The effect of minimalist footwear and instruction on running: an observational study

Massimo Giuseppe Barcellona, Linda Buckley, Lisa J M Palmer, Roisin M Ormond, Gwawr Owen, Daniel J Watson, Roger Woledge, Di Newham

ABSTRACT

Background It is not known whether the effects on altered running style which are attributed to minimalist footwear can be achieved by verbal instructions in standard running shoes (SRS).

Aim To explore the effect of Vibram FiveFingers (VFF) versus SRS plus running instruction on lower extremity spatiotemporal parameters and lower limb joint kinematics.

Methods 35 healthy subjects (mean=30 years, 18 females) were assessed on two occasions with 3D motion analysis. At each session subjects ran on a treadmill (3.58 m/s) for 2 min in either VFF or SRS (randomised order); with and without running instruction. Differences between spatiotemporal parameters and lower limb joint kinematics between conditions were assessed using a 2x2 repeated-measures ANOVA.

Results Wearing VFF significantly increased cadence (p<0.001) and reduced stride length (p<0.01). Prior to initial contact, both instruction and VFF significantly increased foot (p<0.001 and p=0.02, respectively) and ankle (p<0.001 and p=0.02, respectively) plantarflexion, while wearing VFF significantly increased knee extension (p=0.04). At initial contact, instruction significantly increased knee flexion (p=0.04), and foot (p=0.001) and ankle (p=0.03) plantarflexion. At midstance and toe-off, instruction significantly increased knee flexion (p=0.048 and p<0.001, respectively) and foot plantarflexion (p=0.001 and p=0.01, respectively). Instruction had a greater effect on increasing knee flexion (p=0.007) and plantarflexion angle (p<0.001) when subjects wore SRS and VFF, respectively.

Conclusion Alterations in spatiotemporal parameters observed when running in VFF are likely to be attributable to the minimalist footwear. However, the kinematic adaptations observed following instruction suggests that changes in joint angles previously attributed to minimalist footwear alone may be similarly achieved with instruction.

INTRODUCTION

Running is associated with a number of physical and mental health benefits including improved cardiovascular fitness, increased bone mineral density and stress reduction. However, the incidence of running-related injuries in the lower extremity has been reported to be as high as 79%; with at least half of these being defined as related to overuse. Different running styles and their possible effects on injury prevalence and running performance have generated significant interest in the lay media and the scientific community. Proponents of barefoot running, or running in minimalist footwear, claim that these reduce the risk of injury. There are reports of biomechanical and physiological differences between shod and barefoot running conditions, which have been proposed to explain a theoretical basis for a potential reduction in injury risk. This has contributed to a growth in the popularity of minimalist footwear.

Some minimalist shoes do not appear to replicate the mechanics of barefoot running, but others appear to be effective in imitating barefoot conditions such as increased ankle plantarflexion on landing and reduced vertical loading rate. A forefoot striking pattern refers to where the ball of the foot first strikes the ground first. This forefoot strike pattern has been suggested to be associated with reduced injury prevalence. A proposed mechanism for reduced injury risk with a forefoot strike (FFS) pattern, although not all authors report that increased vertical loading rates lead to a greater prevalence of running injury involves the reduction of vertical loading rate and peak loading. In habitually minimally shod runners it has been shown that there is significant individual variability in vertical loading rate with some individuals shown to have increased vertical loading rate in barefoot conditions. This is not surprising given that recent work reports that habitual rearfoot strikers have different kinetic and
kinematic responses to habitual mid/forefoot strikers during both shod and barefoot conditions.\textsuperscript{20} It has been shown that 12 weeks of running training in minimalist footwear can lead to a forefoot strike posture at follow-up when tested in both barefoot and shod conditions.\textsuperscript{21} However, an uninstructed progressive barefoot running programme of 8 weeks duration lead to individual variability in both ankle angle during landing, and the associated vertical loading rate tested under barefoot conditions; with only 25\% of individuals demonstrating reduced vertical loading rate.\textsuperscript{18} Thus, instruction regarding running style may be more important than footwear used when it comes to injury risk,\textsuperscript{16} although it is evident that footwear can affect running style.\textsuperscript{6}

To facilitate a forefoot strike without changing footwear, some trainers and authors have used verbal running instructions, for example ‘run softer’\textsuperscript{22} or ‘run on your toes’.\textsuperscript{23} This aims to reduce vertical loading rate and peak loading\textsuperscript{22} and encourage habitual rearfoot strike runners to replicate the sagittal plane joint kinematics of habitual FFS runners.\textsuperscript{23} No studies to date have explored the effects of both footwear and instruction in the same population. This is important because it will inform both clinical decision making for running prescription and rehabilitation and also future prospective studies on injury prevalence as a result of running in different types of footwear and with different running styles. Therefore, the main purpose of this study was to compare spatiotemporal parameters and lower limb kinematics during running in either minimalist footwear or standard running shoes (SRS) while considering the effect of running instructions.

The main hypothesis was that there will be significant differences in spatiotemporal parameters and in knee, ankle and foot kinematics as a result of both running in minimalist footwear and also in SRS plus running instructions.

**METHODS**

**Study design**

This was a randomised, within subject, repeated measures cross-sectional study.

**Participants**

The study was conducted in accordance with the Declaration of Helsinki and approved by the King’s College London Research Ethics Committee (REC Protocol No: BDM/11/12–66). Subjects were recruited via email advertising and snowball sampling within the university population of King’s College London from July 2012 to September 2013. Subjects were provided with an information sheet. Thirty-seven healthy adults (19 female and 18 male) provided written consent to participate. Inclusion criteria were aged 18–50 years and with previous experience of running on a treadmill. Exclusion criteria were any medical conditions presenting a risk when running, lower extremity injuries requiring medical attention in the past 6 months, previous or current use of minimalist footwear and the use of medically prescribed orthotics. All subjects completed a questionnaire detailing running behaviours and preconceived opinions on minimalist footwear. They received a complimentary pair of Vibram FiveFingers (VFF) as compensation for their time, along with instructions for use in accordance with the manufacturer’s recommendations.\textsuperscript{24}

**Instrumentation**

A single Cartesian Optoelectronic Dynamic Anthropometer motion analysis system (CODA mpx30 - Charnwood Dynamics, Leicestershire, UK) was used to record kinematic data of the right lower extremity. Data were captured using Codamotion software with a sampling frequency of 200 Hz. A Reebok-i run treadmill (RE-14301, RF International, Milton Keynes, UK) with belt dimensions of 40×124 cm was used and earthed to the mains supply to reduce signal interference.

The footwear were the VFF sprint model (Vibram SpA, Albizzate, Italy) and a conventional running shoe (ASCOT, Birmingham, West Midlands, UK; figure 1) (mass 117–172 g and 372–477 g, respectively, depending on size).

**Procedures**

Subjects attended on two occasions at least 48 hours apart. The protocol for each session was the same apart from the footwear worn. At the first session, subjects were randomly assigned to wearing either VFF or SRS and the other type was worn at the second session. Subjects performed a 2-min warm up at 1.8 m/s.

**Motion analysis**

Eleven infrared markers were applied to the right leg. Marker locations (figure 2) were chosen in accordance with previous running kinematic studies for comparison.\textsuperscript{9,17} Markers were attached to the skin after palpation using double-sided adhesive and overlay tape. Markers for the tuber calcaneum and the head of 55th metatarsal were attached following palpation over the footwear.

Following marker placement, a 20 s static standing stance on the horizontal treadmill was recorded. Subjects then undertook a 2-min run at 3.58 m/s to allow for familiarisation. This speed ensured that subjects were running\textsuperscript{25} but remained below the proposed threshold for sprinting.\textsuperscript{26} If subjects verbally reported difficulty with maintaining that speed it was reduced to 3.13 m/s. Following this, subjects continued to run for 30 s while 20 s of kinematic data were collected.
After a 3-min rest period, subjects were given the standardised verbal instruction ‘we would now like you to run in a light, soft and quiet way’. This was in accordance with suggestions by the distributor and similar to those used in the study by Diebal et al\textsuperscript{27} to encourage a FFS. Subjects ran for another 2 min attempting to follow the instructions, which were repeated after one and 2 min. Thereafter, data were recorded for 20 s.

Data analysis
Kinematic data was digitised and analysed using the motion segments shown in figure 2. All subsequent angles were corrected against angles measured during the static standing stance. This method has been reported to have a measurement precision of ±0.26\textdegree.\textsuperscript{9} Plantar foot angle was calculated as the difference in height between the 5th metatarsal and calcaneus marker on the z-axis.\textsuperscript{13}

A specifically designed programme in Matlab (version 2006a, Mathworks, Natick, MA, USA) allowed for the demarcation of initial contact using the method described by Altman and Davis\textsuperscript{13} and corroborated by identification of the point at which either the 5th metatarsal or calcaneus equalled the velocity of the treadmill. Toe-off was indicated by the point at which the 5th metatarsal started to decelerate. Symmetry between left and right lower extremities was assumed.\textsuperscript{17} Kinematic profiles were derived after averaging a minimum of 10 consecutive strides.\textsuperscript{28} Kinematic data were analysed at four stages of the gait cycle to allow for comparisons with other running trials; prior to initial contact, initial contact, mid-stance and toe-off.\textsuperscript{9,11,17} Although mid-stance is not a discrete point in time, it was defined as occurring at 50\% of stance.\textsuperscript{14}

Results are presented using the following abbreviations for each condition; shoes with no instruction (SI\textsuperscript{−}), shoes with instruction (SI\textsuperscript{+}), VFF with no instruction (VI\textsuperscript{−}) and VFF with instruction (VI\textsuperscript{+}). SI\textsuperscript{−} was assigned as the experimental control.

Statistical analysis
Data were analysed using Statistical Package for the Social Sciences (SPSS) version 20 (IBM, USA). Data were tested for normality by observation of the Q-Q plots and by using Kolmogrov-Smirnov tests. A factorial two-by-two repeated measures analysis of variance was performed for parametric data. Friedman’s analysis of variance was performed to analyse ankle angle at mid-stance, as this variable was found not to be normally distributed. Effect size (\(r\)) was reported as partial eta square; small effect (\(r=0.10\)), medium effect (\(r=0.30\)) and large effect (\(r=0.50\)).\textsuperscript{29}

Results
Subjects
Thirty five subjects completed the study with no reported adverse events. Three requested a lower running speed of 3.12 m/s. One of the 37 subjects recruited withdrew from the study after the first session due to an injury sustained outside the study and one subject’s data were unusable due to a technical error.

The characteristics of the subjects and data from the questionnaire regarding running behaviours and preconceived opinions on minimalist footwear are shown in table 1. The majority were regular runners, performing a mean of 1.5 hours a week. The majority (n=29) had heard of minimalist footwear and 19 of these thought they would have a beneficial effect.
Spatiotemporal parameters
Neither footwear nor instruction had a significant effect on the proportion of time spent in the stance phase during running. There was a main effect of footwear such that cadence was higher (p<0.001, r=0.43) and stride length lower (p<0.01, r=0.27) when wearing VFFs. There was no main effect of instruction on either cadence or stride length (table 2).

Foot plantarflexion
There was a main effect of footwear (p=0.02, r=0.15) at initial contact minus 10%, whereby irrespective of instruction subjects adopted a forefoot strike running pattern in VFF but not in shoes. This effect of footwear was not seen at initial contact (table 3).

Kinematic variables (table 4)
There was a main effect of footwear at initial contact minus 10% at both the ankle (p=0.03, r=0.14) and the knee (p=0.04, r=0.12), whereby in VFF the ankle was in greater plantarflexion and the knee was in less flexion than when wearing shoes. At initial contact minus 10%, there was a main effect of instruction at the ankle (p<0.001, r=0.37) where plantarflexion increased marginally (0.3°) with instructions (table 4).

There was a main effect of instruction at initial contact such that with instructions there was greater ankle plantarflexion (p=0.02, r=0.15) and knee flexion (p=0.04, r=0.12) irrespective of footwear. When subjects wore VFF, instruction had a greater effect on increasing plantarflexion (p<0.001, r=0.28), however when wearing shoes, instruction had a greater effect on increasing knee flexion (p=0.007, r=0.21).

Knee and ankle angles were essentially similar throughout the running cycle with some exceptions (figure 3). In the last 20% of the cycle, the ankle was more dorsiflexed when there were no instructions in both types of footwear and there was a suggestion that the knee was more extended when wearing shoes only. When wearing VFFs there was a slight decrease in knee extension when there were instructions.

Discussion
Our hypothesis that both running in minimalist footwear and running in SRS plus instructions leads to changes in lower limb kinematics, is supported by the results of this study. Importantly, we note that providing simple instructions to run ‘lightly, softly and quietly’ when wearing conventional running shoes leads to similar lower limb kinematic changes to wearing minimalist footwear. This is the first study to

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Table 1  Subject characteristics (mean (SEM) or median (min–max)) and details from questionnaire responses regarding running behaviours and preconceived opinions on minimalist footwear

<table>
<thead>
<tr>
<th>Subject details</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Total n (male/female)</td>
<td>35 (17/18)</td>
</tr>
<tr>
<td>Height (m)</td>
<td>1.68 (0.09)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>30.3 (5.9)</td>
</tr>
<tr>
<td>Mass (kg)</td>
<td>69.5 (11.9)</td>
</tr>
<tr>
<td>Shoe size (UK sizes)</td>
<td>7 (3–12)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Questionnaire response</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Runner/non-runner (n)</td>
<td>29/6</td>
</tr>
<tr>
<td>Running amount (hours/week)</td>
<td>1.5 (0–15)</td>
</tr>
<tr>
<td>Exercise amount (hours/week)</td>
<td>3.5 (0–17)</td>
</tr>
<tr>
<td>Prior awareness of minimalist footwear (n)</td>
<td>29</td>
</tr>
<tr>
<td>Minimalist footwear beneficial? (yes/no/unsure)</td>
<td>19/7/9</td>
</tr>
</tbody>
</table>

Table 2  A comparison of spatiotemporal parameters (mean (SD)) during different running conditions in 35 subjects

<table>
<thead>
<tr>
<th>Variable</th>
<th>Test condition</th>
<th>Combined conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stance (%)</td>
<td>SI</td>
<td>SI*</td>
</tr>
<tr>
<td>Cadence†† (steps/ min)</td>
<td>168.7 (11.4)</td>
<td>167.3 (11.6)</td>
</tr>
<tr>
<td>Stride length† (m)</td>
<td>2.18 (0.18)</td>
<td>2.21 (0.17)</td>
</tr>
</tbody>
</table>

*p<0.01.  
**p<0.001.  
†Footwear main effect.
demonstrate this finding. Both instruction and minimalist footwear can increase the extent of forefoot landing, while the combination of the two had the greatest effect. Wearing minimalist footwear without instruction induced a forefoot strike running pattern prior to landing (IC_{-10\%}). This was not seen at initial contact (IC), which is in contrast to the findings of others who reported that forefoot running is associated with a lower risk of foot and ankle injury. Others have not found this to be the case and may be associated with a lower limb injury risk.

From the clinical perspective some authors have proposed that the more forefoot strike running pattern may be associated with reduced lower limb injury risk. Others have reported that forefoot running is beneficial for those with chronic exertional compartment syndrome and may be associated with a lower incidence of overuse injuries. It seems that the clinical effect of footwear type and running style varies in different parts of the lower limb, which may increase the risk of certain injuries and reduce the risk of others.

### Table 3 Plantarflexion angle (n=35, mean (SD)) during the landing phase of the running cycle

<table>
<thead>
<tr>
<th>Variable</th>
<th>Test condition</th>
<th></th>
<th></th>
<th>Combined conditions</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SI&lt;sup&gt;-&lt;/sup&gt;</td>
<td>SI&lt;sup&gt;*&lt;/sup&gt;</td>
<td>VI&lt;sup&gt;-&lt;/sup&gt;</td>
<td>VI&lt;sup&gt;*&lt;/sup&gt;</td>
<td>S</td>
<td>V</td>
</tr>
<tr>
<td>Initial contact minus 10%&lt;sup&gt;††&lt;/sup&gt; (mm)</td>
<td>−30.2 (26.4)</td>
<td>−14.2 (28.3)</td>
<td>−21.8 (25.4)</td>
<td>−2.8 (23.4)</td>
<td>−22.2 (28.3)</td>
<td>12.3 (26.0)</td>
</tr>
<tr>
<td>Initial contact †† (mm)</td>
<td>0.5 (18.7)</td>
<td>7.9 (14.8)</td>
<td>1.0 (19.9)</td>
<td>10.5 (19.4)</td>
<td>4.2 (17.1)</td>
<td>5.7 (20.1)</td>
</tr>
</tbody>
</table>

*p<0.05, **p<0.01, ***p<0.001.
†Footwear main effect.
‡Instruction main effect.
A positive value is indicative of a more plantarflexed foot position denoted by the fifth metatarsal marker being lower than the calcaneus marker on the z-axis.

### Table 4 Ankle and knee joint angles (degrees) (mean (SD)) during the landing phase of the running cycle

<table>
<thead>
<tr>
<th>Variable</th>
<th>Test condition</th>
<th></th>
<th></th>
<th>Combined conditions</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>SI&lt;sup&gt;-&lt;/sup&gt;</td>
<td>SI&lt;sup&gt;*&lt;/sup&gt;</td>
<td>VI&lt;sup&gt;-&lt;/sup&gt;</td>
<td>VI&lt;sup&gt;*&lt;/sup&gt;</td>
<td>S</td>
<td>V</td>
</tr>
<tr>
<td>Ankle at 10% prior to IC †††&lt;sup&gt;††&lt;/sup&gt; (n=34)</td>
<td>−4.2 (7.7)</td>
<td>−0.4 (9.0)</td>
<td>−0.5 (8.2)</td>
<td>4.3 (8.7)</td>
<td>2.1 (8.5)</td>
<td>1.8 (8.7)</td>
</tr>
<tr>
<td>Ankle at IC&lt;sup&gt;†††&lt;/sup&gt; ††††&lt;sup&gt;††&lt;/sup&gt; (n=33)</td>
<td>−2.5 (6.8)</td>
<td>−2.7 (6.8)</td>
<td>−2.9 (6.1)</td>
<td>0.1 (6.5)</td>
<td>−2.9 (6.8)</td>
<td>−1.5 (6.4)</td>
</tr>
<tr>
<td>Knee at 10% prior to IC ††&lt;sup&gt;†&lt;/sup&gt; (n=34)</td>
<td>6.4 (9.3)</td>
<td>6.5 (8.8)</td>
<td>3.3 (5.4)</td>
<td>4.3 (6.2)</td>
<td>6.4 (8.9)</td>
<td>3.8 (5.8)</td>
</tr>
<tr>
<td>Knee at IC †††&lt;sup&gt;†&lt;/sup&gt; ††††&lt;sup&gt;†&lt;/sup&gt; (n=33)</td>
<td>14.1 (6.2)</td>
<td>16.8 (7.1)</td>
<td>14.0 (7.0)</td>
<td>13.8 (6.0)</td>
<td>15.5 (6.6)</td>
<td>13.9 (6.3)</td>
</tr>
</tbody>
</table>

*p<0.05.
**p<0.01.
***p<0.001.
†Footwear main effect.
‡Instruction main effect.
†Interaction effect.
††When subjects wore Vibram FiveFingers (VFF), instruction had a greater effect on increasing plantarflexion compared with when subjects wore shoes.
†††When subjects wore shoes, instruction had a greater effect on increasing knee flexion compared with when subjects wore VFF.
All knee angles are degrees of flexion. Positive ankle joint angles denote plantarflexion.
IC, initial contact.
We studied lower limb running kinematics during a 20 s period following 2 min of running, which was unlikely to produce fatigue. Longer bouts of running with a forefoot strike require strong contractions of the calf muscle complex, which could be associated with an increased incidence in injuries to the Achilles tendon. Furthermore, such fatigue could lead to heel strike running pattern in minimalist footwear leading to an increased propensity for calcaneal fractures.

The greater foot plantarflexion during the landing phase in the VI+ condition (which equates to a mean change of 27 mm into the forefoot strike posture when compared with the standard running shoe and no instruction condition (effect size r=0.28) can be explained by altered kinematics at both the knee and the ankle. With minimalist footwear and instruction, there was a mean increase in ankle plantarflexion prior to landing of 8° when compared with ankle angle during running with SRS and without instruction. The effect size for this difference was small (r=0.14). Similarly, there was a small effect (r=0.12) of minimalist footwear, equating to a mean increase of 3° in knee extension prior to landing, when compared with running in SRS alone. As was found in this study, others have shown that knee flexion angle at initial contact does not differ depending on type of footwear. Although there was a medium effect size (r=0.37) for the effect of instruction on ankle plantarflexion angle prior to landing it must be noted that the mean difference in ankle angle as a result of instruction was 0.3°. The effect of such small kinematic differences at the knee and the ankle, in terms of performance, injury risk and clinical significance is unknown. The contribution of each joint to the plantarflexion angle varies between footwear and instruction; when in minimalist footwear ankle plantarflexion increases and the knee is more extended. When under instruction both ankle plantarflexion and knee flexion increase.

We monitored kinematics in the lower limb only although clearly the human body is a series of connected segments, so the effect of footwear and instruction on other segments is not known. This could be particularly important in clinical terms if the relative position of the trunk was influenced in a manner thought likely to increase the risk of back pain. Furthermore, a limitation of the work presented is that we did not investigate kinetics, such as ground reaction forces, during the running conditions studied.

Our hypothesis that running in minimalist footwear and running in SRS plus instructions, leads to changes in spatiotemporal parameters, was only true for the effect of minimalist footwear. The increased cadence (a mean increase of four steps per minute, with effect size r=0.43) and decreased stride length, which equates to a mean 5 cm reduction in stride length (effect size r=0.27) when in minimalist footwear corroborates the work of others. This is thought to occur to reduce vertical loading rate of the lower limb such as occurs when running barefoot or in less cushioned shoes. There have been reports of a reduced stance duration and stride length with increased cadence in studies using treadmills with larger belt dimensions than used here, which may explain the different findings.

Our finding that instruction had no main effect is in contrast to that of Diebal et al who observed a significant reduction in stride length and stance time with an increase in cadence following a 6-week period of training combined with a package of instruction three times per week, for approximately 45 min, which included the verbal cue to ‘run quietly’, a digital metronome to stabilise step cadence at 180 steps per minute and visual instruction via a video camera recording to facilitate forefoot strike technique. The varying levels

Figure 3 Mean knee and ankle angles throughout the gait cycle when wearing shoes (A) and Vibram FiveFingers (VFF) (B). The increase in ankle plantarflexion in the landing phase with instruction is circled.

of instruction, and the attempt to control cadence in the study by Diebal et al.\textsuperscript{27} may account for the difference in findings.

Instruction to ‘run in a light, soft and quiet way’ had greater effects on kinematics than wearing minimalist footwear without instruction. The large interindividual variations indicate that a number of subjects responded differently to the same instruction. This may be explained by the fact that less experienced runners have been reported to adopt lower preferred running speeds\textsuperscript{13} and that treadmill speeds 10% greater than an individual’s preferred speed significantly increases ankle plantarflexion at IC.\textsuperscript{36} It is possible that our less experienced runners exceeded their preferred running speed, which is supported by three subjects requesting to run at a reduced speed. Trainers and clinicians should carefully evaluate individual responses to instruction to achieve the desired effect on running style.

We studied only one type of minimalist footwear although there are a variety of different makes and models. The findings of this study demonstrate that instruction alone can influence running style in a way that may reduce the risk of injury and aid injury management and that this can be enhanced by the type of footwear. These findings should be considered in the context of a subject cohort with variable amounts of running experience and in light of this data being unable to reveal whether the kinematic changes observed with instruction would be sustained with longer bouts of running.

CONCLUSION

The kinematic adaptations observed following instruction suggest that changes in joint angles previously attributed to minimalist footwear alone may be similarly achieved with running instruction. Further research is warranted to explore the clinical utility of using minimalist footwear and/or instruction in reducing injury prevalence in runners.

Overall, the results of the current study support previous claims that adaptations in spatiotemporal variables may be attributable to minimalist footwear. However, the results also suggest that changes in joint angles previously attributed to minimalist footwear may be similarly achieved with running instruction alone. To explore the clinical implications arising from the observed effects of instruction and minimalist footwear, longitudinal prospective studies exploring injury rates and performance are warranted.

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Contributors

MGB, LB, LJMP, RMO, GO and DJW: planning, conduct, reporting/analysis. RW and DN: planning, reporting/analysis.

Competing interests

None declared.

Ethics approval

Kings College London Research Ethics Committee (REC Protocol No. BDM/11/12-66).

Provenance and peer review

Not commissioned; externally peer reviewed.

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