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Research Article

Does the use of an orthotic increase comfort, decrease injury and improve running performance?

Abstract

Background: Running is a widely accessible sport with millions of participants in the UK alone. Whilst running has been recognised to have significant health benefits, it does come with a risk of injury. Running-related injuries (RRIs) are seen more commonly in novice runners compared to athletes. Currently, there is ongoing debate as to what is the major cause of RRIs with some suggesting it is down to the differences in striking pattern. RRIs cause a substantial economic burden. There is no clear guidance as to whether the use of an orthotic truly prevents injury and improves running performance.

Methods: The study will include 100 voluntary participants and last a total of six weeks with the first two being an adjustment period and the subsequent four weeks being the true study period. Prior to the start of the study, each participant will have their baseline history recorded which will involve them declaring any previous RRIs and the distance they run per week. An Aetrex® IStep® (Aetrex Worldwide, Inc. 414 Alfred Avenue Teaneck, NJ 07666, USA) scan will also be performed to determine their foot type. In the true study period, participants will be required to wear the orthotic on alternating weeks. Participants will run with the orthotic during week 1 and week 3 and without during week 2 and week 4. They are responsible for recording their own data which will consist of the distance run, whether or not the orthotic was worn and also the level of discomfort felt following the run. The level of discomfort will be measured using an 11 point Likert scale. The data will be stored in password secured computers and analysed using the Students T test.

Abbreviations

RRIs: Running-Related Injuries

Aims

This present study aims to determine whether the Sports Aetrex® orthotic [1], demonstrates significant difference in (i) level of comfort while running, (ii) reducing running-related injuries and (iii) improving the running performance. The orthotic must be properly fitted for each participant to allow for accurate data extrapolation.

Background

Running is one of the most accessible physical activities worldwide [2]. It does not require any specific equipment and individuals can participate at their own pace. It is estimated that 10.5 million people run in the UK alone [3]. There is evidence to suggest that running is beneficial to an individual's health; Lee. D et al. found that runners had 30% and 45% lower adjusted

risks of all-cause and cardiovascular mortality respectively and also had a 3 year life expectancy benefit [4]. Despite the significant health benefits, running-related injuries (RRIs) are common. Data collected from a total of 1000 hours of running demonstrates that incidence of RRIs can range from [2,5], injuries in long-distance track and field athletes to 33.0 injuries in novice runners⁵. Advocates are in disagreement as to what causes the RRIs. Some theories suggest that the majority of RRIs arise from modern shoes, whilst others counter-argue suggesting that bare-foot running is the major cause [6]. It has been shown that there are differences in striking patterns when wearing a shoe compared to running barefoot. The difference in striking pattern is shown by barefoot runners landing on their forefoot whilst those who run when wearing shoes land predominantly on their hind-foot [7, 8]. In addition to this, a Cochrane review suggests that custom-made biomechanical insoles could be more effective for reducing the incidence of shin splints when compared to wearing no insoles [9], which implies that the use of orthotics could reduce risk of RRIs. The economic burden caused by RRIs is substantial. Hesperan

et al. conducted a prospective cohort study consisting of 228 Dutch trail runners aged 18 and over. It was found that the total economic burden of RRIs was estimated at €172.22 per injury and €1849.49 for every 1000 hours of running [10]. Therefore, if orthotic use has the potential to reduce the risk of RRIs, not only would this benefit the individual, it would also be saving costs. However, there is no real clear guidance as to whether orthotic use truly prevents injury and improves running performance.

Methods

Study design

The sample size of this study is 100 voluntary participants and will have a total duration of six weeks. In these six weeks, the first two will be considered as an adjustment period. During this time, each participant will be able to acclimatise to the orthotic as this is a product they will never have experienced before. The subsequent four weeks therefore, will be considered the true study period from which data will be collected and studied. However, should participants choose to leave the study succeeding the adjustment period, they are permitted to do so and the remaining participants will progress into the true study period.

Prior to conducting the study, each of the 100 participants will have their baseline history recorded. This baseline history will include any previous injuries they attained from running as well as the distance they run per week. In addition, each participant will have an IStep® scan conducted. All the participants will be interviewed, examined (short screening of feet) and their feet scanned by an Orthopaedic surgeon. Following that an Orthotic would be fitted and trialled to note if the participant notes any discomfort. The scan will enable researchers to identify the foot type of each participant which in turn will permit for any correlation between foot type and orthotic usage to be identified. There are 4 foot types based on the pedobarograph that is being used.

1. Normal feet
2. Flat feet
3. Normal feet with increased loading in the central part of the forefoot
4. Flat feet with increased loading in the central part of the forefoot

The study has obtained ethical approval from the University of Bolton, UK. The trial is however not registered with any International trial registry.

True study period

The true study period will commence after the preliminary two weeks. In this time, participants will be encouraged to run with and without the orthotic on alternating weeks. Participants will be asked to run with the orthotic during week 1 and week 3 of the study, and without the orthotic during week 2 and week 4. The participants would be running with normal

shoes during week 2 and 4. They would be running with the Orthotic during week 1 and 3. Week 1 and 3 would be the test weeks and week 2 and 4 would be the control weeks. Each participant will be in control of recording their own data in this period. The participants will be instructed to run as how they normally would. Their exertion needs to be as normal for them as possible.

Data collection

Participants will be responsible for their own recordings during the study. Data collected will include the distance run by each individual each day during the true study period, the time taken and whether or not the orthotic was worn. Additionally, an 11 point Likert scale will be used to numerically rate the levels of discomfort felt by participants in their feet at the end of every run. This scale will range from “-5” to “+ 5”. The guidance provided for the scale would be as in table 1 with “-5” representing ‘max discomfort and ++++ Pain’ and “+ 5” representing ‘max comfort. The average score will then be used to determine the comfort rating with and without the orthotic.

The data collected will be stored in password secured computers with only authorised personnel having access to them. The Students T test will be utilised to determine whether there is a statistical significance. Comparison will allow for any variances to be documented and should help conclude whether or not the Sports orthotic improves comfort and running performance whilst reducing the risk of injury.

Table 1:

- 5 - Max Discomfort And ++++ Pain
- 4 - Great Discomfort +++ Pain
- 3 - Moderate Discomfort ++ Pain
- 2 - Some Discomfort + Pain
- 1 - A Little Discomfort
0 - Normal
+ 1 - A Little Comfort
+ 2 - Some Comfort
+ 3 - Moderate Comfort
+ 4 - Great Comfort
+ 5 - Max Comfort

Participants

100 voluntary participants from neighbouring local running clubs will be recruited for this study. Participants from adjacent running clubs are likely to have ran on similar terrains and have comparable running experiences, hence limiting the confounding factor of different running grounds. Participants will be screened to ensure specific eligibility criteria are met. Participants must be between the age of 20 and 75 years old and will need to have been a regular runner for the past two years. A regular runner will be defined as someone who would have run at least 365 miles annually in the preceding two years. This will help ensure that those included in the

study are avid runners with good experience. The study will exclude participants who have used an orthotic in the past or are currently using one; have pain and/or deformity in the foot unrelated to any particular running injury; suffer from a serious health condition; undergone any surgery in the last six months; or have undergone any surgery in the foot during their lifetime. The exclusion criteria eliminate factors that can cause discomfort while running, which are outside the scope of this study. Participants will be instructed to run within their own normal range with and without the orthotic on alternate weeks. Their running performance will then be measured and this will be achieved by asking participants to record the time it takes them to run a route they normally would. Researchers will explain the importance of participants running within their normal, comfortable range and not to either voluntarily increase or decrease their speed or distance. This will help allow for a fairer comparison of running times as it ensures that the effort factor will remain constant throughout the duration of the 4 weeks. Participants would also be instructed to run individually and not in groups so that the measures are for their own run which are not confounded by the speed or fitness of other members of a group.

Discussion

This study will help determine whether or not the use of an Orthotic has any significant benefit in experienced runners. As far as the researchers involved are aware, this study is unique in the fact that it is the only one that will be investigating the use of a Sports orthotic in runners. Running economy is defined as being the steady-state of oxygen consumption for a given running velocity [11]. It would have been ideal to measure running economy in this study. However, to measure running economy, sophisticated equipment is required and ideally has to be done under standardised laboratory conditions on a treadmill. Measuring these parameters is going to be difficult in overground running [12]. Therefore we attempted to measure running performance [13], for an individual runner on his / her normal route without either voluntarily attempting to increase or decrease their speed or distance. This will help allow for a fairer comparison of running times as it ensures that the effort factor will remain constant throughout the duration of the 4 weeks. There would be a strong correlation between run distance and time. The reason to collect both is to determine speed. The multiple comparisons should allow to neutralise individual variations and allow us to determine if the Orthotic provides any advantage with speed. If the orthotic has had a benefit to their running performance it should be evident in their running times, with a shorter time when wearing the orthotic and a longer time without wearing the orthotic.

This study could potentially help determine whether or not orthotic use is beneficial to a runner's performance and if it is, how significant that benefit is. In addition, it will help conclude whether orthotic use actually reduces the risk of RRIs and therefore, whether or not it has noteworthy economic benefits. Unfortunately a review of literature does not clearly show that Orthotics reduces injuries whilst running. This is one of the questions that the trial wishes to answer. It may also help

pave the way for further research regarding orthotic use and running performance.

A sample size of 100 has been considered because this is a pilot study. Lancaster et al [14], suggests a size of 30 for each parameter. Since we are examining speed, comfort and injuries (3 parameters) it was decided to choose 100.

Limitations are present in this study. The relatively small sample size means the reliability of the results may be reduced and should participants decide to exit the study at any point, it would reduce the reliability of the results further. However the results of this study could be used to determine the power of similar future studies. In addition, the effectiveness of the orthotic is largely dependent on how well it is fitted. A poorly fitted orthotic may have detrimental effects upon one's running performance and may have the potential to cause discomfort and increase the risk of RRIs. This limitation should hopefully be eliminated by the fact that every participant has a 2 week adjustment period in which they may experiment with the orthotic and make any necessary changes so it is suited to their foot shape and shoe.

Furthermore, it is difficult to know whether or not participants are entering the study with an already pre-formed opinion of orthotic use. Those that strongly believe that orthotic use is not beneficial may be inclined to rate the comfort of the orthotics as poor compared to someone who is indifferent. It is hoped that the results from different participants should equalise the positive and negative bias.

Conflict of interest

Peter Malkin is in employment with Aetrex Worldwide, Inc.

George Ampat has a commercial relationship with Feet and Spine (www.feetandspine.com) which is an Aetrex Dealer in the UK.

Robert Baxter, Kirk Chalmers, Amber Hurry, Kantida Koysombat and Fionnuala Geoghegan have no conflict of interest.

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