# Body Mass and Weekly Training Distance Influence the Pain and Injuries Experienced by Runners Using Minimalist Shoes

## A Randomized Controlled Trial

Joel T. Fuller,*† BSc, Dominic Thewlis,† PhD, Jonathan D. Buckley,† PhD,
Nicholas A.T. Brown,‡ PhD, Joseph Hamill,§ PhD, and Margarita D. Tsiros,† PhD
*The study was performed at the University of South Australia, Adelaide, Australia*

**Background:** Minimalist shoes have been popularized as a safe alternative to conventional running shoes. However, a paucity of research is available investigating the longer-term safety of minimalist shoes.

**Purpose:** To compare running-related pain and injury between minimalist and conventional shoes in trained runners and to investigate interactions between shoe type, body mass, and weekly training distance.

**Study Design:** Randomized clinical trial; Level of evidence, 2.

**Methods:** Sixty-one trained, habitual rearfoot footfall runners (mean ± SD: body mass, 74.6 ± 9.3 kg; weekly training distance, 25 ± 14 km) were randomly allocated to either minimalist or conventional shoes. Runners gradually increased the time spent running in their allocated shoes over 26 weeks. Running-related pain intensity was measured weekly by use of 100-mm visual analog scales. Time to first running-related injury was also assessed.

**Results:** Interactions were found between shoe type and weekly training distance for weekly running-related pain; greater pain was experienced with minimalist shoes ($P < .05$), and clinically meaningful increases (>10 mm) were noted when the weekly training distance was more than 35 km/wk. Eleven of 30 runners sustained an injury in conventional shoes compared with 16 of 31 runners in minimalist shoes (hazard ratio, 1.64; 95% confidence interval, 0.63-4.27; $P = .31$). A shoe × body mass interaction was found for time to first running-related injury ($P = .01$). For runners using minimalist shoes, relative to runners using conventional shoes, the risk of sustaining an injury became more likely with increasing body mass above 71.4 kg, and the risk was moderately increased (hazard ratio, 2.00; 95% confidence interval, 1.10-3.66; $P = .02$) for runners using minimalist shoes who had a body mass of 85.7 kg.

**Conclusions:** Runners should limit weekly training distance in minimalist shoes to avoid running-related pain. Heavier runners are at greater risk of injury when running in minimalist shoes.

**Registration:** Australian New Zealand Clinical Trials Registry (ACTRN12613000642785).

**Keywords:** footwear; pain; athletic injuries; risk factors

*Address correspondence to Joel T. Fuller, BSc, University of South Australia, City East Campus, Adelaide, SA 5001, Australia (email: joel.fuller@mymail.unisa.edu.au).

†Alliance for Research in Exercise, Nutrition and Activity, Sansom Institute for Health Research, University of South Australia, Adelaide, Australia.

‡Australian Institute of Sport, Bruce, Australia.

§University of Massachusetts, Amherst, Massachusetts, USA.

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Injury prevention is an important issue for runners because of a relatively high incidence of injury in this sport.[33,35,39] Using minimalist shoes has been suggested as a means for preventing injuries because these shoes can facilitate changes to running biomechanics,[21] and thus many runners are interested in using minimalist shoes.[33] To date, the majority of research has attempted to infer the long-term safety of minimalist shoes from short-term biomechanical studies of impact forces, joint kinetics, and muscle activity.[8,30,43] This approach has significant limitations; first, running in minimalist shoes can cause changes to running biomechanics over time[25]; and second, there is a paucity of prospective studies validating these biomechanical changes as predictors of injury risk.[1,22,44] As a result, much debate remains about the safety of using minimalist shoes, despite the large volume of research undertaken in this area.

Running in minimalist shoes can increase stride rate,[3,38,42] decrease stride length,[3,38] and cause a greater proportion of runners to make initial contact with the midfoot or forefoot (instead of the rearfoot).[30,42] Many researchers anticipate that these changes to running gait will affect the type and prevalence of injuries experienced by runners.[5,18,20] Forefoot footfall patterns increase peak Achilles tendon forces and might increase the incidence of injuries to the ankle plantar flexor–Achilles tendon complex.[18] In contrast, forefoot footfall patterns, short stride lengths, and high stride rates reduce patellofemoral tendon forces.[18,20] Forefoot footfall patterns have also been retrospectively associated with reduced incidence of patellofemoral joint injuries.[5] However, no studies have established a causal relationship between changes to running gait and altered risk of injury in runners using minimalist shoes. Additionally, it is unclear to what extent increases in loading forces can be tolerated by tissues in vivo.

Relatively few studies have prospectively compared running-related pain and injury risk between minimalist and conventional shoes.[32,34] In the largest study,[34] a cohort of 99 runners used conventional shoes or 1 of 2 minimalist shoes during a 3-month training program. Runners in each group used their allocated shoes for up to ~60% of weekly training, and a greater severity of calf and shin pain was reported by runners using minimalist shoes. As well, a greater incidence of injury was found in the minimalist shoe groups (20% and 38%) compared with the conventional shoe group (13%). In a smaller study,[32] a cohort of 50 runners were randomized to using either minimalist shoes or their usual running shoes during a 10-week training program. Runners in the minimalist group increased the amount of running in minimalist shoes by 1 to 2 miles during the first 3 weeks and then in a nonstandardized manner for the remaining 7 weeks. Four runners in the minimalist shoe group dropped out of the study due to injury (16% injury incidence) compared with no runners in the control group. Further studies involving longer observational time periods are needed to build on these preliminary findings.

Other intrinsic (eg, body mass[4,23]) and extrinsic (eg, training distance[16,24,41]) injury risk factors, not just footwear, are important for safe participation in running.[39] However, research is lacking that investigates how these risk factors influence the pain and injuries experienced by runners using minimalist shoes. For example, increased calf and shin pain in runners using minimalist shoes could be exacerbated in heavier runners, who are subjected to greater absolute forces and consequently greater tissue loading at impact than lighter runners, and by high weekly training distances that increase exposure to minimalist shoes.[23]

The purpose of this study was to compare running-related pain and injury between minimalist and conventional shoes in trained runners. It was hypothesized a priori that minimalist shoes would increase running-related pain and risk of injury. A secondary purpose of this study was to investigate interactions between shoe type, body mass, and weekly training distance for running-related pain and injury outcomes. We hypothesized post hoc that, compared with conventional shoes, runners with greater body mass or weekly training distance would experience increased running-related pain and injury in minimalist shoes.

## METHODS

### Participants

Sixty-one male distance runners (mean ± SD: age, 27 ± 7 years; body mass, 74.6 ± 9.3 kg; weekly training distance, 25 ± 14 km) were recruited for this study, which was approved by the University of South Australia Human Research Ethics Committee and was registered with the Australian and New Zealand Clinical Trials Registry (ACTR N12613000642785). Participants provided their written informed consent before participation.

This investigation of pain and injury represents a secondary outcome from a clinical trial for which the primary purpose was to investigate the long-term effects of minimalist shoes on running performance.[7] All participants who participated in the clinical trial were included in this secondary analysis. Sample size estimation for the clinical trial was based on detecting changes in the trial's primary outcome (running performance). This a priori estimation predicted that we needed to recruit 76 participants for the clinical trial after accounting for participant dropout and inability to assess running performance due to injury.[7] However, participant retention during the trial was better than expected, and only 61 participants needed to be recruited to achieve sufficient statistical power for the trial's primary outcome (running performance). As a result, the final number of recruited participants (n = 61) is less than the number of participants (n = 76) estimated in the trial's published study protocol.[7]

Eligible participants were aged 18 to 40 years, had no previous experience with minimalist shoes, and used a rearfoot footfall at the time of enrollment.[7] Runners were included if they trained a minimum of 15 km/wk and could run 5 km in less than 23 minutes (95% of runners represented by the cohort of male endurance-trained runners in a study by Laursen and colleagues[19] could run 5 km in less than 23 minutes; ie, mean 5-km time + 2 SDs was 23 minutes).[7] Minimum training and performance requirements were used to ensure that a population representing the majority of recreational runners was evaluated. Runners were excluded if they used orthotics or had a current or recent (<3 months) musculoskeletal injury or history of invasive surgery to the back, pelvis, or lower extremities in the previous year.[7]

### Study Protocol

This study used a parallel-group, randomized controlled trial design. Participants attended the exercise laboratory 1 week before their anticipated start date to complete a 5-km time trial on a motorized treadmill (Model 645, Quinton Instrument Co) while wearing their own shoes. Participants were randomized to shoe group (conventional or minimalist) via a process of minimization,[2] with time trial performance used as the minimization variable.[7]

This ensured balanced running ability across groups.[7] Randomization via minimization offers the only acceptable alternative to simple and restricted randomization[27] and is more effective at balancing the collective attributes of intervention groups in small samples than traditional methods of randomization.[36] Allocation of participants was performed by 1 investigator who was not involved in data collection.[7] It was not possible to blind participants to their allocated shoe group. Investigators were not blinded to intervention group during data collection or data analysis.

Runners in each group gradually increased the amount of time spent running in their allocated shoes (conventional or minimalist) and decreased the amount of time spent running in their regular running shoes over 26 weeks.[7] The amount of time spent running in allocated shoes was ~5% (10 minutes) of total weekly training time in week 1 and increased by 5% each week, before reaching 100% of total weekly training in weeks 20 to 26. Participants recorded all of their weekly running and shoe use in training diaries. We did not monitor how participants used their allocated shoes outside of training. Participants were not encouraged or instructed to modify their running gait in any way. Participants completed all training in their usual training environments (usual training surface, time of day, etc).

## Weekly Training

All participants completed a standardized training program during weeks 1 to 6 of the intervention, which consisted of 2 interval running sessions at 85% to 90% maximum heart rate and 2 continuous running sessions at 65% to 80% maximum heart rate each week.[7] After the initial 6-week run-in period, during which training was controlled, participants were instructed to continue their usual weekly running training for the remainder of the study.[7] This ensured that the effects of minimalist shoes were investigated using an ecologically valid approach and could be generalized to real-life conditions.

## Footwear Conditions

Participants were allocated to conventional (Asics Gel Cumulus; mass [mean ± SD], 333 ± 25 g per shoe; heel stack height, 32 mm; heel drop, 9 mm) or minimalist shoes (Asics Piranha SP4; mass, 138 ± 10 g per shoe; heel stack height, 22 mm; heel drop, 5 mm). The Asics Piranha meets published standards for minimalist shoe classification and scored 72% on the minimalist index for classification of shoes on a scale from least minimalist (0%) to most minimalist (100%).[6] In contrast, the Asics Gel Cumulus scored 12% on the minimalist index.

## Pain and Injury Assessment

Participants completed weekly assessments of the worst running-related pain they experienced in the foot, ankle, calf, shin, knee, thigh, and lower back. Pain in each body area was assessed by means of body charts and 100-mm visual analog scales (VAS) with anchors "no pain" on the left (0 mm) and "worst pain" on the right (100 mm).

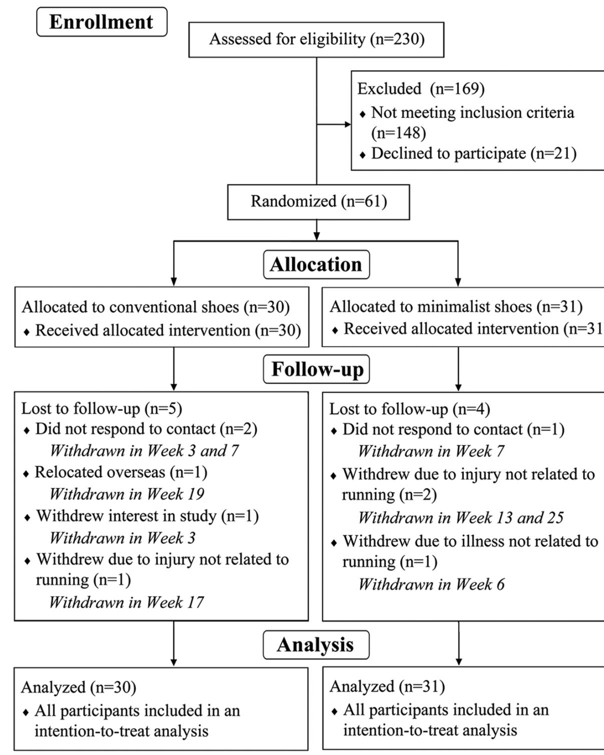


**Figure 1.** Participant flow diagram.

Reliability was determined using test-retest measurements from 10 runners who completed 2 assessments of running-related pain separated by 1 hour. Intraclass correlation coefficients (ICCs) were excellent for the foot (ICC = 0.98), ankle (ICC = 0.83), calf (ICC = 0.87), shin (ICC = 0.87), knee (ICC = 0.94), thigh (ICC = 0.88), and lower back (ICC = 0.97). The standard error of measurement was less than 4 mm for each body area.

A running-related injury was considered any musculoskeletal problem severe enough to cause a visit to a health professional, use of medication, or reduced weekly training.[7,24,41] Injured participants were assessed and treated by medical professionals who were not involved in this study.[7] Study investigators did not have access to participant medical records and could not obtain detailed diagnostic and treatment information. Participants self-reported the location of their injuries to study investigators, who maintained regular contact with injured participants to determine the number of training days missed due to injury. Injuries attributed by runners to an accident that was unrelated to running (eg, sprained ankle walking over uneven ground) were not included.

## Statistical Methods

Running-related pain was compared between shoe groups with a linear fixed-effects model by use of the MIXED procedure in SPSS (version 21, IBM). Fixed effects were shoe, time, and shoe × time interaction. Time was treated as a repeated observation. Participant body mass and weekly

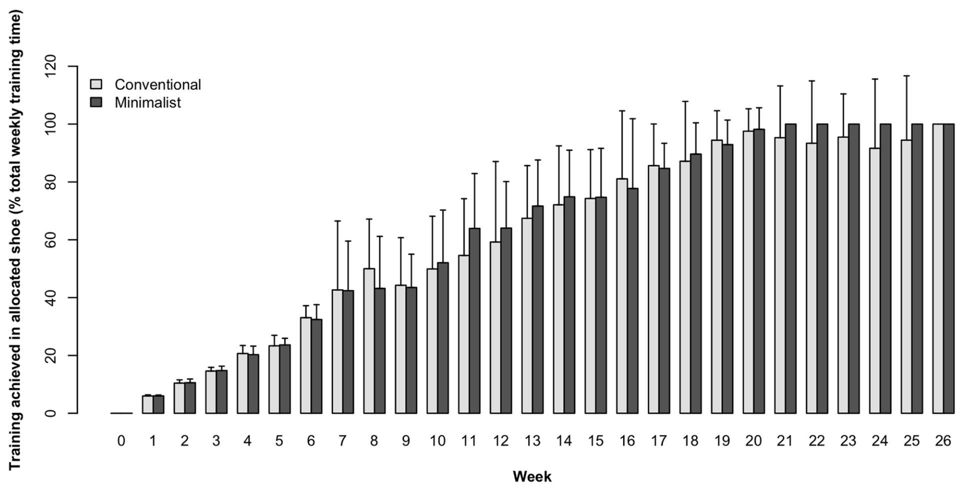


**Figure 2.** Percentage of weekly training time achieved in each shoe type. Values are mean ± standard deviation.

training distance were included as continuous predictor variables. A first-order, autoregressive covariance structure was used for the residual covariance matrix. Quantile-quantile normality plots and residual plots were used to assess normality of data and normality, homoscedasticity, and independence of residuals. Pain data were log-transformed to achieve a normal distribution for model residuals. Effect sizes were quantified using mean difference and were considered trivial (<10 mm) or clinically meaningful (≥10 mm).[15]

Cox proportional hazards regression models were used to investigate differences in time to first running-related injury between shoe groups. This analysis was performed with the statistical software R (version 3.2.1, R Foundation for Statistical Computing). Cox proportional hazards regression models were fit using the *coxph* function from the *survival* package in R. Two separate models were used for analysis to maximize the number of injury events per model factor.[40] Model 1 included shoe as a categorical factor, weekly training distance as a continuous predictor, and shoe × weekly training distance interaction. Model 2 included shoe as a categorical factor, body mass as a continuous predictor, and shoe × body mass interaction. Sensitivity analysis was performed with a third model, which included all 5 terms (shoe, weekly training distance, body mass, shoe × weekly training distance interaction, and shoe × body mass interaction). Body mass and weekly training distance were mean centered for analysis.[17] Schoenfeld residual plots and tests were used to assess proportional hazards assumptions.[11] Statistical significance was assumed for $P < .05$. Effect sizes for injury data were quantified using hazard ratios (HRs) and were considered trivial (<1.30), small (1.30-1.99), moderate (2.00-3.99), and large (≥4.00).[12] Precision of effect size estimates was assessed by use of 95% confidence intervals. We are not aware of any consensus on what should be considered a clinically meaningful HR in studies of running-related injuries. For the purpose of this study, we considered an HR of 2.00 or higher (ie, moderate effect or greater) to be a clinically meaningful effect. To present findings in a clinically meaningful way, we calculated relative risk (RR) statistics from Cox proportional hazards regression model survival curves for any effects with a clinically meaningful magnitude (ie, HR ≥ 2.00).

## RESULTS

Thirty-one runners were allocated to minimalist shoes, and 30 runners were allocated to conventional shoes. Four runners experienced an injury or illness during the study that was not related to running (Figure 1). These runners withdrew from the study at the time of their injury or illness because it prevented them from running. We lost contact with 3 runners who did not respond to email or telephone follow-up (Figure 1). These runners were withdrawn from the study before completing the 26-week observational period. One runner withdrew interest in the study after 3 weeks of observation (Figure 1). One runner withdrew from the study in week 19 after relocating overseas for work (Figure 1). All runners were included in an intention-to-treat analysis.

### Training Distance and Shoe Use

Runners in both groups successfully transitioned to performing 100% of weekly training in allocated shoes with no difference between groups ($P$ = .70) (Figure 2). The mean (±SD) weekly training distance was slightly less in the minimalist shoe group (20.7 ± 7.1 km) compared with the conventional shoe group (24.2 ± 12.4 km), although the difference was not statistically significant ($P$ = .10).

### Running-Related Pain

A shoe × time interaction was found for weekly knee pain ($P$ = .02). Training in minimalist shoes increased knee pain during weeks 7 to 26 (35%-100% shoe use) but not weeks 1 to 6 (5%-30% shoe use) (Figure 3A). A similar trend was seen for weekly calf pain ($P$ = .10; Figure 3B). No shoe × time interactions were found for weekly foot ($P$ = .51),

TABLE 1
Number of Injuries and Severity of Weekly Running-Related Pain at the Foot, Ankle, Calf, Shin, Knee, Thigh, and Lower Back for Conventional and Minimalist Shoes[a]

| | Mean Weekly VAS, mm | | | Number of Injuries (%) | |
|---|---|---|---|---|---|
| Location | Conventional | Minimalist | $P$ Value | Conventional | Minimalist |
| Foot | 7 ± 10 | 8 ± 14 | .58 | 1 (9) | 1 (6) |
| Ankle | 5 ± 10 | 10 ± 18 | .01 | 0 (0) | 2 (13) |
| Calf | 7 ± 12 | 11 ± 17 | .01 | 4 (36) | 4 (25) |
| Shin | 4 ± 7 | 8 ± 13 | .01 | 1 (9) | 3 (19) |
| Knee | 7 ± 11 | 11 ± 15 | .03 | 5 (45) | 5 (31) |
| Thigh | 6 ± 10 | 6 ± 9 | .80 | 0 (0) | 1 (6) |
| Lower back | 6 ± 11 | 7 ± 13 | .24 | 0 (0) | 0 (0) |

[a]Pain data are mean ± standard deviation. VAS, visual analog scale pain scores. $P$ values are provided for the difference in mean weekly VAS between minimalist and conventional shoe groups (assessed by main effect of shoe in linear fixed-effects model).

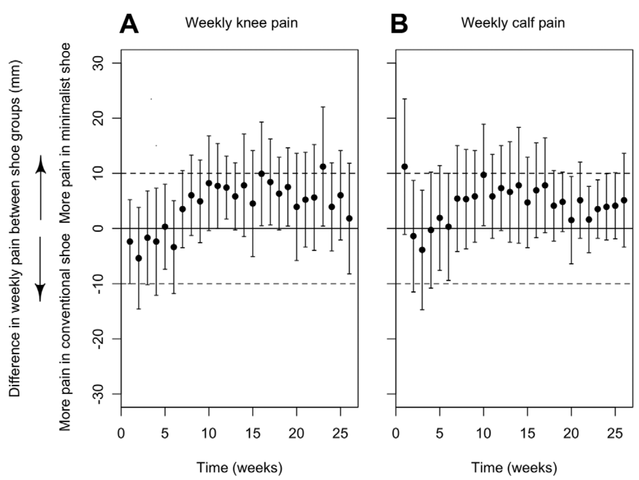


**Figure 3.** Difference in weekly knee (A) and calf (B) pain between minimalist and conventional shoes. Values are means with 95% confidence intervals. Dashed lines indicate clinically meaningful difference.

ankle ($P$ = .67), shin ($P$ = .88), thigh ($P$ = .28), or lower back pain ($P$ = .71). Main effects of shoe were found for weekly ankle, calf, shin, and knee pain but not foot, thigh, or lower back pain (Table 1). Training in minimalist shoes increased ankle, calf, shin, and knee pain, but these differences were not clinically meaningful (<10 mm; Table 1).

We found shoe × weekly training distance interactions for weekly running-related pain at the calf ($P$ = .01), ankle ($P$ = .02), and shin ($P$ = .01) but not at the foot ($P$ = .44), knee ($P$ = .48), thigh ($P$ = .65), or lower back ($P$ = .14). Weekly pain increased in minimalist compared with conventional shoes at greater weekly training distances (Figure 4). The linear fixed-effects models predicted that minimalist shoes could cause clinically meaningful increases (>10 mm increase in VAS scores) in weekly running-related pain at the calf when weekly training distance was more than 35 km/wk and at the ankle and shin when weekly training distance was more than 40 km/wk (Figure 4).

## Running-Related Injury

Eleven (37%) runners sustained a running-related injury in the conventional shoe group compared with 16 (52%) runners in the minimalist shoe group. Ten lower leg and foot injuries occurred in the minimalist shoe group compared with 6 in the conventional shoe group (Table 1). Knee and thigh injuries accounted for the remaining 6 injuries in the minimalist shoe group and 5 injuries in the conventional shoe group (Table 1). Injured runners missed a minimum of 3 training days due to injury. The median number of training days lost to injury was 14 days (interquartile range, 10-27 days) in the minimalist shoe group and 13 days (interquartile range, 7-25 days) in the conventional shoe group.

In model 1, the time to first running-related injury was not affected by shoe type (HR, 1.64; 95% CI, 0.63-4.27; $P$ = .31) or weekly training distance (HR, 1.05; 95% CI, 0.99-1.11; $P$ = .08), and there was no shoe × weekly training distance interaction ($P$ = .10). In model 2, a shoe × body mass interaction was found for time to first running-related injury (HR [minimalist × body mass], 1.13; 95% CI, 1.03-1.24; $P$ = .01). A main effect of body mass was found (HR, 0.93; 95% CI, 0.86-0.99; $P$ = .04) but no main effect of shoe type (HR, 1.45; 95% CI, 0.62-3.39; $P$ = .40). The shoe × body mass interaction was the only statistically significant predictor variable in a sensitivity analysis using all terms in a single model (HR [minimalist × body mass], 1.11; 95% CI, 1.01-1.22; $P$ = .03).

For runners using minimalist shoes, sustaining an injury became increasingly more likely with increasing body mass above 71.4 kg and increasingly less likely with decreasing body mass below 71.4 kg (Figure 5). Runners using minimalist shoes who had a body mass of 85.7 kg experienced a moderate increase in risk of injury (model 2: HR, 2.00; 95% CI, 1.10-3.66; $P$ = .02). The model estimated that 68% of runners weighing 85.7 kg and using minimalist shoes would sustain an injury after 26 weeks of running compared with 22% of runners weighing 85.7 kg and using conventional shoes (RR 3.09; Figure 6). In contrast, runners using minimalist shoes with a body mass of 57.2 kg did not experience statistically significant

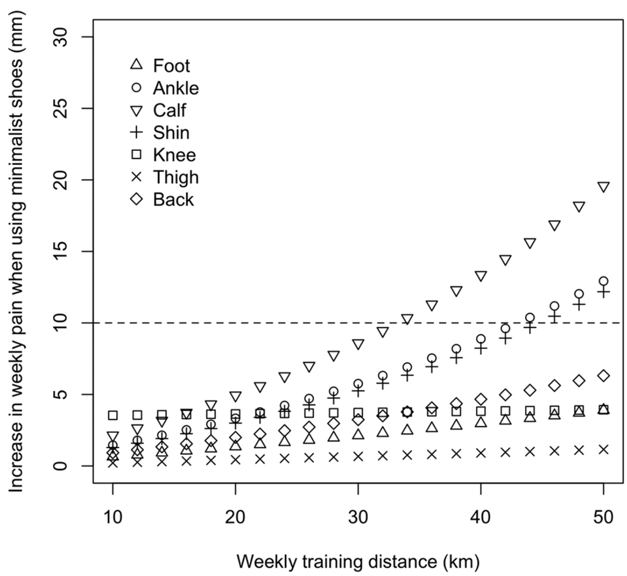


**Figure 4.** Linear fixed-effects model predicted differences in weekly pain between minimalist and conventional shoes relative to weekly training distance. Values are plotted for the range of weekly training distances that were observed in this study. Dashed lines indicate clinically meaningful difference.

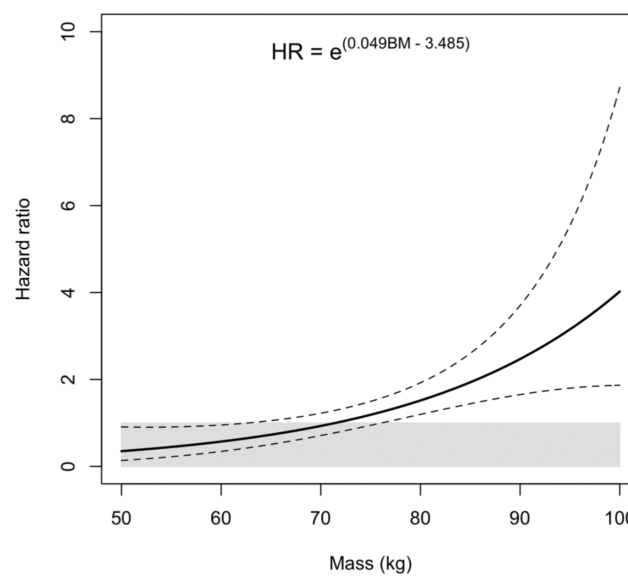


**Figure 5.** The risk of sustaining a running-related injury when using minimalist shoes for runners of different body mass (BM). Error lines represent ±SE. Shaded area indicates hazard ratio (HR) < 1.00. HR = 1.00 when minimalist shoes have no effect on risk of injury relative to conventional shoes. HR < 1.00 when minimalist shoes decrease risk of injury relative to conventional shoes. HR > 1.00 when minimalist shoes increase risk of injury relative to conventional shoes.

reductions in risk of injury (model 2: HR, 0.50; 95% CI, 0.15-1.66; $P$ = .26).

## DISCUSSION

The purpose of this study was to compare running-related pain and injury between minimalist and conventional shoes in trained runners and investigate interactions between shoe type, body mass, and weekly training distance. It was hypothesized that runners with greater body mass or weekly training distance would experience increased running-related pain and injury when using minimalist shoes. Consistent with this hypothesis, minimalist shoes increased running-related pain in runners with greater weekly training distance and increased risk of injury in runners with greater body mass.

This study is one of the few randomized controlled trials investigating pain[34] and injury[32,34] in runners wearing minimalist shoes and the only study to prospectively investigate pain and injury in runners performing 100% of their running in minimalist shoes. The majority of previous research attempted to infer injury risk from biomechanical analysis of runners using minimalist shoes without prospective follow-up[8,30,43] or used retrospective injury survey responses from runners using minimalist shoes, methods that are prone to selection and recall bias.[14] Investigating pain and injury in runners wearing minimalist shoes is important because preventing future injuries is the primary motivating factor for runners interested in using minimalist shoes.[33]

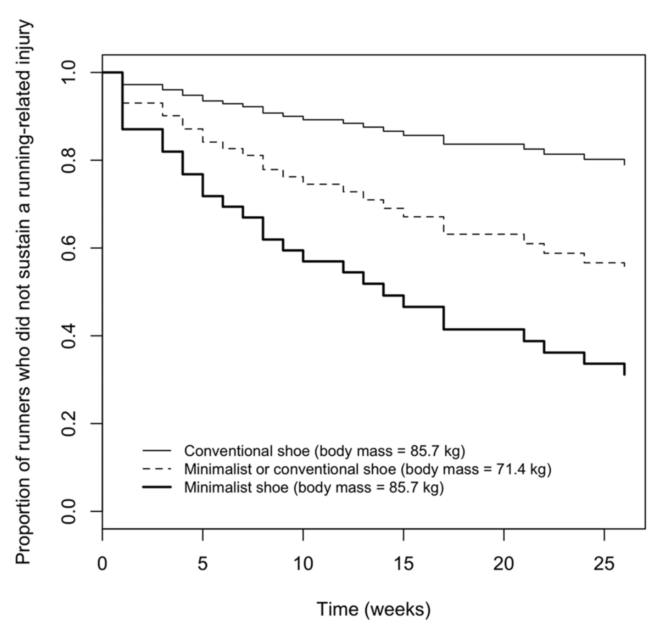


**Figure 6.** Cumulative proportion of runners of differing body mass who did not sustain a running-related injury during 26 weeks of running in minimalist and conventional shoes.

### Running-Related Pain

Minimalist shoes increased ankle, calf, shin, and knee pain throughout the 26-week follow-up even though the minimalist shoe group (weekly distance 20.7 km) performed slightly less weekly running than the conventional shoe group (weekly distance 24.2 km). The average increases in pain were not clinically meaningful.[15] However, knee pain and to a lesser extent calf pain increased over time in runners wearing minimalist shoes and approached clinically meaningful differences during weeks 7 to 26 (35%-100% allocated shoe use) (Figure 3). Several studies have reported that runners experience pain in the lower legs and feet when transitioning to minimalist shoes.[9,14,34] However, the protocol for transitioning to minimalist shoes used in our study appears to prevent pain experienced by runners exceeding clinically meaningful limits, particularly during weeks 1 to 6.

Weekly training distance influenced the amount of pain experienced by runners transitioning to minimalist shoes. Runners training more than ~35 km/wk experienced clinically meaningful increases in weekly running-related pain at the calf and to a lesser extent at the ankle and shin (Figure 4). A greater increase in calf pain with increased weekly training distance is consistent with runners performing increased ankle plantarflexion work in minimalist shoes.[10] Our findings suggest that it might not be appropriate for all runners to increase time spent running in minimalist shoes by the same percentage each week. Increasing by 5% each week appears to be appropriate for runners training less than 35 km/wk. However, more conservative weekly increases might be needed for runners exceeding this training threshold. Our findings indicate that runners should avoid increasing weekly minimalist shoe use by more than 1.70 km (ie, 5% × 35 km = 1.75 km) each week.

## Running-Related Injury

Minimalist shoes increased the risk of running-related injury in runners weighing more than 71.4 kg. The hazard ratio was more than doubled for heavy (>85.7 kg) runners using minimalist shoes, and they were approximately 3 times more likely to sustain an injury during 26 weeks of running (Figure 6). The magnitude of this increase in injury risk is consistent with the study by Ryan and colleagues,[34] who investigated injury incidence in runners transitioning to minimalist shoes over 12 weeks. In this study, runners using 2 different minimalist shoes were 1.6 to 3.1 times more likely to sustain an injury than runners using control shoes.[34] Notably, our findings suggest that heavier runners (>85.7 kg) are most at risk of injuries caused by minimalist shoes.

One possible explanation for the increased risk of injury in heavier runners using minimalist shoes is the direct relationship between force and mass (ie, Newton's second law).[28] Any changes in loading forces caused by minimalist shoes are likely to have greater absolute magnitude (and potential clinical significance) for heavier runners, due to their increased body mass. For example, minimalist shoes can increase vertical ground-reaction force (GRF) loading rates by 37 body weights per second when runners use a rearfoot footfall pattern.[10] For lighter runners (ie, body mass = 57.2 kg), this equates to an increase of $57.2 \times 9.8 \times 37 = 20{,}741\ \mathrm{N{\cdot}s^{-1}}$ when values are not normalized to body mass. In contrast, this equates to an increase of $31{,}075\ \mathrm{N{\cdot}s^{-1}}$ for heavier runners (ie, body mass = 85.7 kg) who are subjected to an additional ~$10{,}000\ \mathrm{N{\cdot}s^{-1}}$ of unaccustomed loading. High vertical GRF loading rates have been retrospectively associated with increased risk of tibial stress fractures,[26] plantar fasciitis,[31] and nonspecific running-related injuries.[13] However, to our knowledge, the only prospective study to investigate the relationship between GRF and running injury found a greater frequency of injuries in runners who had low vertical GRF loading rates.[29]

Notably, the interaction between shoe and body mass indicated that minimalist shoes might decrease the risk of running-related injury in runners weighing less than 71.4 kg. This was an unexpected finding, and for runners weighing between 57.2 and 71.4 kg we could not be certain that it was a true finding (Figure 5). For runners weighing 57.2 kg, the 95% confidence interval suggested that minimalist shoes could cause anything from a small (HR = 1.66) increase in injury risk to a large (HR = 0.15) decrease in injury risk. The potential for moderate or large beneficial effects suggests that further investigation of the effects of minimalist shoes on injury risk in light (<71.4 kg) runners is warranted.

It has been hypothesized that running in minimalist shoes could increase incidence of lower leg injuries, particularly for the foot, ankle, and triceps surae–Achilles tendon complex.[25,30,37] Consistent with this hypothesis, runners in the minimalist shoe group reported almost double the number of lower leg and foot injuries than runners in the conventional shoe group. Unfortunately, the small sample size of injuries in the current study prevented statistical investigation of injury location. The only other studies to prospectively investigate injuries in runners using minimalist shoes have not reported the location of injuries,[32,34] so it was not possible to pool data across studies. Future research investigating injury risk for runners using minimalist shoes should report the location or diagnosis of injuries so that data can be pooled across studies to better inform runners about the types of injuries that can be expected when using minimalist shoes and to facilitate research into methods to prevent such injuries.

## Limitations

Our study has important limitations that should be considered when interpreting our findings. First, our sample size is small, and this may have affected our ability to detect significant main effects of shoe type on injury risk. Second, our Cox proportional hazards regression models each included 3 factors with only 27 total injury events (9 injury events per factor). A minimum of 10 events per factor is desirable for Cox regression models.[40] However, Vittinghoff and McCulloch[40] demonstrated that results of models with 5 to 9 events per factor should still be accepted (with only a minor degree of extra caution), particularly for plausible and highly significant associations. Third, diagnostic information was not available for all injuries; thus, grouping of injuries was limited to anatomic locations. This allows some speculation about the cause of injuries but is not as precise as grouping injuries by diagnosis. Fourth, the results of this study provide only preliminary guidelines for safe use of minimalist shoes. Further research is required to confirm that following these guidelines reduces pain and injury in runners transitioning to minimalist shoes.

## CONCLUSION

Sustaining a running-related injury when transitioning to minimalist shoes was increasingly likely with increasing body mass. The increased risk of injury was moderate for runners with body mass 85.7 kg or higher who used minimalist shoes. Transitioning to minimalist shoes caused clinically meaningful increases in running-related pain at the calf and, to a lesser extent, at the ankle and shin when training distance was more than 35 km/wk. Runners transitioning to minimalist shoes should not increase weekly minimalist shoe distance by more than 1.70 km each week. Heavier runners should consider avoiding running in minimalist shoes.

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