Foot Core Training to Prevent Running-Related Injuries

A Survival Analysis of a Single-Blind, Randomized Controlled Trial

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Background: Running-related injuries (RRIs) are a pervasive menace that can interrupt or end the participation of recreational runners in this healthy physical activity. To date, no satisfactory treatment has been developed to prevent RRIs.

Purpose: To investigate the efficacy of a novel foot core strengthening protocol based on a ground-up approach to reduce the incidence of RRIs in recreational long-distance runners over the course of a 1-year follow-up.

Study Design: Randomized controlled trial; Level of evidence, 1.

Methods: The participants, 118 runners, were assessed at baseline and randomly allocated to either an intervention group (n = 57) or a control group (n = 61). The intervention group received an 8-week training course focused on the foot-ankle muscles, followed by remotely supervised training thereafter. Assessments consisted of 3 separate biomechanical evaluations of foot strength and foot posture and a weekly report on each participant's running distance, pace, and injury incidence over 12 months.

Results: The control group participants were 2.42 times (95% CI, 1.98-3.62) more likely to experience an RRI within the 12-month study period than participants in the intervention group (P = .035). Time to injury was significantly correlated with Foot Posture Index (P = .031; r = 0.41) and foot strength gain (P = .044; r = 0.45) scores. This foot exercise program showed evidence of effective RRI risk reduction in recreational runners at 4 to 8 months of training.

Conclusion: Recreational runners randomized to the new foot core strengthening protocol had a 2.42-fold lower rate of RRIs compared with the control group. Further studies are recommended to better understand the underlying biomechanical mechanisms of injury, types of injuries, and subgroups of runners who might benefit maximally.

Registration: NCT02306148 (ClinicalTrials.gov identifier).

Keywords: running; sports injuries; exercise therapy; foot; strengthening; biomechanics

Recreational running can be considered a "hero" in the quest for better health and quality of life.[6,12,15,33,43,50,56] However, as recreational running increases in popularity, its accompanying nemesis increases proportionally: running-related injuries (RRIs). Annual RRI incidence for long-distance runners can be as high as 79.3%.[52] Common preventive actions,[45] such as warm-up, cool-down, and stretching exercises, lack scientific evidence of effectiveness.[40,41,53]

Many studies have investigated conditions and behaviors that could be risk factors for RRIs. In a systematic review, Nielsen et al[38] reported that weekly running volume appeared to have an effect on rate of RRIs. However, according to Hulme et al,[17] who reviewed risk ratio and several modifiable and nonmodifiable possible risk factors, only a previous RRI and irregular or absent menstruation were associated with an increased risk of RRI. Factors not associated with increased RRI risk included frequency of running, pace and interval of running, body weight, body mass index (BMI), dietary plan and hormonal status, orthotic use, stretching, warm-up, cool-down, and running surface.

Studies on interventions to reduce RRIs have yielded lackluster results. For instance, when examining a graded training program that entailed a slow increase in running mileage, where a rapid mileage increase was considered an RRI risk factor, investigators found no differences in RRI incidence between intervention and control groups.[4] Online interventions that addressed personal, training, biomechanical, and equipment-related risk factors were found to be ineffective in 1 study[11] and reduced RRIs by 13% in another study.[16] The effects of this intervention on preventive behaviors investigated (eg, warming up,

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choosing specific footwear, implementing general conditioning training), however, were considered nonsignificant.[16] A controlled trial[24] found a decreased RRI risk in runners with pronated feet wearing motion-control shoes compared with runners wearing standard shoes (hazard ratio, 0.34; 95% CI, 0.13-0.84). The authors concluded that with cushioned shoes, better motion control might be needed to limit injury risk. However, this begs the question: Is not foot-ankle motion control exerted by runners themselves? Even if cushioned shoes restrain the runner's capacity for movement control or demand more of the foot-ankle muscles, should it not be possible to address this directly through training?

Strengthening of foot-ankle muscles, with the aim of improving postural control and balance, has already proven to be effective in other patient populations. Foot strengthening programs have been reported to be effective in reducing risk of falling by a factor of 7 in elderly people[29] and increasing jump performance in young athletes.[13] Both studies demonstrated benefits for body function and balance when the foot core is strengthened, considering the foot core a musculoskeletal subsystem that manages input and stability to accommodate demands during static and dynamic activities.[27] Because foot muscles play intrinsic roles in dampening impact and propelling the body forward during running,[19,20,42] it is reasonable that training could improve these functions and that this could prevent RRIs. The aim of our single-blind, randomized controlled trial was to investigate the efficacy of a novel foot muscle strengthening protocol in reducing the incidence of RRI in recreational runners over the course of a 1-year follow-up.

METHODS

A 12-month, single-blind, parallel, randomized controlled trial was designed to investigate the possible benefits of a foot muscle training protocol in reducing RRI incidence in recreational long-distance runners. A detailed description of this protocol, following CONSORT (Consolidated Standards of Reporting Trials) recommendations, has been published elsewhere.[26] It was prospectively registered at ClinicalTrials.gov (NCT02306148; November 28, 2014) under the name "Effects of Foot Strengthening on the Prevalence of Injuries in Long Distance Runners." The definition used for RRIs was that of Macera et al[23]: "any musculoskeletal pain or injury caused by running practice that induces changes in the form, duration, intensity, or frequency of training for at least 1 week with an intention-to-treat plan of analysis." Another definition, by Yamato et al,[59] was published after registry of our clinical trial, but use of this definition would not have changed our results, as it is very similar to the Macera et al definition.

Participants and Recruitment

Sample size calculation was conducted using a chi-square design for the primary outcome (between-group differences in RRI incidence) based on a previously recorded, annual lower limb RRI incidence of 28%,[49] statistical power of 80%, level for significance of 5%, and a small effect size (0.25) to avoid undersampling.[10] This yielded a requirement of 101 participants. Assuming a 10% total dropout rate, we aimed to recruit at least 112 participants. Participants were recruited between August 2015 and August 2017 through digital social media advertising and direct contact with runners and running groups in the university surroundings. Eligibility criteria included age between 18 and 55 years, $\geq$1 year of running between 20 and 100 km per week, no RRI in the 2 months before baseline assessment, no experience running barefoot or in minimalist shoes, no history of lower limb surgery, and no chronic diseases or impairments that could influence running performance, such as osteoarthritis.

Participants signed an informed consent form approved by the ethics committee of the School of Medicine of the University of São Paulo (18/03/2015; protocol No. 031/15), according to the Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects. The main researcher (U.T.T.) explained every step of the assessment and follow-up to each eligible participant, described possible risks, and indicated that no compensation or benefits should be expected. When agreeing to participate, participants were asked for written informed consent, according to standard forms. All participants were fully informed about the methods and possible outcomes of the study following the ethics committee recommendations; therefore, they were not blinded to the objective of the research.

Participants were randomly allocated to an intervention group (IG) or control group (CG) after baseline assessment. Using Clinstat software,[10] we created random blocks of up to 8 participants, dividing 120 potential participants into IG or CG. The codes for the groups were kept in opaque, sealed envelopes numbered 1 to 120, and the researchers involved in the allocation and assessments were blinded to the group codes and block size. After the runners agreed to participate in the research and to be assigned to a group, an independent researcher, also blinded to the codes,

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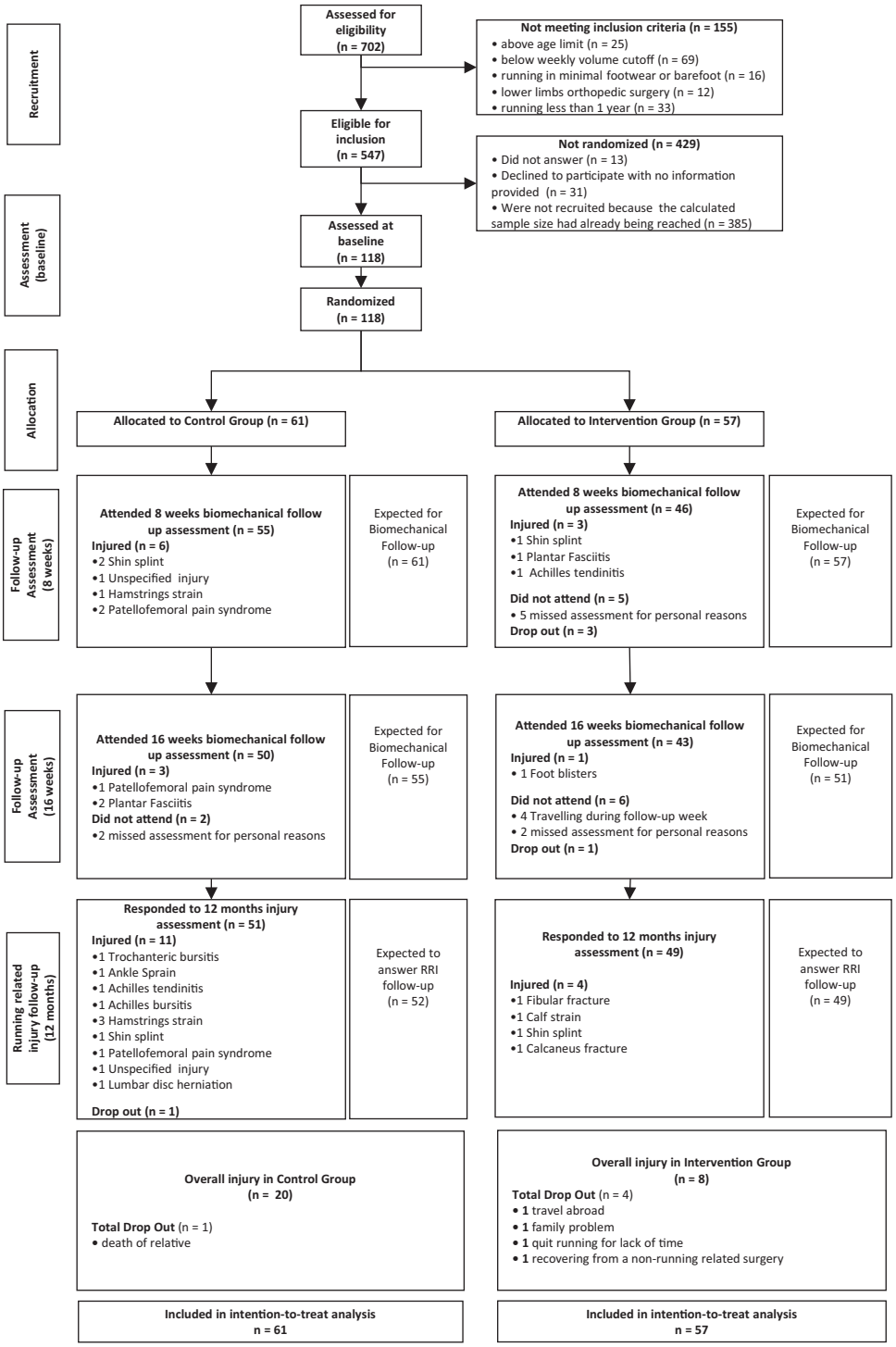

Figure 1. Flowchart of recruitment, assessment, and follow-up process.

performed allocation into the groups. Allocation was performed in order of assessment, and assessments were scheduled over 2 weeks, with missed appointments expected. By the end of the assessment, 118 participants were allocated, surpassing the initial goal of 112. The trial statistician was blinded to treatment allocation until the main analysis had been completed. All participants' data were kept confidential before, during, and after the study by encoding their names. A flowchart summarizing the clinical trial procedures is shown in Figure 1.

Treatment Arms and Assessments

Participants allocated to the IG received 8 weeks of training focused on the foot-ankle muscles, with 12 exercises progressing weekly in volume and difficulty.[26] Participants were trained once a week by a physical therapist and were given online access to the exercise descriptions and videos (web-based software) to perform the same exercises an additional 3 times per week, remotely supervised by the same physical therapist. Participants allocated to the CG were instructed to perform a 5-minute placebo static stretching protocol 3 times per week based on online descriptions (web-based software) and images.[26] Although both groups did not experience the same on-site interaction, CG participants received weekly feedback and interaction with the physical therapist through the web-based software and calls, and they were contacted if their weekly mileage was not recorded. They were also reminded to contact the physical therapist in case of any doubt, pain, or RRI, even if they did not think that the issue they were experiencing matched the RRI definition we used. Both groups were instructed to perform their respective exercises 3 times per week up to the end of the 12-month follow-up and register their adherence in the web software. (After the results indicated effectiveness, the foot training was offered to all participants at the end of the study.)

Assessment consisted of 3 evaluations: at baseline, 8 weeks, and 16 weeks, and a weekly report on participants' running distance, pace, and RRI for 12 months (injury incidence and time to injury were reported). Before baseline assessment, each participant ran barefoot on a treadmill, at a self-selected speed while being filmed by a high-speed camera (200 Hz) placed laterally. The Foot Posture Index (FPI) was measured at baseline as a clinical measure to qualify and quantify 6 characteristics of foot posture, scaling from –12 to + 12, from a more supinated and high-arch foot to a pronated and low-arch foot, respectively.[18]

During each evaluation, foot strength was measured by pressing the hallux and toes against an Emed pressure platform (Novel), as described previously.[28,30] Foot strength gain was defined as flexion strength at the 8-week evaluation minus flexion strength at baseline. The Arch Index was assessed by the plantar pressure data acquired through the pressure plate and calculated according to the Cavanagh and Rodgers[5] definition.

Participants received an explanatory description of RRIs.[23] In the event of a reported injury, the physical therapist scheduled an assessment to determine whether the reported injury fit the RRI definition. Participants were to report their running volume weekly in the web-based software; the physical therapist responsible for the foot training had access to participants' running apps and GPS trackers, which were willingly shared by the runners. If runners failed to report their running mileage or entered a lower mileage than usual, the main researcher would contact them to inquire about the reason and check whether it was related to RRI.

Adherence to the supervised intervention was assessed weekly in the first 2 months and then monthly thereafter, using web-based software developed for this project. Adherence to the remotely supervised training (3 times per week) was monitored using the same web-based software and participants' running apps and GPS trackers, which again were willingly shared by the runners, and the importance of adherence to the training program was reinforced at every contact with the participants. IG participants were expected to attend supervised training with the designated researcher once a week for 8 weeks, to complete 16 additional remote sessions for the first 8 weeks (2 times per week in addition to the supervised session), and to complete 24 remote sessions every 8 weeks thereafter until the end of the study (3 times per week). To calculate adherence to the remotely supervised training, we averaged the participants' sessions performed during the first 8 weeks (baseline to week 8; full adherence would be 16 sessions) and those performed in 8-week blocks after week 8 (full adherence would be 24 sessions for each 8-week block after week 8). Adherence rates for the supervised and remote sessions were reported as percentage of the full adherence value.

Statistical Analysis

An intention-to-treat analysis was performed, and the following procedures were applied for this aim. To identify any postallocation between-group differences, descriptive statistics and *t* tests were performed (with Pearson correlation coefficient calculation) for controlling intervenient independent variables (age, BMI, Arch Index, and FPI), and chi-square tests were used to compare dichotomous variables at baseline. Any significant correlation >0.30 between a controlling variable and the time-to-injury variable[22] was included in the survival analysis. Kaplan-Meier survival analysis was used to identify differences in RRI risk between allocation groups (intervention vs control) at 12 months. An event was defined as any RRI recorded within the 12-month follow-up. Data for participants lost to follow-up for any reason were recorded as censored data from that time on (eg, dropouts). Log-rank tests were performed to compare RRI risk between groups at 12 months and every 2 months. Cox proportional hazards ratio was calculated to estimate RRI risk at 12 months. To account for RRI risk factors described in the literature,[17,51,52] we used Cox proportional hazards models to impute covariates: (1) previous RRI, (2) BMI, and (3) running volume. To address the proportional hazards assumption for Cox regression, we used statistical diagnostic tests based on scaled Schoenfeld residuals. To address the linearity assumption, we used Martingale residuals against continuous covariates, plotting graphs of the covariates against Martingale residuals of the null Cox proportional hazards model (BMI, FPI, years of practice, mileage, and pace).

Due to nonnormal distribution, mean time to injury for the follow-up period was compared between groups using the Mann-Whitney test. Quartile estimation was used to calculate time-to-injury survival times at which 25%, 50%, and 75% of the sample became injured. Then, Mann-Whitney tests were used for between-group comparisons in each percentile.

TABLE 1
Data on Controlling (Intervenient) Variables for Both Groups: Anthropometric, Demographic, and Training Outcomes at Baseline[a]

	Control Group (n = 61)	Intervention Group (n = 57)	Effect Size (95% CI)	*P* Value
Age, y	41.3 ± 6.8	40.5 ± 7.9	0.11 (–0.25 to 0.47)[b]	.796
Height, cm	171.0 ± 9.1	167.4 ± 8.2	0.21 (0.05 to 0.78)[b]	.060
Body mass, kg	72.1 ± 13.2	68.2 ± 12.3	0.30 (–0.07 to 0.69)[b]	.109
Sex, n				
Male	33	28	0.03 (–0.15 to 0.21)[c]	.109
Female	28	29		
Body mass index, kg/m^2	24.5 ± 3.2	24.2 ± 2.9	0.10 (–0.28 to 0.48)[b]	.536
Running experience, y	6.9 ± 5.8	5.4 ± 4.7	0.28 (–0.09 to 0.67)[b]	.182
Foot posture index, AU, median (min:max)				
Right foot	2 (6:9)	0 (7:10)	0.16 (–0.03 to 0.34)[c]	.080
Left foot	2 (6:9)	1 (7:10)	0.19 (0.01 to 0.36)[c]	.056
Arch index, AU				
Right foot	0.20 ± 0.06	0.18 ± 0.07	0.09 (–0.01 to 0.47)[b]	.328
Left foot	0.18 ± 0.087	0.16 ± 0.07	0.06 (–0.02 to 0.39)[b]	.739
Foot strike pattern				
% Rearfoot	78.7	75.4	0.04 (–0.02 to 0.05)[c]	.833
% Nonrearfoot	21.3	24.6		
Previous injury, % of all participants	32.7	45.6	0.13 (–0.05 to 0.30)[c]	.152
Study participation pattern				
Running volume, km/mo	97.7 ± 61.4	82.3 ± 59.5	0.07 (–0.13 to 0.63)[b]	.298
Running pace, min/km	6.6 ± 1.4	6.7 ± 1.9	0.06 (–0.44 to 0.32)[b]	.944
Protocol participation, % of all sessions	NA	88.0	NA	NA

[a]Values for the control group and intervention group are expressed as mean ± SD unless otherwise indicated. Effect sizes were calculated using Cohen *d* for continuous variables and r^2 for discrete variables. Statistical analysis used *P* values for *t* tests (parametric variables) and Mann-Whitney tests (nonparametric variables). Significant differences were considered for $P < .05$. AU, arbitrary units; NA, not applicable.
[b]Continuous variable.
[c]Discrete variable.

Additional Kaplan-Meier plots were performed to verify the influence of previous RRIs on 1-year survival probability, using RRIs as a stratification variable (0 = absent, 1 = present) for the CG participants. This analysis was performed to avoid factors confounding intervention results with RRI history, because a previous RRI is the strongest risk factor for injury.[17,45,51,52]

RESULTS

Baseline Characteristics and Correlations

Of the 118 runners assessed at baseline (61 male, 57 female), 57 were allocated to the IG and 61 to the CG. No differences between groups were found in any of the controlling intervenient independent variables at baseline (Table 1). Running volume was similar for runners in the 2 groups throughout the study period (60-110 km per month) (Appendix Figure A1, available in the online version of this article), including a median follow-up time of 12 months and interquartile range of 3 months. A Kaplan-Meier analysis with log-rank test using reported mileage instead of follow-up time was used to assess whether variability in running volume affected the survival analysis. No differences in RRI risk between groups running 500 km ($P = .088$) and 1000 km ($P = .110$) were seen.

FPI was significantly correlated with time to injury ($r = 0.41$; $P = .031$) (Figure 2), suggesting that the higher a runner's FPI, the longer it would take to develop an RRI. However, a Mann-Whitney test did not show significant differences in baseline FPI between injured and noninjured participants (right foot, $P = .849$; left foot, $P = .583$). Time to injury was also correlated with foot strength gain ($r = 0.45$; $P = .044$). Two other significant correlations were FPI with BMI ($r = 0.21$; $P = .023$) and running volume with pace ($r = –0.32$; $P = .001$).

Regarding running footwear, no significant differences were found for the heel-to-toe drop distance, heel stack height (distance between the plantar surface to the ground at the center of the heel[47]), or shoe mass between groups (Appendix Table A1, available online). Chi-square tests showed no significant association between stack height (stratified according to 4 quartiles; $P = .903$) or heel-to-toe drop distance (stratified according to 4 quartiles; $P = .887$) and RRI incidence (n = 118).

Running-Related Injury

RRI injury occurred in 28 participants (23.5%; 95% CI, 16.1%-31.4%) within 1 year, 20 from the CG (16.9%; 95% CI, 10.2%-23.7%) and 8 from the IG (6.7%; 95% CI, 2.2%-11.3%). Characteristics of RRIs are presented in Table 2

TABLE 2
Running-Related Injuries
During Participation in the Study[a]

	Control Group (n = 61)	Intervention Group (n = 57)
Injury location		
Foot-ankle	5 (8.1)	4 (7.1)
Knee	4 (6.5)	0 (0)
Thigh	4 (6.5)	0 (0)
Legs	3 (4.8)	4 (7.1)
Hip	1 (1.6)	0 (0)
Lower back	1 (1.6)	0 (0)
Unspecified	2 (3.2)	0 (0)
Injury type		
Patellofemoral pain	4 (6.4)	0 (0)
Hamstring strain	4 (6.4)	0 (0)
Shin splints	3 (4.8)	2 (3.6)
Plantar fasciitis	2 (3.2)	1 (1.8)
Trochanteric bursitis	1 (1.6)	0 (0)
Lumbar disk herniation	1 (1.6)	0 (0)
Achilles bursitis	1 (1.6)	0 (0)
Achilles tendinitis	1 (1.6)	1 (1.8)
Ankle sprain	1 (1.6)	0 (0)
Calcaneal fracture	0 (0)	1 (1.8)
Foot blood blister	0 (0)	1 (1.8)
Calf strain	0 (0)	1 (1.8)
Fibular fracture	0 (0)	1 (1.8)
Unspecified injury	2 (3.2)	0 (0)

[a]Values are expressed as n (%).

and a more detailed description of the RRIs can be found in Appendix Table A2 (available online).

Survival Analysis

Kaplan-Meier survival estimates showed a significant between-group difference in the log-rank test at 12 months ($P = .027$) (Figure 3, left). Log-rank analysis comparison by 2-month interval (Table 3) showed significant differences after only 8 months of follow-up. Cox proportional hazards analysis yielded a hazard ratio of 2.42 ($P = .035$; 95% CI, 1.98-3.62); that is, CG participants were 2.42 times more likely to experience an RRI than were IG participants after 1 year.

To address the proportional hazards assumption for Cox regression, we conducted statistical diagnostics based on scaled Schoenfeld residuals. The test was not statistically significant for any covariate, nor was it significant for the global test, assuming proportional hazards. To address the linearity assumption, we used Martingale residuals against continuous covariates, plotting graphs of the covariates against the Martingale residuals of the null Cox proportional hazards model (BMI, FPI, years of practice, mileage, and pace). No nonlinearity was found.

Cox proportional hazards regression was performed considering the risk factors as covariates. With age as a covariate, each increased year of age was associated with a 1.07-fold increase in RRI risk ($P = .015$; 95% CI, 1.013-1.129). Other covariates analyzed (previous injury, BMI, strike pattern, sex, FPI, years of practice, mileage, and pace) did not significantly affect RRI risk ($P > .05$) (Table 4). Kaplan-Meier analysis was performed to verify the influence of previous RRI history on 1-year survival probability for the CG. Although described elsewhere as a risk factor for RRI,[52] previous RRI did not significantly affect RRI risk in our sample (log-rank test $P = .540$) (Figure 3, right).

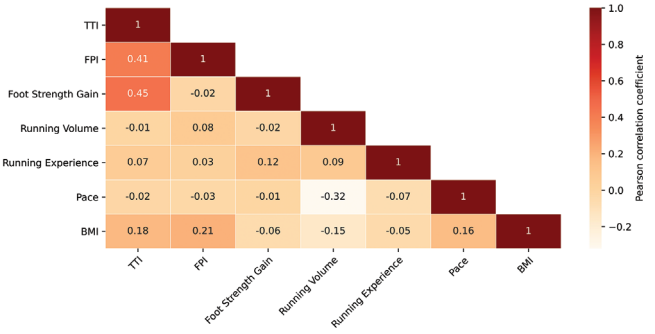

Figure 2. Pearson correlation coefficients between controlling variables. Foot strength gain is the difference between values measured at baseline and at week 8. Running volume is the monthly average (km/mo). Running experience is expressed in years of practice. Time to injury (TTI) is expressed in months. BMI, body mass index; FPI, Foot Posture Index.

Because a significant correlation was found between FPI and time to injury, a Kaplan-Meier analysis was performed to verify the influence of FPI on 1-year survival probability using FPI as stratification variable. FPI values were classified from lower to higher and divided into 2 equal groups for this analysis: $-7 \leq \times \leq 1$ and $1 < \times \leq +10$. The log-rank test did not show significant differences between RRI risk and FPI ($P = .942$).

The Mann-Whitney test comparing the average months until RRI occurrence showed no significant difference between groups ($P = .758$). As for the quartile-estimation calculation of time-to-injury survival time, because the total RRI percentage in the follow-up was 23.5%, the most appropriate quartile estimate would be 25%. The mean time to injury in 25% of the population was 7.63 ± 2.60 months for the CG and 10.15 ± 2.69 months for the IG.

Adherence

Complete adherence to the supervised intervention would entail all 57 participants attending all 8 sessions: that is, 456 completed sessions. Subtracting participants who were injured during the intervention, 100% adherence would be 432 completed sessions. Therefore, the recorded attendance of 380 completed sessions corresponds to 88% adherence to the supervised intervention. The mean number of sessions attended in 8 weeks was 6.6 ± 2.0. Adherence to the remote intervention sessions performed by the IG was on average 90.4% in the first 8 weeks, 83.5%

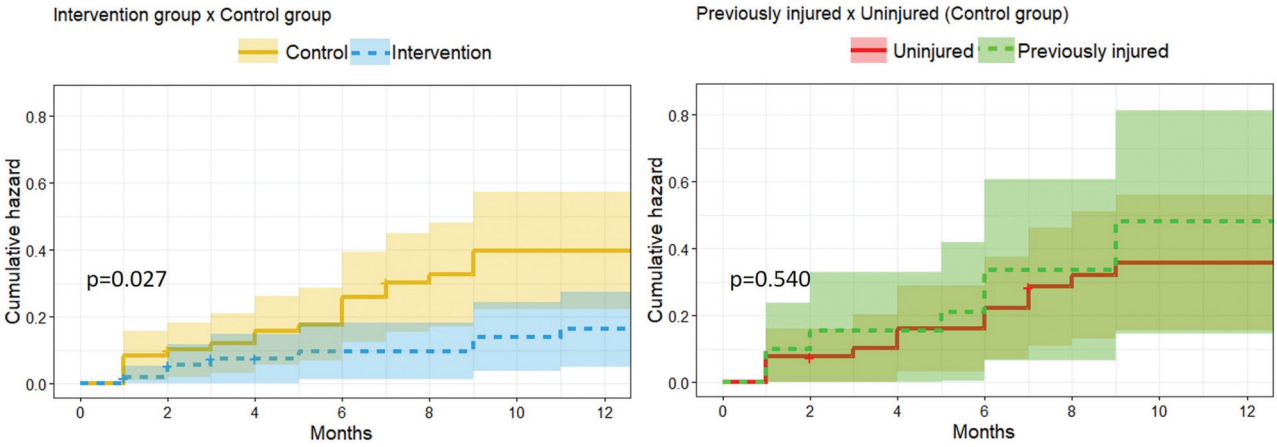

Figure 3. Product-limit survival estimates. *Left*: The cumulative hazard for running-related injury (RRI) after 12 months is shown with a dashed line for the control group and a solid line for the intervention group. Log-rank tests showed significant differences between groups (P = .027). *Right*: Previous RRI did not significantly affect RRI risk in our sample (log-rank test; P = .540).

TABLE 3
Cumulative Survival Probability for Every 2-Month Follow-up for the Control Group and the Intervention Group[a]

	2 Months	4 Months	6 Months	8 Months	10 Months	12 Months
Control group	0.918	0.885	0.801	0.751	0.666	0.666
Intervention group	0.946	0.927	0.908	0.908	0.869	0.850
Log-rank, P	.375	.211	.057	.015[b]	.015[b]	.027[b]
Cumulative risk difference, %	2.75	4.23	10.64	15.65	20.32	18.39

[a]Log-rank tests showed significant differences between groups after the 8-month follow-up period. Cumulative risk difference was calculated as the injury risk in the control group minus that in the intervention group.
[b]Significant P values.

between 8 and 16 weeks, 68.5% between 16 and 24 weeks, 62.5% between 24 and 32 weeks, and 48.9% between 32 and 40 weeks (12 months).

DISCUSSION

Preventing RRI by Strengthening Foot Core Muscles

Our hypothesis that a foot core exercise protocol could reduce the incidence of RRIs was supported: the CG experienced significantly more RRIs than the IG, with a 2.42-fold higher risk. Although Hulme et al[17] reported that only a previous RRI and irregular or absent menstruation were associated with an increased risk of RRI, in our study the only independent factor that was significantly predictive of risk was age. Each year of increased age was associated with a 1.07-fold increase in RRI risk, in accordance with previous studies.[21,50,52]

A gradual increase in load tolerance through repeated training with properly dosed gain in running experience has been shown to reduce RRI risk.[1] For example, a 4-week running program for obese novice runners that started with 3 km per week, compared with 6 km per week, reduced cumulative RRI risk by 16.3%.[8] The protection against cumulative RRI risk conferred by foot exercises in our study is not expected to appear immediately, because the increased load tolerance in the IG runners stemmed from muscle gain obtained through months of foot exercise.

By the fourth month of follow-up, differences in cumulative RRI risk were evident between the CG and IG, although statistical significance for survival probabilities was reached only in the eighth month. This pattern suggests that 4 to 8 months of this foot exercise regimen might be effective in reducing the risk of an RRI in recreational runners.

Risk Factors for RRI

Although some RRI risk factors were controlled or excluded, others (previously described[55]) were included in the Cox proportional hazards models[35,36]: previous RRI,[4,51,52] BMI,[2,3,34,58] running experience,[4,8,34,51] and running volume.[4,51] These factors were unlikely to be responsible for the difference in RRI incidence between groups because the increased hazard ratios were not nearly as high as the

TABLE 4
Z Scores, P Values, and R^2 Results of Cox Proportional Hazards Model Imputing Possible Risk Factors for Running-Related Injuries

Imputed Variables	Z Score	P Value	R^2
Age	2.295	.014	0.000042
Body mass index	–0.474	.635	0.001910
Previous running-related injury	–0.642	.521	0.000005
Running mileage	0.784	.433	0.000166

protective effect of the intervention. One likely reason for the absence of relationships between known risk factors and RRI might be our eligibility criteria[26]: excluding novice runners and runners with a BMI >30. We chose this specific population to gain better external validity, as it best represents the majority of the running population.[14] Although novice runners might also benefit from this intervention, they probably do not have common tissue adaptations to running that may already be present among experienced distance runners.

A significant correlation was found between FPI and time to injury, suggesting a protective effect of everted/pronated feet, as found by Nielsen et al.[37] However, survival analysis using FPI as stratification variable found no difference. A key correlation was seen between time-to-injury and foot strength gain: The stronger the foot, the longer it took the runner to develop an RRI. Similar correlations have been seen between FPI and BMI and between running volume and pace. Despite findings pointing to previous RRIs as a risk factor for new RRIs,[17,54,58] merely using previous RRI as a logistic covariate did not reveal a significant influence in our survival analysis.

Possible Mechanisms of Action of the Foot Exercise Program

Our innovative ground-up intervention approach targeted foot musculoskeletal strength and dynamics with the goal of attenuating mechanical loads directly related to RRI.[7,9,31,32,39,57] We postulate that a stronger foot structure and medial longitudinal arch should better dissipate excessive and cumulative loads through actively supporting a change in the function of the foot from a dampener in the early stance to a spring in the late stance.[19,44] Some studies demonstrate the benefits of strengthening the foot core muscles, and given the intrinsic foot muscles' role in dampening impacts and propelling the body during running,[19,20,42,44] it is logical to think that these roles were also improved with our program. Thus, by reducing shock, reducing cumulative load, and better controlling foot-ankle motion and alignment, strengthening the foot muscles prevented RRIs in the intervention group. We have previously shown that the intrinsic foot muscles increased their anatomic cross-sectional area after 8 weeks of training,[48] and the significant correlation between time-to-injury and foot strength gain might support the hypothesis-driven mechanism we described, where the stronger the runner's foot, the longer it took the runner to develop an RRI.

It could be expected that if the intervention could prevent injuries, it would prevent injuries near the foot region. Importantly, 2 of the 8 RRIs in the IG were related to the foot and ankle (blisters and Achilles tendinitis); however, they occurred after a long race performed with new shoes (as reported by the participants). The number of RRIs in this study was insufficient to allow an analysis differentiating type of injury.

Because of the complexity and redundancy of the motor control strategies, it is plausible that each runner responded biomechanically in different ways to the foot strength improvement, and the different sites of injury between groups could be a proof of that. The most serious RRIs—stress fractures—occurred in runners from the CG; none of the IG participants experienced stress fractures. This could be related to the difference in the effect of dampening mechanisms performed by the musculoskeletal system, more specifically the foot core, which was strengthened in the IG but not the CG.

Strengths and Limitations

Strengths of the study include rigorous method for the randomized controlled trial, inquiry about injury rates on a monthly basis rather than depending purely on injury incidence proportions, and a supervised training approach, which increased adherence to the protocol (88%) and reduced dropout rates. This is the first study to evaluate RRI risk associated with a specific foot training protocol focused on improving intrinsic foot muscle strength for nonnovice recreational long-distance runners.

Certain limitations exist for this study. We did not differentiate between types of RRIs; different RRIs or injury sites are expected to stem from different mechanisms, and enhancing foot strength might be more effective in preventing some types of injuries than others. We adopted a usual and valid RRI definition, and most RRI definitions and studies involve participant self-report of these events, without a clinician's confirmation; however, the self-reported nature of our main outcome could lead to some bias. We tried to overcome a potential RRI underreporting bias by making clear to participants what we understood as an RRI, and we checked the weekly training volume on a regular basis to identify any changes that could be linked to an RRI. Although we expect that the gains in foot muscle strength were the most important factor in our observed reduction in RRI incidence, other aspects of the training, such as information exchange during group sessions, nocebo effects, or placebo effects, might also be relevant factors. Another limitation of this study was the possible selection bias[25] introduced by excluding participants with an RRI in the 2 months before the baseline assessment.

CONCLUSION

Runners randomized to the novel foot training protocol had a lower rate of RRIs compared with runners randomized to the control group, by a factor of 2.42. This foot exercise program showed evidence of effective RRI risk reduction in

recreational runners at 4 to 8 months of training. Although the mechanisms underlying the observed reduction in RRIs are uncertain, future studies with larger sample sizes would help to elucidate outcomes by injury type or site. Including different populations of runners and evaluating other biomechanical and musculoskeletal risk factors would be of value.

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