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Protocol

A randomised control trial to compare comfort, rate of injury and speed whilst running using prefabricated orthotics inserted into running shoes versus running with no additional orthotics inside the running shoe

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ABSTRACT

Background: Running is one of the most accessible and most popular sports globally. However, an increase in popularity has been followed by an increase in running-related injuries. An orthotic is a device fitted into the shoe for the proposed function of improving cushioning, sensory feedback, and comfort whilst also reducing the incidence of running-related injuries. The current study was a randomised control trial to assess the injury incidence, performance and comfort of runners using a prefabricated orthotic, compared to runners not using a prefabricated orthotic.
Methods: One hundred and six runners will be randomised either into the intervention group or the control group. The intervention group will be supplied with prefabricated orthotics and the control group won't be supplied with orthotics. Data will be collected regarding running-related injuries, distance run, time spent running and comfort during running. The study will span eight weeks. The first two and last two weeks will collect injury-related data only. Weeks three, four, five and six will collect both running and injury-related data. Participants must supply data from at least ten runs and eight injury reports.
Conclusions: Running with orthotics has been shown to provide cushioning and improved proprioception, thereby decreasing the incidence of running-related injuries, improving performance, and increasing comfort. This paper aims to present a scientifically sound protocol to add to the existing knowledge surrounding the use of orthotics for runners.
Trial Registration: This trial was registered in May 2021 (NCT04901442).

Keywords: Orthotics, Comfort, Performance, Running, Running-related injury

INTRODUCTION

Running is one of the most popular sports in the world. No entry barriers or specialised equipment are needed to engage in the activity. Despite the many health benefits associated with running, an increase in popularity has been associated with an increase in Running-related injuries (RRIs). The incidence of RRIs has been reported to range between 19% to 79%, with the most common locations being the knee, ankle, and foot.[1,2] There is a large variation in the range of RRIs, likely due to discrepancies in the literature surrounding the definition. Nevertheless, RRIs are a serious issue that requires further investigation.

An orthotic is a device that is placed inside the shoe with the purpose of improving cushioning and comfort. Theoretically, orthotics absorb shock which is transmitted on contact with the ground, resulting in a reduction in the number of movement-related injuries. There is, however, no consensus within the literature regarding the usefulness of orthotics for runners.

A meta-analysis that examined 18 studies found that whilst orthotics reduced the risk of injury, there was no change to soft tissue injuries.[3] Other research, which found a 34% reduction in the number of tibial stress fractures with the use of orthotics, also found an increased risk of an adverse effect such as foot blisters.[4] Injuries can have a detrimental effect on health and wellbeing, the ability to participate in physical activity, and may incur financial costs due to treatment. This highlights the necessity of research into the prevention of RRI's.

The paper presents a protocol to evaluate the effect of orthotics with regards to the incidence of injuries, performance, and comfort in runners. This study will compare an intervention group, running with orthotics, to a control group, running without orthotics. The limitations of previous research on running and orthotics included study design. Ampat et al used the same group to assess both running with orthotics and without orthotics as a crossover design, without an adequate washout period between the two interventions.[5] This weakened the validity of the results. The use of a comparative group without a crossover design allows for a more robust and valid evaluation.

Objectives

The objective of this study is to investigate whether a prefabricated orthotic will decrease injury, increase speed, and improve comfort during running. This study is a randomised control trial that is eight weeks long. Participants will supply injury data during the first two and last two weeks of the study. Running and injury data will be collected during the other weeks. The control group will run as normal whereas the intervention group will run with prefabricated orthotics. superiority study framework will be followed, and it is hypothesised that prefabricated orthotics will decrease injury, improve performance, and increase comfort.

METHODS

Trial design

This study is an eight-week-long randomised control trial. Injury data will be collected once a week for eight weeks and running data will be collected on ten runs. Parallel groups involving an intervention group and a control group will be used with an allocation ratio of 1:1. The intervention group will receive a pair of orthotics and the control group will not. The difference in injury incidence, performance and comfort will be assessed between the two groups.

Sample size

One hundred and six healthy, recreationally active runners will be recruited into this study. The demographic information of the participants will be taken during baseline data collection. These participants must meet the inclusion and exclusion criteria. This sample size was based on the results of a previous study (Ampat et al).[5] Statistical analysis showed that for a significance level of 5% and a power of 80%, a sample size of 84 is required. When allowing for a dropout rate of 20%, it is proposed that 106 participants be recruited.

Recruitment

Participants will be recruited through a social media campaign and by contacting recreational-running clubs. The study setting will be entirely in the participant's environment. The countries where the data will be collected are England, Wales, and Scotland. The recruitment process began in August 2021 and will end on 31st August 2022. The estimated study completion date is 31st December 2022.

Eligibility criteria

The participants recruited for this study are recreational runners. The requirements for participation in this study include being 18 years or older and used to running a distance of at least 5 km during the previous year. The exclusion criteria consist of the current use of a prescription orthotic, having any ongoing pain or deformity in the foot, and having a serious health condition which has led a doctor to advise that the individual should not exercise. In addition, participants must not have undergone any surgery in the last six months or any foot surgery in their lifetime.

Randomisation

This is a randomised control study with an allocation ratio of 1:1. There will be 106 participants in this study, with 53 in each group. Participants will be randomised with the use of sealed envelopes. Inside 53 sealed envelopes will be a label stating, 'group A' and inside another 53 sealed envelopes will be a label stating, 'group B'. Group A will represent the intervention group and Group B will represent the control group. All the envelopes will be shuffled together, and an individual independent of the research study will pick a blinded envelope at random. The label inside the envelope will assign the participant to a group. Following assignment to a group, blinding is not possible due to the nature of the study.

Objectives

The three primary outcomes of this study are injury rate, performance, and comfort. To report injuries, participants will be asked to complete a questionnaire at least once a week. Injury location and injury type are included in the information required for the injury data collection. The questionnaire is accompanied by a definition of RRIs as well as a description of the most common injuries for runners. The definition used for an RRI in this study is as follows 'Running-related musculoskeletal pain in the lower limbs that causes a restriction or stoppage of running

(distance, speed, duration or training) for at least seven days or three consecutive scheduled training sessions, or that which requires the runner to consult a physician or other health professional'.[6] Running data will include the collection of the distance of the run (either in kilometres or miles), the time taken (in hours and minutes) and the comfort of the run. Performance will be measured by using speed. The average speed will be calculated from the distance run and the time spent running. The speed will be reported in miles per hour. Comfort will be measured on a scale of zero to ten, with ten representing maximum comfort and zero representing no comfort.

Intervention

Participants will have a consultation telephone call with our principal investigator to confirm eligibility and answer any questions. Following this, consent will be obtained using a secure website called legalesign.com. After signing the consent form, participants will be randomised into either the control group or the intervention group. Those randomised into the intervention group will receive prefabricated orthotics (Aetrex L700 Speed Orthotics, Figure 1).

The study period for each participant is eight weeks. Injury data will be collected at least once a week for the whole eight-week study period while running data will only be collected during weeks three, four, five and six. The data of ten runs will be collected during this four-week timeframe and is collected following each run that the participant completes. The questionnaires will be available online, at smartsurvey.co.uk, or on paper through the postal service. Each participant can select their preferred method to complete and submit data. For participants using the postal service, a pre-paid, stamped, self-addressed envelope will be provided to ensure that no cost is incurred. If the participant decides to submit the data online, they will be provided with a link via email. Online data will be collected through the secure website www.smartsurvey.

Analysis of outcomes

Once data is collected, it will be exported to Microsoft Excel and kept on a secure, password-protected server. Only the research team will have access to the server. All data will be collected and stored according to the data protection guidelines. Identifiable data will be kept until the study completion date (31/12/2022) when data will be anonymised.

During dissemination, only anonymised data will be published and shared. All information regarding the collection and storage of data will be explained in the participation information sheet and consent form. An independent statistician will perform the statistical analysis. This analysis will be conducted using a mixed Analysis of variance (ANOVA) to compare the mean differences between groups regarding various factors. The between-group analysis will compare injury rate, performance and comfort between group A and group B. The results of the statistical analysis will be illustrated in the form of tables and graphs, which will be further supplemented with a comprehensive statistical analysis.

Monitoring

A data monitoring committee (DMC) has the function of ensuring that data is legitimate and reliable. This research study will include the use of a DMC composed of a member of the public, an independent doctor who is not part of the research team, and an independent statistician. A discussion will be undertaken involving the collection of the data and the progress of the study at various time points. The DMC will reserve the right to recommend study stoppage on the grounds of ethical violation or study feasibility.

Any comments, particularly negative ones, made by participants about the effects of orthotics will be noted. These comments will be presented within the final publication of the study. Negative comments will be discussed with the DMC to ensure participant safety.

Ethics

This study was approved in April 2021 by the Wales Research Committee 5 (reference number 21/WA/0098). Before consent is signed, participants are provided with an information sheet that details the study, how personal information will be used and how it will be archived. Furthermore, during the telephone consultation, the study will be outlined, and any questions will be answered. Ongoing informed consent will be collected at the start of each questionnaire completed by the participant. Personal information will be collected from the participants via the initial consent form and the questionnaires that are completed during the study. This data will be stored on secure servers to which only the research team will have access. At the end of the study, all identifiable information will be deleted, and the data will be completely anonymised.

Figure 1: An image showing Aetrex L700 speed orthotic. This orthotic is provided to the intervention group.

Dissemination

Plans to disseminate the results of this study include publication in peer-reviewed journals and presentations at relevant conferences. The study participants will receive a write-up of the results in lay terms but can also request a copy of the final publication. The protocol is currently available to the public on clinical trials.

DISCUSSION

Running has become one of the most popular sports in the world. The recent global pandemic regarding COVID-19 has influenced behaviours surrounding running. There has been an increase in the number of runs per week, the duration of each run and the number of RRIs.[7] Injuries can have a detrimental effect on health and wellbeing and decrease participation in physical activity, showing the importance of research into RRIs.

The aim of this paper is to present a protocol to evaluate the effects of orthotics with regard to the incidence of injuries, performance, and comfort. This study is eight weeks long. Injury data will be collected at least once a week and run data will be collected ten times. The first two and last two weeks will involve the collection of injury data only. The other weeks include the collection of both run and injury data. This study will aim to help in the investigation as to whether an orthotic can reduce the risk of an RRI and therefore whether it has noteworthy economic benefits.

There is a large variance in the reported rate of injuries for runners. van Gent et al identified a range of 19.4% to 79.3% for the rate of RRIs.[2] It is likely that the discrepancies in the definition of an RRI is the reason for this variation. For example, Bovens et al defined any physical complaint which restricts any component of running (distance, speed, duration, and frequency) as a running-related injury.[8] This is a broad definition that would allow the inclusion of trivial complaints. The current study uses a definition that requires ceasing the activity for seven days, or three consecutive training days.[6] It is therefore important to standardise the definition of an RRI within scientific literature.

Orthotics have been used for the prevention of RRIs, but this has been debated. A double-blinded, parallel-group, randomised control trial, which assessed the use of orthotics in 306 participants over 11 weeks, found a 34% relative reduction in the risk of lower limb injuries with the use of orthotics.[4] Supporting this reduction in injury was a study conducted by Ampat et al which identified that with orthotics, the injury rate was 21% but without orthotics it was 39%.[5] However, this study had several limitations, including the study design. Orthotics have also been investigated in laboratory settings concerning kinematics and kinetics.[9] Such studies provided evidence to support the theory that orthotics reduce RRI rates, but these investigations are not easily reproduced and are not highly generalisable. Recent reviews have suggested that research does not support nor refute the use of orthotics for running injuries, but there is evidence that pain is reduced with the use of orthotics even when biomechanical measurements may not show any significant changes.[10]

The performance during a running event is based on the time taken to cover the event distance.[11] Average velocity can be calculated from recording distance and time. However, running performance is multifactorial and clearly varies with distance. The performance of a recreational runner can be difficult to quantify because not every runner aims to run as fast as possible. Nevertheless, the gold standard measurements of performance, such as VO_2 Max and running economy, can be used for recreational runners.[12] Oxygen consumption and VO_2 max running velocity, which are indicators of performance, have been found to improve with the use of orthotics.[13] However, this requires sophisticated laboratory equipment, which is not replicable in everyday running. Hence, this study will use running speed to measure performance. As both the test and the control group will include multiple runners with different running abilities, the statistical comparison of the speed among the groups should provide a valid indication of performance. There is however limited research comparing running performance and orthotics, therefore revealing the gap in the literature for this research.

Fatigue, performance, and injury development have all been linked with comfort, showing the importance of this in the consideration of shoe and orthotic design. Orthotics have previously been linked with an increase in comfort. When comparing prefabricated and custom orthotics to a regular running shoe, both types of orthotics were rated as significantly more comfortable.[14] Supporting this, Ampat et al found an 18% increase in the comfort when using a prefabricated orthotic compared to without using the orthotic.[5] However, comfort is a subjective measure that can be difficult to quantify. Detailed analysis may include rating the heel, arch and forefoot separately and evaluating the dimensions of cushioning and stability.[15] However, this method was suggested when measuring running shoes and it did not state whether it can be applied to orthotics. Visual analogue scales, whilst being unidimensional and simple, have been identified as a reliable method of assessing comfort.[16]

CONCLUSION

Running with orthotics has been shown to improve cushioning and proprioception, resulting in fewer running-related injuries, improvements in performance, and increases in comfort. This article outlines the protocol for a randomised control trial which aims to assess the use of prefabricated orthotics in recreational runners. Specifically, this trial will assess injury rate, performance and comfort in runners using a prefabricated orthotic compared to runners not using a prefabricated orthotic. The pragmatic design of this study, including a large group

size and the use of recreational runners with varying experience, will ensure that the results are of high quality and generalisable to a large population.

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Conflict of interest: George Ampat, Samantha Rhodes and Jonathan Sims are employees of Talita Cumi Ltd, which is the sponsor of the study. Talita Cumi Ltd has a commercial relationship with Aetrex Worldwide, Inc. 414 Alfred Avenue Teaneck, NJ 07666, USA. J Shaik Ashraf Bin Shaik Ismail has no conflict of interest

Ethical approval: The study was approved by Wales Research Committee 5 Bangor, Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB

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