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The Effect of Flat Flexible Versus Stable Supportive Shoes on Knee Osteoarthritis Symptoms

A Randomized Trial

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Background: Experts recommend that persons with knee osteoarthritis wear stable supportive shoes; however, evidence suggests that flat flexible shoes may be more beneficial.

Objective: To compare flat flexible with stable supportive shoes for knee osteoarthritis symptoms.

Design: Participant- and assessor-blinded randomized trial. (Prospectively registered with the Australian New Zealand Clinical Trials Registry [ACTRN12617001098325])

Setting: Community.

Participants: 164 patients with moderate to severe symptomatic radiographic medial knee osteoarthritis.

Intervention: Flat flexible (n = 82) or stable supportive shoes (n = 82), worn for at least 6 hours a day for 6 months.

Measurements: Primary outcomes were changes in walking pain (measured by an 11-point numerical rating scale) and physical function (as assessed by the Western Ontario and McMaster Universities Osteoarthritis Index subscale of 0 to 68 points) at 6 months. Secondary outcomes included additional pain and function measures, physical activity, and quality of life. Other measures included adverse events.

Results: Of 164 participants recruited, 161 (98%) completed 6-month primary outcomes. No evidence was found that flat flexible shoes were superior to stable supportive shoes in primary outcomes. Evidence did show a between-group difference in change in pain favoring stable supportive shoes (mean difference, 1.1 units [95% CI, 0.5 to 1.8 units]; P = 0.001) but not function (mean difference, 2.3 units [CI, −0.9 to 5.5 units]; P = 0.167). Improvements in knee-related quality of life and ipsilateral hip pain favored stable supportive shoes (mean difference, −5.3 units [CI, −10.0 to −0.5 units] and 0.7 units [CI, 0.0 to 1.4 units], respectively). Flat flexible shoes were not superior to stable supportive shoes for any secondary outcome. Fewer participants reported adverse events with stable supportive shoes (n = 12 [15%]) compared with flat flexible shoes (n = 26 [32%]) (risk difference, −0.17 [CI, −0.30 to −0.05]).

Limitation: No "usual shoes" control group and a select patient subgroup, which may limit generalizability.

Conclusion: Flat flexible shoes were not superior to stable supportive shoes. Contrary to our hypothesis, stable supportive shoes improved knee pain on walking more than flat flexible shoes.

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Knee osteoarthritis affects 263 million persons worldwide and is a leading contributor to global disease burden, accounting for more years lived with disability than ischemic heart disease and cancer and other tumors (1). Knee osteoarthritis has no cure, and arthroplasty is reserved for end-stage disease. Pain and physical dysfunction are the main reasons driving patients to seek care from their primary care physician (2). Paracetamol (acetaminophen) and nonsteroidal anti-inflammatory drugs are the most frequently used treatments in primary care to manage osteoarthritis symptoms (3, 4); however, their use is associated with limited, short-term benefits and adverse events (5, 6). Accordingly, knee osteoarthritis clinical guidelines recommend self-management of symptoms, along with exercise and weight control, as core treatment (7–10).

Abnormal knee joint loading is implicated in knee osteoarthritis pathogenesis (11–13). Knee loads are greater in the medial versus lateral tibiofemoral compartment, probably explaining why medial tibiofemoral osteoarthritis is more common (14). Because some shoes increase medial knee loads more than others (15, 16), knee osteoarthritis clinical guidelines recommend "appropriate" footwear (7, 9, 10). However, because of a lack of high-quality randomized controlled trials (RCTs), a systematic review could not reach a conclusion about which footwear is best for persons with knee osteoarthritis (17). International osteoarthritis organizations have called for footwear trials as an important research priority (7, 9, 10), with reinforcement by a U.S. stakeholder panel that identified biomechanical strategies as a high-priority evidence gap (18). Indeed, the 2019 American College of Rheumatology clinical guidelines recognize that "optimal" footwear is probably of considerable importance for persons with knee osteoarthritis but noted that studies have not defined the best type of footwear to improve outcomes (9).

See also:

Summary for Patients

Web-Only
Supplement

Clinical osteoarthritis guidelines advocate footwear with thick, shock-absorbing soles and arch supports, solely on the basis of expert opinion because of the lack of research assessing the effects of these shoes on symptoms (7, 10). Clinicians also recommend these footwear styles, often called "stable supportive" shoes because of their cushioning and supportive features (15), to self-manage knee osteoarthritis symptoms (19). However, shoes with thinner, flatter, and flexible soles may be more beneficial for persons with knee osteoarthritis. Research shows that knee loading is lower when persons with knee osteoarthritis walk in "flat flexible" shoes compared with stable supportive footwear (15, 16, 20). Preliminary evidence suggests that flat flexible shoes may improve osteoarthritis symptoms. A small uncontrolled study reported a 36% reduction in knee pain in patients with medial knee osteoarthritis after they wore flat flexible shoes for 6 months (21). In the only RCT, greater improvements in pain and physical function were reported in participants with knee osteoarthritis who wore flat flexible "Moleca" shoes for 6 months compared with those who wore their own "neutral" tennis shoes (22). Although these results are promising, this trial was limited because it included unblinded participants, a small sample (n = 56) comprising only women, flat flexible footwear not widely available outside Brazil, and an unstandardized control condition that did not reflect clinical guideline recommendations.

Our study aimed to evaluate the effectiveness of flat flexible shoes for reducing knee osteoarthritis symptoms. We hypothesized that flat flexible shoes would lead to greater improvements in knee pain and physical function at 6 months compared with stable supportive shoes.

METHODS

Trial Design

This study was a 2-group pragmatic, comparative effectiveness, superiority RCT and was approved by The Institutional Human Ethics Committee. It was prospectively registered (Australian New Zealand Clinical Trials Registry: ACTRN12617001098325), and the protocol is published (23) and provided in the **Supplement** (available at Annals.org). Participants provided informed consent.

Participants

We recruited community (Melbourne, Australia) participants by advertising in print and social media as well as through our research volunteer database. Eligible participants were aged 50 years and older, had knee pain on most days of the past month, reported knee pain of an average of 4 or greater on an 11-point numerical rating scale (NRS) during walking in the past week, and had tibiofemoral osteophytes and moderate to severe tibiofemoral osteoarthritis (Kellgren–Lawrence grade 3 [moderate] or 4 [severe] [24]). We have shown that patients with moderate to severe knee osteoarthritis are more likely than those with mild disease to benefit from footwear designed to reduce medial knee loading (25). The present study excluded persons who had lateral joint space narrowing greater than or equal to medial, had recent (past 6 months) or planned (next 6 months) knee surgery, or were currently using shoe orthoses or customized shoes. Detailed inclusion and exclusion criteria are provided in the protocol (**Supplement**) (23).

Randomization and Masking

Participants were randomly assigned to the study groups in a 1:1 ratio. The randomization schedule was prepared by a biostatistician with permuted block sizes of 6 to 12 and stratified by radiographic severity (Kellgren–Lawrence grade 3 or 4). Allocation was concealed in password-protected software (REDCap) and revealed by a researcher uninvolved in recruitment or assessment of primary or secondary outcomes. Limited disclosure was used to blind participants, who were also assessors (because outcomes were self-reported). Participants were not told that the purpose of the study was to compare flat flexible with stable supportive shoes. Instead, they were informed only that the trial was comparing the effects of "different shoes" on knee osteoarthritis symptoms. We did not disclose the hypothesis or the specific footwear classes, characteristics, manufacturers, or models. The biostatistician was blinded for primary analyses.

Interventions

We identified a range of commercially available shoes that fulfill biomechanically validated classification criteria for flat flexible and stable supportive shoes (**Supplement Table 1**, available at Annals.org) (15). These criteria distinguish the shoe classes according to heel height and thickness, pitch, arch support and motion control features, sole flexibility, and weight. Next, we surveyed 131 patients with knee osteoarthritis to determine which of the identified shoes (including available colors) were most acceptable and likely to be worn as instructed. We then selected the 3 most popular men's and women's styles for each trial group (**Supplement Table 2**, available at Annals.org):

Flat flexible shoes (intervention): Merrell Bare Access (men's and women's), Vivobarefoot Primus Lite (men's and women's), Vivobarefoot Mata Canvas (men's), Converse Dainty Low (women's), and Lacoste Marice (substituted for Vivobarefoot Mata Canvas in U.S. sizes 8 and 13 from 6 December 2019 due to unavailability).

Stable supportive shoes (comparator): ASICS Kayano (men's and women's), Merrell Jungle Moc (men's), Nike Air Max 90 Ultra (women's), Rockport Edge Hill (men's), and New Balance 624 (women's).

After randomization, a researcher showed participants the shoes available within their footwear group. Participants chose 2 different pairs to maximize external validity and promote adherence (because persons do not typically wear 1 pair of shoes all the time). Shoes were fitted by a researcher and provided to participants at no cost. Participants were instructed to increase their shoe wear by 1 hour per day until they were wearing the shoes as much as possible (≥6 hours per day) for 6 months.

Outcome Measures

Baseline assessment (questionnaire) was completed on paper or electronically at The University of Melbourne.

Final assessment (questionnaire) was completed on paper or electronically at home 6 months after randomization. To minimize missing data, participants were given an A$50 gift voucher for completing both questionnaires.

Primary outcomes were 6-month change in self-reported measures of pain and physical function, as recommended for knee osteoarthritis clinical trials whose aim is to ameliorate symptoms and facilitate function (26). Overall average pain during walking over the previous week was assessed by using an 11-point NRS with terminal descriptors of 0 (no pain) and 10 (worst pain possible), and a minimal clinically important difference (MCID) of 1.8 units (27). Difficulty with physical function was assessed by using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC; Likert version 3.1) function subscale (28), with the total score ranging from 0 (no dysfunction) to 68 (maximum dysfunction), and an MCID of 6 units (29). Primary outcomes were reported and interpreted separately.

Secondary outcomes included the Knee Injury and Osteoarthritis Outcome Score subscales of knee pain, sport and recreation, quality of life, and patellofemoral

Figure. Flow of participants through the trial.

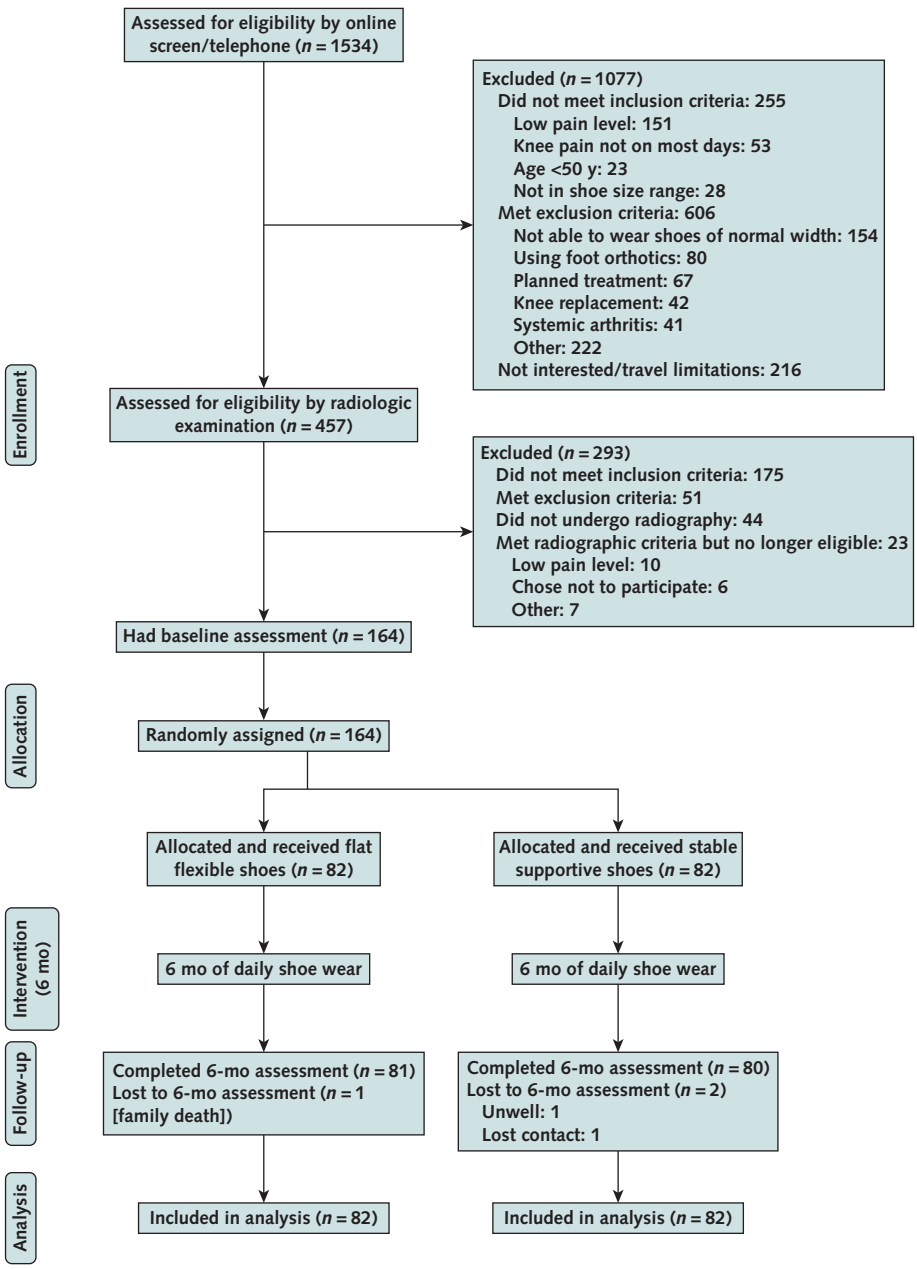

Table 1. Baseline Characteristics of Participants, by Group*

Characteristic	Flat Flexible Shoe Group (*n* = 82)	Stable Supportive Shoe Group (*n* = 82)
Age, *y*	64.7 (7.1)	64.8 (7.5)
Male, *n (%)*	30 (36.6)	33 (40.2)
Symptom duration, *y*	8.6 (8.2)	9.7 (6.7)
Height, *m*	1.7 (0.1)	1.7 (0.1)
Body mass, *kg*	91.6 (19.1)	91.7 (19.0)
Body mass index, kg/m^2	33.5 (6.2)	32.7 (6.2)
Unilateral knee osteoarthritis symptoms, *n (%)*	18 (22.0)	12 (14.6)
Radiographic disease severity, *n (%)*†		
Grade 3 (moderate)	39 (47.6)	39 (47.6)
Grade 4 (severe)	43 (52.4)	43 (52.4)
Foot Posture Index classification, *n (%)*		
Severely supinated	0 (0.0)	0 (0.0)
Supinated	4 (4.9)	1 (1.2)
Normal	39 (47.6)	35 (42.7)
Pronated	27 (32.9)	36 (43.9)
Severely pronated	12 (14.6)	10 (12.2)
Foot Mobility Magnitude, *mm*‡	8.7 (2.8)	8.7 (3.4)
Navicular drop, *mm*‡	6.6 (2.7)	6.4 (3.3)
Currently employed, *n (%)*	44 (53.7)	41 (50.0)
Current drug/supplement use, *n (%)*§	67 (81.7)	66 (80.5)
Analgesics (paracetamol combinations)	55 (67.1)	58 (70.7)
Nonsteroidal anti-inflammatory drugs	31 (37.8)	31 (37.8)
COX-2 inhibitors	9 (11.0)	9 (11.0)
Topical anti-inflammatory agents	44 (53.7)	36 (43.9)
Oral corticosteroids	1 (1.2)	0 (0.0)
Oral opioids	5 (6.1)	3 (3.7)
Arthritis Self-Efficacy Scale‖	5.6 (1.9)	5.5 (1.9)
Co-interventions used in the past 6 mo, *n (%)*		
Land-based exercise	41 (50.0)	40 (48.8)
Heat/cold treatment	38 (46.3)	29 (35.4)
Massage	34 (41.5)	23 (28.0)
Knee braces	22 (26.8)	21 (25.6)
Manual therapy	25 (30.5)	16 (19.5)
Orthotics/arch supports	19 (23.2)	12 (14.6)
Hydrotherapy	16 (19.5)	15 (18.3)
Expectation of treatment, before randomization, *n (%)*		
No change	3 (3.7)	0 (0.0)
Mild improvement	10 (12.2)	10 (12.2)
Moderate improvement	48 (58.5)	46 (56.1)
Large improvement	21 (25.6)	26 (31.7)
Complete recovery	0 (0.0)	0 (0.0)
Classification of participant's own shoes, *n (%)*		
Flat flexible	5 (6.1)	4 (4.9)
Mixed properties	73 (89.0)	72 (87.8)
Stable supportive	4 (4.9)	6 (7.3)

COX-2 = cyclooxygenase-2.
* Reported as mean (SD) unless otherwise stated.
† Based on the Kellgren–Lawrence grading system.
‡ Higher values indicate greater mobility/drop.
§ Defined as at least once per week in the past 6 mo.
‖ Scores range from 1 to 10; higher scores indicate greater self-efficacy.

pain and osteoarthritis. Scores for each subscale range from 0 to 100, with lower scores indicating worse symptoms and function (28). Other secondary outcomes were pain at 7 lower-limb sites (back, hips, knees, and feet and ankles), assessed by 11-point NRSs (0 = no pain to 10 = worst pain possible); health-related quality of life, via the Assessment of Quality of Life instrument (30) (a scale of −0.04 to 1.00, with higher scores indicating better quality of life); and physical activity during the previous week, as measured by the Physical Activity Scale for the Elderly (31) (scores from 0 to >400, with higher scores indicating greater activity). We assessed overall global changes in pain and physical function at 6 months via 7-point Likert scales (terminal descriptors of "much worse" to "much better") (32). Participants indicating that they were "moderately better" or "much better" were classified as "improved," and others as "not improved."

Other baseline measures included age; sex; height; body mass; body mass index; radiographic osteoarthritis severity (Kellgren–Lawrence system) (24); duration of knee osteoarthritis symptoms; employment status; treatment expectations (also measured after randomization in 149 participants), via 5-point ordinal scales (terminal descriptors of "no effect at all" to "complete recovery");

self-efficacy, measured by the Arthritis Self-Efficacy Scale (33); co-interventions, via a custom-developed table (also assessed at 6 months); measures of foot posture and mobility (Foot Posture Index [34], Foot Mobility Magnitude [35], and navicular drop [36]); and characteristics of participants' own, most commonly worn shoes (15).

Adherence was self-reported monthly in log books (shoe wear hours per day for 7 consecutive days), and at 6 months via ratings of overall level of adherence to wearing shoes for 6 hours a day or longer (11-point NRS with terminal descriptors of "shoes not worn at all" and "shoes worn completely as instructed"). Participants indicated whether they stopped wearing either pair of shoes (yes or no), including when and why they stopped. Those who wore the shoes an average of 6 hours a day or longer (summed for each pair) over 6 months were defined as "adherent."

Adverse events (any problem experienced in the study knee or elsewhere in the body because of wearing allocated shoes) were self-reported at 6 months by using a custom-developed table and open-ended questioning. Comfort of each shoe was self-reported at 6 months via an 11-point NRS (terminal descriptors of "extremely uncomfortable" and "extremely comfortable").

Statistical Analysis

We aimed to detect a between-group MCID of 1.8 units for NRS walking pain (27) and 6 units for WOMAC function (29). We assumed between-participant SDs of 2.7 and 11.4, and baseline to 6-month correlations of 0.21 and 0.39, for pain and function, respectively (37). Using analysis of covariance adjusted for baseline score, we needed 46 participants per group to achieve 90% power to detect the MCID in pain and 65 per group for function. We recruited 82 people per group in total (n = 164), allowing for 20% attrition.

Main comparative analyses of the primary outcomes were based on intention to treat. Two patients with missing 6-month follow-up data were excluded from primary analyses. Because fewer than 5% of primary outcomes were missing, multiple imputation was not applied. For continuous outcomes, between-group differences in mean change (baseline minus follow-up) were compared by using linear regression modeling adjusted for baseline values and the stratifying variable (radiographic severity). Improvement based on global change was compared between groups by using log-binomial regression, adjusting for radiographic severity, with results reported as risk ratios and risk differences. The number of participants who had an adverse event was compared between groups by using log-binomial and Poisson regression. These unplanned post hoc analyses were performed because of the large difference in proportions of participants who had adverse events across groups. We also performed unplanned post hoc analyses to compare the proportion of participants in each group who reached the MCID in pain, reported as relative risk and risk differences.

To determine whether effects of shoe class on primary outcomes were moderated by Kellgren–Lawrence grade, Foot Posture Index score, body mass index, or baseline patellofemoral pain and osteoarthritis subscale score, we included appropriate interaction terms between randomly assigned group and moderator variables in regression models for primary outcomes, as well as for each potential effect modifier separately. For each combination of continuous moderator and primary outcome, the *mfpi*

Table 2. Adverse Events and Co-interventions, by Group

Event/Co-intervention	Flat Flexible Shoe Group (n = 82), n (%)	Stable Supportive Shoe Group (n = 82), n (%)
Participants reporting any adverse event	26 (31.7)	12 (14.6)
Knee pain	13 (15.9)	2 (2.4)
Ankle/foot pain	15 (18.3)	9 (11.0)
Shin/calf pain	1 (1.2)	0 (0.0)
Knee swelling	1 (1.2)	0 (0.0)
Pain in other areas	3 (3.7)	0 (0.0)
Fell over in laboratory and hurt back	0 (0.0)	1 (1.2)
Co-intervention use		
Analgesics (paracetamol combinations)	53 (67.9)	52 (65.8)
Nonsteroidal anti-inflammatory drugs	35 (44.9)	29 (36.7)
COX-2 inhibitors	11 (14.1)	14 (17.7)
Topical anti-inflammatory agents	34 (43.6)	27 (34.2)
Oral corticosteroids	2 (2.6)	1 (1.3)
Oral opioids	2 (2.6)	4 (5.1)
Land-based exercise	48 (61.5)	46 (58.2)
Heat/cold treatment	37 (47.4)	26 (32.9)
Massage	28 (35.9)	23 (29.1)
Knee braces	25 (32.1)	21 (26.6)
Manual therapy	22 (28.2)	14 (17.7)
Orthotics/arch supports	11 (14.1)	8 (10.1)
Hydrotherapy	17 (21.8)	14 (17.7)
Arthroscopy	0 (0.0)	1 (1.3)
Total knee replacement	1 (1.3)	3 (3.8)

COX-2 = cyclooxygenase-2.

Table 3. Mean (SD) Scores on Continuous Outcome Measures Across Time, by Group

Outcome Measure	Baseline		6 mo	
	Flat Flexible Shoe Group (*n* = 82)	Stable Supportive Shoe Group (*n* = 82)	Flat Flexible Shoe Group (*n* = 81)*	Stable Supportive Shoe Group (*n* = 80)*
Primary outcomes				
Overall average knee pain while walking (NRS)	6.3 (1.3)	6.1 (1.4)	5.2 (2.3)	4.0 (2.1)
Physical function (WOMAC)	29.9 (10.1)	28.9 (10.5)	25.3 (12.7)	22.4 (12.3)
Secondary outcomes†				
KOOS subscales				
Pain	47.7 (13.3)	50.4 (12.0)	54.6 (16.5)	60.1 (15.3)
Sport and recreation	21.6 (17.2)	24.9 (19.2)	27.8 (22.9)	32.7 (21.8)
Knee-related quality of life	30.9 (16.4)	32.1 (14.7)	34.6 (20.2)	40.7 (17.1)
Patellofemoral pain and osteoarthritis	29.4 (16.3)	30.8 (16.2)	33.8 (20.1)	38.4 (21.8)
Overall average pain (NRS)				
Study knee	6.3 (1.6)	6.2 (1.6)	5.4 (2.4)	4.9 (2.3)
Contralateral knee	3.6 (2.7)	3.2 (2.3)	3.2 (2.7)	2.8 (2.3)
Ipsilateral hip	2.0 (2.3)	1.8 (2.5)	2.4 (2.6)	1.5 (2.3)
Contralateral hip	1.4 (2.2)	1.5 (2.1)	1.5 (2.2)	1.6 (2.2)
Ipsilateral foot/ankle	1.8 (2.6)	1.5 (2.3)	1.6 (2.4)	1.7 (2.5)
Contralateral foot/ankle	1.7 (2.2)	1.9 (2.6)	2.0 (2.4)	1.8 (2.3)
Back	2.9 (2.6)	3.0 (2.6)	2.9 (2.6)	2.6 (2.5)
Quality of life (AQoL-6D)	0.7 (0.1)	0.7 (0.1)	0.7 (0.1)	0.7 (0.2)
PASE	166.2 (72.4)	173.2 (83.4)	171.7 (87.1)	165.7 (79.5)

AQoL-6D = Assessment of Quality of Life 6-domain instrument (−0.04 to 1.0; higher scores indicate better quality of life); KOOS = Knee Injury and Osteoarthritis Outcome Score (0 to 100; lower scores indicate worse pain/symptoms/function/quality of life); NRS = numerical rating scale (0 to 10; higher scores indicate worse pain); PASE = Physical Activity Scale for the Elderly (0 to >400; higher scores indicate greater physical activity); WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index (physical function subscale, 0 to 68; higher scores indicate worse function).

* All 6-month data are missing for 1 participant in the flat flexible group and 2 participants in the stable supportive group.

† Data for all secondary outcomes are available for 78 participants in the flat flexible group (missing for 4) and 79 in the stable supportive group (missing for 3).

command in Stata (StataCorp) (38) was applied. This algorithm fit models with linear terms for the continuous moderator, models with 1 fractional polynomial term for the moderator, and models with 2 fractional polynomial terms for the moderator. The model that minimized the Akaike information criterion was selected (38). We performed post hoc analyses to determine whether foot posture moderated the treatment effect of shoes on comfort, averaged across both chosen shoe pairs, at 6 months. Data were analyzed in Stata (version 15). The a priori statistical analysis plan is provided in the Supplement.

Role of the Funding Source

The National Health and Medical Research Council had no role in study design, conduct, or analysis or in the decision to submit the manuscript for publication.

RESULTS

The Figure summarizes the flow of participants through the study. We enrolled 164 persons from 1534 screened between 22 August 2017 and 26 November 2019. Major reasons for exclusion were mild or no radiographic osteoarthritis or nonmedial osteoarthritis (*n* = 226), lack of interest in participating or inability to attend appointments (*n* = 216), low pain level (*n* = 151), and inability to wear shoes of normal width (*n* = 154). At 6 months, 161 participants (98%) had completed both primary outcomes. Participant characteristics were similar between groups at baseline (Table 1). Treatment expectations were similar across groups before randomization, with expectation shifts more common in the flat flexible shoe group after allocation (Supplement Table 3, available at Annals.org). Most participants typically had been wearing shoes with mixed properties before enrollment.

Participants reported mean shoe wear of 8.2 hours per day (SD, 3.3) with flat flexible shoes and 8.5 hours per day (SD, 2.6) with stable supportive shoes (Supplement Tables 4 and 5, available at Annals.org). Sixty-two persons (76%) assigned to the flat flexible shoe group were adherent over 6 months, compared with 70 participants (85%) in the stable supportive shoe group. More participants reported adverse events with flat flexible shoes (*n* = 26 [32%]) than stable supportive shoes (*n* = 12 [15%]) (Table 2; Supplement Table 6, available at Annals.org). The relative risk for an adverse event with stable supportive shoes compared with flat flexible shoes was 0.46 (95% CI, 0.25 to 0.84), with a risk difference of −0.17 (CI, −0.30 to −0.05) favoring stable supportive shoes. Poisson regression showed that the adverse event rate observed with stable supportive shoes was 0.36 times (CI, 0.19 to 0.70 times) that of flat flexible shoes. Four participants (5%) with flat flexible shoes and 1 participant (1%) with stable supportive shoes stopped wearing their assigned footwear because of foot or knee pain (Supplement Table 7, available at Annals.org). No between-group differences were seen in changes in the use of co-interventions (Supplement Table 8, available at Annals.org).

Table 4. Change Within Groups and Difference in Change Between Groups (Adjusted for Baseline Value of Outcome), for Continuous Outcomes

Outcome Measure	Mean Change Within Groups, Baseline − Month 6 (SD)		Mean Difference in Change Between Groups, Baseline to Month 6 (95% CI)
	Flat Flexible Shoe Group (*n* = 81)*	Stable Supportive Shoe Group (*n* = 80)*	
Primary outcomes			
Overall average knee pain (NRS)†	1.1 (2.3)	2.1 (2.4)	1.1 (0.5 to 1.8)‡
Physical function (WOMAC)†	4.7 (10.7)	6.7 (11.0)	2.3 (−0.9 to 5.5)§
Secondary outcomes‖			
KOOS subscales¶			
Pain	−6.9 (15.4)	−9.7 (15.4)	−4.0 (−8.5 to 0.5)
Sport and recreation	−6.2 (17.8)	−7.5 (22.6)	−2.7 (−8.6 to 3.2)
Knee-related quality of life	−4.2 (16.8)	−9.0 (16.3)	−5.3 (−10.0 to −0.5)
Patellofemoral pain and osteoarthritis	−4.7 (15.7)	−7.2 (18.3)	−3.0 (−8.1 to 2.2)
Overall average pain (NRS)†			
Study knee	0.9 (2.3)	1.2 (2.4)	0.4 (−0.3 to 1.1)
Contralateral knee	0.4 (2.2)	0.4 (2.1)	0.1 (−0.5 to 0.8)
Ipsilateral hip	−0.3 (2.3)	0.2 (2.6)	0.7 (0.0 to 1.4)
Contralateral hip	−0.1 (1.8)	0.0 (2.3)	0.0 (−0.6 to 0.6)
Ipsilateral foot/ankle	0.2 (2.3)	−0.1 (2.4)	−0.2 (−0.8 to 0.5)
Contralateral foot/ankle	−0.3 (2.4)	0.2 (2.4)	0.4 (−0.3 to 1.0)
Back	0.0 (2.5)	0.4 (2.2)	0.3 (−0.3 to 1.0)
Quality of life (AQoL-6D)¶	−0.01 (0.12)	0.00 (0.11)	0.01 (−0.02 to 0.05)
PASE¶	−6.6 (82.2)	5.6 (88.5)	9.0 (−14.6 to 32.6)

AQoL-6D = Assessment of Quality of Life 6-domain instrument (−0.04 to 1.0; higher scores indicate better quality of life); KOOS = Knee Injury and Osteoarthritis Outcome Score (0 to 100; lower scores indicate worse pain/symptoms/function/quality of life); NRS = numerical rating scale (0 to 10; higher scores indicate worse pain); PASE = Physical Activity Scale for the Elderly (0 to >400; higher scores indicate greater physical activity); WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index (physical function subscale, 0 to 68; higher scores indicate worse function).

* All 6-month data are missing for 1 participant in the flat flexible group and 2 participants in the stable supportive group.

† For change within groups, positive changes indicate improvement. For difference in change between groups, positive differences favor stable supportive shoes.

‡ $P = 0.001$.

§ $P = 0.167$.

‖ Data for all secondary outcomes are available for 78 participants in the flat flexible group (missing for 4) and 79 in the stable supportive group (missing for 3).

¶ For change within groups, negative changes indicate improvement. For difference in change between groups, negative differences favor stable supportive shoes.

No evidence was found that flat flexible shoes were superior to stable supportive shoes for either primary outcome (Tables 3 and 4). However, the between-group mean difference in change in pain (1.1 units [CI, 0.5 to 1.8 units]) favored stable supportive shoes, but the mean difference in change in function (2.3 units [CI, −0.9 to 5.5]) did not. More participants wearing stable supportive shoes than flat flexible shoes achieved the MCID in pain (58% vs. 40%, respectively) (Supplement Table 9, available at Annals.org), with a risk difference favoring stable supportive shoes (0.18 [CI, 0.03 to 0.33]).

No evidence was found that flat flexible shoes were superior to stable supportive shoes in any secondary outcome (Table 4). Stable supportive shoe wear resulted in greater improvements over 6 months in knee-related quality of life (−5.3 units [CI, −10.0 to −0.5 units]) and in overall ipsilateral hip pain (0.7 units [CI, 0.0 to 1.4 units]) compared with flat flexible shoe wear (Table 4). Approximately 12% more participants wearing stable supportive shoes reported global improvements in pain, and 11% more reported global improvements in function, compared with those wearing flat flexible shoes (Table 5).

Table 5. Number (Percentage) of Participants Reporting Global Improvement

Improvement	Flat Flexible Shoe Group (*n* = 78), *n* (%)*	Stable Supportive Shoe Group (*n* = 79), *n* (%)*	Relative Risk (95% CI)†	Risk Difference (95% CI)
Pain‡	22 (28.2)	32 (40.5)	1.44 (0.90 to 2.24)	0.12 (−0.02 to 0.27)
Function‡	20 (25.6)	29 (36.7)	1.43 (0.89 to 2.30)	0.11 (−0.03 to 0.25)

* Data are missing for 4 participants in the flat flexible group and 3 in the stable supportive group.

† Relative risks >1 favor stable supportive shoes.

‡ Rated by using 7-point scales with terminal descriptors of much worse to much better, with participants indicating moderately better or much better classified as improved.

However, the difference between relative risks of improvement across groups was not large.

No evidence was found that prespecified variables moderated intervention effects on primary outcomes (**Supplement Tables 10** and **11**, available at Annals.org), or that foot posture influenced intervention effects on comfort (**Supplement Tables 12** and **13**, available at Annals.org).

DISCUSSION

Contrary to our hypothesis, flat flexible shoes were not superior to stable supportive shoes. In fact, stable supportive footwear resulted in greater improvements in walking knee pain (but not function) than flat flexible shoes over 6 months. Although our observed between-group difference in change in walking pain of 1.1 units (CI, 0.5 to 1.8 units) is less than the MCID of 1.8 (27), the CIs include this difference within the plausible range. Furthermore, 58% of participants wearing stable supportive shoes achieved a clinically relevant reduction in walking pain, compared with 40% in the flat flexible shoe group. Within-group changes in both primary outcomes exceeded the MCIDs with stable supportive but not flat flexible shoes. Taken together, these findings suggest that changes in pain observed with stable supportive shoes may be clinically meaningful in many (but not all) persons, particularly given the low-burden, noninvasive nature of the intervention. No evidence was found that either shoe type was superior for secondary knee pain outcomes, possibly because these outcomes were less sensitive than the primary outcomes to changes in weight-bearing pain in the osteoarthritic knee.

Previous research showed that a higher medial knee load is associated with the development of knee pain (39), greater knee osteoarthritis pain severity (11, 12) and physical dysfunction (13), and an increased risk for structural osteoarthritis progression (12, 40, 41). Despite biomechanical evidence showing that flat flexible shoes reduce medial knee load compared with stable supportive shoes (15, 16, 20), our findings show that this does not translate to improved knee osteoarthritis symptoms. This may be because relationships between knee loading and symptoms are not as strong as previously thought (42), or because the small reductions in medial knee load with flat flexible shoes are insufficient to substantively improve pain and function. The slightly lower adherence to flat flexible shoe wear (76% of participants adherent over 6 months vs. 85% wearing stable supportive shoes)—possibly because of more adverse events in the flat flexible shoe group—also may have contributed to our findings.

The mechanism by which stable supportive shoes improved knee pain in our study is unclear. Although we prespecified potential biomechanical moderators of treatment effects (23) (on the basis of the evidence that flat flexible shoes reduce knee joint loads), we did not evaluate mediators. Future research should investigate potential mechanisms by which stable supportive shoes improve knee pain, which would allow footwear manufacturers to incorporate design features that optimize symptom reductions.

Our findings differ from those of the only other RCT investigating flat flexible shoes for knee osteoarthritis (22). That study found greater improvements in WOMAC pain in women randomly assigned to wear flat flexible Moleca shoes for 6 months, compared with participants wearing their own neutral tennis shoes. However, between-group mean differences in pain were not reported, making those findings difficult to compare with ours. Furthermore, participants were unblinded, which may have led to overestimation of treatment benefits on the subjective primary outcome (43). Two other RCTs evaluated footwear inherently different from that of the present study. Our other trial evaluated specially designed "unloading" walking shoes (with soles stiffer laterally than medially and with a mild lateral wedge) and showed no differences in pain or function compared with conventional walking shoes (37). Another RCT evaluated complex "biomechanical" footwear with individually calibrated convex sole pods designed to reduce knee joint loads. It showed improvements in pain at 24 weeks compared with control footwear (nonconvex, unadjustable sole pods) (44), which the authors noted were of uncertain clinical importance.

Our study has several strengths, including its robust RCT design with blinded participants (also the assessors), which is rarely achieved in footwear trials. Our sample of participants with moderate to severe radiographic knee osteoarthritis is also a strength, given that they are the patient subgroup most likely to benefit from unloading footwear (25). In fact, international clinical osteoarthritis guidelines have called for research in subgroups most likely to benefit from biomechanical interventions, such as footwear (7). Our pragmatic approach used simple criteria (15) to classify shoes as flat flexible or stable supportive, allowing our findings to be generalized to other shoes that fulfill the respective criteria. Because most participants usually wore shoes with mixed properties, these criteria may also be used by clinicians and patients when recommending or purchasing shoes. We offered a range of footwear options and allowed participants to choose the 2 styles they liked best to maximize adherence. The success of this approach is confirmed by excellent adherence to the intervention, and by 98% of the participants completing primary outcomes at 6 months.

Our study has limitations. We did not include a "usual shoes" control group; thus, how the footwear effects observed compare with participants' regular footwear is unclear. We recruited English-speaking community volunteers; thus, our findings may not be generalizable to persons seeking tertiary care or those from culturally and linguistically diverse backgrounds. We also tested shoes in isolation to evaluate their unique effects on symptoms, although in practice, footwear is used in combination with other interventions. We excluded a large number of persons (to ensure that we recruited the patient subgroup most likely to benefit from footwear interventions), which may limit the generalizability of our findings. Of note, our findings cannot be generalized to persons with mild knee osteoarthritis; however, it is unlikely that our findings would differ in this subgroup, because our earlier research

showed no relationship between knee pain and joint loads in these persons (42).

In conclusion, we did not find evidence that flat flexible shoes were superior to stable supportive shoes in persons with moderate to severe knee osteoarthritis. Contrary to our hypothesis, stable supportive shoes improved knee pain on walking more than flat flexible shoes. To our knowledge, our study provides the first RCT evidence to suggest that stable supportive shoes may be a useful self-management strategy in this subgroup of patients with knee osteoarthritis, supporting clinical practice guideline recommendations that, to date, have been based solely on expert opinion.

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Data Sharing Statement: The following data will be made available with publication: deidentified participant data and data dictionary (contact Rana Hinman; e-mail, ranash@unimelb.edu.au). The following supporting documents will be made available with publication: statistical/analytic code (contact Rana Hinman; e-mail, ranash@unimelb.edu.au). These data will be made available to researchers whose proposed use of the data has been approved by the corresponding author, with a signed data access agreement.

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