclimatisation period:
During the first 2 weeks (weeks 1 & 2) of the study, you will be asked to run as often as you would like with/without the Orthotic depending on your group. No run data will be collected from participants in either group during this period. This is to allow those in Group A who have been given an Orthotic to get used to them before they begin to provide run data. However, at least once a week for this two week period, participants in both groups will be required to report the following:

- *Injury report* to report if you had any running related injury during that week.

Full data collection period:
During the following 4 weeks of the study (weeks 3 – 6), we will ask participants in both groups to run at least 10 times and record the following data after each run:

- *Date of run*
- *Orthotics* used or not.
- *Distance* run per session in kilometres or miles.
- *Time taken* to run the distance in the format of Hours:Minutes.
- *Comfort level* of the feet at the end of the run on each day on a scale of 0 to 10. "0" indicating “no comfort” to "10" indicating “maximum comfort”.

Follow-through period:
For the final 2 weeks of the study (weeks 7 & 8) you can return to running as often as you would like. We will not ask you for any more running data. Instead, you will return to solely reporting any injuries using the injury report at least once a week. This follow-through period is to observe any injuries which are only detected during the final two weeks, but which could have occurred in the preceding 6 weeks whilst using the Orthotics.

During your runs, you will not be asked to run any further than you normally would. We will accept the data from runs of any length. We will ask you to provide us with data via a survey which you can either complete online (at smartsurvey.co.uk), or on paper and scan or image it across via email or send it by 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. If you choose to provide data online (via smartsurvey.co.uk), we will provide a link by email.

To ensure fairness, we will send all participants a pair of Orthotics. However if you are in the group that will be running with the Orthotics then you will receive the Orthotics at the beginning of the study. If you are in the group that will be running without the Orthotics, you will only receive them at the end of the study after you have submitted the data of the runs without using the Orthotics. This will allow the data from those participants to be collected before being potentially influenced by the use of the Orthotics.

Instructions on how to use Orthotics.
When we send the Orthotics by post, we will also provide an instruction sheet, explaining how to use them. 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.

Expenses and/ or payments
We will give all participants who provide the minimum required data set with a £50 voucher at the end of the study on 31/12/2022 as a token of our appreciation. The minimum required data set will comprise of the personal details and consent on initial enrolment, ongoing consent, data from at least 10 runs carried out during weeks 3 – 6 (there are 5 individual pieces of information from each run - the date of the run, the distance, the time taken, whether Orthotics were used or not and the comfort during the run), and injury data set every week during the entire 8 week study period. We understand that this is only a small token of appreciation for the effort and time that you have incurred. 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 data 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 compare between running with and without the Orthotics. We will use your contact details to provide you with the study materials (Orthotics, information sheets and surveys) and to provide you with 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 via 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, all identifiable data will be deleted at the end of the study.
How will my data be used?	The data will be collated to provide 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 from all stored data.

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. Anonymised results will be stored securely by the researchers in an electronic format indefinitely after the completion of the research project.

What are the possible disadvantages and risks of taking part?
The use of the Orthotics may cause pain or injury. If you experience any new pain or injury, or if you 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. You can withdraw from the study at any time if you experience pain or injury and do not wish to continue with the study. You may feel that completing and submitting the consent form and data is inconvenient. 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 investigates the efficacy of Orthotics on running performance and running related injuries. Additionally, if you complete the 10 running data sets during weeks 3 – 6, you will receive the £50 voucher as reimbursement for your effort.

What will happen to the results of the research study?
We would like to publish the results of 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.

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. 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 and we will remove your details from the study. 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. If you choose to withdraw, you will not receive the £50 voucher.

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 details below and we will be happy to help.

We strive to maintain the highest standards of rigour in the processing of your data. However, if you have any concerns about how your personal 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
You do not need to run any faster, more frequently or further than you would normally do. If you experience pain, please do not fight it or ignore it. We will provide you with an information sheet explaining symptoms and sites of common running related injuries, to make you aware of what to look out for. 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 with the study. If you have any serious health concerns throughout the study, please contact your GP or hospital.

Disclaimer
Dr. Ampat has commercial interest in Ease the Feet which supplies the Orthotics manufactured by Aetrex.

Funding
Orthotics being used for the 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 will to participate or have any questions regarding the study:

Dr George Ampat
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Southport PR8 3NS
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Email: research@ampat.com

We thank you for your time and effort.

George and the research team.