The long-term effect of minimalist shoes on running performance and injury: design of a randomised controlled trial

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The long-term effect of minimalist shoes on running performance and injury: design of a randomised controlled trial.

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ABSTRACT

Introduction The effects of transitioning to a minimalist running shoe are a topic of interest for runners and scientists. However, few studies have investigated the longer-term effects of running in minimalist shoes. The purpose of this randomised controlled trial (RCT) is to investigate the effects of a 26-week transition to minimalist shoe compared to conventional shoe on running performance and injury risk in trained runners unaccustomed to minimalist footwear.

Methods and analysis A randomized parallel intervention trial design will be used. 76 trained runners, unaccustomed to running in minimalist footwear, will be randomised to a minimalist or control shoe condition. Runners will complete a standardised transition to the allocated shoe condition and will be followed up at 6-weeks and 26-weeks post-baseline assessment. 5-km treadmill time-trial (5TTT) performance, running economy, running kinematics and kinetics, triceps surae muscle strength and lower limb bone mineral density will be assessed at each time point. Pain and injury will be recorded weekly. Training will be standardised during the first 6-weeks. Primary statistical analysis will compare 5TTT between shoe groups at the 6-week time point and injury incidence across the entire 26-week study period.

Ethics and dissemination This RCT has been approved by the Human Research Ethics Committee of the University of South Australia. Participants will be required to provide their written informed consent prior to participation in the study. Study findings will be disseminated in the form of journal publications and conference presentations after completion of planned data analysis.
Registration details This RCT has been registered with the Australian New Zealand Clinical Trials Registry (ACTRN12613000642785).

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This is the first study to investigate the effect of minimalist footwear over longer than a 3-month period and the first to include a measure of running performance.
- The standardised gradual transition to minimalist shoes from 0 to 100% of weekly running will inform runners, coaches and clinicians of the effect of these shoes across the entire transitional period.
- A limitation of the study is the inclusion of only one minimalist shoe group.
INTRODUCTION

The effects of running in minimalist shoes is a topic of interest for both runners and scientists [1-7]. Running in minimalist shoes can cause runners to run with a more plantar-flexed ankle at initial contact and adopt a forefoot strike [3, 4, 6], increase stride frequency [1, 7], reduce stride length [1], increase ankle plantar-flexor moments and decrease knee extensor moments [4] and improve running economy [2]. However, while athletes and coaches may be interested in the potential for minimalist shoes to improve running performance, there is also some evidence that minimalist shoes increase injury risk when worn over the longer-term [5]. However, few studies have comprehensively evaluated the longer-term effects of running in these shoes [5, 7-10]. At present, runners, coaches and clinicians attempting to make a more informed purchase or prescription of minimalist shoes are required to base their decision on predominantly short-term or acute studies. The few studies that have investigated the longer-term effects of minimalist shoes have used follow-up periods of only 4 to 12-weeks [5, 7-10]. These studies found that, following the longer-term transition to minimalist shoes, runners improved running economy and reduced peak pressure under the heel [9], but experienced increased calf and shin pain [5, 8], increased foot bone marrow oedema [10] and a higher injury rate [5]. It has been hypothesised that these longer-term effects of minimalist shoes result from the increased loading of the Achilles’ tendon and triceps surae muscle group that is associated with a forefoot strike [11, 12]. If an appropriate, gradual transition to minimalist shoes can be made then it might be possible to derive beneficial training adaptations from this increased loading. However, if the increased loading of the Achilles’ tendon and triceps surae muscle group is too rapid then pain and injury may result.
Primary objective

The purpose of this randomised controlled trial (RCT) is to investigate the effects of a 26-week transition to minimalist shoes compared to conventional shoes on running performance and injury risk in trained runners unaccustomed to minimalist footwear. It is hypothesised that transitioning to minimalist shoes will have longer-term benefits for running performance but be associated with an increased risk of injury.

METHODS

This study protocol was developed according to the 2013 SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) statement[13]. The study will use a two-arm RCT design with a 6-week and 26-week follow-up. Data collection will take place at the University of South Australia. The RCT has been registered with the Australian New Zealand Clinical Trials Registry. Trial registration data is shown in Table 1. Participants will be recruited from a sample of convenience on a volunteer basis. This study will be advertised at local universities, running clubs and running events. Participants will be provided with a $100 shoe voucher at the completion of the study to assist with participant retention.

Study population

Male runners, aged 18-40 years, will be recruited to avoid potential gender effects due to differences in female running performance and running biomechanics, which are likely to impact on study outcomes[14]. Participants will be required to run a minimum of 15-km per week (this will minimise the risk of injuries resulting from a lack of familiarity with regular running), be able to complete a 5-km treadmill time trial (5TTT) in ≤ 23-minutes (mean 5TTT performance for male endurance-trained distance runners in a study by Laursen et al.[15] was 1167 ± 103 s), have no prior experience running in minimalist shoes, run with a rearfoot
strike gait pattern at the time of enrolment in the study (typical of 89% of runners[16]) and
have no current or recent (<3 months) musculoskeletal injury. Participants will be excluded
if they use orthotics in their running shoes because orthotics will not fit inside the
minimalist shoe. Foot-strike pattern will be determined from over-ground running trials at a
self-selected running speed in participants’ own running shoes filmed at 200 Hz using a high-
speed digital camera (Basler Pilot, Ahrensburg, Germany) to ensure only rearfoot strikers
are recruited.

Table 1. Trial registration data.

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<th>Information</th>
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<td>Secondary identifying numbers</td>
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<td>Primary sponsor</td>
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<td>Secondary sponsor</td>
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<td>The effect of footwear on running performance and injury risk</td>
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<tr>
<td>Scientific title</td>
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<td>Health problem studied</td>
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<td>Interventions</td>
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<td></td>
<td>Conventional shoe (Asics Gel Cumulus-14, 15 or 16)</td>
</tr>
<tr>
<td>Key inclusion and exclusion criteria</td>
<td>Inclusion criteria: male, 18-40 years, running ≥15 km per week, habitual rearfoot striker and able to run a 5 km time trial in &lt;23 minutes</td>
</tr>
<tr>
<td></td>
<td>Exclusion criteria: prior experience with minimalist shoes, use of orthotics, having a current or recent (&lt;3 months) musculoskeletal injury or history of recent (&lt;12 months) invasive surgery that affect running.</td>
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<tr>
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<td>Target sample size</td>
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<td>Key secondary outcomes</td>
<td>Injury incidence (time frame: 6-months)</td>
</tr>
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<td></td>
<td>5 km time trial performance (time point: 6-months)</td>
</tr>
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<td></td>
<td>Running economy (time point: 6-weeks and 6-months)</td>
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<tr>
<td></td>
<td>Running biomechanics (time point: 6-weeks and 6-months)</td>
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<tr>
<td></td>
<td>Triceps surae strength (time point: 6-weeks and 6-months)</td>
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<tr>
<td></td>
<td>Bone mineral density (time point: 6-weeks and 6-months)</td>
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Sample size

An a-priori power calculation determined that 50 participants are required to detect a Cohen’s $d$ effect size of 0.3 for the primary outcome (5TTT performance) at 6-week follow-up with 80% power and a 5% significance level using analysis of covariance (ANCOVA). This calculation was performed using the formula described by Borm et al.[17] and South Australian 5-km road race results recorded in 2011 and 2012. The 0.3 effect size was based on the 2.4-5.8% improvement in running economy observed for runners training with or experienced with minimalist shoes[6, 7, 18] and the corresponding improvement in average race pace estimated by Burkett et al.[19]. To allow for a 20% drop out rate and a 25% rate of injury during the 6-week follow-up period it is expected that 76 participants will need to be recruited. An additional 12 participants will be recruited and will complete all outcome assessments on two separate occasions in their own shoes to determine test-retest reliability.

Study protocol

Participants will attend a familiarisation session in the week prior to their anticipated start date. During this session, participants will complete a 30-minute treadmill familiarisation, footstrike pattern will be assessed and a 5TTT will be completed. Randomisation to shoe group will be via a process of minimisation[20], using 5TTT performance times obtained during familiarisation as the minimisation variable and a 1:1 allocation ratio. Allocation via minimisation offers the only acceptable alternative to simple and restricted randomisation[21] and is more effective at balancing the collective attributes of intervention groups in small samples than traditional methods of randomisation[22]. Allocation of participants will be performed by one of the investigators (Jonathan D.
Buckley) who will not be involved directly in data collection, but it will not be possible to
blind outcome assessors to participant shoe condition during testing. Experimental testing
sessions will be undertaken for each shoe condition at baseline, at 6-week follow-up and at
6-month follow-up. Outcomes assessed in order of assessment at each test session will be
over-ground running kinematics and kinetics, treadmill running economy, bone mineral
density (BMD), 5TTT performance and muscle strength. A timeline participant timeline is
shown in Figure 1. All testing sessions will be performed at the same time of the day.
Participants will be required to not complete any training on the day of testing and remain
fasted from food (water permitted ad libitum) in the 3-hours prior to testing.

**** insert Figure 1 approximately here ****

Shoe conditions
Participants allocated to the control condition will run in a traditional running shoe (Asics
Gel Cumulus-14, 15 or 16; mass 324 g per shoe; heel drop 9 mm) and participants allocated
to the minimalist shoe condition will run in a lightweight racing flat (Asics Piranha SP4; mass
125 g per shoe; heel drop 5 mm). Mass is reported for an average U.S. size 9 (European size
42.5) shoe. Participants will be instructed to complete only 5% of running in their allocated
shoes on each day that they run in the first week. This amount will then be increased by 5%
each week until week 20, when participants will complete 100% of running in the allocated
shoes. From week 20-26, runners will perform all running in their allocated shoe condition.
To investigate how the runners perceive the comfort of the two shoe conditions, they will
complete an assessment of shoe comfort for their respective shoe condition at the
beginning of each testing session. Assessments of shoe comfort will be made using a 100-
mm visual analogue scale (VAS) with anchors “not comfortable at all” on the left hand end
and “most comfortable imaginable” on the right[23]. Shoe comfort will be assessed before and following a 2-minute sub-maximal run on a motorised treadmill at self-selected running speed (Model 645, Quinton Instrument Co., Washington, USA). Four familiarisation comfort assessments will be used to achieve stability of shoe comfort results[23].

**Training program**

Running training will be standardised during the first 6-weeks of the study so that relative training intensity and volume will be the same for all participants. Training intensity will be prescribed relative to the peak heart rate ($HR_{peak}$) achieved during the 5TTT. Participants will monitor training intensity throughout the training program using a heart rate monitor (Polar F1 heart rate monitor, Polar Electro Oy, Kempele, Finland). The training program is adapted from a 6-week training program used by Billat et al.[24] that was shown to increase $VO_{2\text{max}}$ by 3.6% in trained runners. The training program is described in Table 2. During weeks 7-26, training will not be standardised and participants will complete their usual training to evaluate the effects of the shoe under non-controlled conditions so as to provide ecologically valid outcome data, but the transition to the allocated shoe will continue to be increased by 5% per week during this period until participants are completing 100% of training in the allocated shoe. Adherence to training and shoe allocation will be monitored using a participant training diary. Participants reporting an injury during the study period will be advised to stop the gradual increase in allocated shoe use until they have recovered. Injured participants will be invited to have their injury assessed and treated at the University of South Australia physiotherapy clinic. No study investigators will be involved in the assessment or treatment of injured participants.

**Running kinematics and kinetics**
Running kinematics and kinetics will be assessed during overground running trials performed at 18-km·h\(^{-1}\) ± 10% over a 40-m runway. Marker trajectories will be measured using a 12 camera VICON MX F20 system (Vicon, Oxford, UK) sampling at 300 Hz. Ground reaction force (GRF) will be measured using four force platforms aligned in series and sampling at 1200 Hz. Each participant will be required to complete five successful trials. A trial will be considered successful if the full plantar surface of the foot contacts the force platform in between the pylons of the force platform at the prescribed running speed without obvious modification of gait. Participants will not be provided with any instructions in regards to contacting the force platform. Instead, the runway starting point will be adjusted as needed to facilitate a successful trial.

### Table 2. Six week standardised running training program.

<table>
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<tr>
<th>Week</th>
<th>Method</th>
<th>Training session duration (min)</th>
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<tr>
<td></td>
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<td>2</td>
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<tr>
<td>3</td>
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<td>–</td>
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<td>3x14</td>
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<tr>
<td>4</td>
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<td>–</td>
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<td></td>
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<td>3x16</td>
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<tr>
<td>5</td>
<td>LSD</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>HIIT</td>
<td>3x18</td>
</tr>
<tr>
<td>6</td>
<td>LSD</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>HIIT</td>
<td>3x20</td>
</tr>
</tbody>
</table>

LSD, long slow distance running at 65-80% peak heart rate (HR\(_{peak}\)); HIIT, high-intensity interval training running at 85-90% HR\(_{peak}\). Intervals separated by 5 minutes of walking.

A full body marker set-up will be used and will include the feet, shanks, thighs, pelvis, trunk (including head), upper arms and lower arms (including hands). Spherical retro-reflective calibration markers will be used to define the position and orientation in space (POSE) of each segment and will be placed over the 1st and 5th metatarsal head, lateral and medial malleolus, lateral and medial femoral epicondyle, greater trochanter, anterior superior iliac
spine, posterior superior iliac spine C7 spinous process, acromioclavicular joint, lateral and medial humeral epicondyle and radial and ulnar styloid process. Tracking markers will be used to track the POSE of each segment. A minimum of three non-collinear markers will be used to track each segment in six degrees of freedom.

Running economy

Participants will complete a 5-minute warm-up on the treadmill at 8-km∙h⁻¹. Running economy will then be assessed during three 6-minute sub-maximal runs on the treadmill at 11 km∙h⁻¹, 13 km∙h⁻¹ and 15 km∙h⁻¹ in a fixed order. Running economy will be assessed by indirect calorimetry (True One, ParvoMedics, Utah, USA) and expressed as the rate of energy expenditure (REE; kJ∙min⁻¹) during the final 60-seconds of each 6-minute run. Participant data will be excluded if the respiratory exchange ratio increases above 1.0 during the final 60-seconds.

Spatiotemporal parameters

Force-sensitive resistors will be placed underneath the heel and first metatarsal head regions of each shoe insole and used to assess stride rate and length during each 6-minute run. Foot contacts will be recorded wirelessly at 2000-Hz using a Delsys Trigno system (DeSys Inc, Natick, USA). Stride rate (strides per minute) will be considered the number of right foot contacts recorded during the final 60-seconds of each 6-minute run. Average stride length will be calculated using the following equation:

\[ SL = ST \times V \]

SL is the stride length, ST is the time taken for each stride (right foot contact to right foot contact) and V is the treadmill speed[25] from the known distance covered during the 60-seconds because speed will remain fixed.
Running endurance performance will be assessed using a 5TTT on a motorised treadmill set at 0% grade. Participants will be instructed to complete the 5TTT in the fastest possible time and will be free to adjust the treadmill speed throughout the test. Starting speed will remain constant across testing sessions and will be selected by participants prior to completion of their baseline 5TTT. Participants will be blinded to treadmill speed and time throughout performance of the 5TTT. Peak oxygen consumption during the 5TTT will be assessed by indirect calorimetry.

**Bone mineral density**

BMD of the right proximal tibia, calcaneus and metatarsals will be measured by dual X-ray absorptiometry (DXA; Lunar Prodigy, General Electric Corporation, Madison, USA) using two separate scans. For assessment of the tibia and calcaneus, participants will be positioned in a side lying position[26]. For assessment of the metatarsals, participants will be positioned in an upright, seated position with the foot in the plantar position[27]. For each participant, goniometer measurements for the knee and ankle in the sagittal plane will be recorded and standardised between scans to help reproduce the same scan position.

**Muscle strength**

Muscle strength assessment of the triceps surae muscle group will be performed on an isokinetic dynamometer (Biodex System 4, Biodex Medical Systems, New York, USA) with participants in a reclined seated position with knees positioned in 20-30° flexion. Peak isometric torque (PIT) will be measured with the ankle positioned in the anatomical neutral position and defined as the peak torque achieved during the better of two 5-second efforts. Peak concentric torque (PCT) and Peak concentric torque (PET) torque will be measured at
an angular velocity of 30°·s\(^{-1}\). Two sets of three repetitions will be performed for both PCT and PET measurements, with the peak torque achieved across repetitions considered the participants PCT and PET. Torque data will be sampled at 1000-Hz using a PowerLab data acquisition system (PowerLab 16/30, ADInstruments, Bella Vista, Australia).

**Pain and injury monitoring**

Pain will be assessed using a study diary for seven regions of interest using a 100 mm VAS with anchor points consisting of ‘no pain’ on the left hand end and ‘worst pain’ on the right hand end. Regions of interest will include the foot, ankle, calf, shin, knee, thigh, and lumbopelvic area. At the end of each week, participants will be asked to record the worst running-related pain that they experience during the previous 7 days for each of the 7 regions of interest. An injury will be considered to be any musculoskeletal problem that is attributed by the participant to running. The problem will need to be severe enough to cause a reduction in weekly running distance, a visit to a health professional or the use of medication[28, 29]. Injuries attributed to an accident will not be considered. Injury events will be reported to the University of South Australia Human Research Ethics Committee who will independently monitor the safety of the study interventions.

**Data management**

Outcome data will be entered electronically and stored in a password protected folder on the University of South Australia network server at the time of collection. Only study investigators will have access to the data and investigators will meet weekly to monitor progress of data collection. All outcome data will be de-identified using a participant identification numbering system.

**Statistical methods**
Per-protocol analysis will be used to assess the effect of shoe group at the end of the 6-week standardised training program. Participants unable to complete a follow-up assessment at the end of the 6-week training program due to injury will not be included in the per-protocol analysis. An ANCOVA will be used to compare 5TTT performance, running kinematics and kinetics and muscle strength between shoe groups after adjusting for baseline time. Running economy and spatiotemporal parameters will be analysed using a linear mixed model with independent variables shoe, speed and shoe*speed interaction. Shoe mass will be included as a covariate in the statistical model for running economy.

Intention-to-treat analysis will be used to assess the effect of shoe group at the end of the 26-week study period. 5TTT performance, running economy, muscle strength, BMD, spatiotemporal parameters and running kinematics and kinetics will be compared between shoe groups using a linear mixed model with independent variables shoe and time. The independent variable speed will be included in the statistical models for running economy and spatiotemporal parameters. Shoe mass will be included as a covariate in the statistical model for running economy. Injury rate will be analysed by log binomial generalized linear model with independent variable group. Sensitivity analysis will be undertaken to determine whether the effect of shoes is influenced by adherence to training program and training volume by including adherence and training volume as covariates. All statistical analysis will be performed in SPSS (v22, IBM, New York, USA). Statistical significance will be assumed for p<0.05.

ETHICAL CONSIDERATIONS

This protocol has received ethical approval from the Human Research Ethics Committee of the University of South Australia. The Ethics Committee will be notified of any planned...
amendments to the original protocol. Amendments will not be made without the prior approval of the Ethics Committee and all members of the investigatory team.

Joel T. Fuller will manage all expressions of interests and will provide all potential participants with a study information sheet. At the beginning of the initial familiarisation session, participants will be briefed on all aspects of the study and provided with an opportunity to have any questions answered. Eligible participants will be required to provide their written informed consent prior to participation in the study (see supplementary material).

**DISSEMINATION OF FINDINGS**

Study results will be released to participants in a de-identified format. Participants will be provided with a separate copy of their personal results. Study findings will be released to the public in the form of journal publications and conference presentations.

**DISCUSSION**

Investigation of the longer-term effects of running in minimalist shoes is important to inform runners, coaches and clinicians about their safety and efficacy. Although short-term studies are informative for describing any immediate effects of minimalist shoes on running parameters, they are not useful for informing evidenced based prescription for longer-term use[30]. We propose to use an RCT to provide high-quality evidence regarding the safety and efficacy of training in minimalist shoes.

There is still no consensus definition for minimalist shoes[5]. Instead, footwear is considered to be minimalist if shoe mass, heel drop and cushioning are reduced compared with a conventional running shoe[1, 5]. Choice of minimalist shoe is an important consideration for studies investigating the effects of these shoes. In this RCT a racing flat will be used as the
minimalist shoe condition. Racing flats differ from conventional running shoes by having reduced shoe mass, heel drop and cushioning and as such can be categorised as a form of minimalist shoe[1]. Additionally, racing flats have been used by runners and coaches in competition for many years[1, 31] and can be considered representative of the footwear condition that runners used prior to the introduction of the modern conventional running shoe, which has increased shoe mass, heel drop and cushioning. It has been suggested that the introduction of the modern conventional running shoe may have caused changes to the natural human running gait and resulted in an increased injury rate[32]. To adequately test this hypothesis, conventional running shoes should be compared with racing flats, which were the predominant running shoe available to runners prior to the introduction of shoe cushioning and heel raise.

It has been proposed that carefully transitioning from conventional to minimalist running shoes can avoid injuries attributed to sudden changes in footwear[5, 7-10]. Several methods have been suggested for making this transition[5, 7-10] (Table 3) but currently there is insufficient evidence available upon which to base informed recommendations. The percentage of running performed in minimalist shoes during the first week of transition has ranged from 3-33% and has then been progressed each week by small amounts (Table 3)[5, 7-10]. Across studies, runners progressed the volume of minimalist shoe running by 3-20% each week (Table 3)[5, 7, 8, 10]. This heterogeneity across studies suggests that it is currently unclear what is an appropriate rate of progression for transition to running in minimalist shoes. In the present study, runners will use a 5% per week progression in the amount of time spent running in minimalist shoes until they reach 100% (by Week 20). They will then continue to run 100% in minimalist shoes during the final 6-weeks of the study.
Onset of injury and weekly pain scores will be used to determine if there is a threshold amount of running in minimalist shoes that is associated with an increased risk of injury in runners transitioning from conventional shoes. This will provide important information to runners, coaches and clinicians who are planning a transition to minimalist shoes about optimal transition rates to reduce the risk of injury.

To maximise recruitment, allow for longer-term study follow-up, and in order to achieve ecological validity, this RCT will use a period of non-standardised training between 6-week and 26-week follow-up during which participants will perform their own usual training program. The outcomes at Week 26 are likely to be affected by the different training regimes followed by participants during this non-standardised phase between Weeks 6 and 26, but any heterogeneity of usual training regimes should be balanced across groups through the randomisation process.

The efficacy of minimalist shoes for improving performance and their safety in terms of injury risk is thought to be influenced by the running kinematics that are adopted when running in this type of footwear[5, 7]. Running in minimalist shoes has previously been shown to reduce stride length[1] and the amount of ankle dorsiflexion at initial ground contact[6], with the latter promoting a forefoot strike[4, 7]. Changing to a forefoot strike increases ankle joint contact forces and plantar flexor muscle forces[12]. Increased involvement of the ankle plantar flexor muscle could result in greater elastic energy storage and recovery in the Achilles’ tendon, which may contribute to improved running economy and performance[4, 33]. We hypothesise that, over the longer-term, the increased loading on these structures may contribute to greater adaptation with resultant greater increases in performance in response to training. However, these unaccustomed high forces could also
Table 3. Methods of transitioning from conventional to minimalist footwear used in the literature.

<table>
<thead>
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<th>Date</th>
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<th>Week 1</th>
<th>Method for transitioning to minimalist footwear</th>
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<tbody>
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<td>Giandolini et al. [8]</td>
<td>2013</td>
<td>Salomon Sense S-Lab</td>
<td>33%</td>
<td>Increase by 3-17% each week until reaching 100% in week 4</td>
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<tr>
<td>Ridge et al. [10]</td>
<td>2013</td>
<td>Vibram FiveFingers</td>
<td>3-13%</td>
<td>100% of running performed in minimalist shoes from week 5-12</td>
</tr>
<tr>
<td>Ridge et al. [10]</td>
<td>2013</td>
<td>Vibram FiveFingers</td>
<td>3-13%</td>
<td>Increase by 3-13% each week until week 3</td>
</tr>
<tr>
<td>Ryan et al. [5]</td>
<td>2013</td>
<td>Vibram FiveFingers</td>
<td>19%</td>
<td>Participants made further increases as they felt comfortable during weeks 4-10</td>
</tr>
<tr>
<td>Ryan et al. [5]</td>
<td>2013</td>
<td>Nike Free V.5.0</td>
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<td>Gradual increases were made from week 1-12</td>
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<tr>
<td>Warne et al. [7]</td>
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<td>58% of running performed in minimalist shoes during week 12</td>
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<td>Moore et al. [9]</td>
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<td>3-10 miles</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>25% of running performed in minimalist shoes during week 4</td>
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*values indicate percentage of weekly running performed in the minimalist shoe condition.
increase risk of injury until sufficient adaptation has occurred in muscular and articular
tissue[12]. In the present study, examining effects of minimalist shoes on running
biomechanics, muscle strength, BMD, and running economy, will allow for investigation of
the factors underlying any effects on performance and/or injury over the longer-term to be
explored.

CONCLUSION

In conclusion, this RCT will provide high-quality evidence regarding the safety and efficacy of
minimalist shoes in terms of injury risk and effects on performance that is currently lacking
in the field of running footwear research. The longer-term follow-up and gradual transition
to minimalist shoes used in this study will provide information that can be used to inform
runners, coaches and clinicians of any longer-term effects of minimalist shoes. Assessments
of running biomechanics, muscle strength and BMD will allow this RCT to explore the
mechanisms underlying any longer-term effects of minimalist shoes on running
performance and/or injury.

ACKNOWLEDGMENTS

Joel T. Fuller is the recipient of an Australian Postgraduate Award from the Australian
Commonwealth Government. The authors would like to thank ASICS Oceania (ASICS Oceania
Pty Ltd, Eastern Creek, NSW, Australia) for donating 20 pairs of Asics Gel Cumulus-16
running shoes to support this research. No other sources of industry support have been
provided to support the completion of this RCT. Purchase of footwear will be arranged
through a local running shoe store (Jogger’s World, Adelaide SA, Australia) using funds
obtained from a University of South Australia Vice Chancellor & President’s Scholarship
($10,000) awarded to Joel T. Fuller. ASICS Oceania and the University of South Australia had
no role in the design of this RCT and will not have any role during its execution, analysis, interpretation or the decision to disseminate findings.

CONTRIBUTORS

J.T.F, D.T, M.D.T, N.A.T.B and J.D.B conceived the study, participated in its design and helped to draft this manuscript. J.T.F will be responsible for data collection and statistical analysis. All authors will contribute to the dissemination of research findings in the form of journal publications and conference presentations.

CONFLICT OF INTEREST

Dr. Dominic Thewlis has been a recipient of funding from ASICS Oceania (ASICS Oceania Pty Ltd, Eastern Creek, NSW, Australia) to undertake separate research. All other authors declare no potential conflicts of interest and have no financial relationships with any organisations that might have an interest in the submitted work.

REFERENCES


FIGURE LEGENDS

Figure 1. Participant timeline. ITT, intention-to-treat; 5TTT, 5 km treadmill time trial; RE, running economy; BMD, bone mineral density.
Figure 1. Participant timeline. ITT, intention-to-treat; STTT, 5 km treadmill time trial; RE, running economy; BMD, bone mineral density.

254x190mm (300 x 300 DPI)
PROJECT CONSENT FORM

PROJECT TITLE: The effect of footwear on distance running performance & injury – a long term study

INVESTIGATORS: Joel Fuller    Dr Margarita Tsiros
              Professor Jon Buckley    Dr Nick Brown
              Dr Dominic Thewlis

1. I have read the Information Sheet, and the nature and the purpose of the research project and the risks inherent in my participation have been explained to me. I understand and agree to take part.

2. I agree to my running pattern being video recorded for biomechanical analysis.

3. I understand that I may not directly benefit from taking part in the study.

4. I understand that while information gained during the study may be published, I will not be identified and my personal results will remain confidential.

5. I understand that I can withdraw from the study at any stage and that this will not affect my rights or the responsibilities of the researchers in any respect.

6. I have had the opportunity to discuss taking part in this study with a family member or friend or a GP.

7. I confirm that I am over 18 years of age.

☐ I agree to my data being retained for use in future research in the same or related research area. Data will be de-identified and stored in a secure room at the Nutritional Physiology Research Centre until the research has been published. After the research has been published, data will be stored in a de-identified form at the University of South Australia’s commercial data storage archive for 10 years before being destroyed.

☐ I agree to my personal details being retained so that I may be informed regarding future opportunities to participate in similar research.

Name of participant .....................................................................................

Signed ......................................................................................................

Date ........................................................................................................

I have explained the study to the participant and consider that he/she understands what is involved.

Signed ........................................................... Date .............................
### SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

#### Administrative information

<table>
<thead>
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<th>Item No</th>
<th>Description</th>
<th>Addressed on page number</th>
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<tr>
<td>Title</td>
<td>1</td>
<td>Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym</td>
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<td>Trial identifier and registry name. If not yet registered, name of intended registry</td>
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<td>Date and version identifier</td>
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<td>Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities</td>
<td>19, 20</td>
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<tr>
<td>Roles and responsibilities</td>
<td>5d</td>
<td>Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)</td>
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</table>
Introduction

Background and rationale

6a Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention

6b Explanation for choice of comparators

Objectives

7 Specific objectives or hypotheses

Trial design

8 Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)

Methods: Participants, interventions, and outcomes

Study setting

9 Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained

Eligibility criteria

10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)

Interventions

11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered

11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)

11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)

11d Relevant concomitant care and interventions that are permitted or prohibited during the trial

Outcomes

12 Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended

Participant timeline

13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
### Sample size
14 Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations

### Recruitment
15 Strategies for achieving adequate participant enrolment to reach target sample size

### Methods: Assignment of interventions (for controlled trials)
#### Allocation:

| 16a | Method of generating the allocation sequence (e.g., computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (e.g., blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions |
| 16b | Mechanism of implementing the allocation sequence (e.g., central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned |
| 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions |

### Blinding (masking)

| 17a | Who will be blinded after assignment to interventions (e.g., trial participants, care providers, outcome assessors, data analysts), and how |
| 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial |

### Methods: Data collection, management, and analysis

<p>| 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g., duplicate measurements, training of assessors) and a description of study instruments (e.g., questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol |
| 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols |</p>
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<tr>
<td>Data management</td>
<td>19</td>
<td>Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol</td>
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<td>Statistical methods</td>
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<td>Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol</td>
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<td>20b</td>
<td>Methods for any additional analyses (eg, subgroup and adjusted analyses)</td>
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<td></td>
<td>20c</td>
<td>Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)</td>
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<tr>
<td>Methods: Monitoring</td>
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<td></td>
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<td>Data monitoring</td>
<td>21a</td>
<td>Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed</td>
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<td>21b</td>
<td>Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial</td>
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<td>Harms</td>
<td>22</td>
<td>Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct</td>
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<td>Auditing</td>
<td>23</td>
<td>Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor</td>
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<td>Ethics and dissemination</td>
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<td>Research ethics approval</td>
<td>24</td>
<td>Plans for seeking research ethics committee/institutional review board (REC/IRB) approval</td>
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<tr>
<td>Protocol amendments</td>
<td>25</td>
<td>Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)</td>
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<tr>
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<td>---------</td>
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<tr>
<td>26a</td>
<td>Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)</td>
<td>14</td>
</tr>
<tr>
<td>26b</td>
<td>Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>27</td>
<td>How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial</td>
<td>13</td>
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<tr>
<td>28</td>
<td>Financial and other competing interests for principal investigators for the overall trial and each study site</td>
<td>19, 20</td>
</tr>
<tr>
<td>29</td>
<td>Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators</td>
<td>13, 19, 20</td>
</tr>
<tr>
<td>30</td>
<td>Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation</td>
<td>9</td>
</tr>
<tr>
<td>31a</td>
<td>Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (e.g., via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions</td>
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<tr>
<td>31b</td>
<td>Authorship eligibility guidelines and any intended use of professional writers</td>
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<tr>
<td>31c</td>
<td>Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code</td>
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**Appendices**

- **Informed consent materials**
  - Model consent form and other related documentation given to participants and authorised surrogates
  - Supplementary material file

- **Biological specimens**
  - Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable
  - N/A

---

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons “Attribution-NonCommercial-NoDerivs 3.0 Unported” license.*
The long-term effect of minimalist shoes on running performance and injury: design of a randomised controlled trial

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The long-term effect of minimalist shoes on running performance and injury: design of a randomised controlled trial.

Joel T Fuller¹, Dominic Thewlis¹, Margarita D Tsiros¹, Nicholas A.T Brown², Jonathan D Buckley³

1. Alliance for Research in Exercise, Nutrition and Activity (ARENA), Sansom Institute for Health Research, University of South Australia, Adelaide 5001, SA, Australia.

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Adelaide, South Australia 5001
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Email: joel.fuller@mymail.unisa.edu.au

Word Count: 4,698

Key Words: footwear; running economy; biomechanics; muscle strength; bone mineral density
ABSTRACT

Introduction The effects of transitioning to a minimalist running shoe are a topic of interest for runners and scientists. However, few studies have investigated the longer-term effects of running in minimalist shoes. The purpose of this randomised controlled trial (RCT) is to investigate the effects of a 26-week transition to minimalist shoes on running performance and injury risk in trained runners unaccustomed to minimalist footwear.

Methods and analysis A randomized parallel intervention design will be used. 76 trained male runners will be recruited. To be eligible, runners must be aged 18-40 years, run with a habitual rearfoot footfall pattern, train with conventional shoes and have no prior experience running in minimalist shoes. Runners will complete a standardised transition to minimalist or control shoes and undergo assessments at baseline, 6-weeks and 26-weeks. 5-km time-trial (5TT) performance, running economy, running biomechanics, triceps surae muscle strength and lower limb bone mineral density will be assessed at each time point. Pain and injury will be recorded weekly. Training will be standardised during the first 6-weeks. Primary statistical analysis will compare 5TT between shoe groups at the 6-week time point and injury incidence across the entire 26-week study period.

Ethics and dissemination This RCT has been approved by the Human Research Ethics Committee of the University of South Australia. Participants will be required to provide their written informed consent prior to participation in the study. Study findings will be disseminated in the form of journal publications and conference presentations after completion of planned data analysis.

Registration details This RCT has been registered with the Australian New Zealand Clinical Trials Registry (ACTRN12613000642785).
STRENGTHS AND LIMITATIONS OF THIS STUDY

- This is the first study to investigate the effect of minimalist footwear over longer than a 3-month period and the first to include a measure of running performance.

- The standardised gradual transition to minimalist shoes from 0 to 100% of weekly running will inform runners, coaches and clinicians of the effect of these shoes across the entire transitional period.

- Limitations of the study are the inclusion of only male runners aged 18-40 years and the inclusion of only one minimalist shoe group.
INTRODUCTION

The effects of running in minimalist shoes is a topic of interest for both runners and scientists[1-7]. Running in minimalist shoes can cause runners to run with a more plantar-flexed ankle at initial contact and adopt a forefoot footfall (FF) pattern[4, 6, 7], increase stride frequency[1, 7], reduce stride length[1], increase ankle plantar-flexor moments and decrease knee extensor moments[4] and improve running economy[2]. Although athletes and coaches may be interested in the potential for minimalist shoes to improve running performance, there is also some evidence that minimalist shoes increase injury risk[5]. However, few studies have comprehensively evaluated the longer-term effects (>2 weeks) of running in these shoes[5, 7-11]. At present, runners, coaches and clinicians attempting to make a more informed purchase or prescription of minimalist shoes are required to base their decision on predominantly short-term (<2 weeks) or acute studies[1, 3, 4, 6].

The few studies that have investigated the longer-term effects of minimalist shoes have used follow-up periods of only 4 to 12-weeks[5, 7-11]. These studies found that, following the longer-term transition to minimalist shoes, runners improved running economy[7], reduced peak pressure under the heel[9] and increased intrinsic foot muscle cross-sectional area[11], but experienced increased calf and shin pain[5, 8], increased foot bone marrow oedema[10] and a higher injury rate[5]. It has been hypothesised that these longer-term effects of minimalist shoes result from runners adopting a FF pattern, which causes increased loading of musculoskeletal structures at the foot and ankle[11-13]. If an appropriate, gradual transition to minimalist shoes can be made then it might be possible to derive beneficial training adaptations from this increased loading[7, 11]. However, if the increased loading is too rapid then pain and injury may result[5]. Indeed, the only study to...
investigate the effect of transitioning to minimalist shoes on injury risk reported a higher incidence of injury for two different minimalist shoes (20% and 38%) compared to a conventional shoe (13%)[5].

Choice of running shoe is an important issue for distance runners who view minimalist shoes as a means for enhancing running performance but have concerns about the potential for minimalist shoes to cause injury[14]. Avoiding injuries resulting from minimalist shoes is important for runners to minimise the economic burden associated with medical treatment and absenteeism from work as well as to maximise the positive health effects of maintaining an active lifestyle[15]. This issue is particularly relevant given the popularity of running, which is performed by 10% of the Australian population[16]. In order to provide runners with sufficient instructions on how to implement minimalist shoes, further longitudinal studies investigating methods for transitioning to minimalist shoes over longer periods are needed. Current longitudinal studies involving minimalist shoes have been limited to follow-up periods of 12-weeks or less[5, 7-11], only transitioned runners to using minimalist shoes for up to 60% of weekly running[5, 7, 11], not used standardised methods for transitioning to minimalist shoes[10] or not investigated injury incidence[7-11] and running performance[5, 8-11], which are the two most significant outcomes for runners interested in minimalist shoes[14].

**Primary objective**

The purpose of this randomised controlled trial (RCT) is to investigate the effects of a 26-week transition to minimalist shoes compared to conventional shoes on running performance and injury risk in trained runners unaccustomed to minimalist footwear. It is
hypothesised that transitioning to minimalist shoes will have longer-term benefits for running performance but be associated with an increased risk of injury.

METHODS

This study protocol was developed according to the 2013 SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) statement[17]. The study will use a two-arm RCT design with a 6-week and 26-week follow-up. Data collection will take place at the University of South Australia. The RCT has been registered with the Australian New Zealand Clinical Trials Registry. Trial registration data is shown in Table 1. Participants will be recruited from a sample of convenience on a volunteer basis. This study will be advertised at local universities, running clubs and running events. To assist with participant retention, participants will be provided with a $100 shoe voucher if they successfully complete the 26-week study commitment. Participants who withdraw from the study due to injury will also receive the $100 shoe voucher after independent assessment of the injury by a registered physiotherapist or medical practitioner not associated with the study.

Study population

Male runners, aged 18-40 years, will be recruited to avoid potential gender and age effects on running biomechanics and injury risk[18, 19]. Participants will be required to run a minimum of 15-km per week[3] (this will minimise the risk of injuries resulting from a lack of familiarity with regular running[19]), be able to complete a 5-km treadmill time trial (5TT) in ≤ 23-minutes (95% of runners represented by the cohort of male endurance-trained runners in a study by Laursen et al.[20] would complete a 5TT in less than 23-minutes i.e. mean 5TT +2 standard deviations was 23-minutes), train with conventional running shoes, have no prior experience running in shoes with reduced cushioning, drop height and mass, run with
a rearfoot footfall (RF) pattern at the time of enrolment in the study (typical of 89% of runners[21]) and have no current or recent (<3 months) musculoskeletal injury. Participants will be excluded if they have a history of invasive surgery to the back, pelvis or lower extremities in the previous year or they use orthotics in their running shoes because orthotics will not fit inside the minimalist shoe. Footfall pattern will be determined from over-ground running trials at a self-selected running speed in participants’ own running shoes filmed at 200 Hz using a high-speed digital camera (Basler Pilot, Ahrensburg, Germany) to ensure only habitual RF runners are recruited.

Table 1. Trial registration data.

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<td>Date of registration in primary registry</td>
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<td>Secondary identifying numbers</td>
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<td>Source of monetary or material support</td>
<td>University of South Australia</td>
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<tr>
<td>Primary sponsor</td>
<td>University of South Australia</td>
</tr>
<tr>
<td>Contact person: J.D.B [<a href="mailto:jon.buckley@unisa.edu.au">jon.buckley@unisa.edu.au</a>]</td>
<td></td>
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<tr>
<td>Secondary sponsor</td>
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<tr>
<td>Contact for public queries</td>
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<tr>
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<td></td>
<td>Conventional shoe (Asics Gel Cumulus-14, 15 or 16)</td>
</tr>
<tr>
<td>Key inclusion and exclusion criteria</td>
<td>Inclusion criteria: male, 18-40 years, running ≥15 km per week, habitual rearfoot footfall and able to run a 5 km time trial in &lt;23 minutes</td>
</tr>
<tr>
<td></td>
<td>Exclusion criteria: prior experience with minimalist shoes, use of orthotics, having a current or recent (&lt;3 months) musculoskeletal injury or history of recent (&lt;12 months) invasive surgery that affect running.</td>
</tr>
<tr>
<td>Study type</td>
<td>Randomised controlled trial</td>
</tr>
<tr>
<td>Date of first enrolment</td>
<td>24th June 2013</td>
</tr>
<tr>
<td>Target sample size</td>
<td>76</td>
</tr>
<tr>
<td>Recruitment status</td>
<td>Closed: follow-up continuing</td>
</tr>
<tr>
<td>Primary outcome</td>
<td>5 km time trial performance (time point: 6-weeks)</td>
</tr>
<tr>
<td>Key secondary outcomes</td>
<td>Injury incidence (time frame: 26-weeks)</td>
</tr>
<tr>
<td></td>
<td>5 km time trial performance (time point: 26-weeks)</td>
</tr>
<tr>
<td></td>
<td>Running economy (time point: 6-weeks and 26-weeks)</td>
</tr>
<tr>
<td></td>
<td>Running biomechanics (time point: 6-weeks and 26-weeks)</td>
</tr>
</tbody>
</table>
Sample size

An *a-priori* power calculation determined that 50 participants are required to detect a Cohen’s *d* effect size of 0.3 for the primary outcome (5TT performance) at 6-week follow-up with 80% power and a 5% significance level using analysis of covariance (ANCOVA). This calculation was performed using the formula described by Borm et al.[22] and South Australian 5-km road race results recorded in 2011 and 2012 (average race time 1139 ± 140 s). The 0.3 effect size was based on the 2.4-5.8% improvement (mean improvement 3.6%) in running economy observed for runners training with or experienced with minimalist shoes[6, 7, 23] and a corresponding 10.6 m·min⁻¹ improvement in average race pace (44 s improvement in average race time) estimated by Burkett et al.[24]. To allow for a 20% drop out rate and a 25% rate of injury[5] during the 6-week follow-up period it is expected that 76 participants will need to be recruited. An additional 12 participants will be recruited and will complete all outcome assessments on two separate occasions in their own shoes to determine test-retest reliability.

Study protocol

Participants will attend a familiarisation session in the week prior to their anticipated start date. During this session, information about previous injury and shoe use will be collected and participants will complete a 30-minute treadmill familiarisation, footfall pattern will be assessed and a 5TT will be completed. Randomisation to shoe group will be via a process of minimisation[25], using 5TT performance times obtained during familiarisation as the minimisation variable and a 1:1 allocation ratio. Allocation via minimisation offers the only acceptable alternative to simple and restricted randomisation[26] and is more effective at
balancing the collective attributes of intervention groups in small samples than traditional methods of randomisation[27]. Allocation of participants will be performed by one of the investigators (Jonathan D. Buckley) who will not be involved directly in data collection, but it will not be possible to blind outcome assessors to participant shoe condition during testing. Experimental testing sessions will be undertaken for each shoe condition at baseline, at 6-week follow-up and at 26-week follow-up. Outcomes assessed in order of assessment at each test session will be over-ground running kinematics and kinetics, treadmill running economy, bone mineral density (BMD), 5TT performance and muscle strength. A participant timeline is shown in Figure 1. All testing sessions will be performed at the same time of the day. Participants will be required to not complete any training on the day of testing and remain fasted from food (water permitted ad libitum) in the 3-hours prior to testing.

*** insert Figure 1 approximately here ***

**Shoe conditions**

Participants allocated to the control condition will run in a traditional running shoe (Asics Gel Cumulus-14, 15 or 16; mass 324 g per shoe; heel drop 9 mm) and participants allocated to the minimalist shoe condition will run in a lightweight racing flat (Asics Piranha SP4; mass 125 g per shoe; heel drop 5 mm). Mass is reported for an average U.S. size 9 (European size 42.5) shoe. Participants will be instructed to complete only 5% of running in their allocated shoes on each day that they run in the first week. This amount will then be increased by 5% each week until week 20, when participants will complete 100% of running in the allocated shoes. From week 20-26, runners will perform all running in their allocated shoe condition. To investigate how the runners perceive the comfort of the two shoe conditions, they will complete an assessment of shoe comfort for their respective shoe condition at the
beginning of each testing session. Assessments of shoe comfort will be made using a 100-
mm visual analogue scale (VAS) with anchors “not comfortable at all” on the left hand end
and “most comfortable imaginable” on the right[28]. Shoe comfort will be assessed before
and following a 2-minute sub-maximal run on a motorised treadmill at self-selected running
speed (Model 645, Quinton Instrument Co., Washington, USA). Four familiarisation comfort
assessments will be used to achieve stability of shoe comfort results[28].

Training program

Running training will be standardised during the first 6-weeks of the study so that relative
training intensity and volume will be the same for all participants. Training intensity will be
prescribed relative to the peak heart rate (HR_{peak}) achieved during the 5TT. Participants will
monitor training intensity throughout the training program using a heart rate monitor (Polar
F1 heart rate monitor, Polar Electro Oy, Kempele, Finland). The training program is adapted
from a 6-week training program used by Billat et al.[29] that was shown to increase VO_{2max}
by 3.6% in trained runners. The training program is described in Table 2. During weeks 7-26,
training will not be standardised and participants will complete their usual training to
evaluate the effects of the shoe under non-controlled conditions so as to provide
ecologically valid outcome data, but the transition to the allocated shoe will continue to be
increased by 5% per week during this period until participants are completing 100% of
training in the allocated shoe. Adherence to training and shoe allocation will be monitored
using a participant training diary. Participants reporting an injury during the study period
will be advised to stop the gradual increase in allocated shoe use until they have recovered.
Injured participants will be invited to have their injury assessed and treated at the University
of South Australia physiotherapy clinic. No study investigators will be involved in the assessment or treatment of injured participants.

**Running kinematics and kinetics**

Running kinematics and kinetics will be assessed during overground running trials performed at 18-km·h⁻¹ ± 10% over a 40-m runway. Consistency of running speed will be monitored using photoelectric sensors (SpeedLight V2, Swift Performance Equipment, Queensland, Australia). Marker trajectories will be measured using a 12 camera VICON MX F20 system (Vicon, Oxford, UK) sampling at 300 Hz. Ground reaction force (GRF) will be measured using four force platforms aligned in series and sampling at 1200 Hz. Each participant will be required to complete five successful trials. A trial will be considered successful if the full plantar surface of the foot contacts the force platform in between the pylons of the force platform at the prescribed running speed without obvious modification of gait. Participants will not be provided with any instructions in regards to contacting the force platform. Instead, the runway starting point will be adjusted as needed to facilitate a successful trial.

<table>
<thead>
<tr>
<th>Table 2. Six week standardised running training program.</th>
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<tr>
<td><strong>Week</strong></td>
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<td>6</td>
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</tr>
</tbody>
</table>

LSD, long slow distance running at 65-80% peak heart rate (HR<sub>peak</sub>); HIIT, high-intensity interval training running at 85-90% HR<sub>peak</sub>. Intervals separated by 5-minutes of walking.
A full body marker set-up will be used and will include the feet, shanks, thighs, pelvis, trunk (including head), upper arms and lower arms (including hands). Spherical retro-reflective calibration markers will be used to define the position and orientation in space (POSE) of each segment and will be placed over the 1st and 5th metatarsal head, lateral and medial malleolus, lateral and medial femoral epicondyle, greater trochanter, anterior superior iliac spine, posterior superior iliac spine, C7 spinous process, acromioclavicular joint, lateral and medial humeral epicondyle and radial and ulnar styloid process. Tracking markers will be used to track the POSE of each segment. A minimum of three non-collinear markers will be used to track each segment in six degrees of freedom. This marker set-up will be used to investigate footfall pattern as well as kinematics and kinetics at the knee and ankle.

**Running economy**

Participants will complete a 5-minute warm-up on the treadmill at 8-km·h\(^{-1}\). Running economy will then be assessed during three 6-minute sub-maximal runs on the treadmill at 11 km·h\(^{-1}\), 13 km·h\(^{-1}\) and 15 km·h\(^{-1}\) in a fixed order. Running economy will be assessed by indirect calorimetry (True One, ParvoMedics, Utah, USA) and expressed as the rate of energy expenditure (REE; kJ·min\(^{-1}\)) during the final 60-seconds of each 6-minute run. Participant data will be excluded if the respiratory exchange ratio (RER) increases above 1.0 during the final 60-seconds or a steady state of oxygen consumption is not achieved.

**Spatiotemporal parameters**

Force-sensitive resistors (FSR) will be placed underneath the heel and forefoot regions of each shoe and used to assess footfall pattern, stride rate and stride length during each 6-minute run. Foot contacts will be recorded wirelessly at 2000-Hz using a DelSys Trigno system (DelSys Inc, Natick, USA). Runners will be classified with a RF pattern if initial contact
is made with the FSR positioned at the heel or a FF pattern if initial contact is made with the
FSR positioned at the forefoot. Footfall pattern will be assessed throughout each 6-minute
run and classification will be based on the mode (i.e. whichever pattern is most frequent)
during the final 60-seconds. Stride rate (strides per minute) will be considered the number
of right foot contacts recorded during the final 60-seconds of each 6-minute run. Average
stride length will be calculated using the following equation:

\[ SL = ST \times V \]

SL is the stride length, ST is the time taken for each stride (right foot contact to right foot
contact) and V is the treadmill speed [30] from the known distance covered during the 60-
seconds because speed will remain fixed. Footfall pattern, stride length and stride rate
computations will be performed using a custom written code in MATLAB (R2013a, MathWorks, MA, USA).

5-km treadmill time trial

Running endurance performance will be assessed using a 5TT on a motorised treadmill set
at 0% grade. Participants will be instructed to complete the 5TT in the fastest possible time
and will be free to adjust the treadmill speed throughout the test. Starting speed will remain
constant across testing sessions and will be selected by participants prior to completion of
their baseline 5TT. Participants will be blinded to treadmill speed and time but not distance
throughout performance of the 5TT. Peak oxygen consumption during the 5TT will be
assessed by indirect calorimetry.

Bone mineral density

BMD of the right proximal tibia, calcaneus and metatarsals will be measured by dual X-ray
absorptiometry (DXA; Lunar Prodigy, General Electric Corporation, Madison, USA) using two
separate scans. These peripheral sites were chosen for the assessment of BMD because it was hypothesised that they would be most likely to change in response to the potential alterations in running biomechanics that can result from running in minimalist shoes[4, 6, 7].

For assessment of the tibia and calcaneus, participants will be positioned in a side lying position[31]. For assessment of the metatarsals, participants will be positioned in an upright, seated position with the foot in the plantar position[32]. For each participant, goniometer measurements for the knee and ankle in the sagittal plane will be recorded and standardised between scans to help reproduce the same scan position.

Muscle strength

Muscle strength assessment of the triceps surae muscle group will be performed on an isokinetic dynamometer (Biodex System 4, Biodex Medical Systems, New York, USA) with participants in a reclined seated position with knees positioned in 20-30° flexion. Peak isometric torque (PIT) will be measured with the ankle positioned in the anatomical neutral position and defined as the peak torque achieved during the better of two 5-second efforts.

Peak concentric torque (PCT) and Peak concentric torque (PET) torque will be measured at an angular velocity of 30°·s⁻¹. Two sets of three repetitions will be performed for both PCT and PET measurements, with the peak torque achieved across repetitions considered the participants PCT and PET. Torque data will be sampled at 1000-Hz using a PowerLab data acquisition system (PowerLab 16/30, ADInstruments, Bella Vista, Australia).

Pain and injury monitoring

Pain will be assessed using a study diary for seven regions of interest using a 100 mm VAS with anchor points consisting of ‘no pain’ on the left hand end and ‘worst pain’ on the right hand end. Regions of interest will include the foot, ankle, calf, shin, knee, thigh, and
lumbopelvic area. At the end of each week, participants will be asked to record the worst running-related pain that they experience during the previous 7 days for each of the 7 regions of interest. A difference in VAS score of 10 mm will be considered clinically significant[33]. An injury will be considered to be any musculoskeletal problem that is attributed by the participant to running. The problem will need to be severe enough to cause a reduction in weekly running distance, a visit to a health professional or the use of medication[34, 35]. Injuries attributed to an accident will not be considered. Injury events will be reported to the University of South Australia Human Research Ethics Committee who will independently monitor the safety of the study interventions.

Data management

Outcome data will be entered electronically and stored in a password protected folder on the University of South Australia network server at the time of collection. Only study investigators will have access to the data and investigators will meet weekly to monitor progress of data collection. All outcome data will be de-identified using a participant identification numbering system.

Statistical methods

Per-protocol analysis will be used to assess the effect of shoe group at the end of the 6-week standardised training program. Participants unable to complete a follow-up assessment at the end of the 6-week training program due to injury will not be included in the per-protocol analysis. An ANCOVA will be used to compare 5TT performance, running kinematics and kinetics and muscle strength between shoe groups after adjusting for baseline time. Running economy and spatiotemporal parameters will be analysed using a linear fixed-effects model with independent variables shoe, speed, time and
shoe*speed*time interaction. Shoe mass will be included as a covariate in the statistical
model for running economy. Cases with missing running economy data (i.e. RER >1.00) will
be included in the model.

Intention-to-treat analysis will be used to assess the effect of shoe group at the end of the
26-week study period. 5TT performance, running economy, muscle strength, BMD,
spatiotemporal parameters and running kinematics and kinetics will be compared between
shoe groups using a linear fixed-effects model with independent variables shoe, time and
shoe*time interaction. The independent variables speed and shoe*speed*time will be
included in the statistical models for running economy and spatiotemporal parameters.

Shoe mass will be included as a covariate in the statistical model for running economy.

Cases with missing running economy data (i.e. RER >1.00) will be included in the model.

Injury rate will be analysed by log binomial generalized linear model with independent
variable group. Sensitivity analysis will be undertaken to determine whether the effect of
shoes is influenced by adherence to training program and training volume by including
adherence and training volume as covariates. All statistical analysis will be performed in
SPSS (v22, IBM, New York, USA). Statistical significance will be assumed for p<0.05.

ETHICAL CONSIDERATIONS

This protocol has received ethical approval from the Human Research Ethics Committee of
the University of South Australia. The Ethics Committee will be notified of any planned
amendments to the original protocol. Amendments will not be made without the prior
approval of the Ethics Committee and all members of the investigatory team.

Joel T. Fuller will manage all expressions of interests and will provide all potential
participants with a study information sheet. At the beginning of the initial familiarisation
session, participants will be briefed on all aspects of the study and provided with an
opportunity to have any questions answered. Eligible participants will be required to
provide their written informed consent prior to participation in the study (see
supplementary material).

DISSEMINATION OF FINDINGS

Study results will be released to participants in a de-identified format. Participants will be
provided with a separate copy of their personal results. Study findings will be released to
the public in the form of journal publications and conference presentations.

DISCUSSION

Investigation of the longer-term effects of running in minimalist shoes is important to
inform runners, coaches and clinicians about their safety and efficacy. Although short-term
studies are informative for describing any immediate effects of minimalist shoes on running
parameters, they are not useful for informing evidenced based prescription for longer-term
use[36]. We propose to use an RCT to provide high-quality evidence regarding the efficacy
of transitioning from a conventional shoe to a minimalist shoe.

There is still no consensus definition for minimalist shoes[5]. Instead, footwear is considered
to be minimalist if shoe mass, heel drop and cushioning are reduced compared with a
conventional running shoe[1, 5]. Choice of minimalist shoe is an important consideration for
studies investigating the effects of these shoes. In this RCT a racing flat will be used as the
minimalist shoe condition. Racing flats differ from conventional running shoes by having
reduced shoe mass, heel drop and cushioning and as such can be categorised as a form of
minimalist shoe[1]. Additionally, racing flats have been used by runners and coaches in
competition for many years[1, 37] and can be considered representative of the footwear
condition that runners used prior to the introduction of the modern conventional running
shoe, which has increased shoe mass, heel drop and cushioning[14]. It has been suggested
that the introduction of the modern conventional running shoe may have caused changes to
the natural human running gait and resulted in an increased injury rate[38]. To adequately
test this hypothesis, conventional running shoes should be compared with racing flats,
which were the predominant running shoe available to runners prior to the introduction of
shoe cushioning and heel raise.

It has been proposed that carefully transitioning from conventional to minimalist running
shoes can avoid injuries attributed to sudden changes in footwear[5, 7-11]. Several methods
have been suggested for making this transition[5, 7-11] (Table 3) but currently there is
insufficient evidence available upon which to base informed recommendations. The
percentage of running performed in minimalist shoes during the first week of transition has
ranged from 3-33% and has then been progressed each week by small amounts (Table 3)[5,
7-11]. Across studies, runners progressed the volume of minimalist shoe running by 3-20%
each week (Table 3)[5, 7, 8, 10, 11]. This heterogeneity across studies suggests that it is
currently unclear what is an appropriate rate of progression for transition to running in
minimalist shoes. In the present study, runners will use a 5% per week progression in the
amount of time spent running in minimalist shoes until they reach 100% (by Week 20). They
will then continue to run 100% in minimalist shoes during the final 6-weeks of the study.

Onset of injury and weekly pain scores will be used to determine if there is a threshold
amount of running in minimalist shoes that is associated with an increased risk of injury in
runners transitioning from conventional shoes. This will provide important information to
Table 3. Methods of transitioning from conventional to minimalist footwear used in the literature.

<table>
<thead>
<tr>
<th>Author</th>
<th>Date</th>
<th>Minimalist shoe</th>
<th>Week 1 *</th>
<th>Method for transitioning to minimalist footwear *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Giandolini et al. [8]</td>
<td>2013</td>
<td>Salomon Sense S-Lab</td>
<td>33%</td>
<td>Increase by 3-17% each week until reaching 100% in week 4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>100% of running performed in minimalist shoes from week 5-12</td>
</tr>
<tr>
<td>Ridge et al. [10]</td>
<td>2013</td>
<td>Vibram FiveFingers</td>
<td>3-13%</td>
<td>Increase by 3-13% each week until week 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Participants made further increases as they felt comfortable during weeks 4-10</td>
</tr>
<tr>
<td>Ryan et al. [5]</td>
<td>2013</td>
<td>Vibram FiveFingers</td>
<td>19%</td>
<td>Gradual increases were made from week 1-12</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nike Free V.5.0</td>
<td></td>
<td>58% of running performed in minimalist shoes during week 12</td>
</tr>
<tr>
<td>Miller et al. [11]</td>
<td>2014</td>
<td>New Balance Road Minimus Merrel Pace/Trail Glove</td>
<td>7%</td>
<td>Increase by &lt;10% each week from week 1-12</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Up to 43% of running performed in minimalist shoes during final weeks</td>
</tr>
<tr>
<td>Warne et al. [7]</td>
<td>2014</td>
<td>Vibram FiveFingers</td>
<td>10%</td>
<td>Gradual increases were made from week 1-4</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>25% of running performed in minimalist shoes during week 4</td>
</tr>
<tr>
<td>Moore et al. [9]</td>
<td>2015</td>
<td>Vibram FiveFingers</td>
<td>3-10 miles</td>
<td>Increase by no more than 20% each week</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No running performed in conventional shoes throughout the transition</td>
</tr>
</tbody>
</table>

*a* values indicate percentage of weekly running performed in the minimalist shoe condition.
runners, coaches and clinicians who are planning a transition to minimalist shoes about optimal transition rates to reduce the risk of injury.

To maximise recruitment, allow for longer-term study follow-up, and in order to achieve ecological validity, this RCT will use a period of non-standardised training between 6-week and 26-week follow-up during which participants will perform their own usual training program. The outcomes at Week 26 are likely to be affected by the different training regimes followed by participants during this non-standardised phase between Weeks 6 and 26, but any heterogeneity of usual training regimes should be balanced across groups through the randomisation process.

The efficacy of minimalist shoes for improving performance and their safety in terms of injury risk is thought to be influenced by the running kinematics that are adopted when running in this type of footwear\[5, 7\]. Running in minimalist shoes has previously been shown to reduce stride length\[1\] and the amount of ankle dorsiflexion at initial ground contact\[6\], with the latter promoting a FF pattern\[4, 7\]. Changing to a FF pattern increases ankle joint contact forces and plantar flexor muscle forces\[13\]. Increased involvement of the ankle plantar flexor muscle could result in greater elastic energy storage and recovery in the Achilles’ tendon, which may contribute to improved running economy and performance\[4, 39\]. We hypothesise that, over the longer-term, the increased loading on these structures may contribute to greater adaptation with resultant greater increases in performance in response to training\[7\]. However, these unaccustomed high forces could also increase risk of injury until sufficient adaptation has occurred in muscular and articular tissue\[5, 10, 11, 13\]. Previous research has observed changes in muscle and bone tissue when transitioning to minimalist shoes over 10-12 weeks\[10, 11\] and the 26-week transition used in the present study will add to this knowledge. Additionally, examining effects of minimalist shoes
on running biomechanics, muscle strength, BMD, and running economy in the present
study, will allow for investigation of the factors underlying any effects on performance
and/or injury over the longer-term to be explored.

CONCLUSION

In conclusion, this RCT will provide high-quality evidence regarding the longer-term effects
on running performance of transitioning from conventional to minimalist shoes, which is
currently lacking in the field of running footwear research. Additionally, observation of
injury rates during this transition will be used to inform the design of larger studies
investigating the effect of minimalist shoes on injury risk. The longer-term follow-up and
gradual transition to minimalist shoes used in this study will provide information that can be
used to inform runners, coaches and clinicians of any longer-term effects of minimalist
shoes. Assessments of running biomechanics, muscle strength and BMD will allow this RCT
to explore the mechanisms underlying any longer-term effects of minimalist shoes on
running performance and/or injury.

ACKNOWLEDGMENTS

Joel T. Fuller is the recipient of an Australian Postgraduate Award from the Australian
Commonwealth Government. The authors would like to thank ASICS Oceania (ASICS Oceania
Pty Ltd, Eastern Creek, NSW, Australia) for donating 20 pairs of Asics Gel Cumulus-16
running shoes to support this research. No other sources of industry support have been
provided to support the completion of this RCT. Purchase of footwear will be arranged
through a local running shoe store (Jogger’s World, Adelaide SA, Australia) using funds
obtained from a University of South Australia Vice Chancellor & President’s Scholarship
($10,000) awarded to Joel T. Fuller. ASICS Oceania and the University of South Australia had
no role in the design of this RCT and will not have any role during its execution, analysis, interpretation or the decision to disseminate findings.

CONTRIBUTORS

J.T.F, D.T, M.D.T, N.A.T.B and J.D.B conceived the study, participated in its design and helped to draft this manuscript. J.T.F will be responsible for data collection and statistical analysis. All authors will contribute to the dissemination of research findings in the form of journal publications and conference presentations.

CONFLICT OF INTEREST

Dr. Dominic Thewlis has been a recipient of funding from ASICS Oceania (ASICS Oceania Pty Ltd, Eastern Creek, NSW, Australia) to undertake separate research. All other authors declare no potential conflicts of interest and have no financial relationships with any organisations that might have an interest in the submitted work.

REFERENCES


**FIGURE LEGENDS**

518 Figure 1. Participant timeline. ITT, intention-to-treat; 5TT, 5 km treadmill time trial; RE, running economy; BMD, bone mineral density.
Figure 1. Participant timeline. ITT, intention-to-treat; 5TT, 5 km treadmill time trial; RE, running economy; BMD, bone mineral density.

254x190mm (300 x 300 DPI)
PROJECT CONSENT FORM

PROJECT TITLE: The effect of footwear on distance running performance & injury – a long term study

INVESTIGATORS: Joel Fuller    Dr Margarita Tsiros
               Professor Jon Buckley    Dr Nick Brown
               Dr Dominic Thewlis

1. I have read the Information Sheet, and the nature and the purpose of the research project and the risks inherent in my participation have been explained to me. I understand and agree to take part.

2. I agree to my running pattern being video recorded for biomechanical analysis.

3. I understand that I may not directly benefit from taking part in the study.

4. I understand that while information gained during the study may be published, I will not be identified and my personal results will remain confidential.

5. I understand that I can withdraw from the study at any stage and that this will not affect my rights or the responsibilities of the researchers in any respect.

6. I have had the opportunity to discuss taking part in this study with a family member or friend or a GP.

7. I confirm that I am over 18 years of age.

☐ I agree to my data being retained for use in future research in the same or related research area. Data will be de-identified and stored in a secure room at the Nutritional Physiology Research Centre until the research has been published. After the research has been published, data will be stored in a de-identified form at the University of South Australia’s commercial data storage archive for 10 years before being destroyed.

☐ I agree to my personal details being retained so that I may be informed regarding future opportunities to participate in similar research.

Name of participant ..................................................................................................................

Signed .................................................................................................................................

Date .................................................................................................................................

I have explained the study to the participant and consider that he/she understands what is involved.

Signed ........................................................................... Date ...............................

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<td>Date and version identifier</td>
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<td>Sources and types of financial, material, and other support</td>
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<tr>
<td>Roles and responsibilities</td>
<td>5a</td>
<td>Names, affiliations, and roles of protocol contributors</td>
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<tr>
<td></td>
<td>5b</td>
<td>Name and contact information for the trial sponsor</td>
<td>Table 1</td>
</tr>
<tr>
<td></td>
<td>5c</td>
<td>Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities</td>
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<tr>
<td></td>
<td>5d</td>
<td>Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)</td>
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</table>
Introduction

Background and rationale 6a Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention 4, 5, 6

6b Explanation for choice of comparators 17, 18

Objectives 7 Specific objectives or hypotheses 5, 6

Trial design 8 Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) 6, 8

Methods: Participants, interventions, and outcomes

Study setting 9 Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained 6

Eligibility criteria 10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) 6, 7

Interventions 11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered 9-11, Table 2

11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) 10-11

11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) 6, 10

11d Relevant concomitant care and interventions that are permitted or prohibited during the trial 10, 11

Outcomes 12 Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended 11-15, Figure 1

Participant timeline 13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) 8, 9, Figure 1
Sample size 14 Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations ______ 8______

Recruitment 15 Strategies for achieving adequate participant enrolment to reach target sample size ______ 6______

Methods: Assignment of interventions (for controlled trials)

Allocation: 16a Method of generating the allocation sequence (e.g., computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (e.g., blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions ______ 8,9______

 Allocation concealment mechanism 16b Mechanism of implementing the allocation sequence (e.g., central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned ______ 8,9______

Implementation 16c Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions ______ 8,9______

Blinding (masking) 17a Who will be blinded after assignment to interventions (e.g., trial participants, care providers, outcome assessors, data analysts), and how ______ 8,9______

17b If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant’s allocated intervention during the trial ______ 8,9______

Methods: Data collection, management, and analysis

Data collection methods 18a Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g., duplicate measurements, training of assessors) and a description of study instruments (e.g., questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol ______ 11-15______

18b Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols ______ 6,10-11,15-16______
<table>
<thead>
<tr>
<th>Section</th>
<th>Code</th>
<th>Description</th>
<th>References</th>
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</thead>
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<tr>
<td>Data management</td>
<td>19</td>
<td>Plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g., double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol</td>
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<tr>
<td>Statistical methods</td>
<td>20a</td>
<td>Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol</td>
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<td>20b</td>
<td>Methods for any additional analyses (e.g., subgroup and adjusted analyses)</td>
<td>15, 16</td>
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<tr>
<td></td>
<td>20c</td>
<td>Definition of analysis population relating to protocol non-adherence (e.g., as randomised analysis), and any statistical methods to handle missing data (e.g., multiple imputation)</td>
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<td>Methods: Monitoring</td>
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<tr>
<td>Data monitoring</td>
<td>21a</td>
<td>Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed</td>
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<tr>
<td></td>
<td>21b</td>
<td>Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial</td>
<td>15</td>
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<tr>
<td>Harms</td>
<td>22</td>
<td>Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct</td>
<td>14-15</td>
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<tr>
<td>Auditing</td>
<td>23</td>
<td>Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor</td>
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<td></td>
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<tr>
<td>Research ethics approval</td>
<td>24</td>
<td>Plans for seeking research ethics committee/institutional review board (REC/IRB) approval</td>
<td>16</td>
</tr>
<tr>
<td>Protocol amendments</td>
<td>25</td>
<td>Plans for communicating important protocol modifications (e.g., changes to eligibility criteria, outcomes, analyses) to relevant parties (e.g., investigators, REC/IRBs, trial participants, trial registries, journals, regulators)</td>
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<tr>
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<td>Consent or assent</td>
<td>16-17</td>
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<td>26b</td>
<td>Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable</td>
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<td>27</td>
<td>Confidentiality</td>
<td>15</td>
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<td>28</td>
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<td>29</td>
<td>Access to data</td>
<td>15, 21-22</td>
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<td>30</td>
<td>Ancillary and post-trial care</td>
<td>10-11</td>
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<td>31a</td>
<td>Dissemination policy</td>
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<td>31b</td>
<td>Authorship eligibility guidelines and any intended use of professional writers</td>
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<tr>
<td>31c</td>
<td>Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code</td>
<td>17</td>
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</table>

### Appendices

- Informed consent materials
  - 32 Model consent form and other related documentation given to participants and authorised surrogates

- Biological specimens
  - 33 Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.
The long-term effect of minimalist shoes on running performance and injury: design of a randomised controlled trial

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Buckley, Jon; University of South Australia, Alliance for Research in Exercise, Nutrition and Activity

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Secondary Subject Heading: Research methods

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The long-term effect of minimalist shoes on running performance and injury: design of a randomised controlled trial.

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Word Count: 4,777 words

Key Words: footwear; running economy; biomechanics; muscle strength; bone mineral density
ABSTRACT

Introduction The effects of transitioning to a minimalist running shoe are a topic of interest for runners and scientists. However, few studies have investigated the longer-term effects of running in minimalist shoes. The purpose of this randomised controlled trial (RCT) is to investigate the effects of a 26-week transition to minimalist shoes on running performance and injury risk in trained runners unaccustomed to minimalist footwear.

Methods and analysis A randomized parallel intervention design will be used. 76 trained male runners will be recruited. To be eligible, runners must be aged 18-40 years, run with a habitual rearfoot footfall pattern, train with conventional shoes and have no prior experience with minimalist shoes. Runners will complete a standardised transition to minimalist or control shoes and undergo assessments at baseline, 6-weeks and 26-weeks. 5-km time-trial performance (5TT), running economy, running biomechanics, triceps surae muscle strength and lower limb bone mineral density will be assessed at each time point. Pain and injury will be recorded weekly. Training will be standardised during the first 6-weeks. Primary statistical analysis will compare 5TT between shoe groups at the 6-week time point and injury incidence across the entire 26-week study period.

Ethics and dissemination This RCT has been approved by the Human Research Ethics Committee of the University of South Australia. Participants will be required to provide their written informed consent prior to participation in the study. Study findings will be disseminated in the form of journal publications and conference presentations after completion of planned data analysis.

Registration details This RCT has been registered with the Australian New Zealand Clinical Trials Registry (ACTRN12613000642785).
STRENGTHS AND LIMITATIONS OF THIS STUDY

- This is the first study to investigate the effect of minimalist footwear over longer than a 3-month period and the first to include a measure of running performance.

- The standardised gradual transition to minimalist shoes from 0 to 100% of weekly running will inform runners, coaches and clinicians of the effect of these shoes across the entire transitional period.

- Limitations of the study are the inclusion of only male runners aged 18-40 years and the inclusion of only one minimalist shoe group.
INTRODUCTION

The effects of running in minimalist shoes is a topic of interest for both runners and scientists[1-7]. Running in minimalist shoes can cause runners to run with a more plantar-flexed ankle at initial contact and adopt a forefoot footfall (FF) pattern[4, 6, 7], increase stride rate[1, 7], reduce stride length[1], increase ankle plantar-flexor moments and decrease knee extensor moments[4] and improve running economy[2]. Although athletes and coaches may be interested in the potential for minimalist shoes to improve running performance, there is also some evidence that minimalist shoes increase injury risk[5]. However, few studies have included a prospective longitudinal follow-up of runners that change from conventional to minimalist running shoes[5, 7-11]. At present, runners, coaches and clinicians attempting to make a more informed purchase or prescription of minimalist shoes are required to base their decision on predominantly acute studies with no longitudinal follow-up[1, 3, 4, 6].

The authors are not aware of any consensus on what should be an appropriate follow-up period to investigate the long-term effects of minimalist shoes. However, the few studies that have included a prospective longitudinal follow-up of runners who change to minimalist shoes have used follow-up periods of only 4 to 12-weeks[5, 7-11]. These studies found that, following the transition to minimalist shoes, runners improved running economy[7], reduced peak pressure under the heel[9] and increased intrinsic foot muscle cross-sectional area[11], but experienced increased calf and shin pain[5, 8], increased foot bone marrow oedema[10] and a higher injury rate[5]. It has been hypothesised that these effects of minimalist shoes result from runners adopting a FF pattern, which causes increased loading of musculoskeletal structures at the foot and ankle[11-13]. If an appropriate, gradual
transition to minimalist shoes can be made then it might be possible to derive beneficial training adaptations from this increased loading[7, 11]. However, if the increased loading is too rapid, pain and injury may result from the increased forces experienced by the ankle plantar flexor muscles[4, 5]. Indeed, the only study to investigate the effect of transitioning to minimalist shoes on injury risk reported greater calf pain and a higher incidence of injury for two different minimalist shoes (20% and 38%) compared to a conventional shoe (13%)[5].

Choice of running shoe is an important issue for distance runners who view minimalist shoes as a means for enhancing running performance but have concerns about the potential for minimalist shoes to cause injury[14]. Avoiding injuries resulting from minimalist shoes is important for runners to minimise the economic burden associated with medical treatment and absenteeism from work as well as to maximise the positive health effects of maintaining an active lifestyle[15]. This issue is particularly relevant given the popularity of running, which is performed by 10% of the Australian population[16]. In order to provide runners with sufficient instructions on how to implement minimalist shoes, further longitudinal studies investigating methods for transitioning to minimalist shoes over longer periods are needed. Current longitudinal studies involving minimalist shoes have been limited to follow-up periods of 12-weeks or less[5, 7-11], only transitioned runners to using minimalist shoes for up to 60% of weekly running[5, 7, 11], not used standardised methods for transitioning to minimalist shoes[10] or not investigated injury incidence[7-11] and running performance[5, 8-11], which are the two most significant outcomes for runners interested in minimalist shoes[14].

**Primary objective**
The purpose of this randomised controlled trial (RCT) is to investigate the effects of a 26-week transition to minimalist shoes compared to conventional shoes on running performance and injury risk in trained runners unaccustomed to minimalist footwear. It is hypothesised that transitioning to minimalist shoes will have benefits for running performance but be associated with an increased risk of injury. The increased risk of injury is expected to result from the increased forces experienced by the ankle plantar flexor muscles when running with a flatter foot position at initial contact in the minimalist shoe.

METHODS

This study protocol was developed according to the 2013 SPIRIT (Standard Protocol Items: Recommendations for Interventionsal Trials) statement[17]. The study will use a two-arm RCT design with a 6-week and 26-week follow-up. Data collection will take place at the University of South Australia. The RCT has been registered with the Australian New Zealand Clinical Trials Registry. Trial registration data are shown in Table 1. Participants will be recruited from a sample of convenience on a volunteer basis. This study will be advertised at local universities, running clubs and running events. To assist with participant retention, participants will be provided with a $100 shoe voucher if they successfully complete the 26-week study commitment. Participants who withdraw from the study due to injury will also receive the $100 shoe voucher after independent assessment of the injury by a registered physiotherapist or medical practitioner not associated with the study.

Study population

Male runners will be recruited to avoid potential gender effects on running biomechanics[18]. Only runners aged 18-40 years will be recruited because 18-40 years is the most popular age for participation in running in Australia[16]. Participants will be...
required to run a minimum of 15-km per week[3] (this will minimise the risk of injuries resulting from a lack of familiarity with regular running[19]), be able to complete a 5-km treadmill time trial (5TT) in ≤ 23-minutes (95% of runners represented by the cohort of male endurance-trained runners in a study by Laursen et al.[20] would complete a 5TT in less than 23-minutes i.e. mean 5TT +2 standard deviations was 23-minutes), train with conventional running shoes, have no prior experience running in shoes with reduced cushioning, drop height and mass, run with a rearfoot footfall (RF) pattern at the time of enrolment in the study (typical of 89% of runners[21]) and have no current or recent (<3 months) musculoskeletal injury. Participants will be excluded if they have a history of invasive surgery to the back, pelvis or lower extremities in the previous year or they use orthotics in their running shoes because orthotics will not fit inside the minimalist shoe.

Footfall pattern will be determined from over-ground running trials at a self-selected running speed in participants’ own running shoes filmed at 200 Hz using a high-speed digital camera (Basler Pilot, Ahrensburg, Germany) to ensure only habitual RF runners are recruited.

Table 1. Trial registration data.

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<td>Primary sponsor</td>
<td>University of South Australia</td>
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<tr>
<td>Contact person: J.D.B <a href="mailto:jon.buckley@unisa.edu.au">jon.buckley@unisa.edu.au</a></td>
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<tr>
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</tr>
<tr>
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<td>Conventional shoe (Asics Gel Cumulus-14, 15 or 16)</td>
</tr>
</tbody>
</table>
Key inclusion and exclusion criteria

Inclusion criteria: male, 18-40 years, running ≥15 km per week, habitual rearfoot footfall and able to run a 5 km time trial in <23 minutes

Exclusion criteria: prior experience with minimalist shoes, use of orthotics, having a current or recent (<3 months) musculoskeletal injury or history of recent (<12 months) invasive surgery that affected running.

Study type
Randomised controlled trial

Date of first enrolment
24th June 2013

Target sample size
76

Recruitment status
Closed: follow-up continuing

Primary outcome
5 km time trial performance (time point: 6-weeks)

Key secondary outcomes
Injury incidence (time frame: 6-months)
5 km time trial performance (time point: 6-months)
Running economy (time point: 6-weeks and 6-months)
Running biomechanics (time point: 6-weeks and 6-months)
Triceps surae strength (time point: 6-weeks and 6-months)
Bone mineral density (time point: 6-weeks and 6-months)

Sample size

An a-priori power calculation determined that 50 participants are required to detect a Cohen’s $d$ effect size of 0.3 for the primary outcome (5TT performance) at 6-week follow-up with 80% power and a 5% significance level using analysis of covariance (ANCOVA). This calculation was performed using the formula described by Borm et al.[22] and South Australian 5-km road race results recorded in 2011 and 2012 (average race time 1139 ± 140 s). The 0.3 effect size was based on the 2.4-5.8% improvement (mean improvement 3.6%) in running economy observed for runners training with or experienced with minimalist shoes[6, 7, 23] and a corresponding 10.6 m·min$^{-1}$ improvement in average race pace (44 s improvement in average race time) estimated by Burkett et al.[24]. To allow for a 20% drop out rate and a 25% rate of injury[5] during the 6-week follow-up period it is expected that 76 participants will need to be recruited. An additional 12 participants will be recruited and will complete all outcome assessments on two separate occasions in their own shoes to determine test-retest reliability.

Study protocol
Participants will attend a familiarisation session in the week prior to their anticipated start
date. During this session, information about previous injury and shoe use will be collected
and participants will complete a 30-minute treadmill familiarisation, footfall pattern will be
assessed and a 5TT will be completed. Randomisation to shoe group will be via a process of
minimisation[25], using 5TT performance times obtained during familiarisation as the
minimisation variable and a 1:1 allocation ratio. Allocation via minimisation offers the only
acceptable alternative to simple and restricted randomisation[26] and is more effective at
balancing the collective attributes of intervention groups in small samples than traditional
methods of randomisation[27]. Allocation of participants will be performed by one of the
investigators (Jonathan D. Buckley) who will not be involved directly in data collection, but it
will not be possible to blind outcome assessors to participant shoe condition during testing.

Experimental testing sessions will be undertaken for each shoe condition at baseline, at 6-
week follow-up and at 6-month follow-up. Outcomes assessed in order of assessment at
each test session will be overground running kinematics and kinetics, treadmill running
economy, bone mineral density (BMD), 5TT performance and muscle strength. A participant
timeline is shown in Figure 1. All testing sessions will be performed at the same time of the
day. Participants will be required to not complete any training on the day of testing and
remain fasted from food (water permitted ad libitum) in the 3-hours prior to testing.

**** insert Figure 1 approximately here ****

**Shoe conditions**

Participants allocated to the control condition will run in a conventional running shoe (Asics
Gel Cumulus-14, 15 or 16; mass 324 g per shoe; heel drop 9 mm) and participants allocated
to the minimalist shoe condition will run in a lightweight racing flat (Asics Piranha SP4; mass
125 g per shoe; heel drop 5 mm). Mass is reported for an average U.S. size 9 (European size 42.5) shoe. Participants will be instructed to complete only 5% of running in their allocated shoes on each day that they run in the first week. This amount will then be increased by 5% each week until week 20, when participants will complete 100% of running in the allocated shoes. From week 20-26, runners will perform all running in their allocated shoe condition.

To investigate how the runners perceive the comfort of the two shoe conditions, they will complete an assessment of shoe comfort for their respective shoe condition at the beginning of each testing session. Assessments of shoe comfort will be made using a 100-mm visual analogue scale (VAS) with anchors “not comfortable at all” on the left hand end and “most comfortable imaginable” on the right[28]. Shoe comfort will be assessed before and following a 2-minute sub-maximal run on a motorised treadmill at self-selected running speed (Model 645, Quinton Instrument Co., Washington, USA). Four familiarisation comfort assessments will be used to achieve stability of shoe comfort results[28].

Training program

Running training will be standardised during the first 6-weeks of the study so that relative training intensity and volume will be the same for all participants. Training intensity will be prescribed relative to the peak heart rate (HR_{peak}) achieved during the 5TT. Participants will monitor training intensity throughout the training program using a heart rate monitor (Polar F1 heart rate monitor, Polar Electro Oy, Kempele, Finland). The training program is adapted from a 6-week training program used by Billat et al.[29] that was shown to increase VO_{2max} by 3.6% in trained runners. The training program is described in Table 2. During weeks 7-26, training will not be standardised and participants will complete their usual training to evaluate the effects of the shoe under non-controlled conditions so as to provide
ecologically valid outcome data, but the transition to the allocated shoe will continue to be increased by 5% per week during this period until participants are completing 100% of training in the allocated shoe. Adherence to training and shoe allocation will be monitored using a participant training diary. Participants reporting an injury during the study period will be advised to stop the gradual increase in allocated shoe use until they have recovered. Injured participants will be invited to have their injury assessed and treated at the University of South Australia physiotherapy clinic. No study investigators will be involved in the assessment or treatment of injured participants.

| Table 2. Six week standardised running training program. |
|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Week | Method | Training session duration (min) |
|      |       | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 |
| 1    | LSD    | –     | 50    | –     | –     | 50    | –     | –     |
|      | HIIT   | 3x10  | –     | 4x15  | –     | –     | –     | –     |
| 2    | LSD    | –     | 50    | –     | –     | 50    | –     | –     |
|      | HIIT   | 3x12  | –     | 2x18  | –     | –     | –     | –     |
| 3    | LSD    | –     | 50    | –     | –     | 50    | –     | –     |
|      | HIIT   | 3x14  | –     | 2x21  | –     | –     | –     | –     |
| 4    | LSD    | –     | 50    | –     | –     | 50    | –     | –     |
|      | HIIT   | 3x16  | –     | 2x24  | –     | –     | –     | –     |
| 5    | LSD    | –     | 50    | –     | –     | 50    | –     | –     |
|      | HIIT   | 3x18  | –     | 2x27  | –     | –     | –     | –     |
| 6    | LSD    | –     | 40    | –     | 40    | –     | –     | –     |
|      | HIIT   | 3x20  | –     | –     | –     | –     | –     | –     |

LSD, long slow distance running at 65-80% peak heart rate (HR_{peak}); HIIT, high-intensity interval training running at 85-90% HR_{peak}. Intervals separated by 5 minutes of walking.

Running kinematics and kinetics

Running kinematics and kinetics will be assessed during overground running trials performed at 18-km·h\(^{-1}\) ± 10% over a 40-m runway. Consistency of running speed will be monitored using photoelectric sensors (SpeedLight V2, Swift Performance Equipment, Queensland, Australia). Marker trajectories will be measured using a 12 camera VICON MX F20 system (Vicon, Oxford, UK) sampling at 300 Hz. Ground reaction force (GRF) will be measured using four force platforms aligned in series and sampling at 1200 Hz. Each
participant will be required to complete five successful trials. A trial will be considered successful if the full plantar surface of the foot contacts the force platform in between the pylons of the force platform at the prescribed running speed without obvious modification of gait. Participants will not be provided with any instructions in regards to contacting the force platform. Instead, the runway starting point will be adjusted as needed to facilitate a successful trial.

A full body marker set-up will be used and will include the feet, shanks, thighs, pelvis, trunk (including head), upper arms and lower arms (including hands). Spherical retro-reflective calibration markers will be used to define the position and orientation in space (POSE) of each segment and will be placed over the 1st and 5th metatarsal head, lateral and medial malleolus, lateral and medial femoral epicondyle, greater trochanter, anterior superior iliac spine, posterior superior iliac spine C7 spinous process, acromioclavicular joint, lateral and medial humeral epicondyle and radial and ulnar styloid process. Tracking markers will be used to track the POSE of each segment. A minimum of three non-collinear markers will be used to track each segment in six degrees of freedom. This marker set-up will be used to investigate footfall pattern as well as kinematics and kinetics at the knee and ankle.

**Running economy**

Participants will complete a 5-minute warm-up on the treadmill at 8-km·h⁻¹. Running economy will then be assessed during three 6-minute sub-maximal runs on the treadmill at 11 km·h⁻¹, 13 km·h⁻¹ and 15 km·h⁻¹ in a fixed order. Running economy will be assessed by indirect calorimetry (True One, ParvoMedics, Utah, USA) and expressed as the rate of energy expenditure (REE; kJ·min⁻¹) during the final 60-seconds of each 6-minute run.
Participant data will be excluded if the respiratory exchange ratio (RER) increases above 1.0 during the final 60-seconds or a steady state of oxygen consumption is not achieved.

**Spatiotemporal parameters**

Force-sensitive resistors (FSR) will be placed underneath the heel and forefoot regions of each shoe and used to assess footfall pattern, stride rate and stride length during each 6-minute run. Foot contacts will be recorded wirelessly at 2000-Hz using a Delsys Trigno system (DelSys Inc, Natick, USA). Runners will be classified with a RF pattern if initial contact is made with the FSR positioned at the heel or a FF pattern if initial contact is made with the FSR positioned at the forefoot. Footfall pattern will be assessed throughout each 6-minute run and classification will be based on the mode (i.e. whichever pattern is most frequent) during the final 60-seconds. Stride rate (strides per minute) will be considered the number of right foot contacts recorded during the final 60-seconds of each 6-minute run. Average stride length will be calculated using the following equation:

\[ SL = ST \times V \]

SL is the stride length, ST is the time taken for each stride (right foot contact to right foot contact) and V is the treadmill speed from the known distance covered during the 60-seconds because speed will remain fixed. Footfall pattern, stride length and stride rate computations will be performed using a custom written code in MATLAB (R2013a, MathWorks, MA, USA).

**5-km treadmill time trial**

Running endurance performance will be assessed using a 5TT on a motorised treadmill set at 0% grade. Participants will be instructed to complete the 5TT in the fastest possible time and will be free to adjust the treadmill speed throughout the test. Starting speed will remain
constant across testing sessions and will be selected by participants prior to completion of their baseline 5TT. Participants will be blinded to treadmill speed and time throughout performance of the 5TT. Peak oxygen consumption during the 5TT will be assessed by indirect calorimetry.

**Bone mineral density**

BMD of the right proximal tibia, calcaneus and metatarsals will be measured by dual X-ray absorptiometry (Lunar Prodigy, General Electric Corporation, Madison, USA) using two separate scans. These peripheral sites were chosen for the assessment of BMD because it was hypothesised that they would be most likely to change in response to the potential alterations in running biomechanics that can result from running in minimalist shoes[4, 6, 7]. For assessment of the tibia and calcaneus, participants will be positioned in a side lying position[31]. For assessment of the metatarsals, participants will be positioned in an upright, seated position with the foot in the plantar position[32]. For each participant, goniometer measurements for the knee and ankle in the sagittal plane will be recorded and standardised between scans to help reproduce the same scan position.

**Muscle strength**

Muscle strength assessment of the triceps surae muscle group will be performed on an isokinetic dynamometer (Biodex System 4, Biodex Medical Systems, New York, USA) with participants in a reclined seated position with knees positioned in 20-30° flexion. Peak isometric torque (PIT) will be measured with the ankle positioned in the anatomical neutral position and defined as the peak torque achieved during the better of two 5-second efforts. Peak concentric torque (PCT) and peak eccentric torque (PET) will be measured at an angular velocity of 30°·s⁻¹. Two sets of three repetitions will be performed for both PCT and
PET measurements, with the peak torque achieved across repetitions considered the participants PCT and PET. Torque data will be sampled at 1000-Hz using a PowerLab data acquisition system (PowerLab 16/30, ADInstruments, Bella Vista, Australia).

Pain and injury monitoring

Pain will be assessed using a study diary for seven regions of interest using a 100 mm VAS with anchor points consisting of ‘no pain’ on the left hand end and ‘worst pain’ on the right hand end. Regions of interest will include the foot, ankle, calf, shin, knee, thigh, and lumbopelvic area. At the end of each week, participants will be asked to record the worst running-related pain that they experience during the previous 7 days for each of the 7 regions of interest. A difference in VAS score of 10 mm will be considered clinically significant[33]. An injury will be considered to be any musculoskeletal problem that is attributed by the participant to running. The problem will need to be severe enough to cause a reduction in weekly running distance, a visit to a health professional or the use of medication[34, 35]. Injuries attributed to an accident will not be considered. Injury events will be reported to the University of South Australia Human Research Ethics Committee who will independently monitor the safety of the study interventions.

Data management

Outcome data will be entered electronically and stored in a password protected folder on the University of South Australia network server at the time of collection. Only study investigators will have access to the data and investigators will meet weekly to monitor progress of data collection. All outcome data will be de-identified using a participant identification numbering system.

Statistical methods
Per-protocol analysis will be used to assess the effect of shoe group at the end of the 6-week standardised training program. Participants unable to complete a follow-up assessment at the end of the 6-week training program due to injury will not be included in the per-protocol analysis. An ANCOVA will be used to compare 5TT performance, running kinematics and kinetics and muscle strength between shoe groups after adjusting for baseline time. Running economy and spatiotemporal parameters will be analysed using a linear fixed-effects model with independent variables shoe, speed, time and shoe*speed*time interaction. Shoe mass will be included as a covariate in the statistical model for running economy. Cases with missing running economy data (i.e. RER >1.00) will be included in the model.

Intention-to-treat analysis will be used to assess the effect of shoe group at the end of the 26-week study period. 5TT performance, running economy, muscle strength, BMD, spatiotemporal parameters and running kinematics and kinetics will be compared between shoe groups using a linear fixed-effects model with independent variables shoe, time and shoe*time interaction. The independent variables speed and shoe*speed*time will be included in the statistical models for running economy and spatiotemporal parameters. Shoe mass will be included as a covariate in the statistical model for running economy. Cases with missing running economy data (i.e. RER >1.00) will be included in the model.

Injury rate will be analysed by log binomial generalized linear model with independent variable group. Sensitivity analysis will be undertaken to determine whether the effect of shoes is influenced by adherence to training program and training volume by including adherence and training volume as covariates. All statistical analysis will be performed in SPSS (v22, IBM, New York, USA). Statistical significance will be assumed for p<0.05.
ETHICAL CONSIDERATIONS

This protocol has received ethical approval from the Human Research Ethics Committee of the University of South Australia. The Ethics Committee will be notified of any planned amendments to the original protocol. Amendments will not be made without the prior approval of the Ethics Committee and all members of the investigatory team.

Joel T. Fuller will manage all expressions of interests and will provide all potential participants with a study information sheet. At the beginning of the initial familiarisation session, participants will be briefed on all aspects of the study and provided with an opportunity to have any questions answered. Eligible participants will be required to provide their written informed consent prior to participation in the study (see supplementary material).

DISSEMINATION OF FINDINGS

Study results will be released to participants in a de-identified format. Participants will be provided with a separate copy of their personal results. Study findings will be released to the public in the form of journal publications and conference presentations.

DISCUSSION

Prospective longitudinal follow-up of runners who change to minimalist shoes is important to inform runners, coaches and clinicians about their safety and efficacy. Although short-term studies are informative for describing any immediate effects of minimalist shoes on running parameters, they are not useful for informing evidenced based prescription for longer-term use[36]. We propose to use an RCT to provide high-quality evidence regarding the efficacy of transitioning from a conventional shoe to a minimalist shoe.
There is still no consensus definition for minimalist shoes\[5\]. Instead, footwear is considered to be minimalist if shoe mass, heel drop and cushioning are reduced compared with a conventional running shoe\[1, 5\]. Choice of minimalist shoe is an important consideration for studies investigating the effects of these shoes. In this RCT a racing flat will be used as the minimalist shoe condition. Racing flats differ from conventional running shoes by having reduced shoe mass, heel drop and cushioning and as such can be categorised as a form of minimalist shoe\[1\]. Additionally, racing flats have been used by runners and coaches in competition for many years\[1, 37\] and can be considered representative of the footwear condition that runners used prior to the introduction of the modern conventional running shoe, which has increased shoe mass, heel drop and cushioning\[14\]. It has been suggested that the introduction of the modern conventional running shoe may have caused changes to the natural human running gait and resulted in an increased injury rate\[38\]. To adequately test this hypothesis, conventional running shoes should be compared with racing flats, which were the predominant running shoe available to runners prior to the introduction of shoe cushioning and heel raise.

It has been proposed that carefully transitioning from conventional to minimalist running shoes can avoid injuries attributed to sudden changes in footwear\[5, 7-11\]. Several methods have been suggested for making this transition\[5, 7-11\] (Table 3) but currently there is insufficient evidence available upon which to base informed recommendations. The percentage of running performed in minimalist shoes during the first week of transition has ranged from 3-33% and has then been progressed each week by small amounts (Table 3)\[5, 7-11\]. Across studies, runners progressed the volume of minimalist shoe running by 3-20% each week (Table 3)\[5, 7, 8, 10, 11\]. This heterogeneity across studies suggests that it is
currently unclear what is an appropriate rate of progression for transition to running in
minimalist shoes. In the present study, runners will use a 5% per week progression in the
amount of time spent running in minimalist shoes until they reach 100% (by Week 20). They
will then continue to run 100% in minimalist shoes during the final 6-weeks of the study.
Onset of injury and weekly pain scores will be used to determine if there is a threshold
amount of running in minimalist shoes that is associated with an increased risk of injury in
runners transitioning from conventional shoes. This will provide important information to
runners, coaches and clinicians who are planning a transition to minimalist shoes about
optimal transition rates to reduce the risk of injury.
To maximise recruitment, allow for a longer follow-up period, and in order to achieve
ecological validity, this RCT will use a period of non-standardised training between 6-week
and 26-week follow-up during which participants will perform their own usual training
program. The outcomes at Week 26 are likely to be affected by the different training
regimes followed by participants during this non-standardised phase between Weeks 6 and
26, but any heterogeneity of usual training regimes should be balanced across groups
through the randomisation process.
The efficacy of minimalist shoes for improving performance and their safety in terms of
injury risk is thought to be influenced by the running kinematics that are adopted when
running in this type of footwear[5, 7]. Running in minimalist shoes has previously been
shown to reduce stride length[1] and the amount of ankle dorsiflexion at initial ground
contact[6], with the latter promoting a FF pattern[4, 7]. Changing to a FF pattern increases
ankle joint contact forces and plantar flexor muscle forces[13]. Increased involvement of the
Table 3. Methods of transitioning from conventional to minimalist footwear used in the literature.

<table>
<thead>
<tr>
<th>Author</th>
<th>Date</th>
<th>Minimalist shoe</th>
<th>Week 1*</th>
<th>Method for transitioning to minimalist footwear</th>
</tr>
</thead>
<tbody>
<tr>
<td>Giandolini et al. [8]</td>
<td>2013</td>
<td>Salomon Sense S-Lab</td>
<td>33%</td>
<td>Increase by 3-17% each week until reaching 100% in week 4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>100% of running performed in minimalist shoes from week 5-12</td>
</tr>
<tr>
<td>Ridge et al. [10]</td>
<td>2013</td>
<td>Vibram FiveFingers</td>
<td>3-13%</td>
<td>Increase by 3-13% each week until week 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Participants made further increases as they felt comfortable during weeks 4-10</td>
</tr>
<tr>
<td>Ryan et al. [5]</td>
<td>2013</td>
<td>Vibram FiveFingers</td>
<td>19%</td>
<td>Gradual increases were made from week 1-12</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nike Free V.5.0</td>
<td></td>
<td>58% of running performed in minimalist shoes during week 12</td>
</tr>
<tr>
<td>Miller et al. [11]</td>
<td>2014</td>
<td>New Balance Road Minimus</td>
<td>7%</td>
<td>Increase by &lt;10% each week from week 1-12</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Merrel Pace/Trail Glove</td>
<td></td>
<td>Up to 43% of running performed in minimalist shoes during final weeks</td>
</tr>
<tr>
<td>Warne et al. [7]</td>
<td>2014</td>
<td>Vibram FiveFingers</td>
<td>10%</td>
<td>Gradual increases were made from week 1-4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>25% of running performed in minimalist shoes during week 4</td>
</tr>
<tr>
<td>Moore et al. [9]</td>
<td>2015</td>
<td>Vibram FiveFingers</td>
<td>3-10 miles</td>
<td>Increase by no more than 20% each week</td>
</tr>
</tbody>
</table>

* values indicate percentage of weekly running performed in the minimalist shoe condition.
ankle plantar flexor muscle could result in greater elastic energy storage and recovery in the
Achilles' tendon, which may contribute to improved running economy and performance[4, 39]. We hypothesise that the increased loading on these structures may contribute to
greater adaptation with resultant greater increases in performance in response to
training[7]. However, these unaccustomed high forces could also increase risk of injury until
sufficient adaptation has occurred in muscular and articular tissue[5, 10, 11, 13]. Previous
research has observed changes in muscle and bone tissue when transitioning to minimalist
shoes over 10-12 weeks[10, 11] and the 26-week transition used in the present study will
add to this knowledge. Additionally, examining the effects of minimalist shoes on running
biomechanics, muscle strength, BMD, and running economy in the present study, will allow
for investigation of the factors underlying any effects on performance and/or injury to be
explored.

CONCLUSION

In conclusion, this RCT will provide high-quality evidence regarding the effect on running
performance of transitioning from conventional to minimalist shoes, which is currently
lacking in the field of running footwear research. Additionally, observation of injury rates
during this transition will be used to inform the design of larger studies investigating the
effect of minimalist shoes on injury risk. The 26-week longitudinal follow-up period used in
this study will be the longest prospective follow-up of runners changing to minimalist shoes
that has been reported in the literature to date. Assessments of running biomechanics,
muscle strength and BMD will allow this RCT to explore the mechanisms underlying any
effects of minimalist shoes on running performance and/or injury.

ACKNOWLEDGMENTS
Joel T. Fuller is the recipient of an Australian Postgraduate Award from the Australian Commonwealth Government. The authors would like to thank ASICS Oceania (ASICS Oceania Pty Ltd, Eastern Creek, NSW, Australia) for donating 20 pairs of Asics Gel Cumulus-16 running shoes to support this research. No other sources of industry support have been provided to support the completion of this RCT. Purchase of footwear will be arranged through a local running shoe store (Jogger’s World, Adelaide SA, Australia) using funds obtained from a University of South Australia Vice Chancellor & President’s Scholarship ($10,000) awarded to Joel T. Fuller. ASICS Oceania and the University of South Australia had no role in the design of this RCT and will not have any role during its execution, analysis, interpretation or the decision to disseminate findings.

CONTRIBUTORS

J.T.F, D.T, M.D.T, N.A.T.B and J.D.B conceived the study, participated in its design and helped to draft this manuscript. J.T.F will be responsible for data collection and statistical analysis. All authors will contribute to the dissemination of research findings in the form of journal publications and conference presentations.

CONFLICT OF INTEREST

Dr. Dominic Thewlis has been a recipient of funding from ASICS Oceania (ASICS Oceania Pty Ltd, Eastern Creek, NSW, Australia) to undertake separate research. All other authors declare no potential conflicts of interest and have no financial relationships with any organisations that might have an interest in the submitted work.

REFERENCES


**FIGURE LEGENDS**

525. Figure 1. Participant timeline. ITT, intention-to-treat; 5TT, 5-km treadmill time trial; RE, running economy; BMD, bone mineral density.
Figure 1. Participant timeline. ITT, intention-to-treat; 5TT, 5-km treadmill time trial; RE, running economy; BMD, bone mineral density.

254x190mm (300 x 300 DPI)
PROJECT CONSENT FORM

PROJECT TITLE: The effect of footwear on distance running performance & injury – a long term study

INVESTIGATORS: Joel Fuller Dr Margarita Tsiros
              Professor Jon Buckley Dr Nick Brown
              Dr Dominic Thewlis

1. I have read the Information Sheet, and the nature and the purpose of the research project and the risks inherent in my participation have been explained to me. I understand and agree to take part.

2. I agree to my running pattern being video recorded for biomechanical analysis.

3. I understand that I may not directly benefit from taking part in the study.

4. I understand that while information gained during the study may be published, I will not be identified and my personal results will remain confidential.

5. I understand that I can withdraw from the study at any stage and that this will not affect my rights or the responsibilities of the researchers in any respect.

6. I have had the opportunity to discuss taking part in this study with a family member or friend or a GP.

7. I confirm that I am over 18 years of age.

   [ ] I agree to my data being retained for use in future research in the same or related research area. Data will be de-identified and stored in a secure room at the Nutritional Physiology Research Centre until the research has been published. After the research has been published, data will be stored in a de-identified form at the University of South Australia’s commercial data storage archive for 10 years before being destroyed.

   [ ] I agree to my personal details being retained so that I may be informed regarding future opportunities to participate in similar research.

Name of participant .................................................................

Signed ...............................................................................................

Date ..................................................................................................

I have explained the study to the participant and consider that he/she understands what is involved.

Signed ....................................................... Date ...............................
<table>
<thead>
<tr>
<th>Section/item</th>
<th>Item No</th>
<th>Description</th>
<th>Addressed on page number</th>
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<td>Date and version identifier</td>
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<td>Funding</td>
<td>4</td>
<td>Sources and types of financial, material, and other support</td>
<td>21, 22</td>
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<td>Roles and responsibilities</td>
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<td>Names, affiliations, and roles of protocol contributors</td>
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<td></td>
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<td>Name and contact information for the trial sponsor</td>
<td>Table 1</td>
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<td></td>
<td>5c</td>
<td>Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities</td>
<td>21, 22</td>
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<tr>
<td></td>
<td>5d</td>
<td>Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)</td>
<td>N/A</td>
</tr>
</tbody>
</table>
Introduction

Background and rationale
6a Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention

6b Explanation for choice of comparators

Objectives
7 Specific objectives or hypotheses

Trial design
8 Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)

Methods: Participants, interventions, and outcomes

Study setting
9 Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained

Eligibility criteria
10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)

Interventions
11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered

11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)

11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)

11d Relevant concomitant care and interventions that are permitted or prohibited during the trial

Outcomes
12 Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended

Participant timeline
13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
Sample size 14 Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations

Recruitment 15 Strategies for achieving adequate participant enrolment to reach target sample size

**Methods: Assignment of interventions (for controlled trials)**

Allocation:

Sequence generation 16a Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions

Allocation concealment mechanism 16b Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned

Implementation 16c Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions

Blinding (masking) 17a Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how

17b If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant’s allocated intervention during the trial

**Methods: Data collection, management, and analysis**

Data collection methods 18a Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol

18b Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols

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For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
Data management  19  Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol

Statistical methods  20a  Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol

20b  Methods for any additional analyses (eg, subgroup and adjusted analyses)

20c  Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)

Methods: Monitoring

Data monitoring  21a  Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed

21b  Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial

Harms  22  Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct

Auditing  23  Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor

Ethics and dissemination

Research ethics approval  24  Plans for seeking research ethics committee/institutional review board (REC/IRB) approval

Protocol amendments  25  Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Details</th>
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</thead>
<tbody>
<tr>
<td>26a</td>
<td>Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)</td>
<td>17</td>
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<tr>
<td>26b</td>
<td>Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable</td>
<td>N/A</td>
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<td>27</td>
<td>How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial</td>
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<tr>
<td>28</td>
<td>Financial and other competing interests for principal investigators for the overall trial and each study site</td>
<td>21, 22</td>
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<tr>
<td>29</td>
<td>Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators</td>
<td>15, 21-22</td>
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<td>30</td>
<td>Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation</td>
<td>11</td>
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<tr>
<td>31a</td>
<td>Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions</td>
<td>17</td>
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<tr>
<td>31b</td>
<td>Authorship eligibility guidelines and any intended use of professional writers</td>
<td>22</td>
</tr>
<tr>
<td>31c</td>
<td>Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code</td>
<td>17</td>
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</table>

### Appendices

<table>
<thead>
<tr>
<th>Item</th>
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<th>Details</th>
</tr>
</thead>
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<tr>
<td>32</td>
<td>Model consent form and other related documentation given to participants and authorised surrogates</td>
<td>Supplementary material file</td>
</tr>
<tr>
<td>33</td>
<td>Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.*
The long-term effect of minimalist shoes on running performance and injury: design of a randomised controlled trial

Joel T Fuller, Dominic Thewlis, Margarita D Tsiros, Nicholas A T Brown and Jonathan D Buckley

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These include:

Supplementary Material
Supplementary material can be found at:
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