

Do biomechanical foot-based interventions reduce patellofemoral joint loads in adults with and without patellofemoral pain or osteoarthritis? A systematic review and meta-analysis

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ABSTRACT

Objective To evaluate the effects of biomechanical foot-based interventions (eg, footwear, insoles, taping and bracing on the foot) on patellofemoral loads during walking, running or walking and running combined in adults with and without patellofemoral pain or osteoarthritis.

Design Systematic review with meta-analysis.

Data sources MEDLINE, CINAHL, SPORTdiscus, Embase and CENTRAL.

Eligibility criteria for selecting studies English-language studies that assessed effects of biomechanical foot-based interventions on peak patellofemoral joint loads, quantified by patellofemoral joint pressure, reaction force or knee flexion moment during gait, in people with or without patellofemoral pain or osteoarthritis.

Results We identified 22 footwear and 11 insole studies (participant n=578). Pooled analyses indicated low-certainty evidence that minimalist footwear leads to a small reduction in peak patellofemoral joint loads compared with conventional footwear during running only (standardised mean difference (SMD) (95% CI) = -0.40 (-0.68 to -0.11)). Low-certainty evidence indicated that medial support insoles do not alter patellofemoral joint loads during walking (SMD (95% CI) = -0.08 (-0.42 to 0.27)) or running (SMD (95% CI) = 0.11 (-0.17 to 0.39)). Very low-certainty evidence indicated rocker-soled shoes have no effect on patellofemoral joint loads during walking and running combined (SMD (95% CI) = 0.37 (-0.06 to 0.79)).

Conclusion Minimalist footwear may reduce peak patellofemoral joint loads slightly compared with conventional footwear during running only. Medial support insoles may not alter patellofemoral joint loads during walking or running and the evidence is very uncertain about the effect of rocker-soled shoes during walking and running combined. Clinicians aiming to reduce patellofemoral joint loads during running in people with patellofemoral pain or osteoarthritis may consider minimalist footwear.

INTRODUCTION

Patellofemoral pain is a highly prevalent condition affecting young people through to older adults, including both active and sedentary populations.¹ Clinical guidelines recommend exercise, and education on load, self-management strategies and the

WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Patellofemoral pain and patellofemoral osteoarthritis are conditions characterised by retro/peripatellar pain during activities that load the patellofemoral joint, such as running.
- ⇒ Clinicians commonly use biomechanical foot-based interventions (footwear, insoles, taping or bracing placed on the foot) to treat these conditions due to their potential to reduce patellofemoral joint load.

WHAT THIS STUDY ADDS

- ⇒ Minimalist footwear may reduce patellofemoral joint loads slightly compared with conventional footwear in people with and without patellofemoral pain during running only.
- ⇒ Medial support insoles may not alter patellofemoral joint loads during walking or running in people with patellofemoral pain or osteoarthritis and the evidence is very uncertain about the effect of rocker-soled shoes during walking and running combined.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ Clinicians managing people with patellofemoral pain or osteoarthritis may consider minimalist footwear instead of medial support insoles to reduce patellofemoral joint loads during running.
- ⇒ Future research is needed to determine whether minimalist footwear can also reduce patellofemoral pain or osteoarthritis symptoms.
- ⇒ Minimalist footwear may be recommended for the management of patellofemoral pain or osteoarthritis with more research into these populations.

nature of patellofemoral pain, as the cornerstones of patellofemoral pain treatment.²⁻⁴ However, 57% of people still report symptoms 5-8 years following diagnosis,⁵ showing that current treatment is suboptimal for this non-self-limiting condition. The persistent nature of patellofemoral pain symptoms, the poor long-term prognosis and limited evidence on effective treatment options, means patients may also be at an increased risk of developing patellofemoral osteoarthritis compared with



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the general population, although this is yet to be confirmed by prospective studies.^{6,7}

Patellofemoral pain is defined as pain at or around the patella during activities that load the patellofemoral joint, such as running, squatting or descending stairs.^{3,8} It is postulated that treatment strategies that reduce patellofemoral joint load may be efficacious for patellofemoral pain. Biomechanical foot-based interventions, such as footwear, insoles and foot/ankle taping or bracing, have been proposed as low-burden treatment approaches that may reduce patellofemoral joint loads and, therefore, improve symptoms. For example, minimalist footwear (ie, lightweight shoes with thin flexible soles that do not possess any motion control properties)⁹ can reduce knee flexion and quadriceps muscle force, thereby reducing patellofemoral joint load.¹⁰ Likewise, insoles with medial support, taping and bracing can reduce foot pronation,^{11,12} a motion theoretically linked to an increase in patellofemoral joint load via tibial and femoral internal rotation.¹³ As such, these interventions are commonly used in the clinical setting¹⁴ and insoles are recommended as best practice in international guidelines for managing patellofemoral pain.^{3,4}

Despite the biomechanical rationale and widespread use of these interventions, no study has systematically reviewed research investigating the effects of biomechanical foot-based interventions on patellofemoral joint loads. Although one recent systematic review included some studies that evaluated foot-based interventions,¹⁵ its focus was on comparing patellofemoral joint reaction force across everyday activities, and it did not conduct a subgroup analysis of intervention effects. Thus, the specific effect(s) of biomechanical foot-based interventions on patellofemoral joint loads remains unclear.

Patellofemoral joint loads may be quantified using direct (reaction force and pressure)¹⁶ or surrogate (external flexion or internal extension moment)¹⁷ measures. Although three-dimensional models are considered more accurate,¹⁸ the majority of researchers have estimated patellofemoral joint reaction force using sagittal plane two-dimensional (2D) models that combine the knee flexion angle and moment with mathematical representations of the extensor mechanism.^{15,16} To calculate pressure, the reaction force is divided by the contact area obtained from previous studies.¹⁶ Where there are high amounts of pressure during gait, the knee moment will also be high.^{19,20} To fully understand the effects of interventions designed to reduce patellofemoral loads, it is thus important to consider research that has investigated each of these direct and surrogate estimates of patellofemoral joint loads.

Aim

This systematic review and meta-analysis aimed to evaluate the effect(s) of biomechanical foot-based interventions (eg, footwear, insoles, taping and bracing placed on the foot) on patellofemoral loads (as quantified by pressure, reaction force and external knee flexion moment) during walking, running or walking and running combined in adults with and without patellofemoral pain or osteoarthritis.

METHODS

This study was guided by the Methodological Expectations of Cochrane Intervention Reviews standards,²¹ Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 checklist²² (online supplemental file 2) and the implementing PRISMA in Exercise, Rehabilitation, Sport medicine and Sports science (PERSiST) guidance.²³ The systematic review protocol

was prospectively registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 4 April 2022 (CRD42022315207) and has been published.²⁴ Deviations from the protocol are described in online supplemental file 1. We did not involve patients or the public in our research.

Inclusion and exclusion criteria

Study selection criteria were established a priori using the Population, Intervention, Comparison, Outcome framework.²⁵ Original published studies in the English-language were considered for inclusion. Study designs may have included but were not limited to: randomised cross-over, randomised controlled, cross-sectional and parallel group designs. We followed the recommendation of Adams *et al*.²⁶ and excluded grey literature as the academic field is relatively mature. Editorials, comments, letters, abstracts, review articles, theses and dissertations were excluded. Studies that met the following criteria were included: (1) human participants who were either apparently healthy (ie, free from pathology that may affect gait) or diagnosed with patellofemoral pain or osteoarthritis, (2) used a biomechanical foot-based intervention (footwear, insertable shoe worn orthotic or insert (herein called insole) ankle brace or foot/ankle taping) with the stated objective of reducing patellofemoral joint loads, (3) had a control group which received either no intervention (excluding barefoot) or another eligible biomechanical foot-based intervention and (4) assessed peak patellofemoral loads during regular walking or running using data obtained from motion analysis. Patellofemoral joint loads had to be quantified by (1) peak patellofemoral joint pressure (patellofemoral joint reaction force divided by a unit of contact area), (2) peak patellofemoral joint reaction force (resultant compressive force from the pull of the quadriceps and patella tendon) or (3) peak external knee flexion moment (combination of the ground reaction force and the perpendicular distance of this force from the joint centre or the equivalent peak internal knee extension moment) during stance in the relevant unit of measurement. Full inclusion and exclusion criteria are outlined in our published protocol.²⁴

Literature search strategy

With assistance from an academic librarian, one reviewer (SAK) conducted the search that combined relevant terms for population, intervention and outcome. These relevant terms were based on other similar reviews.^{15,27} We searched the following databases from inception to 4 October 2022: Medline, the Cumulative Index to Nursing and Allied Health Literature, The Cochrane Central Register of Controlled Trials, SPORTdiscus and Embase and screened the reference lists of included studies and relevant systematic reviews.^{15,16} The complete search strategy for all databases is presented in online supplemental file 1.

Study selection

First, two reviewers (SAK and PLR) independently assessed the titles and abstracts of all identified studies and studies within relevant systematic reviews to determine potential eligibility. Second, both reviewers retrieved the potentially eligible full-text articles and independently assessed against the a priori inclusion and exclusion criteria. Studies deemed eligible by both reviewers at this stage were included in the review. Any disagreements at either step were resolved through consensus with a third reviewer (KLP).

Data extraction

One reviewer (SAK) independently extracted data from included studies into a prepiloted data extraction form. A

second reviewer (PLR) independently audited all extracted data for accuracy. Any disagreement was resolved through consultation between the two reviewers. If the two reviewers could not agree, a third reviewer (KLP) was involved until consensus was reached. We attempted to contact the study authors via email to request data that were either missing or published in graphical form. A reminder email was sent after 2 weeks if there was no response. Where the authors could not be contacted or declined to provide data, we used Web Plot Digitizer software (Ankit Rohatgi, California, USA; available at <https://automeris.io/WebPlotDigitizer>) to extract eligible data from graphical form.²⁸ Studies that could not be extracted using Web Plot Digitizer software were excluded. Information relating to the studies where authors were contacted for data can be found in online supplemental file 1. The following was extracted from eligible studies:

- ▶ Study characteristics: Sample size, inclusion/exclusion criteria and year of publication.
- ▶ Participant characteristics: Age, sex, population and whether they were apparently healthy or diagnosed with patellofemoral pain or osteoarthritis. Where applicable, we extracted the severity of patellofemoral joint pain or osteoarthritis according to the relevant measure used.
- ▶ Intervention and comparator characteristics: Where applicable, we extracted the brand, type, weight, heel-to-toe drop, angulation and heel height of the footwear and insoles used in the intervention and comparator conditions. If insufficient information was provided in the manuscript, we sourced it from either a similar publication by the same author or the manufacturer online. We listed N/A in our characteristics table (online supplemental file 1) if no information was available from these sources. In addition, we extracted the speed and the surface (eg, treadmill or runway) used for gait analysis.
- ▶ Patellofemoral joint load outcomes: All available data on the patellofemoral joint loads from each study's intervention and comparator arm were extracted, including the point estimate and the corresponding measure of variability (SD, p value or 95% CI). We established a priori decision rules in case a study reported multiple eligible outcome measures. Specifically, we used the following hierarchy to extract data, prioritising direct over indirect estimates of patellofemoral joint loads: (1) patellofemoral joint pressure, (2) patellofemoral joint reaction force and (3) external knee flexion/internal knee extension moment. All outcomes were the peak during stance.

Risk of bias assessment

Two reviewers (SAK and PLR) independently assessed the risk of bias for each study outcome using the Revised Cochrane Risk of Bias 2 tool for randomised cross-over trials.²⁹ We considered six domains: (1) bias arising from the randomisation process, (1S) bias arising from period and carryover effects, (2) bias due to deviations from intended interventions, (3) bias due to missing outcome data, (4) bias in measurement of the outcome and (5) bias in selection of the reported result. The two reviewers independently rated each domain as either low risk, some concerns or high risk of bias. In the case of disagreement, a third author (KLP) appraised the study independently, and the research team convened until consensus was reached. One study was not a cross-over trial,³⁰ thus, we omitted domain 1S.

Data synthesis and analysis

We pooled data across studies that were sufficiently similar by intervention (1) minimalist footwear, (2) medial support insoles or (3) rocker-soled footwear; comparator (1) conventional footwear, (2) no insole or (3) non-rocker footwear and task (1) walking, (2) running or (3) walking and running combined. The designation of the intervention and comparator shoes were based on the author's rationale of which footwear or insole type was more likely to reduce patellofemoral joint loads (ie, the one considered to be load-reducing intervention) or the characteristics (eg, weight, heel height, heel-to-toe drop) presented in online supplemental tables 1 and 2. Where a study investigated multiple variations of a given intervention and/or control, we used the intervention variant postulated to have the maximal load reducing effect on patellofemoral joint load and conversely, the control condition postulated to have the least load reducing effect. For example, where a study investigated different types of 'minimalist' footwear, we analysed data for the footwear with the least weight, heel height and/or heel-to-toe drop as the intervention condition. For insole interventions, we analysed data relating to the insole with the greatest degree of wedging or arch support as the intervention, given these are postulated to reduce patellofemoral joint loads.^{10 12}

Standardised mean differences (SMDs) were calculated using Review Manager statistical software (RevMan V.5, Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014) with 95% CIs to allow for pooling and comparison of outcomes in individual studies. Where studies reported 95% CIs only, we calculated the SD according to Cochrane guidelines.²¹ SMDs were interpreted as: minimal <0.2, small 0.2–0.49, medium 0.50–0.79 and large >0.8. Interpretation of effect estimates and Grading of Recommendations Assessment, Development and Evaluation (GRADE) findings followed published recommendations.³¹ The SMDs were calculated so that a negative value represented a reduction in patellofemoral joint loads in the intervention footwear or insole relative to the comparator. Where there were three or more studies that were sufficiently similar, random effects meta-analysis with the inverse variance method was performed using Review Manager.³² The random effects model was used as heterogeneity was expected in the intervention, comparator and population. Patellofemoral joint loads for individual studies and pooled estimates were summarised in forest plots for the following comparisons (due to available studies): minimalist footwear versus conventional footwear during running, and walking and running combined, rocker-soled footwear versus conventional footwear during walking and running combined and medial support insoles versus no insole during walking, running, and walking and running combined. Results for outcomes in studies ineligible for pooling are presented in tables 1 and 2 and as a narrative synthesis. Heterogeneity was assessed by visually inspecting forest plots and examining the χ^2 test for heterogeneity. I^2 values of 30%, 50% and 75% were considered moderate, substantial and considerable heterogeneity, respectively.^{21 33} Assessment of publication bias was not possible as there were less than 10 studies in each pool.²¹ We subgrouped each pooled analysis by population (eg, healthy, patellofemoral pain and patellofemoral osteoarthritis).

Quality of the body of evidence

We used the GRADE framework^{31 34} to assess the body of evidence for each pooled analysis. Two reviewers (SAK and PLR) used GRADEpro software (McMaster University, 2015,

Table 1 Footwear study outcome data

Measure of peak patellofemoral loads	Unit	Study	Task measured	Intervention mean (SD)	Comparator mean (SD)	SMD (95% CI)
Results of studies that evaluated minimalist versus conventional footwear						
Patellofemoral joint pressure	MPa	Bonacci 2018 ³⁶	Running at self-selected speed on treadmill	Minimalist 10.39 (1.93)	Conventional 12.27 (2.92)	-0.74 (-1.48, 0.00)
		Sinclair 2014 ³⁸	Running over 22 m runway at 4.0 m/s±5%	9.65 (3.77)	10.28 (3.33)	-0.17 (-0.91, 0.57)
		Sinclair 2016A ³⁹	Running at 4.0 m/s±5%	11.59 (2.63)	13.34 (2.43)	-0.68 (-1.32, 0.04)
		Yang 2019 ⁴¹	Running over 20 m runway at 3.33 m/s±5%	12.08 (3.27)	13.48 (2.64)	-0.46 (-1.18, 0.27)
External flexion moment	Nm/kg	Esculier 2022 ⁵⁵	Self-selected running on treadmill mean speed 2.3 m/s	0.91 (0.42)	0.99 (0.52)	-0.17 (-0.79, 0.46)
		Hannigan 2021 ³⁷	Walking at self-selected speed±5% between trials	0.78 (0.36)	0.77 (0.33)	0.03 (-0.66, 0.72)
		Sinclair 2016B ⁴⁰	Running at 4.0 m/s±5%	2.75 (0.90)	2.91 (0.78)	-0.18 (-0.90, 0.53)
Internal extension moment	Nm/kg	Ogaya 2022 ⁵⁶	Walking on treadmill at 1.0 m/s	7.50 (3.80)	7.73 (3.79)	-0.06 (-0.66, 0.55)
Results of studies that evaluated rocker versus non-rocker footwear						
External flexion moment	Nm/kg	Buchecker 2012 ⁴³	Walking at self-selected speed±0.2 km/hour	Rocker 1.51 (0.32)	Non-rocker 1.50 (0.30)	0.03 (-0.85, 0.91)
Internal extension moment	Nm/kg	Farzadi 2018 ⁴⁴	Walking at self-selected speed, speed N/A	0.58 (0.43)	0.49 (0.40)	0.21 (-0.44, 0.87)
		Sobhani 2017 ⁴⁵	Running at self-selected speed±5%	2.86 (0.20)	2.70 (0.20)	0.78 (0.06, 1.50)
Results of footwear studies ineligible to pool						
Patellofemoral joint pressure	MPa	Sinclair 2015A ⁴⁸	Running over 22 m walkway at 4.0 m/s±5%	Boot 10.38 (1.34)	Trainer 11.53 (0.93)	-0.96 (-1.82, 0.11)
Internal extension moment	Nm/%BM	Shamsoddini 2022 ⁵⁷	Running at 3.3 m/s±5%	2.58 (0.28)	2.68 (0.33)	-0.32 (-1.00, 0.36)
Patellofemoral joint pressure	MPa	Zhang 2022 ⁴⁶	Running over 20 m runway at 4.0 m/s±5%	Low heel-to-toe drop 15.97 (5.30)	High heel-to-toe drop 18.41 (4.21)	-0.50 (-1.16, 0.17)
External flexion moment	Nm/kg	Besson 2019 ⁴⁷	Running on 15 m runway at 2.54–2.55 m/s	2.21 (0.54)	2.34 (0.47)	-0.25 (-0.97, 0.47)
Internal extension moment	Nm/kg	Lee 2011 ⁴⁹	Running over runway at 4.0 m/s±0.02	Trainer 2368 (563)	Men's dress 2413 (544)	-0.08 (-0.95, 0.80)
Internal extension moment	Nm/kg	Jafarnejadgero 2019 ⁵¹	Running on treadmill at 3.30 m/s in intervention and 3.29 m/s in control	Anti-pronation 1.32 (0.51)	Neutral 1.62 (0.55)	-0.56 (-1.11, 0.00)
Internal extension moment	Nm	Hoogkamer 2019 ⁵²	Running at on treadmill at 4.44 m/s	Nike Vaporfly 175.5 (25.5)	Adidas marathon 176.0 (26.4)	-0.02 (-0.89, 0.86)
Internal extension moment	Nm/BW/H/LL	Liu 2020 ⁵³	Running over 13 m runway at 3.0 m/s±0.1	Oblique heel 0.213 (0.003)	Short parallel heel 0.212 (0.004)	0.28 (-0.35, 0.90)
Patellofemoral joint pressure	MPa	Sinclair 2016C ⁵⁴	Running over 22 m walkway at 4.0 m/s	Energy boost 9.02 (1.71)	Conventional 10.05 (1.87)	-0.55 (-1.45, 0.35)
Internal extension moment	Nm/kg/m	Bonacci 2013 ⁵⁰	Running over 110 m runway at 4.48 m/s±1.6	Minimalist 1.92 (0.2)	Range of running shoes 1.91 (0.2)	0.05 (-0.54, 0.64)
External flexion moment	Nm/BW	Chambon 2014 ⁴²	Running at 3.33 m/s±5%	No midsole 2.78 (0.46)	High midsole 2.76 (0.46)	0.04 (-0.67, 0.76)

SMD of <0.2, 0.2–0.49, 0.50–0.80 and >0.80 represents a minimal, small, medium and large effect, respectively; Intervention corresponds to the bold footwear in online supplemental table 1; Comparator corresponds to footwear in italics in online supplemental table 1.

%BM, percentage of body mass; BW, body weight; H, height; N/A, not available; SMD, standardised mean difference.

Table 2 Insole study outcome data

Measure of peak patellofemoral loads	Unit	Study	Task measured	Intervention mean (SD)	Comparator mean (SD)	SMD (95% CI)
Results of studies that evaluated medial support insoles versus no insole				Medial support insole	No insole	
Patellofemoral joint pressure	MPa	Almonroeder 2015 ⁵⁸	Running at 4.0 m/s±5% on 15 m runway	11.00 (2.64)	10.40 (2.44)	0.23 (−0.42, 0.89)
		Sinclair 2018A ⁶¹	Running at 4.0 m/s±5%	9.33 (2.71)	8.81 (2.68)	0.19 (−0.62, 0.99)
	KPa/BW	Sinclair 2018B ³⁰	Running at 4.0 m/s±5%	6.39 (1.51)	6.82 (1.66)	−0.26 (−1.10, 0.58)
		Sinclair 2018C ³⁰	Running at 4.0 m/s±5%	6.28 (2.59)	7.66 (2.64)	−0.49 (−1.64, 0.67)
	KPa/kg	Sinclair 2019A ⁶²	Running at 4.0 m/s±5%	70.56 (22.11)	68.92 (19.93)	0.08 (−0.62, 0.77)
Patellofemoral joint reaction force	N(BW)	Sinclair 2019B ⁶²	Running at 4.0 m/s±5%	100.28 (24.13)	96.57 (17.88)	0.22 (−0.40, 0.84)
		Peng 2020 ⁶⁶	Walking at self-selected pace, speed N/A	1.179 (0.63)	1.324 (0.69)	−0.21 (−0.93, 0.50)
External knee flexion moment	Nm/kg	Burston 2018 ⁵⁹	Walking at self-selected speed	0.86 (0.25)	0.89 (0.23)	−0.12 (−0.84, 0.59)
		Burston 2018 PFF ⁵⁹	Walking at self-selected speed	0.87 (0.25)	0.87 (0.28)	0.00 (−0.72, 0.72)
		Tan 2020 ⁶³	Walking at self-selected speed on 12 m walkway	0.58 (0.23)	0.58 (0.25)	0.00 (−0.62, 0.62)
Internal knee extension moment	Nm	Maclean 2006 ⁶⁰	Running at 3.6 m/s±5%	128.64 (27.14)	121.61 (22.11)	0.28 (−0.44, 1.00)
Results of studies ineligible to pool				11 mm heel lift	No heel lift	
Patellofemoral joint pressure	MPa	Mestelle 2017 ⁶⁷	Running at 3.46 m/s±2.5%	11.56 (2.01)	12.04 (1.92)	−0.24 (−0.93, 0.46)
Patellofemoral joint pressure	MPa	Sinclair 2015 ⁶⁴	Running at 4.0 m/s	Prefabricated insole	No insole	−0.47 (−1.20, 0.26)
				Semi-custom insole	No insole	
Patellofemoral joint pressure	MPa	Sinclair 2016D ⁶⁵	Running at 4.0 m/s±5% on 22 m walkway	9.30 (2.56)	8.18 (2.43)	0.43 (−0.38, 1.24)

SMD of <0.2, 0.2–0.49, 0.50–0.80 and >0.80 represents a minimal, small, medium and large effect, respectively; Intervention corresponds to the bold orthotic in online supplemental table 2.

BW, body weight; N/A, not available; SMD, standardised mean difference.

developed by Evidence Prime, available from gradepr.org) to assess the body of evidence for each outcome independently. Evidence was considered high certainty but was downgraded if there was a concern with the risk of bias, indirectness, inconsistency or imprecision. Any disagreement was resolved through consultation between the two reviewers. If there was disagreement between the two reviewers, a third (KLP) was engaged until consensus was reached.

Equity, diversity and inclusion statement

Our research and author team consisted of two women and four men with a range of experience, including two PhD students. We captured studies from a range of geographical regions, including North America, Asia, The Middle East and Europe. The studies included men and women with a mean age range from 23 to 59 years. Due to a lack of information, we are unaware if the studies included participants from marginalised groups. When considering the generalisability of our results and limitations, we acknowledge that our results do not explore the effects of sex or include the elderly or children. Finally, we limited our search to studies in English due to a lack of translation resources.

RESULTS

Study selection characteristics

The PRISMA flow chart for study selection is outlined in [figure 1](#).^{22 35} We identified 11 953 records through database searches and 9 through other sources, with 7377 remaining after removing duplicates. Thirty-three studies were included in the

final review. Of these, 22^{36–57} (n=371 participants) investigated the effect of footwear and 11^{30 58–67} (n=207 participants) the effect of shoe insoles on patellofemoral joint loads. We did not identify any studies that investigated effects of taping or bracing. The populations in the included studies were apparently healthy (30 studies,^{37–62 64–67} n=496 participants) and people diagnosed with patellofemoral pain (3 studies,^{30 36 59} n=61 participants) or osteoarthritis (1 study,⁶³ n=21 participants). Measurement outcomes included peak external flexion/internal extension knee moment (18 studies,^{37 40 42–45 47 49–53 55–57 59 60 63} peak patellofemoral joint pressure (14 studies^{30 36 38 39 41 46 48 54 58 61 62 64 65 67} and peak patellofemoral joint reaction force (1 study.⁶⁶ Study outcomes are outlined in [table 1](#) (footwear interventions) and [table 2](#) (insole interventions). The participants' mean age, mass and height ranged from 23–59 years, 55–91 kg and 159–179 cm, respectively. Median sample size was 15 (range=10–36). Detailed study characteristics, studies that met the inclusion criteria but were excluded, and forest plots for subgroup analyses by population and studies ineligible to pool, are presented in online supplemental file 1.

Risk of bias

We rated 31 outcomes as 'some concerns',^{30 36–42 45–55 57–59 61–67} and 4^{43 44 56 60} as 'high risk' of bias ([figure 2](#)). The risk of bias was largely consistent between the studies and was mostly due to a lack of randomisation, a lack of information regarding the randomisation process (when randomisation was used), and/

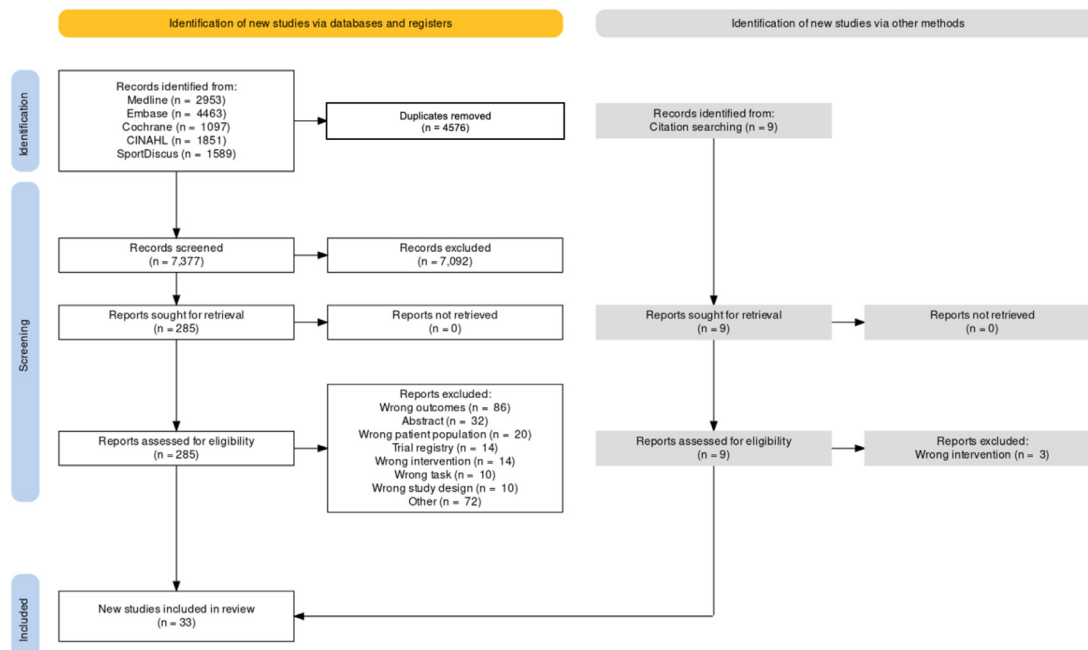


Figure 1 PRISMA flow chart. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

or did not report sufficient rest time for carryover effects to disappear.

Data synthesis

Results from pooled analyses and certainty of the evidence are summarised in table 3.

Minimalist footwear

Eight studies^{36–41 55 56} (n=136 participants) compared minimalist footwear with conventional footwear (figure 3A). Pooled analysis indicated that there is low certainty evidence with low heterogeneity ($I^2=0\%$) to suggest that minimalist footwear leads to a small reduction (SMD (95% CI) = -0.29 (-0.53 to -0.05), $p=0.02$) in peak patellofemoral joint loads during walking and running combined when compared with conventional footwear. This equated to a 7.4% difference on average. After subgrouping by population, the effect estimate in those with patellofemoral pain increased (SMD (95% CI) = -0.74 (-1.48 to 0.00)), although this was based on runners in one study.³⁶ In contrast, in the apparently healthy subgroup,^{37–41 55 56} the pooled effect estimate was no longer significant (SMD (95% CI) = -0.24 (-0.49 to 0.01)). After subgrouping by task, the pooled effect estimate for studies that used a running task increased (SMD (95% CI) = -0.40 (-0.68 to -0.11)) (figure 3B),^{36 38–41 55} equating to a

9.5% difference on average. In contrast, the effect estimate for the studies that used a walking task were not significant.^{37 56}

Rocker-soled footwear

Three studies^{43–45} (n=44 participants) compared rocker-soled footwear with non-rocker footwear in healthy people only (figure 3B). There is very low certainty evidence to suggest rocker-soled shoes do not alter peak patellofemoral joint loads during walking and running combined (SMD (95% CI) = 0.37 (-0.06 to 0.79), $p=0.09$) with low heterogeneity ($I^2=2\%$). After subgrouping by task, the effect estimates in two studies^{43 44} for walking were non-significant. In contrast, the effect estimate during running showed patellofemoral joint loads were increased in rocker-soled footwear (SMD (95% CI) = 0.78 (0.06 to 1.50)), although this was based on one study.⁴⁵

Medial support insoles

Eight (8) studies (n=163 participants)^{30 58–63 66} investigated medial support insoles compared with no insoles (figure 3D). There is low certainty evidence to suggest that medial support insoles do not alter peak patellofemoral joint loads during walking and running combined (SMD (95% CI) = 0.03 (-0.18 to 0.25), $p=0.75$) with low heterogeneity ($I^2=0\%$). After subgrouping by population and task, there was little

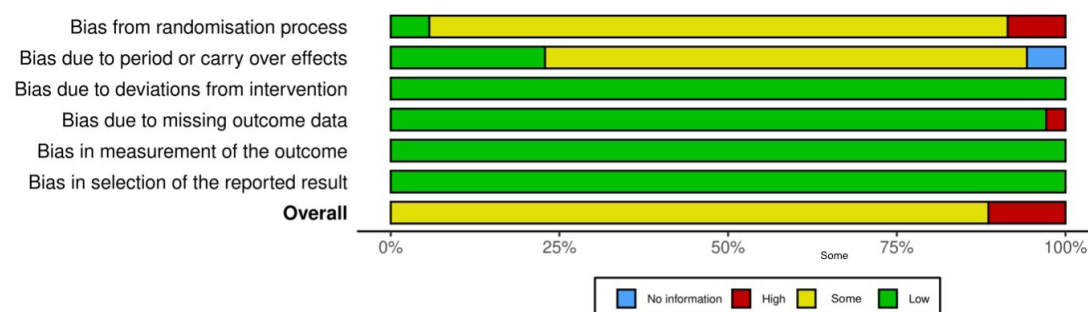


Figure 2 Risk of bias in included studies summary; each domain rated as high, some concerns or low risk of bias or no information.

Table 3 Summary of findings

Outcomes Task	SMD (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
Minimalist vs conventional footwear <i>Walking and running</i>	SMD 0.29 lower (0.53 lower to 0.05 lower)	136 (8)	⊕⊕○○ Low	Downgraded because of indirectness (walking and running tasks, varied footwear and patellofemoral pain and healthy populations) and risk of bias within studies
Minimalist vs conventional footwear <i>Running</i>	SMD 0.40 lower (0.68 lower to 0.11 lower)	99 (6)	⊕⊕○○ Low	Downgraded because of indirectness, (varied footwear and patellofemoral pain and healthy populations) and risk of bias within studies
Minimalist vs conventional footwear <i>Walking</i>	N/A	37 (2)	N/A	Two studies available, GRADE not performed
Rocker vs non-rocker footwear <i>Walking and running</i>	SMD 0.37 higher (0.06 lower to 0.79 higher)	44 (3)	⊕○○○ Very low	Downgraded because of indirectness (walking and running tasks, variations in footwear) imprecision (wide CI) and risk of bias within studies
Rocker vs non-rocker footwear <i>Running</i>	N/A	16 (1)	N/A	One study available, GRADE not performed
Rocker vs non-rocker footwear <i>Walking</i>	N/A	28 (2)	N/A	Two studies available, GRADE not performed
Medial support insole vs no insole <i>Walking and running</i>	SMD 0.04 higher (0.17 lower to 0.24 higher)	163 (8)	⊕⊕○○ Low	Downgraded because of indirectness (walking and running tasks, varied footwear and patellofemoral pain/osteoarthritis and healthy populations) and risk of bias within studies
Medial support insole vs no insole <i>Running</i>	SMD 0.11 higher (0.17 lower to 0.39 higher)	98 (6)	⊕⊕○○ Low	Downgraded because of indirectness (varied footwear and patellofemoral pain/osteoarthritis and healthy populations) and risk of bias within studies
Medial support insole vs no insole <i>Walking</i>	SMD 0.08 lower (0.42 lower to 0.27 higher)	163 (3)	⊕⊕○○ Low	Downgraded because of indirectness (varied footwear and patellofemoral pain/osteoarthritis and healthy populations) and risk of bias within studies

Bold: significant SMD; **N/A:** Too few studies available for meta-analysis, SMD (95% CI) and GRADE not available.
 GRADE Working Group grades of evidence:
 High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
 Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
 Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
 Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.
 SMD of <0.2, 0.2–0.49, 0.50–0.80 and >0.80 represents a minimal, small, medium and large effect, respectively.
 GRADE, Grading of Recommendations Assessment, Development and Evaluation; NA, not available; SMD, standardised mean difference.

change in the effect estimates for the healthy^{58–62 66} (SMD (95% CI) = 0.10 (–0.16 to 0.36)), patellofemoral pain^{30 59} (SMD (95% CI) = –0.18 (–0.67 to 0.31)), patellofemoral osteoarthritis⁶³ (SMD (95% CI) = 0.00 (–0.62 to 0.62)) (online supplemental file 1) cohorts, or for studies that used a walking^{59 63 66} (SMD (95% CI) = –0.08 (–0.42 to 0.27)) (figure 3E) or running^{30 58 60–62} (SMD (95% CI) = 0.11 (–0.17 to 0.39)) (figure 3F) task.

Studies ineligible for pooling

Of the 14 studies that were ineligible to pool, 7 footwear^{42 47 49 50 52 53 57} and 2 insole^{64 65} studies found no difference in peak patellofemoral joint loads. In contrast, Sinclair *et al*⁴⁸ showed a running trainer reduced peak patellofemoral joint pressure compared with a military boot; Sinclair⁵⁴ showed an energy boost shoe reduced peak patellofemoral joint pressure compared with conventional footwear; Jafarnejadgero *et al*⁵¹ demonstrated that anti-pronation footwear reduced peak internal knee extension moment compared with a neutral shoe; Zhang *et al*⁴⁶ observed that footwear with a 0 mm heel-to-toe drop reduced peak patellofemoral joint pressure compared with footwear with a 15 mm heel-to-toe drop; and Mestelle *et al*⁶⁷ showed an 11 mm heel lift reduced peak patellofemoral joint pressure compared with no heel lift.

DISCUSSION

Summary of findings

Our systematic review aimed to evaluate the effects of biomechanical foot-based interventions on patellofemoral joint loads in apparently healthy people and those diagnosed with patellofemoral pain or osteoarthritis. We identified 33 footwear and insoles studies and no studies investigating the effects of foot taping or bracing on patellofemoral joint loads. Pooled analyses indicated minimalist footwear may reduce peak patellofemoral joint loads slightly compared with conventional footwear during walking and running combined. However, after subgrouping, these differences were only evident during running. Medial support insoles may not alter patellofemoral joint loads during walking or running. Finally, the evidence is very uncertain about the effect of rocker-soled shoes during walking and running combined.

Minimalist footwear reduces patellofemoral joint loads

We found that minimalist footwear reduced peak patellofemoral joint loads by 7.4% on average compared with conventional footwear during walking and running combined. These findings are similar to a previous systematic review and meta-analysis that found high-heeled footwear increase the knee flexion angle and moment during walking.¹⁰ The novel findings from our study show that even conventional footwear with a moderate heel and/

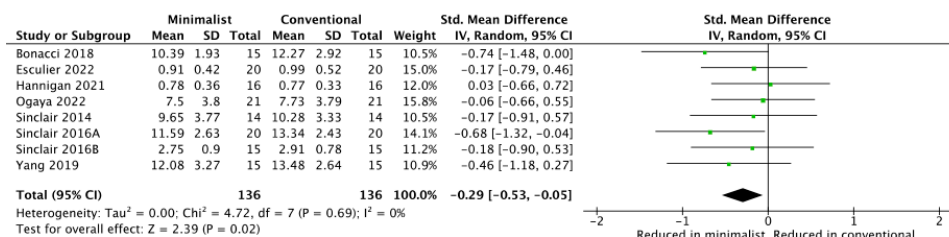
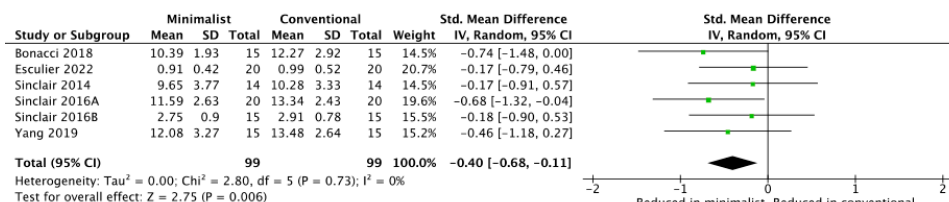
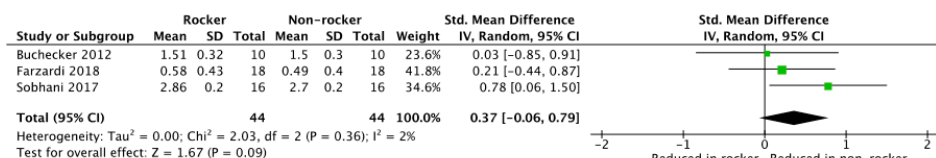
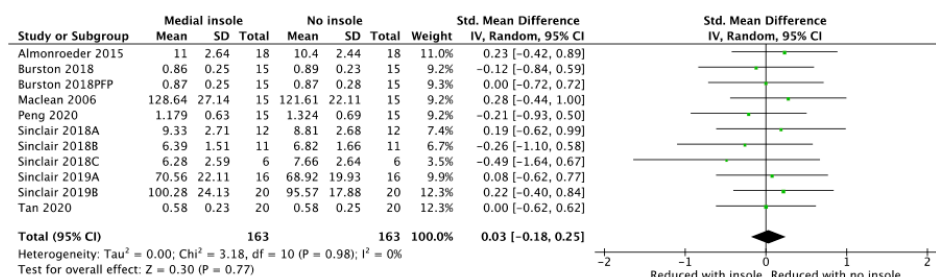
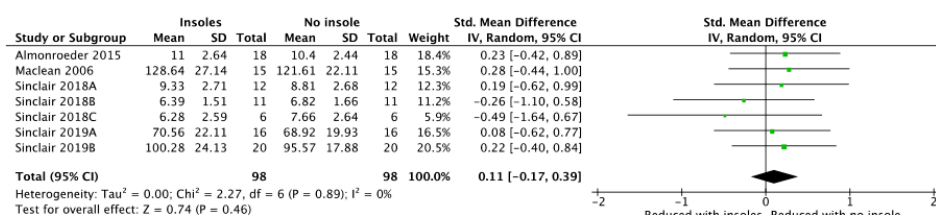
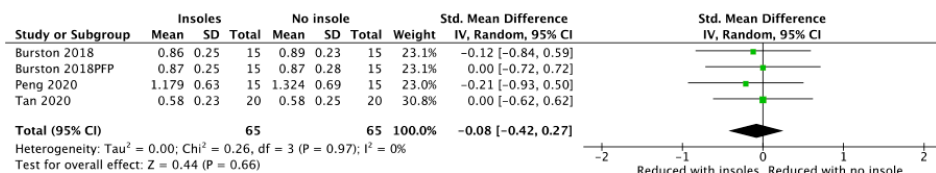
A. Minimalist vs conventional footwear during walking and running combined**B. Minimalist vs conventional footwear during running****C. Rocker vs non-rocker footwear during walking and running combined****D. Medial support insoles vs no insole during walking and running combined****E. Medial support insoles vs no insole during running****F. Medial support insoles vs no insole during walking**

Figure 3 Forest plots (standardised mean differences and 95% CIs) for eligible meta-analyses. Forest plots for individual studies can be found in online supplemental file 1; PFP: patellofemoral pain.

or increased amounts of cushioning will increase patellofemoral joint loads when compared with minimalist footwear.

We attribute the reduction in patellofemoral joint loads observed with minimalist footwear to two primary mechanisms. First, minimalist footwear reduces step length (increasing cadence). A reduction in step length brings the stance limb closer to the centre of mass, reducing knee flexion and quadriceps demand.³⁸ Studies consistently show a shorter step length in minimalist footwear^{39 50 68}; and an increased cadence reduces patellofemoral joint load.^{36 69} The second factor is the combination of reduced stack height,³⁹ weight,⁷⁰ and heel-to-toe drop⁴⁶ and increased flexibility⁷⁰ in minimalist footwear. These characteristics lower the knee flexion angle, moment and quadriceps muscle force, resulting in a reduced patellofemoral reaction force.⁷¹

Interestingly, Mestelle *et al*⁶⁷ found a reduction in peak patellofemoral pressure when running in footwear with an 11 mm heel lift. The authors concluded this was due to an anterior shift in the centre of pressure during the heel lift condition, which can reduce patellofemoral joint load.^{72–74} The same study showed no difference in step length, cadence and knee flexion between the heel lift and control conditions, possibly contributing to the contradictory finding.

After subgrouping by task (walking or running) or population (healthy, patellofemoral pain or patellofemoral osteoarthritis), differences in patellofemoral joint load between minimalist and conventional footwear were only evident during running (9.5% difference on average) or in participants with patellofemoral pain (although, only one study on runners was available). This suggests that minimalist shoes may only be effective during activities that provoke higher joint loads, such as running, or only in people with patellofemoral pain. Patellofemoral pain is particularly prevalent among runners,¹ likely because patellofemoral joint loads are high over numerous loading cycles. As such, the differences in patellofemoral loads will become greater when considering cumulative load. For example, runners will experience 18.28*BW (1462 kg for an 80 kg person) less joint force in minimalist footwear (despite an increase in cadence and the number of loading cycles) compared with conventional footwear over 1 km (based on a calculation of total force impulse (BW × stance time) × number of steps per kilometre).³⁹ Therefore, clinicians may consider recommending minimalist footwear to reduce patellofemoral joint loads in runners or people with patellofemoral pain.

Medial support insoles and rocker-soled footwear have no effect on patellofemoral joint loads

The results from our pooled analysis indicated that medial support insoles and rocker-soled footwear do not alter patellofemoral joint loads when compared with no insole and non-rocker footwear during walking, running, and walking and running combined. In contrast, two previous studies showed medial support insoles are effective for the treatment of patellofemoral pain. One was a cohort study⁷⁵ that gave insoles to people with patellofemoral pain over a 12-week period. The other was a randomised controlled trial that compared medial support insoles to 'wait and see'.⁷⁶ However, when comparing flat sham insoles to medial support insoles for the treatment of patellofemoral pain and osteoarthritis, studies have found no difference in pain between groups in the immediate,⁷⁷ medium (12 weeks),⁷⁸ and long-term (1 year).⁷⁸ Additionally, medial support insoles are of no additional benefit to a physiotherapy programme over the short, medium and long term,⁷⁸ although

the same study did find medial support insoles were effective compared with sham insoles at 6 weeks.⁷⁸ Our finding of no load reduction with medial support insoles in combination with the above studies indicates that the pain reducing effects of insoles may largely be contextual, rather than biomechanical (medial support reducing pronation, femoral motion and patellofemoral joint pressure). Contextual effects contribute to a significant proportion of treatment effects in clinical practice. For example, researchers have found that contextual effects, such as a credible placebo/sham and a positive therapeutic relationship, are responsible for around 61% of the overall effect of interventions used to treat knee osteoarthritis.⁷⁹

Clinical implications

We found that minimalist footwear reduces patellofemoral joint load during running. However, it is uncertain whether these biomechanical effects translate to symptomatic benefits. For instance, a recent systematic review found that patellofemoral joint reaction force did not differ between adults with and without patellofemoral pain during everyday activities, including running,¹⁵ suggesting that increased patellofemoral joint loads are not a consistent feature of patellofemoral pain. Furthermore, the relationship between patellofemoral joint load and pain is uncertain. In fact, there is evidence that pain may be more closely related to factors other than load, such as kinesiophobia.^{80 81} Thus, even though minimalist footwear reduces patellofemoral joint loads, further research is needed to determine whether clinicians should advise patients to use minimalist footwear to manage patellofemoral pain.

Limitations

There were some limitations of our review processes. We did not search grey literature as the academic field is relatively mature,²⁶ and we also limited our search to English language studies, risking publication and language biases. Our subgroup analyses did not investigate the effects of sex on patellofemoral joint loads and we limited the number of subgroup analyses to minimise the risk of false-positives.²¹ Finally, only one author conducted data extraction, which was audited for accuracy by a second author. Having two authors conduct an independent data extraction may have increased the accuracy. We mitigated this risk by having a third author resolve any discrepancies.

There are a number of limitations regarding the evidence included in our review. Most studies in this review estimate patellofemoral joint force using a 2D model of the knee in the sagittal plane and calculate patellofemoral joint pressure by dividing the force by a contact area from previous studies.¹⁶ These methods will neglect any changes in patellofemoral joint contact area arising from a biomechanical foot-based intervention. Studies use these methods as in vivo measurements of joint force and pressure are invasive and impractical. The quality of the included studies is another limitation of the evidence. No studies were rated as low risk of bias—all were either rated as high (n=4) or some concerns (n=31) of bias. Additionally, each intervention in our pooled analyses had inherent differences that may have increased the variability of our findings. As a result, we had low certainty in the effect estimate for the minimalist footwear and medial support insole analyses. As the rocker-soled footwear result had very-low certainty, the true effect estimate may be different with more high-quality studies. Due to the paucity of research into biomechanical foot-based interventions in people with patellofemoral pain and osteoarthritis, we pooled these populations with healthy people in our analyses. We

investigated this effect on our results by conducting subgroup analyses separately on apparently healthy and patellofemoral pain populations (online supplemental file 1). However, many of these analyses are based on only one or two studies, and we cannot make firm conclusions. Given the lack of research, future high-quality studies should investigate the effects of biomechanical foot-based interventions on patellofemoral joint loads in people with patellofemoral pain and/or osteoarthritis rather than apparently healthy populations. Finally, the populations in the included studies did not include the elderly or children and did not provide information regarding the representation of marginalised groups. As such, our findings may not be generalisable to these populations.

CONCLUSION

Minimalist footwear may reduce peak patellofemoral joint loads slightly compared with conventional footwear during running only. Medial support insoles may not alter patellofemoral joint loads during walking or running and the evidence is very uncertain about the effect of rocker-soled shoes during walking and running combined. Clinicians aiming to reduce patellofemoral joint loads during running may consider minimalist footwear.

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1.0 Detailed study characteristics

Table 1: Characteristics of studies (n=22) that investigated footwear

Authors and year	Population	Sample characteristics (M:F)	Eligible footwear intervention(s)
*Besson 2019 ¹	Healthy recreational rearfoot runners	n = 15 (0:15) Age = 23 Mass = 57 Height = 163	<div><div>i. Shoe with 0mm drop; weight 246g, heel height N/A, heel to toe drop 0mm, sole thickness 25mm</div><div>ii. Shoe with 6mm drop; weight 242g, heel height N/A, heel to toe drop 6mm, sole thickness 25mm</div><div>iii. Shoe with 10mm drop; weight 236g, heel height N/A, heel to toe drop 10mm, sole thickness 25mm</div></div>
*Bonacci 2013 ²	Healthy highly trained runners	n = 22 (14:8) Age = 29 Mass = 66 Height = 176	<div><div>i. Minimalist shoe (Nike free 3.0); weight 195g, heel height 21mm, heel to toe drop 4mm</div><div>ii. Lightweight racing flat (Nike lunar racer2); weight 184g, heel height N/A, heel to toe drop 6mm</div><div>iii. Regular shoe (Participant's own running shoe, types unknown); mean weight 323g, heel height N/A, heel to toe drop N/A</div></div>
Bonacci 2018 ³	Recreational runners with diagnosed patellofemoral pain >6 weeks in duration	n = 15 (3:12) Age = 33 Mass = 69 Height = 171 AKPS = 79.67 Worst pain = 45.7	<div><div>i. Control shoe (Asics gel-cumulus 16); weight 345g, heel height 31mm, heel to toe drop 11mm</div><div>ii. Minimalist shoe (Vibram seeya); weight 136g, heel height 5mm, heel to toe drop 0mm</div></div>
Buchecker 2012 ⁴	Healthy and overweight	n = 10 (10:0) Age = 32 Mass = 91 Height = 179	<div><div>i. Participant's conventional street shoe; mean weight 374g, heel height N/A, heel to toe drop N/A</div><div>ii. Masai barefoot technology curved rocker shoe; weight 650g, heel height N/A, heel to toe drop N/A</div></div>
*Chambon 2014 ⁵	Healthy runners	n = 15 (15:0) Age = 24	<div><div>All shoes had 0mm heel to toe drop. Weight N/A.</div><div>i. No midsole (0mm)</div></div>

		Mass = 73 Height = 177	ii. 2mm midsole iii. 4mm midsole iv. 8mm midsole v. 16mm midsole
Esculier 2022 ⁶	Healthy runners aged >40 years	n = 20 (0:20) Age = 52 Mass = 22.5 BMI Height = N/A	i. Merrell vapor glove; weight 147g, heel height 6mm, heel to toe drop 0mm, MI 96% ii. Merrell bare access; weight 148g, heel height 16mm, heel to toe drop 4mm, MI: 72% iii. Brooks pure flow; weight 218g, heel height 30mm, heel to toe drop 4mm, MI: 38% iv. <i>Habitual shoes; weight N/A, heel height N/A, heel to toe drop N/A, MI: 33.1%</i>
Farzadi 2018 ⁷	Healthy	n = 18 (0:18) Age = 24 Mass = 55 Height = 159	All rocker shoes had a heel-toe rocker sole with the toe apex positioned at 63% of the foot length and angles at 25 degrees. The heel rocker apex was angled at 15 degrees. i. Rocker shoe with rocker placed anterior to the medial malleolus ii. Rocker shoe with rocker placed at the medial malleolus iii. Rocker shoe with rocker placed posterior to the medial malleolus iv. <i>Unaltered control shoe</i>
Hannigan 2021 ⁸	Healthy females aged between 50-70 years that walked >1 hour per day	n = 16 (0:16) Age = 59 Mass = 62 Height = 165	i. <i>Traditional shoe (New Balance 880); weight 298g, heel height 28mm, heel to toe drop 12mm</i> ii. Minimal shoe (Merrell Trail Glove); weight N/A, heel height 7mm, heel to toe drop 0mm iii. Maximal shoe (Hoka One One Bondi); weight 252g, heel height 33mm, heel to toe drop 4mm
*Hoogkamer 2019 ⁹	Rearfoot striking runners with a <35 min 10km time	n = 10 (10:0) Age = 26 Mass = 63 Height = 177	i. Marathon racing shoe (Nike zoom streak 6); weight 193, heel height 23mm, heel to toe drop 8mm ii. <i>Marathon racing shoe (Adidas adizero adios boost 2); weight N/A, heel height 23mm, heel to toe drop 10mm</i>

			iii. Marathon racing shoe (Nike vaporfly prototype); weight N/A, heel height 31mm, heel to toe drop 10mm
*Jafarnezhadgero 2019 ¹⁰	Healthy recreational heel striking runners with excessive pronation	n = 26 (0:26) Age = 24 Mass = 64 Height = 166	i. Anti-pronation shoe (Asics Gel-kayano 24); weight 315g, heel height 24mm, heel to toe drop 10mm ii. <i>Neutral running shoe (Asics Gel-nimbus 19); weight 309g, heel height 25mm, heel to toe drop 10mm</i>
*Lee 2011 ¹¹	Healthy novice runners	n = 10 (10:0) Age = 21 Mass = 70 Height = 176	i. <i>Formal dress shoes; weight 360g, heel height N/A, heel to toe drop N/A</i> ii. Running shoes (Asics Gel-kenbarra 3); weight 316g, heel height 21mm, heel to toe drop 10mm
*Liu 2020 ¹²	Healthy rearfoot striking runners who ran >30km weekly and <50-minute 10km PB	n = 20 (20:0) Age = 26 Mass = 72 Height = 176	i. Shoe with short parallel heel curvature ii. <i>Shoe with oblique heel curvature</i> iii. <i>Shoe with long parallel heel curvature</i>
Ogaya 2022 ¹³	Healthy young adults	n = 21 (7:14) Age = 22 Mass = 60 Height = 160	i. Flat flexible shoe (RS88); weight 200g, heel height 13mm, heel to toe drop 4mm ii. <i>Standard athletic shoe (Mizuno wave rider 23); weight 400g, heel height 33mm, heel to toe drop 10mm</i>
Sinclair 2014 ¹⁴	Healthy runners	n = 30 (30:0) Age = 26 Mass = 73 Height = 177	i. Minimalist shoe (Inov-8 Evoskin); weight 100g, heel height N/A, heel to toe drop 0mm ii. <i>Minimalist shoe (Vibram five fingers); weight 167g, heel height 7mm, heel to toe drop 0mm</i> iii. <i>Minimalist shoe (Nike free 3.0); weight 221g, heel height 21mm, heel to toe drop 4mm</i> iv. <i>Conventional shoe (Saucony pro grid guide II); weight N/A, heel height N/A, heel to toe drop N/A</i>

*Sinclair 2015A ¹⁵	Healthy rearfoot striking recreational runners	n = 12 (12:0) Age = 26 Mass = 74 Height = 176	<ul style="list-style-type: none"> i. Army issue cross trainer; weight N/A, heel height 38mm, heel to toe drop 15mm ii. UK running shoe (PT1000); weight N/A, heel height 32mm, heel to toe drop 12mm iii. <i>Military boot; weight N/A, heel height 24mm, heel to toe drop 11mm</i>
Sinclair 2016A ¹⁶	Healthy rearfoot striking recreational runners	n = 20 (20:0) Age = 24 Mass = 78 Height = 177	<ul style="list-style-type: none"> i. Maximal shoe (Hoka one-one); weight 318g, heel height 45mm, heel to toe drop 6mm ii. <i>Conventional shoe (new balance 1260 v2); weight 285g, heel height 25mm, heel to toe drop 14mm</i> iii. Minimal (Vibram five fingers); weight 167g, heel height 7mm, heel to toe drop 0mm
Sinclair 2016B ¹⁷	Healthy runners completing >35km per week	n = 15 (15:0) Age = 24 Mass = 72 Height = 175	<ul style="list-style-type: none"> i. <i>Conventional shoe (Saucony Pro Grid Guide II) weight N/A, heel height N/A, heel to toe drop N/A</i> ii. Barefoot inspired (Vibram Five Fingers); weight 167g, heel height 7mm, heel to toe drop 0mm iii. Barefoot inspired (Merrell Bare Access); weight 240, heel height 17.2mm, heel to toe drop 0mm iv. Barefoot inspired (Inov-8 Evoskin); weight 100g, heel height N/A, heel to toe drop 0mm v. Structured barefoot (Nike Free 3.0); weight 221g, heel height 21mm, heel to toe drop 4mm vi. Structured barefoot (Vivo barefoot Ultra); weight N/A, heel height N/A, heel to toe drop 0mm
*Sinclair 2016C ¹⁸	Healthy males	n = 10 (10:0) Age = 24 Mass = 78 Height = 177	<ul style="list-style-type: none"> i. <i>Conventional footwear (New Balance 1260 v2); weight 285g, heel height 25mm, heel to toe drop 14mm</i> ii. Energy boost footwear (Adidas energy boost); weight N/A, heel height N/A, heel to toe drop N/A iii. Spring footwear (Adidas springblade drive 2); weight N/A, heel height N/A, heel to toe drop N/A
*Shamsoddini 2022 ¹⁹	Healthy physically active males	n = 17 (17:0) Age = 23 Mass = 72	<ul style="list-style-type: none"> i. <i>Boot; weight 1228g, heel height 35mm, heel to toe drop 20mm</i>

		Height = 176	ii. Running shoe; weight 627g, heel height 25mm, heel to toe drop 5mm
Sobhani 2017 ²⁰	Healthy experienced endurance runners	n = 16 (0:16) Age = 24 Mass = 62 Height = 171	i. <i>Control shoe (standard running shoe); weight 541g, heel height N/A, heel to toe drop N/A</i> ii. Rocker shoe with rocker location proximal to metatarsal region at 53% of shoe length. Rocker thickness at 2.2 +/- 0.1 cm
Yang 2019 ²¹	Healthy rearfoot striking recreational runners	n = 15 (15:0) Age = 31 Mass = 73 Height = 175	i. <i>Cushioned shoe (Nike air zoom Pegasus 34); weight 285g, heel height 30mm, Heel to toe drop 7mm</i> ii. Minimalist shoe (Inov-8 bare-XF 210 v2); weight 227g, heel height 3mm, heel to toe drop 0mm,
*Zhang 2022 ²²	Healthy runners with foot inclination angle >8 degrees	n = 18 (18:0) Age = 23 Mass = 65 Height = 174	i. Shoe with 0mm heel to toe drop ii. Shoe with 5mm heel to toe drop iii. Shoe with 10mm heel to toe drop iv. <i>Shoe with 15mm heel to toe drop</i>

Bold: Intervention condition used for meta-analysis *Italics: Comparator condition used for meta-analysis*; AKPS: Anterior Knee Pain Scale; PB: Personal best; BMI: Body mass index; M: Male sex; F: Female sex; N/A: Not available; Healthy: free from pathology that would affect gait; Age reported in years; Mass reported in kilograms; Height reported in centimetres; *: Study ineligible to be pooled; MI: Minimalist index where a higher percentage equates to a higher degree of minimalism

Table 2: Characteristics of studies (n=11) that investigated insoles

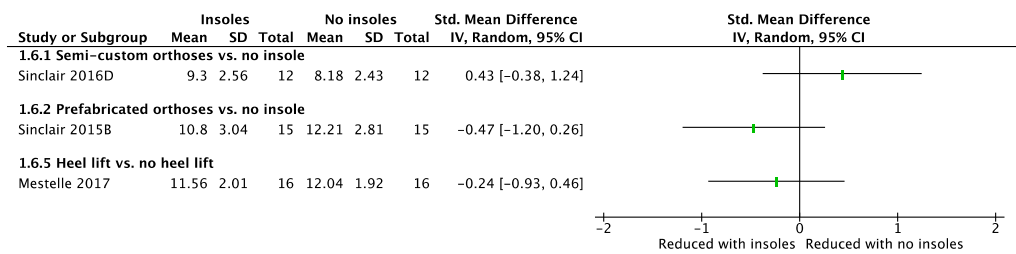
Authors and year	Population	Sample characteristics (M:F)	Intervention(s)	Comparator (Footwear)
Almonroeder 2015 ²³	Healthy and recreationally active	n = 18 (0:18) Age = 24 Mass = 62 Height = 165	i. Prefabricated three-quarter length insole with 5° medial wedge	No insole (New balance NBA-801 with no heel counter)
Burston 2018 ²⁴	Healthy	n = 15 (7:8) Age = 30 Mass = N/A Height = N/A	i. Full length customised insoles with 5° medial wedge ii. ¾ length customised insoles with 5° medial wedge	No insole (Participant's own training shoe)
Burston 2018PFP ²⁴	Diagnosed with patellofemoral pain	n = 15 (8:7) Age = 29 Mass = N/A Height = N/A	i. Full length customised insoles with 5° medial wedge ii. ¾ length customised insoles with 5° medial wedge	No insole (Participant's own training shoe)
Maclean 2006 ²⁵	Healthy recreational runners	n = 15 (0:15) Age = 21 Mass = 60 Height = 162	i. Custom foot insole posted with 5 degrees of inversion	No insole (New balance 801)
*Mestelle 2017 ²⁶	Healthy runners	n = 16 (0:16) Age = 22 Mass = 61 Height = 170	i. 11mm heel lift	No heel lift (New balance 625SB)
Peng 2020 ²⁷	18 – 25-year-olds with flat feet	n = 15 (9:6) Age = 22	i. Prefabricated insole with 3cm thick medial arch and 6° medial post	No insole (Reebok run supreme 4.0)

		Mass = 58 Height = 169			
*Sinclair 2015B ²⁸	Healthy runners	n = 15 (15:0) Age = 26 Mass = 71 Height = 174	i.	Prefabricated insole	No insole (Not reported)
*Sinclair 2016D ²⁹	Healthy recreational runners	n = 12 (0:12) Age = 21 Mass = 61 Height = 168	i.	Semi-custom insole	No insole (Not reported)
			i.	Prefabricated insole	
Sinclair 2018A ³⁰	Healthy recreational runners	n = 12 (12:0) Age = 26 Mass = 73 Height = 179	i.	Prefabricated full length insole with 11mm heel thickness and 5° medial configuration	No insole (ASCIS patriot 6 weight 265g, heel to toe drop 12mm)
			ii.	Prefabricated full length insole with 11mm heel thickness and 5° lateral configuration	
Sinclair 2018B ³¹	Strong runners with patellofemoral pain according to Selfe, et al. ³²	n = 11 (N/A) Age = 34 Mass = 74 Height = 175 KOOS-PF = 63.84	i.	Semi-custom insole moulded to the participant's longitudinal arch	No insole (Participant's own footwear)
Sinclair 2018C ³¹	Weak and tight runners with patellofemoral pain according to Selfe, et al. ³²	n = 6 (N/A) Age = 35 Mass = 71 Height = 172 KOOS-PF = 53.03	i.	Semi-custom insole moulded to the participant's longitudinal arch	No insole (Participant's own footwear)
Sinclair 2019 ³³	Healthy recreational runners	n = 36 (16:20) Sex: Male	i.	Medial wedge insole 5° varus configuration, heel thickness 11mm	No insole (Asics Patriot 6, weight 265g, heel height 22mm, heel to toe drop 10mm)

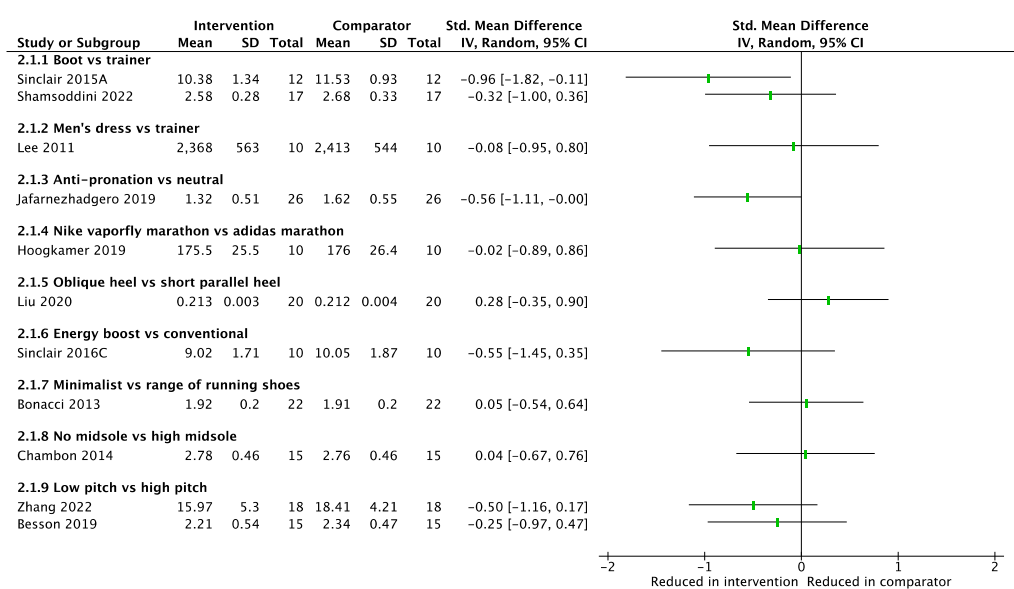
		Age = 29 Mass = 77 Height = 178	ii. iii. ii.	Lateral wedge insole 5° valgus configuration, heel thickness 11mm Semi-custom insole moulded to longitudinal arch, heel thickness 6mm Prefabricated insole heel thickness 6mm	
		Sex: Female Age = 32 Mass = 66 Height = 161			
Tan 2020 ³⁴	Aged 50 to 75 years diagnosed patellofemoral osteoarthritis	n = 21 (7:14) Age = 58 Mass = 27 BMI Height = N/A AKPS = 50	i. iv.	Prefabricated insoles with arch support and 6° varus wedge Flat shoe insert	No insole (Participant's own shoe or control shoe (Mizuno Wave Rider))

Bold: Intervention condition used for meta-analysis; AKPS: Anterior Knee Pain Scale; BMI: Body mass index; M: Male sex; F: Female sex; SD: Standard deviation; N/A: Not available; Healthy: free from pathology that would affect gait; Age reported in years; Mass reported in kilograms; Height reported in centimetres; *: Study ineligible to be pooled

2.0 Forest plots for shoe insole studies not suitable for pooling



3.0 Forest plots for footwear studies not suitable for pooling



Intervention corresponds to the bold footwear in Table 1 and 2; Comparator corresponds to footwear in italics in Table 1

4.0 Deviations from protocol

In the protocol:

“Two reviewers (SAK and PLR) will independently assess the methodological quality of the included studies using the Revised Cochrane Risk of Bias tool for randomised trials (RoB 2)³⁵ or the Cochrane Risk Of Bias In Non-Randomized Studies – of Interventions (ROBINS-I) tool³⁶ for non-randomised trials.”

In the review:

The studies identified in the final review were randomised cross-over trials. We did not identify any non-randomised or randomised controlled trials. As such, we used the Cochrane Risk of Bias 2 (RoB 2) tool for cross-over trials. By using the RoB 2 for cross-over trials, we were able to address two issues that are specific to cross-over study designs: carryover and period effects. If these two issues were not addressed, we risked underestimating bias for each outcome.

In the protocol:

Two reviewers (SAK and PLR) will independently extract relevant data. We will use a structured pre-piloted electronic data collection form. A third reviewer will resolve any discrepancies.

In the review:

One reviewer independently extracted relevant data. The second reviewer independently audited all relevant data for accuracy. Although this deviation may have led to inaccurate data extraction, the third reviewer was still available to resolve any discrepancies thus preventing inaccuracy.

In the protocol:

We plan to perform subgroup analyses on each type of biomechanical foot-based intervention (e.g., footwear, foot orthoses, taping or bracing). In addition, we will investigate the biomechanical foot-based intervention effects on healthy, patellofemoral pain and patellofemoral osteoarthritis populations by subgrouping these three populations.

In the review:

We sub-grouped each primary analysis by diagnosis (e.g., healthy, patellofemoral pain and patellofemoral osteoarthritis) and task (e.g., walking and running). Joint moments, force and pressure are sensitive to changes in gait speed.³⁸ As such, we decided to subgroup each analysis by task to investigate whether a biomechanical foot-based intervention is more or less effective during walking or running.

5.0 Risk of bias summary for included studies

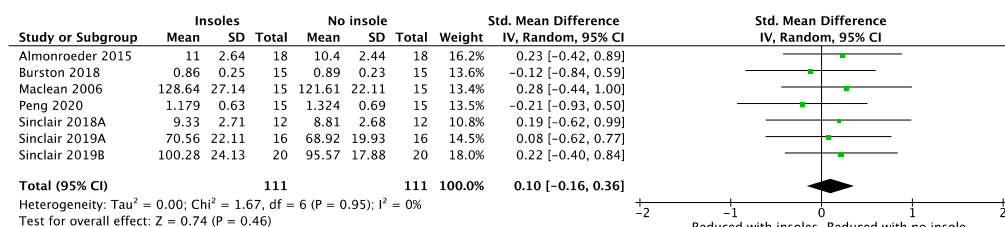
5.1 Figure 1: Traffic Light Plot



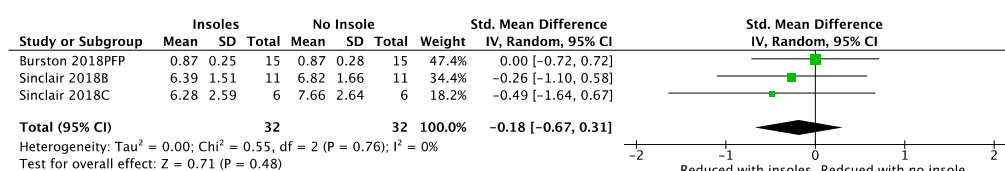
PFP: Patellofemoral pain

6.1 Subgroup analyses by population

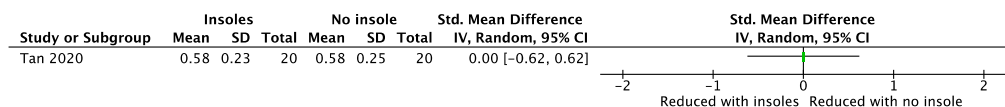
6.1.1 Comparing insoles with medial support to control in healthy people



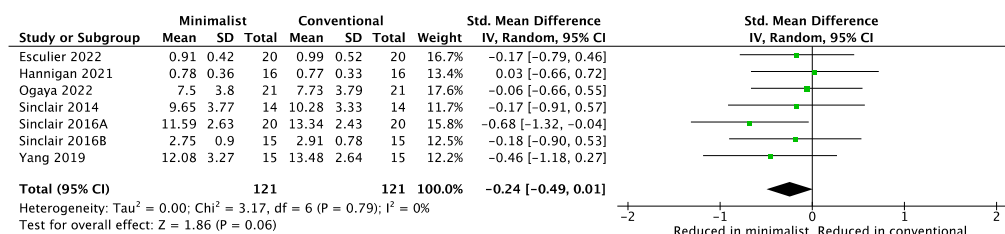
6.1.2 Comparing insoles with medial support to control in people with patellofemoral pain



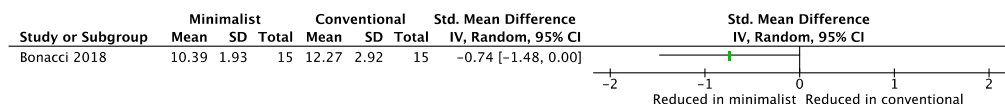
6.1.3 Comparing insoles with medial support to control in people with patellofemoral osteoarthritis



6.1.4 Comparing minimalist footwear with conventional footwear in healthy people

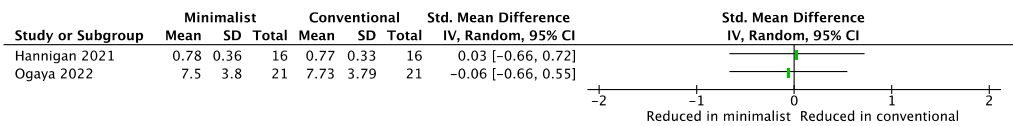


6.1.5 Comparing minimalist footwear with conventional footwear in people with patellofemoral pain

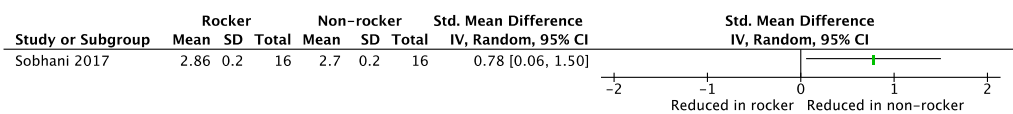


6.2 Comparisons ineligible for meta-analysis sub-grouped by task

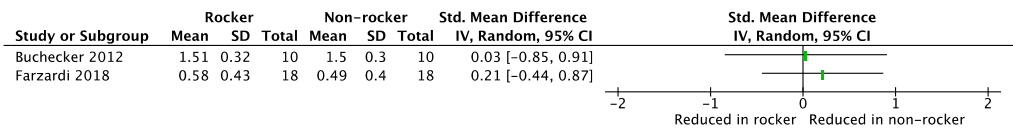
6.2.1 Comparing minimalist footwear with conventional footwear during walking



6.2.1 Comparing rocker soled footwear with control during running



6.2.2 Comparing rocker soled footwear with control during walking



7.0 Search strategies

Medline

1	(patellofemoral or patello-femoral or patella or knee).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
2	(footwear or shoe or wedge or insole or orthotic or orthoses or minimalist or heel or insert or orthosis or taping).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
3	exp Shoes/
4	exp orthotic devices/ or exp athletic tape/ or exp braces/ or exp foot orthoses/
5	2 or 3 or 4
6	(kinetics or load or stress or pressure or moment or torque or biomechanic or reaction force or quadriceps force).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
7	exp Biomechanical Phenomena/
8	6 or 7
9	1 and 5 and 8
10	limit 9 to human

Embase

1	(patellofemoral or patello-femoral or patella or knee).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword heading word, floating subheading word, candidate term word]
2	(footwear or shoe or wedge or insole or orthotic or orthoses or minimalist or heel or insert or orthosis or taping).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword heading word, floating subheading word, candidate term word]
3	exp Shoes/
4	exp orthotic devices/ or exp athletic tape/ or exp braces/ or exp foot orthoses/
5	2 or 3 or 4
6	(kinetics or load or stress or pressure or moment or torque or biomechanic or reaction force or quadriceps force).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword heading word, floating subheading word, candidate term word]
7	exp Biomechanical Phenomena/
8	6 or 7
9	1 and 5 and 8
10	limit 9 to human

Cochrane

(patellofemoral OR patello-femoral OR patella OR knee)
AND
(footwear OR shoe OR wedge OR insole OR orthotic OR orthoses OR minimalist OR heel OR insert OR orthosis OR taping

OR mh Shoes
OR mh "orthotic devices" OR mh "athletic tape" OR mh braces OR mh "foot orthoses"
AND
(kinetics OR load OR stress OR pressure OR moment OR torque OR biomechanic OR "reaction force" OR "quadriceps force"
OR mh "Biomechanical Phenomena")

CINAHL

(patellofemoral OR patello-femoral OR patella OR knee)
(footwear OR shoe OR wedge OR insole OR orthotic OR orthoses OR minimalist OR heel OR insert OR orthosis OR taping)
(MH Shoes+)
(MH "orthotic devices"+) OR (MH "athletic tape"+) OR (MH braces+) OR (MH "foot orthoses"+)
S2 OR S3 OR S4
(kinetics OR load OR stress OR pressure OR moment OR torque OR biomechanic OR "reaction force" OR "quadriceps force")
(MH "Biomechanical Phenomena"+)
S6 OR S7
S1 AND S5 AND S8

SportDiscus

(TX "patellofemoral" OR TX "patello-femoral" OR TX "patella" OR TX "knee")
(TX "footwear" OR TX "shoe" OR TX "wedge" OR TX "insole" OR TX "orthotic" OR TX "orthoses" OR TX "minimalist" OR TX "heel" OR TX "insert" OR TX "orthosis" OR TX "taping")
DE "Shoes"
DE "orthotic devices" OR DE "athletic tape" OR DE "braces" OR DE "foot orthoses"
S2 OR S3 OR S4
(TX "kinetics" OR TX "load" OR TX "stress" OR TX "pressure" OR TX "moment" OR TX "torque" OR TX "biomechanic" OR TX "reaction force" OR TX "quadriceps force")
DE "Biomechanical Phenomena"
S6 OR S7
S1 AND S5 AND S8

8.0 Studies where authors were contacted for data

Author Names	Ref	Date of initial correspondence	Date data received	Data requested from authors
Nigg et al. 2003	³⁹	May 17th 2022	N/A	<i>Data requested:</i> means and standard deviation of knee extension moment. Paper reported mean group changes in graphical format. Author replied, May 18th 2022 that they no longer have access to the data. Paper excluded.
Maclean et al. 2006	²⁵	May 17th 2022	Extracted using Web Plot Digitizer	<i>Data requested:</i> means and standard deviation of peak knee extension moment. Unable to contact authors: data extracted using Web Plot Digitizer.
Besson et al. 2019	¹	June 30th 2022	July 7th 2022	<i>Data requested:</i> means of knee flexion moment
Myers et al. 2006	⁴⁰	June 30th 2022	N/A	<i>Data requested:</i> means and standard deviation of knee sagittal moment. Paper reported differences and means in graphical format. Author replied June 30th 2022 saying they no longer had access to the data. Paper excluded.
Nester et al. 2003	⁴¹	June 30th 2022	N/A	<i>Data requested:</i> means and standard deviation of sagittal knee moment. Author and co-authors unable to be contacted. Data unable to be extracted by Web Plot Digitizer. Paper excluded.
Ogaya et al. 2022	¹³	October 6th 2022	October 7th 2022	<i>Data requested:</i> means and standard deviation of knee extension moment. Paper reported peak in graphical format and values appeared incorrect in the table provided. Author replied on October 6th 2022 saying values in table were an error and sent the correct values.
Hart et al. 2020	⁴²	October 28th 2022	N/A	<i>Data requested:</i> means and standard deviation of knee flexion moment

Ref: Reference; N/A: Not available

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PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	2-3
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	26-59
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	85-128
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	130-135
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	147-168;234-249
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	170-177
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	SFile
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	179-185
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	187-199
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	201-221
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	201-221
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	223-232
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	251-257
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	234-249
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	254-255
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	263-268
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	234-274
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	269-274
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N/A
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	271-272



PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	276-285
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	316
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	SFile
Study characteristics	17	Cite each included study and present its characteristics.	317-319;SFile
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	319-326
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	317-319
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	317-367
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	330-367
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	332-365;SFile
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	SFile
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	N/A
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	330-365
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	380-463
	23b	Discuss any limitations of the evidence included in the review.	465-473
	23c	Discuss any limitations of the review processes used.	475-497
	23d	Discuss implications of the results for practice, policy, and future research.	77-83
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	141-144
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	141-144
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	SFile
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	514-518
Competing interests	26	Declare any competing interests of review authors.	530-531
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	312-314



PRISMA 2020 Checklist

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71. doi: 10.1136/bmj.n71

For more information, visit: <http://www.prisma-statement.org/>

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1.0 Detailed study characteristics

Table 1: Characteristics of studies (n=22) that investigated footwear

Authors and year	Population	Sample characteristics (M:F)	Eligible footwear intervention(s)
*Besson 2019 ¹	Healthy recreational rearfoot runners	n = 15 (0:15) Age = 23 Mass = 57 Height = 163	<div><div>i. Shoe with 0mm drop; weight 246g, heel height N/A, heel to toe drop 0mm, sole thickness 25mm</div><div>ii. Shoe with 6mm drop; weight 242g, heel height N/A, heel to toe drop 6mm, sole thickness 25mm</div><div>iii. Shoe with 10mm drop; weight 236g, heel height N/A, heel to toe drop 10mm, sole thickness 25mm</div></div>
*Bonacci 2013 ²	Healthy highly trained runners	n = 22 (14:8) Age = 29 Mass = 66 Height = 176	<div><div>i. Minimalist shoe (Nike free 3.0); weight 195g, heel height 21mm, heel to toe drop 4mm</div><div>ii. Lightweight racing flat (Nike lunar racer2); weight 184g, heel height N/A, heel to toe drop 6mm</div><div>iii. Regular shoe (Participant's own running shoe, types unknown); mean weight 323g, heel height N/A, heel to toe drop N/A</div></div>
Bonacci 2018 ³	Recreational runners with diagnosed patellofemoral pain >6 weeks in duration	n = 15 (3:12) Age = 33 Mass = 69 Height = 171 AKPS = 79.67 Worst pain = 45.7	<div><div>i. Control shoe (Asics gel-cumulus 16); weight 345g, heel height 31mm, heel to toe drop 11mm</div><div>ii. Minimalist shoe (Vibram seeya); weight 136g, heel height 5mm, heel to toe drop 0mm</div></div>
Buchecker 2012 ⁴	Healthy and overweight	n = 10 (10:0) Age = 32 Mass = 91 Height = 179	<div><div>i. Participant's conventional street shoe; mean weight 374g, heel height N/A, heel to toe drop N/A</div><div>ii. Masai barefoot technology curved rocker shoe; weight 650g, heel height N/A, heel to toe drop N/A</div></div>
*Chambon 2014 ⁵	Healthy runners	n = 15 (15:0) Age = 24	<div><div>All shoes had 0mm heel to toe drop. Weight N/A.</div><div>i. No midsole (0mm)</div></div>

		Mass = 73 Height = 177	ii. 2mm midsole iii. 4mm midsole iv. 8mm midsole v. 16mm midsole
Esculier 2022 ⁶	Healthy runners aged >40 years	n = 20 (0:20) Age = 52 Mass = 22.5 BMI Height = N/A	i. Merrell vapor glove; weight 147g, heel height 6mm, heel to toe drop 0mm, MI 96% ii. Merrell bare access; weight 148g, heel height 16mm, heel to toe drop 4mm, MI: 72% iii. Brooks pure flow; weight 218g, heel height 30mm, heel to toe drop 4mm, MI: 38% iv. <i>Habitual shoes; weight N/A, heel height N/A, heel to toe drop N/A, MI: 33.1%</i>
Farzadi 2018 ⁷	Healthy	n = 18 (0:18) Age = 24 Mass = 55 Height = 159	All rocker shoes had a heel-toe rocker sole with the toe apex positioned at 63% of the foot length and angles at 25 degrees. The heel rocker apex was angled at 15 degrees. i. Rocker shoe with rocker placed anterior to the medial malleolus ii. Rocker shoe with rocker placed at the medial malleolus iii. Rocker shoe with rocker placed posterior to the medial malleolus iv. <i>Unaltered control shoe</i>
Hannigan 2021 ⁸	Healthy females aged between 50-70 years that walked >1 hour per day	n = 16 (0:16) Age = 59 Mass = 62 Height = 165	i. <i>Traditional shoe (New Balance 880); weight 298g, heel height 28mm, heel to toe drop 12mm</i> ii. Minimal shoe (Merrell Trail Glove); weight N/A, heel height 7mm, heel to toe drop 0mm iii. Maximal shoe (Hoka One One Bondi); weight 252g, heel height 33mm, heel to toe drop 4mm
*Hoogkamer 2019 ⁹	Rearfoot striking runners with a <35 min 10km time	n = 10 (10:0) Age = 26 Mass = 63 Height = 177	i. Marathon racing shoe (Nike zoom streak 6); weight 193, heel height 23mm, heel to toe drop 8mm ii. <i>Marathon racing shoe (Adidas adizero adios boost 2); weight N/A, heel height 23mm, heel to toe drop 10mm</i>

			iii. Marathon racing shoe (Nike vaporfly prototype); weight N/A, heel height 31mm, heel to toe drop 10mm
*Jafarnezhadgero 2019 ¹⁰	Healthy recreational heel striking runners with excessive pronation	n = 26 (0:26) Age = 24 Mass = 64 Height = 166	i. Anti-pronation shoe (Asics Gel-kayano 24); weight 315g, heel height 24mm, heel to toe drop 10mm ii. <i>Neutral running shoe (Asics Gel-nimbus 19); weight 309g, heel height 25mm, heel to toe drop 10mm</i>
*Lee 2011 ¹¹	Healthy novice runners	n = 10 (10:0) Age = 21 Mass = 70 Height = 176	i. <i>Formal dress shoes; weight 360g, heel height N/A, heel to toe drop N/A</i> ii. Running shoes (Asics Gel-kenbarra 3); weight 316g, heel height 21mm, heel to toe drop 10mm
*Liu 2020 ¹²	Healthy rearfoot striking runners who ran >30km weekly and <50-minute 10km PB	n = 20 (20:0) Age = 26 Mass = 72 Height = 176	i. Shoe with short parallel heel curvature ii. <i>Shoe with oblique heel curvature</i> iii. <i>Shoe with long parallel heel curvature</i>
Ogaya 2022 ¹³	Healthy young adults	n = 21 (7:14) Age = 22 Mass = 60 Height = 160	i. Flat flexible shoe (RS88); weight 200g, heel height 13mm, heel to toe drop 4mm ii. <i>Standard athletic shoe (Mizuno wave rider 23); weight 400g, heel height 33mm, heel to toe drop 10mm</i>
Sinclair 2014 ¹⁴	Healthy runners	n = 30 (30:0) Age = 26 Mass = 73 Height = 177	i. Minimalist shoe (Inov-8 Evoskin); weight 100g, heel height N/A, heel to toe drop 0mm ii. <i>Minimalist shoe (Vibram five fingers); weight 167g, heel height 7mm, heel to toe drop 0mm</i> iii. <i>Minimalist shoe (Nike free 3.0); weight 221g, heel height 21mm, heel to toe drop 4mm</i> iv. <i>Conventional shoe (Saucony pro grid guide II); weight N/A, heel height N/A, heel to toe drop N/A</i>

*Sinclair 2015A ¹⁵	Healthy rearfoot striking recreational runners	n = 12 (12:0) Age = 26 Mass = 74 Height = 176	<ul style="list-style-type: none"> i. Army issue cross trainer; weight N/A, heel height 38mm, heel to toe drop 15mm ii. UK running shoe (PT1000); weight N/A, heel height 32mm, heel to toe drop 12mm iii. <i>Military boot; weight N/A, heel height 24mm, heel to toe drop 11mm</i>
Sinclair 2016A ¹⁶	Healthy rearfoot striking recreational runners	n = 20 (20:0) Age = 24 Mass = 78 Height = 177	<ul style="list-style-type: none"> i. Maximal shoe (Hoka one-one); weight 318g, heel height 45mm, heel to toe drop 6mm ii. <i>Conventional shoe (new balance 1260 v2); weight 285g, heel height 25mm, heel to toe drop 14mm</i> iii. Minimal (Vibram five fingers); weight 167g, heel height 7mm, heel to toe drop 0mm
Sinclair 2016B ¹⁷	Healthy runners completing >35km per week	n = 15 (15:0) Age = 24 Mass = 72 Height = 175	<ul style="list-style-type: none"> i. <i>Conventional shoe (Saucony Pro Grid Guide II) weight N/A, heel height N/A, heel to toe drop N/A</i> ii. Barefoot inspired (Vibram Five Fingers); weight 167g, heel height 7mm, heel to toe drop 0mm iii. Barefoot inspired (Merrell Bare Access); weight 240, heel height 17.2mm, heel to toe drop 0mm iv. Barefoot inspired (Inov-8 Evoskin); weight 100g, heel height N/A, heel to toe drop 0mm v. Structured barefoot (Nike Free 3.0); weight 221g, heel height 21mm, heel to toe drop 4mm vi. Structured barefoot (Vivo barefoot Ultra); weight N/A, heel height N/A, heel to toe drop 0mm
*Sinclair 2016C ¹⁸	Healthy males	n = 10 (10:0) Age = 24 Mass = 78 Height = 177	<ul style="list-style-type: none"> i. <i>Conventional footwear (New Balance 1260 v2); weight 285g, heel height 25mm, heel to toe drop 14mm</i> ii. Energy boost footwear (Adidas energy boost); weight N/A, heel height N/A, heel to toe drop N/A iii. Spring footwear (Adidas springblade drive 2); weight N/A, heel height N/A, heel to toe drop N/A
*Shamsoddini 2022 ¹⁹	Healthy physically active males	n = 17 (17:0) Age = 23 Mass = 72	<ul style="list-style-type: none"> i. <i>Boot; weight 1228g, heel height 35mm, heel to toe drop 20mm</i>

		Height = 176	ii. Running shoe; weight 627g, heel height 25mm, heel to toe drop 5mm
Sobhani 2017 ²⁰	Healthy experienced endurance runners	n = 16 (0:16) Age = 24 Mass = 62 Height = 171	i. <i>Control shoe (standard running shoe); weight 541g, heel height N/A, heel to toe drop N/A</i> ii. Rocker shoe with rocker location proximal to metatarsal region at 53% of shoe length. Rocker thickness at 2.2 +/- 0.1 cm
Yang 2019 ²¹	Healthy rearfoot striking recreational runners	n = 15 (15:0) Age = 31 Mass = 73 Height = 175	i. <i>Cushioned shoe (Nike air zoom Pegasus 34); weight 285g, heel height 30mm, Heel to toe drop 7mm</i> ii. Minimalist shoe (Inov-8 bare-XF 210 v2); weight 227g, heel height 3mm, heel to toe drop 0mm,
*Zhang 2022 ²²	Healthy runners with foot inclination angle >8 degrees	n = 18 (18:0) Age = 23 Mass = 65 Height = 174	i. Shoe with 0mm heel to toe drop ii. Shoe with 5mm heel to toe drop iii. Shoe with 10mm heel to toe drop iv. <i>Shoe with 15mm heel to toe drop</i>

Bold: Intervention condition used for meta-analysis *Italics: Comparator condition used for meta-analysis*; AKPS: Anterior Knee Pain Scale; PB: Personal best; BMI: Body mass index; M: Male sex; F: Female sex; N/A: Not available; Healthy: free from pathology that would affect gait; Age reported in years; Mass reported in kilograms; Height reported in centimetres; *: Study ineligible to be pooled; MI: Minimalist index where a higher percentage equates to a higher degree of minimalism

Table 2: Characteristics of studies (n=11) that investigated insoles

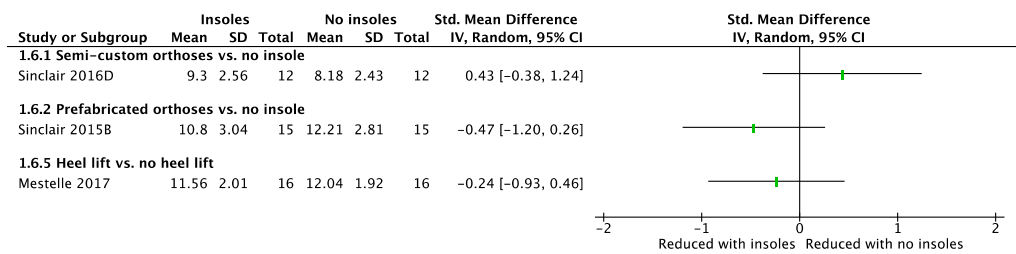
Authors and year	Population	Sample characteristics (M:F)	Intervention(s)	Comparator (Footwear)
Almonroeder 2015 ²³	Healthy and recreationally active	n = 18 (0:18) Age = 24 Mass = 62 Height = 165	i. Prefabricated three-quarter length insole with 5° medial wedge	No insole (New balance NBA-801 with no heel counter)
Burston 2018 ²⁴	Healthy	n = 15 (7:8) Age = 30 Mass = N/A Height = N/A	i. Full length customised insoles with 5° medial wedge ii. ¾ length customised insoles with 5° medial wedge	No insole (Participant's own training shoe)
Burston 2018PFP ²⁴	Diagnosed with patellofemoral pain	n = 15 (8:7) Age = 29 Mass = N/A Height = N/A	i. Full length customised insoles with 5° medial wedge ii. ¾ length customised insoles with 5° medial wedge	No insole (Participant's own training shoe)
Maclean 2006 ²⁵	Healthy recreational runners	n = 15 (0:15) Age = 21 Mass = 60 Height = 162	i. Custom foot insole posted with 5 degrees of inversion	No insole (New balance 801)
*Mestelle 2017 ²⁶	Healthy runners	n = 16 (0:16) Age = 22 Mass = 61 Height = 170	i. 11mm heel lift	No heel lift (New balance 625SB)
Peng 2020 ²⁷	18 – 25-year-olds with flat feet	n = 15 (9:6) Age = 22	i. Prefabricated insole with 3cm thick medial arch and 6° medial post	No insole (Reebok run supreme 4.0)

		Mass = 58 Height = 169			
*Sinclair 2015B ²⁸	Healthy runners	n = 15 (15:0) Age = 26 Mass = 71 Height = 174	i.	Prefabricated insole	No insole (Not reported)
*Sinclair 2016D ²⁹	Healthy recreational runners	n = 12 (0:12) Age = 21 Mass = 61 Height = 168	i.	Semi-custom insole	No insole (Not reported)
			i.	Prefabricated insole	
Sinclair 2018A ³⁰	Healthy recreational runners	n = 12 (12:0) Age = 26 Mass = 73 Height = 179	i.	Prefabricated full length insole with 11mm heel thickness and 5° medial configuration	No insole (ASCIS patriot 6 weight 265g, heel to toe drop 12mm)
			ii.	Prefabricated full length insole with 11mm heel thickness and 5° lateral configuration	
Sinclair 2018B ³¹	Strong runners with patellofemoral pain according to Selfe, et al. ³²	n = 11 (N/A) Age = 34 Mass = 74 Height = 175 KOOS-PF = 63.84	i.	Semi-custom insole moulded to the participant's longitudinal arch	No insole (Participant's own footwear)
Sinclair 2018C ³¹	Weak and tight runners with patellofemoral pain according to Selfe, et al. ³²	n = 6 (N/A) Age = 35 Mass = 71 Height = 172 KOOS-PF = 53.03	i.	Semi-custom insole moulded to the participant's longitudinal arch	No insole (Participant's own footwear)
Sinclair 2019 ³³	Healthy recreational runners	n = 36 (16:20) Sex: Male	i.	Medial wedge insole 5° varus configuration, heel thickness 11mm	No insole (Asics Patriot 6, weight 265g, heel height 22mm, heel to toe drop 10mm)

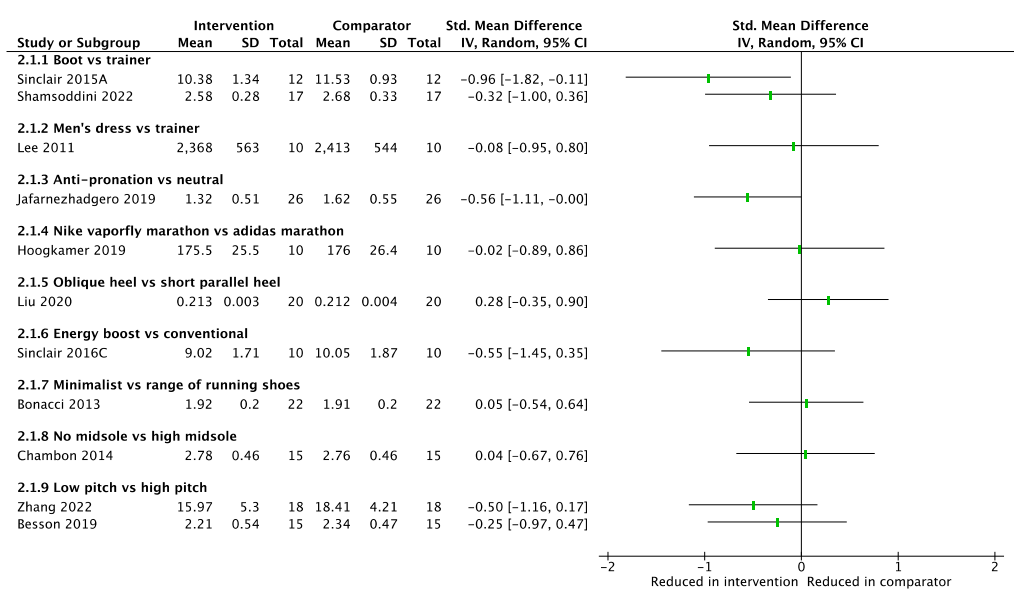
		Age = 29 Mass = 77 Height = 178	ii. iii. ii.	Lateral wedge insole 5° valgus configuration, heel thickness 11mm Semi-custom insole moulded to longitudinal arch, heel thickness 6mm Prefabricated insole heel thickness 6mm	
		Sex: Female Age = 32 Mass = 66 Height = 161			
Tan 2020 ³⁴	Aged 50 to 75 years diagnosed patellofemoral osteoarthritis	n = 21 (7:14) Age = 58 Mass = 27 BMI Height = N/A AKPS = 50	i. iv.	Prefabricated insoles with arch support and 6° varus wedge Flat shoe insert	No insole (Participant's own shoe or control shoe (Mizuno Wave Rider))

Bold: Intervention condition used for meta-analysis; AKPS: Anterior Knee Pain Scale; BMI: Body mass index; M: Male sex; F: Female sex; SD: Standard deviation; N/A: Not available; Healthy: free from pathology that would affect gait; Age reported in years; Mass reported in kilograms; Height reported in centimetres; *: Study ineligible to be pooled

2.0 Forest plots for shoe insole studies not suitable for pooling



3.0 Forest plots for footwear studies not suitable for pooling



Intervention corresponds to the bold footwear in Table 1 and 2; Comparator corresponds to footwear in italics in Table 1

4.0 Deviations from protocol

In the protocol:

“Two reviewers (SAK and PLR) will independently assess the methodological quality of the included studies using the Revised Cochrane Risk of Bias tool for randomised trials (RoB 2)³⁵ or the Cochrane Risk Of Bias In Non-Randomized Studies – of Interventions (ROBINS-I) tool³⁶ for non-randomised trials.”

In the review:

The studies identified in the final review were randomised cross-over trials. We did not identify any non-randomised or randomised controlled trials. As such, we used the Cochrane Risk of Bias 2 (RoB 2) tool for cross-over trials. By using the RoB 2 for cross-over trials, we were able to address two issues that are specific to cross-over study designs: carryover and period effects. If these two issues were not addressed, we risked underestimating bias for each outcome.

In the protocol:

Two reviewers (SAK and PLR) will independently extract relevant data. We will use a structured pre-piloted electronic data collection form. A third reviewer will resolve any discrepancies.

In the review:

One reviewer independently extracted relevant data. The second reviewer independently audited all relevant data for accuracy. Although this deviation may have led to inaccurate data extraction, the third reviewer was still available to resolve any discrepancies thus preventing inaccuracy.

In the protocol:

We plan to perform subgroup analyses on each type of biomechanical foot-based intervention (e.g., footwear, foot orthoses, taping or bracing). In addition, we will investigate the biomechanical foot-based intervention effects on healthy, patellofemoral pain and patellofemoral osteoarthritis populations by subgrouping these three populations.

In the review:

We sub-grouped each primary analysis by diagnosis (e.g., healthy, patellofemoral pain and patellofemoral osteoarthritis) and task (e.g., walking and running). Joint moments, force and pressure are sensitive to changes in gait speed.³⁸ As such, we decided to subgroup each analysis by task to investigate whether a biomechanical foot-based intervention is more or less effective during walking or running.

5.0 Risk of bias summary for included studies

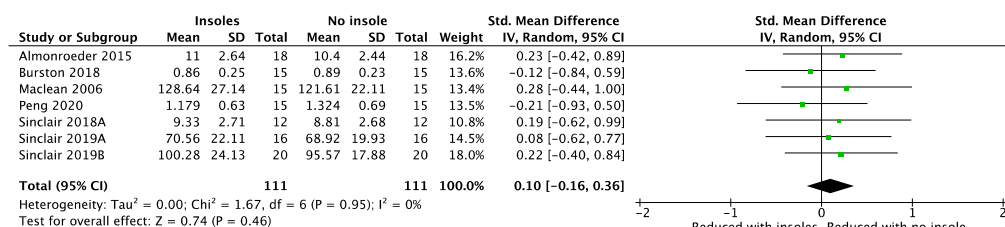
5.1 Figure 1: Traffic Light Plot



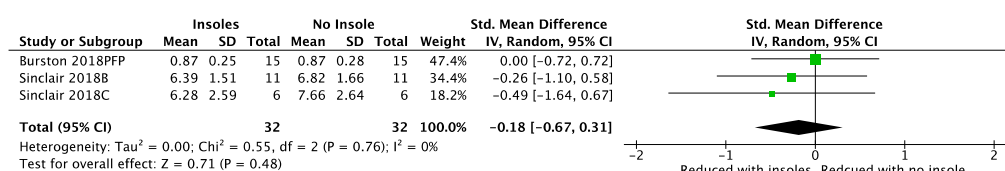
PFP: Patellofemoral pain

6.1 Subgroup analyses by population

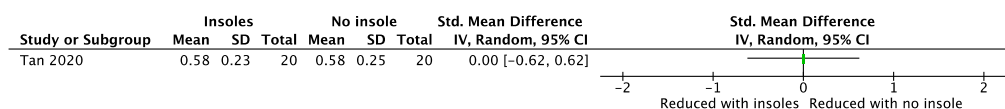
6.1.1 Comparing insoles with medial support to control in healthy people



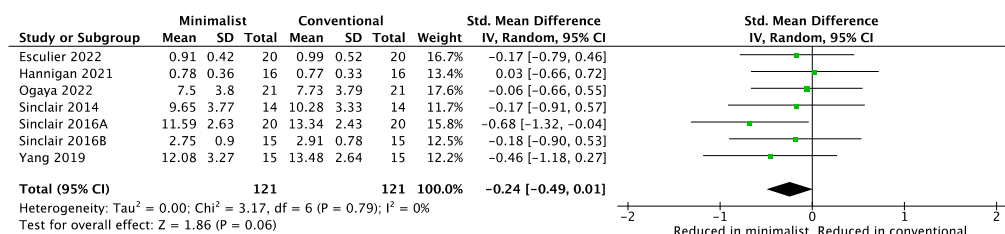
6.1.2 Comparing insoles with medial support to control in people with patellofemoral pain



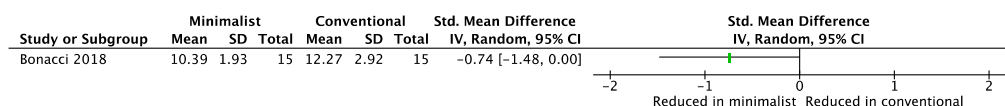
6.1.3 Comparing insoles with medial support to control in people with patellofemoral osteoarthritis



6.1.4 Comparing minimalist footwear with conventional footwear in healthy people

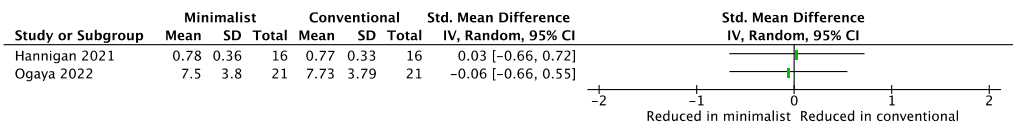


6.1.5 Comparing minimalist footwear with conventional footwear in people with patellofemoral pain

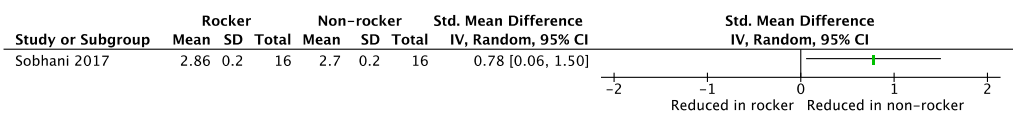


6.2 Comparisons ineligible for meta-analysis sub-grouped by task

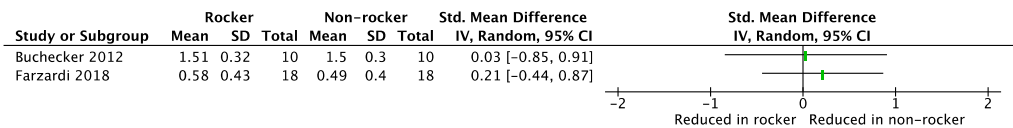
6.2.1 Comparing minimalist footwear with conventional footwear during walking



6.2.1 Comparing rocker soled footwear with control during running



6.2.2 Comparing rocker soled footwear with control during walking



7.0 Search strategies

Medline

1	(patellofemoral or patello-femoral or patella or knee).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
2	(footwear or shoe or wedge or insole or orthotic or orthoses or minimalist or heel or insert or orthosis or taping).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
3	exp Shoes/
4	exp orthotic devices/ or exp athletic tape/ or exp braces/ or exp foot orthoses/
5	2 or 3 or 4
6	(kinetics or load or stress or pressure or moment or torque or biomechanic or reaction force or quadriceps force).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
7	exp Biomechanical Phenomena/
8	6 or 7
9	1 and 5 and 8
10	limit 9 to human

Embase

1	(patellofemoral or patello-femoral or patella or knee).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword heading word, floating subheading word, candidate term word]
2	(footwear or shoe or wedge or insole or orthotic or orthoses or minimalist or heel or insert or orthosis or taping).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword heading word, floating subheading word, candidate term word]
3	exp Shoes/
4	exp orthotic devices/ or exp athletic tape/ or exp braces/ or exp foot orthoses/
5	2 or 3 or 4
6	(kinetics or load or stress or pressure or moment or torque or biomechanic or reaction force or quadriceps force).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword heading word, floating subheading word, candidate term word]
7	exp Biomechanical Phenomena/
8	6 or 7
9	1 and 5 and 8
10	limit 9 to human

Cochrane

(patellofemoral OR patello-femoral OR patella OR knee)
AND
(footwear OR shoe OR wedge OR insole OR orthotic OR orthoses OR minimalist OR heel OR insert OR orthosis OR taping

OR mh Shoes
OR mh "orthotic devices" OR mh "athletic tape" OR mh braces OR mh "foot orthoses"
AND
(kinetics OR load OR stress OR pressure OR moment OR torque OR biomechanic OR "reaction force" OR "quadriceps force"
OR mh "Biomechanical Phenomena")

CINAHL

(patellofemoral OR patello-femoral OR patella OR knee)
(footwear OR shoe OR wedge OR insole OR orthotic OR orthoses OR minimalist OR heel OR insert OR orthosis OR taping)
(MH Shoes+)
(MH "orthotic devices"+) OR (MH "athletic tape"+) OR (MH braces+) OR (MH "foot orthoses"+)
S2 OR S3 OR S4
(kinetics OR load OR stress OR pressure OR moment OR torque OR biomechanic OR "reaction force" OR "quadriceps force")
(MH "Biomechanical Phenomena"+)
S6 OR S7
S1 AND S5 AND S8

SportDiscus

(TX "patellofemoral" OR TX "patello-femoral" OR TX "patella" OR TX "knee")
(TX "footwear" OR TX "shoe" OR TX "wedge" OR TX "insole" OR TX "orthotic" OR TX "orthoses" OR TX "minimalist" OR TX "heel" OR TX "insert" OR TX "orthosis" OR TX "taping")
DE "Shoes"
DE "orthotic devices" OR DE "athletic tape" OR DE "braces" OR DE "foot orthoses"
S2 OR S3 OR S4
(TX "kinetics" OR TX "load" OR TX "stress" OR TX "pressure" OR TX "moment" OR TX "torque" OR TX "biomechanic" OR TX "reaction force" OR TX "quadriceps force")
DE "Biomechanical Phenomena"
S6 OR S7
S1 AND S5 AND S8

8.0 Studies where authors were contacted for data

Author Names	Ref	Date of initial correspondence	Date data received	Data requested from authors
Nigg et al. 2003	³⁹	May 17th 2022	N/A	<i>Data requested:</i> means and standard deviation of knee extension moment. Paper reported mean group changes in graphical format. Author replied, May 18th 2022 that they no longer have access to the data. Paper excluded.
Maclean et al. 2006	²⁵	May 17th 2022	Extracted using Web Plot Digitizer	<i>Data requested:</i> means and standard deviation of peak knee extension moment. Unable to contact authors: data extracted using Web Plot Digitizer.
Besson et al. 2019	¹	June 30th 2022	July 7th 2022	<i>Data requested:</i> means of knee flexion moment
Myers et al. 2006	⁴⁰	June 30th 2022	N/A	<i>Data requested:</i> means and standard deviation of knee sagittal moment. Paper reported differences and means in graphical format. Author replied June 30th 2022 saying they no longer had access to the data. Paper excluded.
Nester et al. 2003	⁴¹	June 30th 2022	N/A	<i>Data requested:</i> means and standard deviation of sagittal knee moment. Author and co-authors unable to be contacted. Data unable to be extracted by Web Plot Digitizer. Paper excluded.
Ogaya et al. 2022	¹³	October 6th 2022	October 7th 2022	<i>Data requested:</i> means and standard deviation of knee extension moment. Paper reported peak in graphical format and values appeared incorrect in the table provided. Author replied on October 6th 2022 saying values in table were an error and sent the correct values.
Hart et al. 2020	⁴²	October 28th 2022	N/A	<i>Data requested:</i> means and standard deviation of knee flexion moment

Ref: Reference; N/A: Not available

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PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	2-3
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	26-59
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	85-128
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	130-135
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	147-168;234-249
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	170-177
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	SFile
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	179-185
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	187-199
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	201-221
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	201-221
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	223-232
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	251-257
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	234-249
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	254-255
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	263-268
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	234-274
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	269-274
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N/A
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	271-272



PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	276-285
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	316
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	SFile
Study characteristics	17	Cite each included study and present its characteristics.	317-319;SFile
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	319-326
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	317-319
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	317-367
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	330-367
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	332-365;SFile
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	SFile
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	N/A
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	330-365
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	380-463
	23b	Discuss any limitations of the evidence included in the review.	465-473
	23c	Discuss any limitations of the review processes used.	475-497
	23d	Discuss implications of the results for practice, policy, and future research.	77-83
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	141-144
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	141-144
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	SFile
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	514-518
Competing interests	26	Declare any competing interests of review authors.	530-531
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	312-314



PRISMA 2020 Checklist

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71. doi: 10.1136/bmj.n71

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