

Effects of Minimalist Shoes on Pelvic Floor Activity in Nulliparous Women During Running at Different Velocities: a Randomized Cross-over Clinical Trial

María García-Arrabe

Universidad Europea de Madrid

Pablo García-Fernández (✉ pablga25@ucm.es)

Complutense University of Madrid

Beatriz Ruiz-Ruiz

Universidad Europea de Madrid

Rebeca Prado-Álvarez

Universidad Europea de Madrid

Carlos Romero-Morales

Universidad Europea de Madrid

María José Díaz-Arribas

Complutense University of Madrid

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Abstract

Background: women's participation in running has grown dramatically, leading to an increased number of female pelvic floor pathologies (PFM), such as stress urinary incontinence.

Objective: to determine the short-term effects of minimalist versus traditional running shoes on PFM EMG activity, femoral range of motion (ROM) and cadence variables in nulliparous women.

Methods: prospective, randomized, crossover clinical trial. Fifty-one participants were randomized in two sequences (AB/BA crossover design). Femoral ROM, cadence and PFM activity were recorded.

Results: Femur ROM at 6 km/h was higher with minimalist shoes by 1.62 degrees than with traditional shoes ($p = 0.001$). A main effect of shoe type ($p=0.015$) consistently observed a higher running cadence with the minimalist shoe compared to the traditional shoe. PFM electromyographic activity reports differences for 11km/h for the total mean ($p=0.027$) and minimum peaks at 9 km/h ($p=0.011$) and 11km/h ($p=0.048$) for the minimalist shoe compared to the traditional ones.

Conclusions: Minimalist shoes produce effects on biomechanical running variables. Femur ROM increased to 6 km/h and cadence to 11 km/h with the use of minimalist shoes. The minimalist shoe increased electromyographic activation of PFM in the minimum peaks at speeds of 9 and 11km/h and total mean at speeds of 11km/h.

Introduction

The practice of running as a sport, experienced a boom in the 70s. Between 3 and 6 million Americans become new endurance runners (1), but running was considered a men sport, and women were not considered able to do it (2). However, over the past 35 years, participation by women in running has grown dramatically and performance have improved at a remarkable rate (3).

Due to the delay in women's access to careers, there are not as many scientific studies on the benefits and risks of running based on samples of female subjects, compared to men. However, injuries or dysfunctions derived from running and specific to women are currently being investigated, concretely the urinary incontinence (UI), that specially affects women who perform high-impact sports (4). Despite this, to date there is little knowledge about the effect of PFM training among elite female athletes, for both treatment and prevention (5).

In 1996, Neyggard et al., raised the influence of the absorption of the impact derived from the race, on UI dysfunctions present in female athletes, concluding that there is a statistically significant association between decreased foot flexibility and the presence of UI, thus demonstrating the importance of plantar arch flexibility as an effective mechanism for absorption of impact forces and thus for the prevention of stress urinary incontinence (SUI) (6).

Over the last 50 years, running shoes have undergone an immense change, since the appearance of the minimalist footwear used by our ancestors (7) to nowadays, saw the boom in cushioned shoes, new materials, elevated heel, corrective devices and technological materials (8). However, in the last decade, minimalist shoes have gained popularity as an alternative to traditional shoes. Minimalist footwear was developed by running shoes companies in response to the "movement of barefoot" (9), which advocates a natural race where humans have adapted naturally over millions of years of evolution.

Followers of the minimalist side support that being a more efficient and reducing injury risk (10) due to modification through forefoot strike (11), increasing stride cadence, decreasing active peak vertical force (12) and modification kinematics and factors of the lower limb (13), aiming as mean goal that human body actively get organized to decrease load rate. Contrarely, opponents discuss that foot needs to be protected by the stability, cushioning and support that high-tech devices provides, specific to traditional shoes (14), in order to improve the comfort, safety, performance and running economy.

Therefore, reducing injuries and improving performance through the use of running shoes have become a major issue in both the sports industry and investigation (15). However, has not been possible to reduce the incidence of injuries, with 68.3% of runners reported having an injury in the last year and 81.45% of these injuries it's believed to be running related (16).

Several studies compare the different types of footwear without reaching any consensus (17) (18). Despite this, no prior research has studied the activity of the PFM during running using different footwear despites of the high prevalence of stress urinary incontinence derivate to high impact exercise in nulliparous women (19).

The aim of the present study was to determine the short-time effects of minimalist shoes versus traditional shoes for the EMG activity on the PFM, the femur range of motion (ROM) and cadence variables, in nulliparous women running. We hypothesize that minimalist shoes may improve PFM activation, and biomechanics factors with respect to traditional shoes.

Materials And Methods

Study design

The study is a randomized, prospective cross-over clinical trial design was used for the study. 51 participants were randomly allocated into two groups according to the order of use of the shoe, having two-sequence crossover design (2×2 or AB/BA crossover design). The intervention A use minimalist shoes, the intervention B use traditional shoes. The randomization of sequence of the footwear was done based on the table of random permutations of Moses and Oakford (20). It complies with the guidelines prescribed by the CONSORT guidelines (Figure 1).

Ethical considerations

The study was approved by the local Research and Ethics Committee of Hospital Clinical San Carlos, (code 19/570-E_TFM) which complied with all the principles set forth in the Declaration of Helsinki. All participants signed informed written consent forms to participate in this study. This trial was also registered 07/07/2020 in clinicaltrials.gov (CI: NCT04457141).

Participants

Participants were recruited from the Complutense University in Madrid. A total sample of 51 nulliparous women were included in the met all of the following criteria: aged between 18-38 years, were clinically healthy, physically able to run of treadmill, had BMI less than 30 Kg/m², and using traditional shoes in their sport practice. The exclusion criteria were pregnant women, autoimmune illness, lower limb surgery in the last 6 months, neurologic disorders, and inability to run for 90 seconds.

Sample size calculation

The selection of the sample size was determined by convenience based on the only previous study on the evaluation of PFM during running at different speeds carried out by Koenig et al. (21) with a sample of 50 participants. According to a possible 10% loss to follow-up, a total sample size of 51 participants were recruited.

Type of footwear

Two types of footwear were used: minimalist shoes and traditional shoes (Figure 2).

Procedure

Age, weight, body mass index, health, and daily physical activity information were recorded. Regarding the EMG evaluation, an intracavitary EMG probe PeriformTM (Neen, HealthCare, Dereham, United Kingdom) was used to collect PFM data. Besides, a ground electrode and amplifier is placed on the right iliac crest to reduce noise in accordance to the SENIAM recommendations (22). The EMG system used was a mDurance® (211) (mDurance Solutions SL, Granada, España) to the analysis of the sEMG activity of the PFM. One accelerometers (Shimmer3 Consensys IMU, Dublin, Ireland) were attached at the proximal third of rectus femoris to objectively space-temporal parameters of the running cycle. Maximal voluntary isometric contraction (MVIC) for the PFM was measured in order to normalize the electromyographic signal during the 3 times 10 seconds with 20 seconds of rest between each contraction. This test was performed in supine position with the knees flexed at 90 degrees.

Finally, the subjects walked on a treadmill HP Cosmos, model Mercury (Ref.cos 30000va08, Hp/cosmos Sport & Medical, Nussdorf-Traunstein, Germany for 5 minutes to warm-up at low intensity (less 6km/h) in free velocity; and then EMG and accelerometers was measured while the women ran for 30 seconds 6 km/h, 30 seconds at 9 km/h and 30 seconds at 11 km/h under different footwear conditions: minimalist and traditional shoes with a wash time of 5 minutes between each intervention, in which subject remains seated, rest and change their shoes for repeat the same protocol with the other shoes.

Statistical analysis

SPSS software (IBM, Armonk, NY, USA) and Jamovi (Jamovi 2.0) was employed for the statistical analysis. The Kolmogorov-Smirnov test was used to check the normality assumption of each variable. A descriptive analysis was carried out with the mean and SD for each variable in both groups. Repeated-measures analysis of variance (ANOVA) with 2 factors (considering the significance of Greenhouse-Geisser correction when the Mauchly test rejected the sphericity) and Bonferroni correction were applied to determine the intergroup comparison for ROM, cadence and EMG (2 groups: minimalist and traditional group x 3 measurements: 6, 9 and 11 km/h). In addition, for the effect size calculation the partial eta coefficient (η^2) was employed. To the effect size interpretation values of 0.01, 0.06 and 0.14 for small, medium and large effects were considered, respectively (23). All the statistical tests were performed with a 95% confidence interval ($P < 0.05$).

Results

Demographics

The sample included in the study was 51 participants. Table 1 shows the demographic characteristics of the total sample. (Table 1) A large intersubject variability can be observed in the descriptive data of the sample, with large standard deviations in some characteristics, especially in weight and age. The demographic characteristics of the sample are heterogeneous.

Biomechanical variables

Femur ROM

The descriptive statistics of the femur ROM can be consulted in Table 3. The variations of the scores were due in 93% to the speed factor, $F(1.25, 21912.82) = 703.79$, $p < 0.001$, $\eta^2 = 0.93$, finding significant differences in all the comparisons between the three speeds. No main effect of shoes on femur ROM was found, $F(1,50) = 1.95$, $p = 0.169$, $\eta^2 = 0.04$. However, the pairwise analysis revealed differences between the shoes in the speed of 6 km/h (Table 2). The range of the femur at 6 km/h was greater with the minimalist shoes by 1.62 degrees than with the traditional ones (Table 2). Unlike femur ROM was found to differ by shoe in the comparison between speeds of 6 and 11 km/h.

Cadence

Running cadence ranged from 74 to 82 steps per minute (Table 2). ANOVA found a large effect of speed on cadence, $F(1.22, 59.99) = 268.40$, $p < 0.001$, $\eta^2 = 0.85$. The ANOVA found a main effect of the type of shoe, $F(1,49) = 6.42$, $p = 0.015$, $\eta^2 = 0.12$, systematically observing a higher running cadence with the minimalist shoe compared to the traditional one (Figure 2). Subsequent pairwise analysis revealed significant differences in cadence only at the speed of 11 km/h (Table 2). With the minimalist's shoes, the women took 1.20 steps more than with the traditional's shoes. No interactions were found between speed

and shoes, leaving the simple interaction effect closest to significance in the comparison of shoes between speeds 9 and 11 km/h, $p = 0.073$. (Table 2) (Figure 3).

Electromyography variables

Three variables of the electromyographic data were studied: the average of the maximum peaks recorded, the average of the minimum peaks, and the total average of the EMG trace. The exploratory and descriptive analysis revealed a great variability in the distribution of these 3 variables. In the descriptive statistics of the 3 electromyographic variables, the difference between the mean and the median, the wide confidence intervals, or the high standard deviation can be consulted.

The asymmetry analysis of the sample distributions presented abnormally positive values, with values of up to 7.24 points. In these cases, the right tails extended to very high values. For this reason, we decided to carry out a logarithmic transformation (LN) of the data with the SPSS program. After this transformation, the histograms presented normalized shapes, with a maximum asymmetry value of 1.86 –within acceptable margins. Therefore, MR ANOVAs were carried out taking these transformed scores as reference.

Maximum peaks: The ANOVA also found large differences in the maximum peaks as a function of speed, the higher the speed, the greater the activation.). EMG activation with the minimalist shoe was consistently higher than the traditional shoe with. However, despite this continued behaviour, the difference was very small, far from being significant. Thus, ANOVA ruled out any effect (neither main nor interaction effects) of shoe type on EMG peaks. The subsequent post-hoc analysis also revealed no difference between traditional and minimalist shoes and speed (Table 3).

Minimum peaks: The post-hoc analysis revealed significant differences between shoes. The minimalist shoe did reflect a greater activation than the traditional shoe in the PFM at the speed of 9 km/h and 11 km/h (Table 3)

Total average: As was the case with the previous EMG variables, it was observed that the electromyographic activations were slightly higher with the minimalist shoe compared to the traditional shoe. Despite this repetitive trend, the effect of shoe type was not significant overall. On the other hand, in the post-hoc analyzes in which the contrasts between shoes are described in detail, it corroborated that the minimalist shoes induced a greater total electromyographic activation in the PFM at the speed of 11 km/h (Table 3), (Figure 4).

Discussion

The results of the present study concluded that during the race with minimalist shoes, there is an increase in the femur ROM in the sagittal plane and an increase in cadence, compared to traditional footwear, what traduce in variations in running technique.

In respect to the EMG results, there is an increase in electromyographic activity of the PFM with minimalist shoes.

During the race with minimalist shoes there was a ROM increase hip in the sagittal plane at 6 km/h (24), that may be due to a greater activation of the surrounding muscles, due to increase in sensory information with minimalist shoes. According to previous studies, the use of this footwear produces a modification of the tread pattern towards this increased support in the forefoot (25) and changes in the angles of the knee (26) and the hip (24) during the movement; these modification of kinematics of the lower limb leads to decrease load rate while running (27).

In the sample of the present study, the implementation of minimalist shoes was made without a previous transition. Therefore, the results obtained could differ from the usual runners with minimalist shoes (28). The lack of concordance between previous studies and our results, could be explained by differences in gender and training load of the subjects.

The results of the present work reported an improvement on hip mobility when running slowly with a minimalist shoe, but not at higher speeds, in which there could be a greater loss of control.

A systematic increase in cadence when the runners used the minimalist shoes compared to the traditional shoes were found in our study, and significant differences were given at high speeds (11km/h). Increasing the cadence races the time of the flight phase and decreases the support time. In this way, the total impact forces are reduced and a more uniform load distribution (29) is achieved, which is especially necessary when running fast, since the higher the speed, the more impact. It also produces energy absorption in lower limb joints, and reduces maximal hip adduction movements, which are associated with injuries such as patellofemoral pain syndrome (30) and iliotibial band syndrome (31) with higher incidence in female runners compared to men (32).

The EMG activation in this study was collected through 3 variables: total average, minimum peaks and maximum peaks. Statistically significant differences have been found in the total average at high speeds (11km/h), as well as in the minimum peaks of electrical activation of the PFM both at speeds of 9 km/h and 11 km/h, in both cases obtaining higher values with the use of minimalist footwear compared to traditional shoes.

Higher muscle activation is related to increases in joint stability and improvements in urinary continence capacity by increasing the absorption of the impact derived from running in PFM (33). Likewise, in the race at fast speeds, the highest activation values are associated with a reflex activity by the PFM as a preventive mechanism of the impact (34). In addition, it has been theorized that greater activation is an active mechanism that the body uses as a buffer (35), that it is associated with structural changes such as an increase in the cross section of the muscle (36), and may be a potential aid for prevention and treatment of injuries in runners.

It could be thought that if with the measurements carried out in a short period of time such as those carried out in this study, differences in muscle activation have already been found, it could be the case

that after a period of training, more powerful results were achieved in all the musculature tested.

Clinical applications

The use of minimalist footwear can be a modifying factor of the running technique in nulliparous female runners, directing the biomechanics of this race to protective parameters against musculoskeletal injuries of the lowers limbs, in relation to cadence and femur biomechanics changes given in our study.

Besides, minimalist shoes in comparison to traditional shoes may represent a preventive factor against the appearance of SUI in female runners thanks to the increase in PFM activation during running with minimalist shoes.

Methodological considerations

This study was not single blinded. Neither the therapist who carried out the measurements, nor the patient, could have been blinded to different characteristics of both shoes, being easily recognizable. Only the therapist who evaluated the data obtained was blinded.

Discomfort that the use of the intravaginal EMG probe could entail for novice runners was taken into account, but the benefit of obtaining these variables was weighed over the slight discomfort of using the internal probe.

Finally, the running speeds were chosen externally, with the runners having to adapt to these speeds, so that a free run was not carried out, which could lead to involuntary changes in the running style.

Future studies

New lines of research are opened, especially to study the effect of minimalist footwear in women with stress urinary incontinence (SUI).

Conclusion

Minimalist shoes produce immediate effects on the biomechanical variables of the race. Finding an increase in the femur ROM at 6km/h and in the cadence at 11km/h with the use of minimalist shoes. An exploratory and descriptive analysis of the electrical activation of the PFM during the race revealed a great variability in the distribution of the total average, of the minimum peaks and of the maximum peaks. In addition, it was observed that the use of minimalist shoes increased the electromyographic activation of PFM in the minimum peaks at speeds of 9 and 11km/h and of the total average at speeds of 11km/h compared to the traditional shoe.

Abbreviations

UI: urinary incontinence

EMG: electromyography

PFM: pelvic floor pathologies

ROM: range of motion

SUI: stress urinary incontinence

LN: logarithmic transformation

SD: Standard deviation

Declarations

Author Contributions: Conceptualisation, M.G.A., M.D.A. and P.G.-F.; methodology, M.G.A., M.D.A., and P.G.-F.; Database searching: M.G.A., P.G.F., C.R.M., B.R.R., and R.dP.A.; Data screening: C.R.M., B.R.R., and R.dP.A.; Data extraction: C.R.M., B.R.R., and R.dP.A.; formal analysis, M.D.A. and M.G.A.; investigation M.G.A., M.D.A. and P.G.-F.; writing—original draft preparation, C.R.M.; writing— review and editing, M.G.A., M.D.A. and P.G.-F.; visualisation, B.R.R; supervision, P.G.-F.; study submission, P.G.F.; All authors have read and agreed to the published version of the manuscript.

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Availability of Data and Materials: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Consent for publication: Not applicable.

Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki and approved by Ethics Committee of Hospital Clinical San Carlos (code 19/570-E_TFM).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Competing Interest: The authors declare that they have no competing interests.

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Tables

Table 1. Sociodemographic data of the sample

	Mean±SD
Age	26.55±5.11
Weight	58.24±7.06
Height	1.65±0.06
BMI	21.29±2.07

Table 2. Effects of shoes in biomechanical variables

Pairwise comparisons						Time value
Measure	Minimalist shoes n=51	Traditional shoes n=51	Differences(minimalist-traditional)	IC 95%	P _{bonferroni}	F (Df); P (Eta ²)
Fémur ROM						F(1,50) = 1.95, p = 0.169, η_p^2 = 0.04.
6km/h	38.13±4.22	36.51±4.28	1.62	0.77-2.47	< 0.001*	
9km/h	50.16±6.35	49.44±5.80	0.73	-0.63-2.08	0.285	
11km/h	57.95±7.86	57.84±7.41	0.11	-1.64-1.85	0.904	
Cadence						F(1,49) = 6.42, p = 0.015, η_p^2 = 0.12*
6km/h	74.23 ±4.06	73.87 ±4.04	0.41	-0.32-1.14	0.261	
9km/h	79.88 ±4.40	79.53 ±4.05	0.42	-0.22-1.06	0.196	
11km/h	84.01 ±5.14	82.82 ±5.06	1.20	0.36-2.04	0.006*	

Table 3. Effects of shoes in electromyographic variables

Measure	Difference(mini-trad)	IC(95%)	P _{bonferroni}
Peak max			
6km/h	0.08	-0.01-0.18	0.088
9km/h	0.06	-0.02-0.14	0.111
11km/h	0.06	0.01-0.13	0.057
Peak min			
6km/h	0.03	-0.01-0.07	0.096
9km/h	0.05	0.01-0.09	0.011*
11km/h	0.04	0.00-0.08	0.048*
Total average			
6km/h	0.06	0.00-0.12	0.058
9km/h	0.04	-0.01-0.08	0.092
11km/h	0.05	0.01-0.09	0.027*

Figures

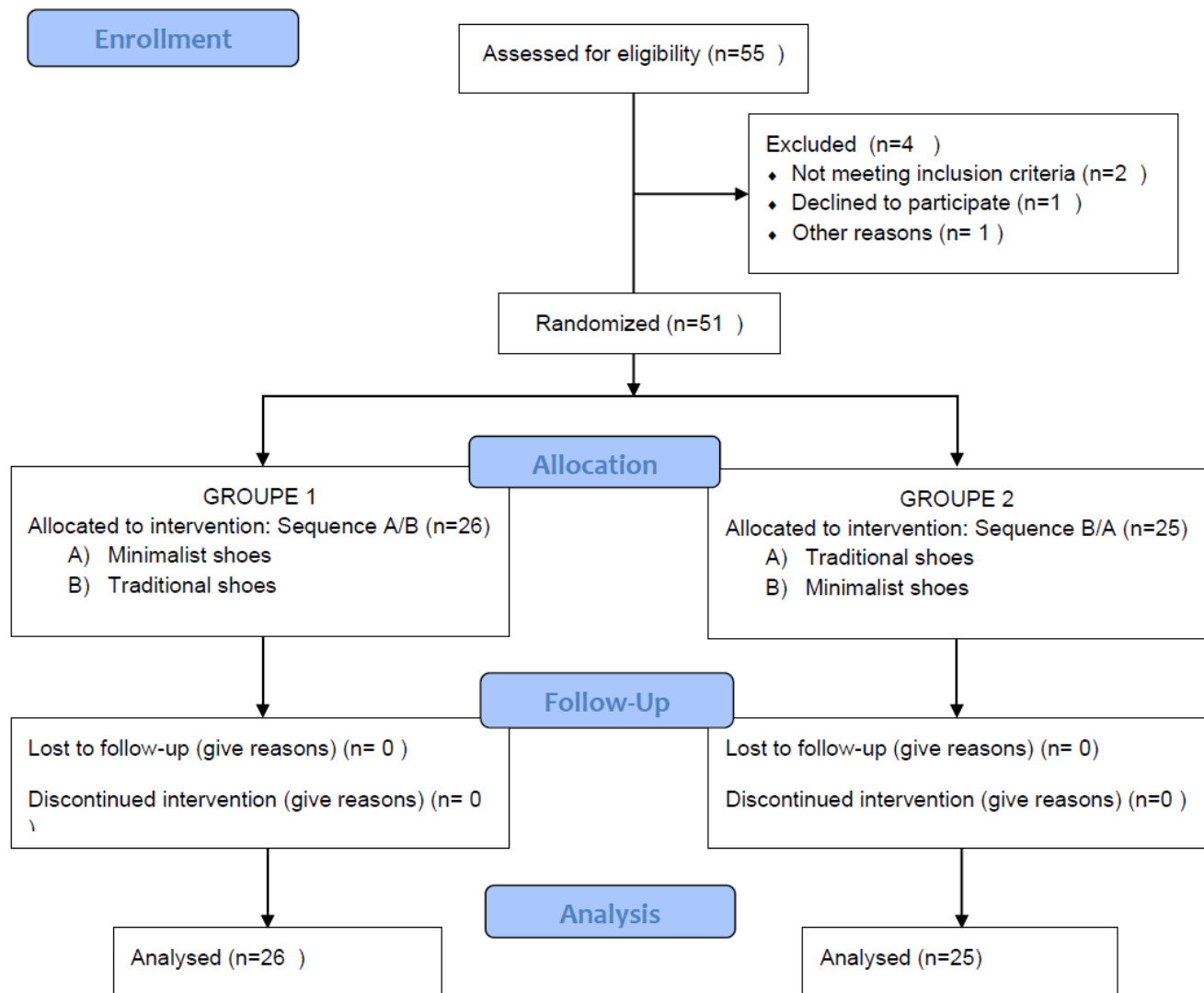


Figure 1

CONSORT guideline.

WEIGHT	181 g
DROP	0 mm
FLEXIBILITY	Longitudinal and torsional (4/5)
HEEL THICKNESS	10mm
TECHNOLOGY	0 devices
% MINIMALIST INDEX	84%



WEIGHT	214 g
DROP	20mm
FLEXIBILITY	Longitudinal (2/5)/Torsional (1/5)
HEEL THICKNESS	30mm
TECHNOLOGY	4 devices
% MINIMALIST INDEX	34%



Figure 2

Minimalist and traditional shoe description.

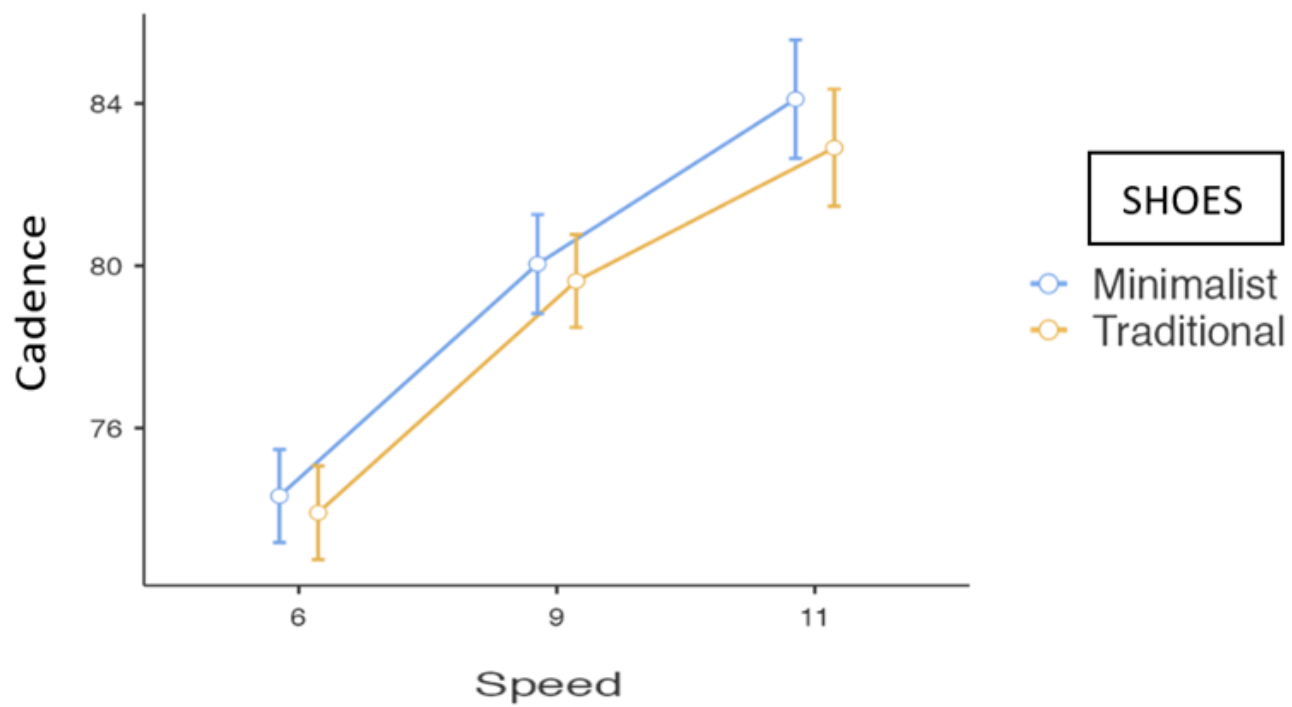


Figure 3

Estimated marginal mean of cadence scores by speeds and by shoes. Error bars represent the standard error of the mean.

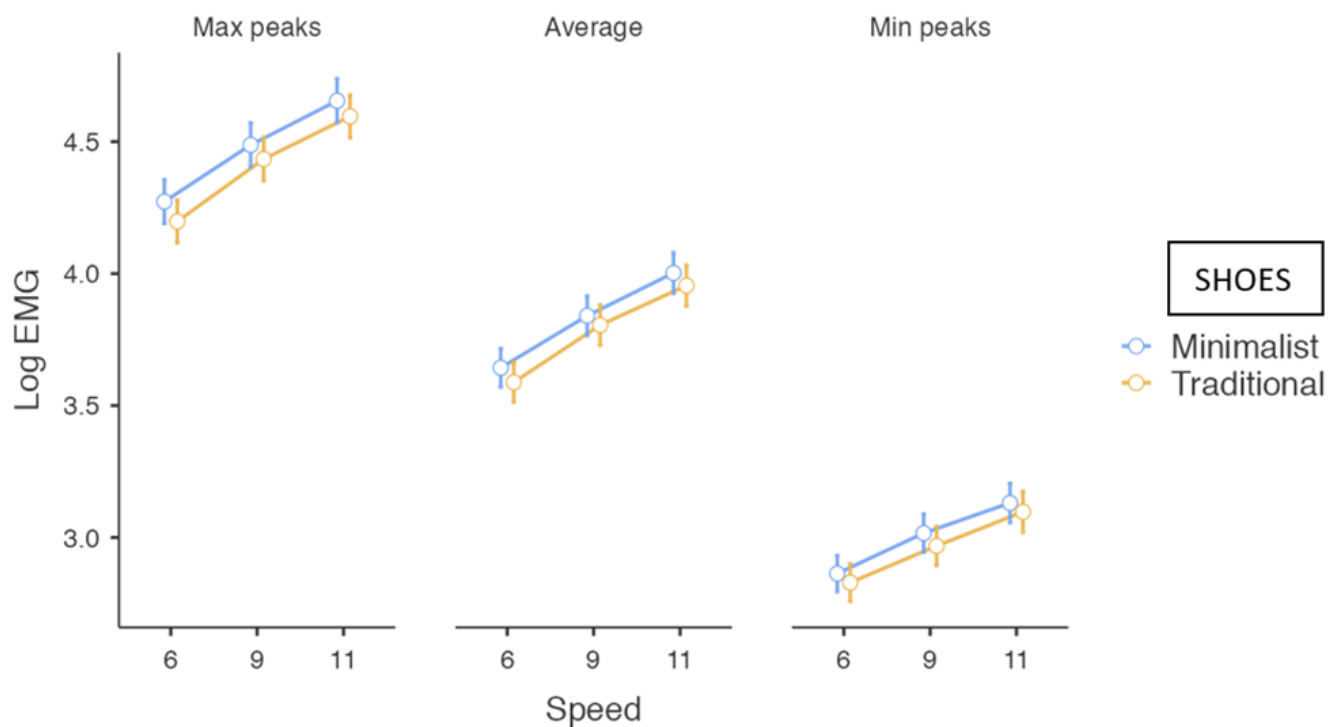


Figure 4

Estimated marginal mean of activity electromyographic scores by speeds and by shoes in PFM. Error bars represent the standard error of the mean.