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Flat flexible school shoes for adolescents with patellofemoral pain: a randomised, assessor-blinded, parallel-group feasibility trial

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ABSTRACT

Objectives To determine the feasibility of conducting a large-scale randomised controlled trial on the efficacy of flat, flexible school footwear versus traditional school footwear in adolescents (aged 12–18 years) with patellofemoral pain (PFP).

Methods Adolescents with PFP were recruited for this study. Participants were randomised to wear either a (1) flat, flexible school shoe or (2) a traditional school shoe. Participants wore the shoes as per school requirements for 12 weeks. Feasibility was assessed by (1) adherence to allocated shoe wear of ≥75% of total weekly school shoe wear time (recorded through weekly log sheets), (2) a recruitment rate of one participant per fortnight and (3) a dropout rate of ≤20%. Descriptive statistics were used for feasibility outcomes.

Results 24 adolescents (15 men, 9 women, mean (SD) age 14.3 (1.7) years) participated in this study. Two participants (8%) were lost to follow-up. The recruitment rate was 1.7 participants per fortnight. 11 of 12 participants (91%) in the flat flexible shoe group and 9 of 10 participants (90%) in the traditional shoe group met the minimum adherence for shoe wear. Mean weekly shoe wear was 20 (7.6) and 21 (4.5) hours per week in the flat, flexible, and traditional shoe groups, respectively.

Conclusion Our results indicate that progression to a full-scale randomised controlled trial is feasible based on the current protocol. A full-scale randomised controlled trial powered to detect estimates of treatment efficacy using flat, flexible school shoes versus traditional school shoes is warranted and will guide evidence-based management of adolescent PFP.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Patellofemoral pain is common in adolescence, but management options for this cohort are limited. Flat, flexible shoes can lower patellofemoral joint loads, a proposed contributor to patellofemoral pain.

WHAT THIS STUDY ADDS

⇒ A flat, flexible school shoe is a feasible option for adolescents who experience patellofemoral pain. The high adherence observed supports investigating a school footwear intervention for adolescents with patellofemoral pain.

HOW MIGHT THIS STUDY AFFECT RESEARCH, PRACTICE OR POLICY

⇒ A full-scale randomised controlled trial of flat, flexible school shoes versus traditional ones is warranted and will guide evidence-based management of adolescent patellofemoral pain.

INTRODUCTION

One in four adolescents experience knee pain, with patellofemoral pain (PFP) the most prevalent diagnosis.[1] Knee pain in adolescence is associated with significant health-related consequences, with PFP believed to carry the worst prognosis when compared with other diagnoses of knee pain.[1–3] Forty per cent of adolescents with PFP continue to report pain and dysfunction more than 6 years after their initial presentation.[3 4] PFP in adolescence leads to changes in long-term health-related behaviour and lifestyle choices.[2 4] There are limited evidence-based treatment options for adolescent PFP. Current management of adolescent PFP is focused on exercise therapy, load management, foot orthoses and education.[5] The efficacy of these interventions is low in an adolescent cohort.[6 7]

Footwear could be an intervention option for adolescents with PFP as footwear is considered a low burden, easily implemented treatment, which allows self-management of symptoms.[8 9] School footwear guidelines for adolescents in Australia require students to wear leather shoes with a closed-toe box and raised heel.[10] Raised heels, such as that in athletic and dress footwear, have been shown to increase patellofemoral joint (PFJ) loads during walking and running; activities known to aggravate PFP.[11 12] Elevated PFJ loads are a proposed contributor to the development of PFP.[13] Flat, flexible footwear effectively lowers PFJ loads in adults with PFP,[12 14] but

their clinical efficacy has not been established. A school footwear intervention may be appropriate for adolescents with PFP as they spend up to 8 hours daily in their school shoes,[10] while participating in bouts of moderate to vigorous physical activity.[15] An estimate of project feasibility and procedures is required before conducting any large-scale randomised controlled trial (RCT).[16]

The primary objective of this study was to establish the feasibility of conducting a large-scale RCT on the efficacy of flat, flexible school shoes in adolescents with PFP. The secondary outcome was to describe changes in knee pain and function using a flat, flexible school shoe compared with a traditional school shoe in adolescents with PFP.

METHODS

This study was a 12-week, assessor-blinded, randomised feasibility trial with two parallel groups of adolescents with PFP. The research was developed and is reported according to the Standard Protocol Items: Recommendations for Interventional Trials 2013 statement[17] and the Consolidated Standard of Reporting Trials 2010 guidelines for randomised pilot and feasibility trials.[18] The published protocol for this feasibility trial provides a detailed account of the methodology.[19]

The trial was prospectively registered on the Australian and New Zealand Clinical Trials Registry (ACTRN12621001525875, date registered: 9 November 2021). Written informed consent was obtained from all participants and their parents/guardians (for those under the age of 18 years) prior to participation.

Patient and public involvement

Patient perspectives from a previous feasibility trial of adolescent PFP informed this study's online data collection methods.[20] The public was otherwise not involved in the research's design, conduct, reporting, or dissemination plans.

Participants

Adolescent volunteers were recruited from Geelong and Melbourne in Australia. The inclusion criteria were (1) aged between 12 and 18 years, (2) have anterior knee pain from a non-traumatic onset of at least 6-weeks duration, (3) have knee pain ≥3/10 on a numeric rating scale and (4) have knee pain which was aggravated by activities such as squatting, stair ascent or descent, prolonged sitting or running. Adolescents were excluded if they (1) had pain at sites other than the anterior knee, (2) had a history of hip, knee or spine surgery or other suspected knee joint pathology, (3) had planned lower limb surgery, (4) had a neurological condition or systemic arthritis, (5) were currently wearing flat flexible footwear for school and/or (6) had any condition that prevented them from wearing flat flexible footwear.

Participants were screened for inclusion via telephone and/or email and underwent a physical screening to confirm the diagnosis of PFP. All screening procedures were performed by the primary investigator (NM). Participants' baseline data were obtained at the university 3D Gait Laboratory after inclusion. Participants were then randomly allocated to receive either (1) a flat, flexible school shoe or (2) a traditional school shoe to be worn for the 12-week intervention period. Randomisation procedures were performed via fixed concealed allocation using sequentially numbered opaque-sealed envelopes. The randomisation sequence was computer generated with permuted blocks of four participants. A research assistant not involved in outcome measurement and data analysis allocated the footwear. Assessors responsible for measuring and analysing outcomes were blinded to participant allocation. Limited disclosure of the differences between shoes and the study's hypotheses was used to blind participants, consistent with other RCTs using footwear interventions.[8]

Sample size

The sample size was calculated based on the primary outcome of shoe wear adherence. A minimum of 23 participants was required to observe the feasibility outcome of adherence ≥75% allocated shoe wear (alpha <0.05, β 0.2).[8 21 22] Adherence to allocated shoe wear of ≤50% (ie, two school days per week, excluding a sporting day) indicated that progression to a large-scale RCT was not feasible. Adherence to allocated shoe wear of >50% to <75% indicated progression to a large-scale RCT was potentially feasible with trial modifications. To achieve equal participant numbers in both groups, we recruited 24 participants with PFP.

Interventions

Flat, flexible school shoe

Participants randomised to the flat, flexible school shoes received either the Vivobarefoot Primus Lite and/or the Vivobarefoot RA II (Vivobarefoot, Freiburg, Germany). Both the Primus Lite and the RA II are lightweight, have zero heel-toe offset, a mass of 180 g and no stability or motion control features. The Primus Lite and the RA II score 23/25 on the minimalist shoe index.[23]

Traditional school shoe

Participants randomised to the traditional school shoe received a pair of Clarks Daytona (Clarks, Street, England). The Clarks Daytona has a stiff midsole and heel counter, a 12 mm heel-toe offset, and a mass of 350 g. The Clarks Daytona scores 2/25 on the minimalist shoe index.[23]

Outcome assessment

The primary outcome was the feasibility of conducting a full-scale RCT in adolescents with PFP. Feasibility was assessed by (1) adherence to allocated shoe wear of ≥75% of their total weekly school shoe wear time, (2) a recruitment rate of one participant per fortnight and (3) a dropout rate of ≤20%.

Throughout the study, participants were asked to keep a weekly log of the type of shoe worn each day, hours spent wearing that shoe, any adverse events associated with the

allocated school shoe, use of cointerventions (eg, pain medication, other footwear, taping) and any comments. Participants completed this weekly via self-reported questionnaires distributed via Qualtrics (Qualtrics, Provo, USA). Participant's beliefs on the logic and credibility of the intervention were evaluated using the Credibility and Expectancy Questionnaire,[24] collected at baseline and 1 week after participants had received their allocated shoe.

Secondary self-reported outcome measures were collected at baseline, 6 weeks and 12 weeks via Qualtrics. Further detail of each outcome measure are provided in the published protocol.[19] In brief, secondary outcome measures included: (1) usual and worst pain severity over the past week using an 11-point numeric rating scale (minimal clinically important difference (MCID) =1.2 points)[25 26]; (2) all subscales of the Knee Injury and Osteoarthritis Outcome Score Child (KOOS-Child) (MCID=14.6–22.6 points)[27]; (3) Knee Injury and Osteoarthritis Outcome Score Patellofemoral (KOOS-PF) (MCID=16.4 points)[28]; (4) Anterior Knee Pain Scale (AKPS) (MCID=10 points)[26 29]; (5) Youth Quality of Life Short Form[30] and (6) Global Rating of Change.[31]

Protocol deviations

There was one change from the published protocol. Participants reported pain on an 11-point numerical scale rather than a 100 mm visual analogue scale. A numerical scale was considered more appropriate for online data collection.

Statistical analyses

Statistical analyses were performed by a blinded assessor (JB) using SPSS V.28.0 (SPSS, Chicago, USA). Baseline data were assessed for normality using q–q plots and Shapiro-Wilk tests and presented as mean and SD for normally distributed data or median and IQR for not normally distributed data. Feasibility outcomes were assessed from logbook data and participant recruitment and were presented using descriptive statistics. Secondary outcome measures are described with means and SD for continuous data and counts and percentages for categorical data.

RESULTS

Participants

Between March 2022 and January 2023, 409 volunteers responded to advertisements. Participant recruitment ceased once an *a priori* sample size was obtained. Due to the school calendar year, recruitment was paused from September 2022 to January 2023 to allow for the holiday period. We assessed 112 participants through phone or online screening and 52 were physically screened for confirmation of PFP (27%). Following screening, 24 participants were eligible for the study. Participant flow through the study is outlined in figure 1.

Participant demographics are outlined in table 1. There were imbalances in groups for sex, duration of symptoms and the minimalist shoe rating of current footwear worn to school.

Feasibility outcomes

Adherence

All participants allocated to the flat, flexible school shoe (100%), and 9 of 10 (90%) participants in the traditional school shoe returned ≥11 log sheets (table 2). Participants in both groups wore their allocated shoes for an average of 3 (0.8) days per week. When participants did not wear their school shoes, athletic footwear was worn by all participants for physical education studies.

Recruitment

We successfully enrolled 24 participants in 7 months. The recruitment rate was 1.7 participants per fortnight.

Dropout rate

Two participants did not complete the follow-up assessment at 12 weeks (8%). Both participants were allocated to the traditional school shoe group and were lost to contact.

Participant expectations and credibility of treatment

There were no differences between groups for credibility (mean difference (MD) 1.1 (95% CI −3.5 to 5.7)) or expectancy (MD 3.4 (−0.5 to 7.3)) at baseline, and at week 1 for credibility (MD 0.1 (−5.4 to 5.67)) and expectancy (MD −0.26 (−5.58 to 5.04)).

Secondary outcomes

Clinical outcomes

Table 3 outlines patient-reported outcome measures. At 12 weeks, the mean improvement in worst pain was 1.8 points from baseline in the flat, flexible shoe group and 0.7 points in the traditional shoe group. The difference between groups at 12 weeks was 1.7 points on the numeric rating scale for worst pain. Adolescents allocated to the flat, flexible school shoe had an average 15.7-point increase in KOOS-PF scores, compared with 13 points for those allocated to the traditional shoe. Changes in the AKPS were similar between groups (~7 points).

At 12 weeks, 33% of those allocated to the flat, flexible school shoe reported recovery (ie, completely or strongly recovered) on the global rating of change scale, compared with 20% of participants allocated to the traditional school shoe (figure 2). No participants from either group reported being 'much worse' or 'worse than ever'.

Adverse events

Five participants allocated to the flat, flexible school shoe reported foot pain, and one reported toe pain. In week 1, 66% of adverse events were reported and resolved within 2 weeks. Two participants allocated to the traditional school shoe experienced blisters, and two reported foot pain. Seventy-five per cent of adverse events were reported in week 1 and resolved within 3 weeks. All adverse events for both groups were reported through weekly logbooks,

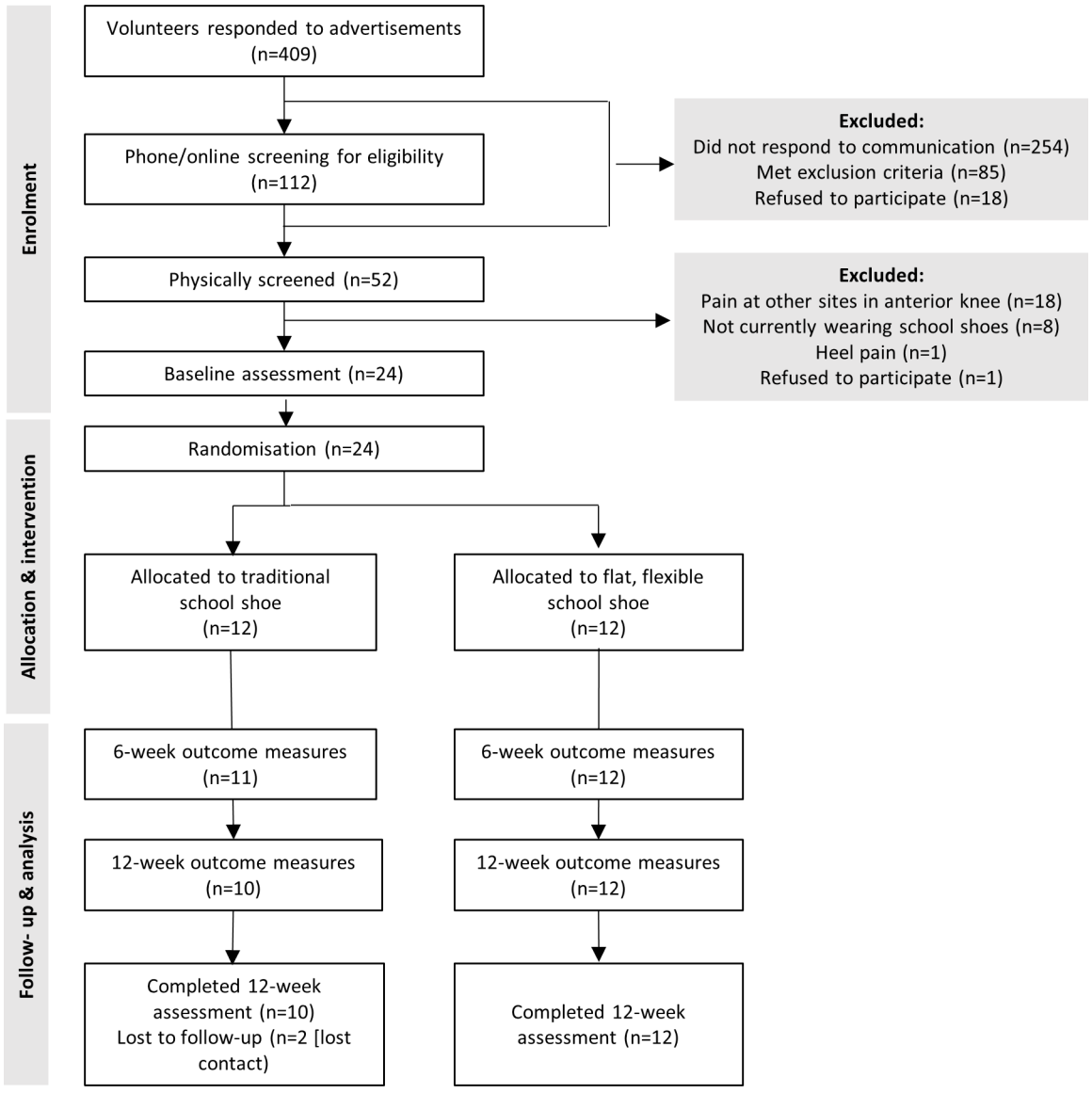

Figure 1 Participant flow through the study.

and participants did not contact the primary investigator directly, nor were any intervention adjustments required.

Use of co-interventions

Five and four participants allocated to the flat, flexible and traditional school shoe groups, respectively, used paracetamol or ibuprofen once throughout the study period. Two participants allocated to the traditional school shoe used knee taping, and one participant used a knee brace.

DISCUSSION

Our results indicate that progression to a full-scale RCT investigating the efficacy of flat, flexible school shoes versus traditional school shoes for treating adolescent PFP is feasible. Our recruitment rate exceeded our *a priori* calculation for feasibility. All participants were recruited from social media advertising, a recommended strategy from a previous trial in adolescents with PFP.[21] Most participants were excluded during physical screening due to other diagnoses of knee pain, comparable to previous trials in adolescent PFP.[6 21] Many participants were excluded during telephone and online screening due to not responding to communication. Before conducting future RCTs, efforts to understand why participants do not respond to communication could be a strategy to enhance the recruitment rate. It took 7 months to recruit 24 participants, suggesting that the recruitment strategy is effective for future trials involving adolescents with PFP.

Adherence to the intervention was assessed through logbook completion and footwear wear time. Adherence to the prespecified shoe wear criteria met feasibility requirements for more than 90% of participants in both groups. Shoe wear time was similar between groups and consistent with other trials investigating flat, flexible footwear in those with knee osteoarthritis.[8 32] Participants allocated to the flat, flexible shoe wore the shoe for 6.7

Table 1 Participant characteristics at baseline

Characteristics	Flat, flexible school shoe (n=12)	Traditional school shoe (n=12)	Total (n=24)
Age, years	14.3 (1.7)	14.4 (1.8)	14.4 (1.7)
Height, cm	171.4 (10.2)	166.0 (8.2)	168.7 (9.5)
Body mass, kg	68.1 (15.3)	64.2 (8.0)	65.6 (12.1)
Body mass index, kg/m^2	23 (4.2)	23.3 (2.2)	23.2 (3.2)
Sex, male (%)	11 (92)	4 (33)	15 (63)
Bilateral PFP, n (%)	8 (67)	10 (83.3)	18 (75)
Duration of symptoms in months, median (IQR)	15 (4-24)	39 (24-54)	24 (9-39)
Sports participation, yes (%)	11 (92)	9 (75)	20 (83)
Physical activity participation, days/week	4 (2.2)	3 (2.1)	4 (2.3)
Worst pain*	6.1 (1.4)	6.7 (1.9)	6.4 (1.7)
Average pain*	3.4 (1.4)	3.7 (1.9)	3.5 (1.6)
Classification of current school footwear†	4.8 (3.0)	7.3 (3.5)	6.0 (3.4)

Values are mean (SD) unless otherwise indicated.
*Worst & average pain measured on an 11-point numeric rating scale with 0 indicating no pain and 10 indicating worse pain imaginable over the past week.
†Classification of current school footwear performed using the minimalist index (scored from 0 to 25 with lower scores indicating greater minimalism and flexibility).
PFP, patellofemoral pain.

hours per day and 7 hours per day in the traditional school shoe. The only other study investigating foot-based interventions in adolescents with PFP reported foot orthoses or flat insoles wear time of 4.5 hours per day.[21] The high adherence rates and comparable wear times to other footwear studies indicate that a school footwear intervention is feasible for adolescents with PFP.

Table 2 Outcome measures gathered from participant logbook data are presented as mean (SD) unless otherwise indicated

Outcome	Flat, flexible school shoe (n=12)	Traditional school shoe (n=12)
Adherence ≥75% of shoe wear time, n (%)	11 (91)	9 (90)
Hours worn per week	20.0 (7.6)	20.9 (4.5)
Days worn per week	2.8 (0.8)	3.2 (0.8)
Logbook completion, n (%)	12 (100)	9 (90)
Dropout rate, n (%)	0 (0)	2 (16.7)
Adverse events reported, n (%)	6 (50)	4 (33)
Baseline credibility/27*	19.9 (2.2)	18.4 (1.8)
Baseline expectancy/27*	21.2 (1.9)	17.3 (1.7)
Week 1 credibility/27*	15.8 (2.7)	15.3 (1.9)
Week 1 expectancy/27*	13.6 (2.6)	14.1 (1.9)

*Credibility and expectancy of treatment at baseline and 1 week after randomisation. Higher scores indicate greater credibility and expectancy of the intervention.

Minor adverse events were common and consistent with previous studies utilising flat, flexible footwear.[8] In an RCT of 164 adults with knee osteoarthritis, 32% of participants allocated to a flat, flexible shoe reported an adverse event, compared with only 15% of those wearing a traditional stability shoe. In our study, more adverse events were reported in the flat, flexible school shoe group (50% of participants) than in the traditional school shoe group (33%). Several reasons may contribute to this. Almost all participants previously wore school footwear with low flexibility and high cushioning. The lack of cushioning in the flat, flexible shoe used in our study may have contributed to the ankle and foot pain reported by participants. Flat, flexible footwear has also increased the demand for calf musculature, possibly contributing to calf and foot pain.[33 34] Prior studies indicate that most adverse events observed with flat, flexible footwear occur when transitioning from a traditional shoe.[35] Almost all adverse events reported by our participants resolved within 2 weeks of wearing the shoe, suggesting that they are transient and likely to resolve quickly. The two participants lost to follow-up in this study received the traditional shoe, demonstrating no attrition with the flat, flexible footwear intervention. Longer term RCTs investigating flat, flexible footwear in older adults with knee osteoarthritis demonstrate no long-term adverse effects associated with their use.[8 32] Flat, flexible school footwear appears to be a well-tolerated intervention for a PFP cohort.

Table 3 Secondary outcome measures at baseline, 6 weeks and 12 weeks

	Flat, flexible school shoe			Traditional school shoe		
	Baseline	6 weeks*	12 weeks†	Baseline	6 weeks‡	12 weeks§
Worst pain¶	6.1 (1.4)	4.8 (1.9)	4.3 (1.8)	6.7 (1.9)	5.2 (2.3)	6.0 (2.1)
Usual pain¶	3.4 (1.4)	3.2 (1.4)	2.7 (2.3)	3.7 (1.9)	3.4 (1.9)	3.3 (1.3)
KOOS-Child**						
KOOS-Pain	63.5 (11.7)	55.8 (9.8)	60.3 (13.4)	49.3 (15.1)	56.9 (10.7)	52.6 (10.4)
KOOS-Symptoms	60.8 (20.3)	71.5 (14.3)	77.1 (17.4)	47.4 (8.8)	67.2 (17.6)	65.6 (15.5)
KOOS-ADL's	77.4 (9.2)	83.9 (16.7)	82.9 (16.7)	69.2 (17.4)	75.7 (18.4)	78.4 (13.0)
KOOS-Sport	55.0 (10.4)	61.8 (18.4)	68.4 (19.1)	47.5 (19.5)	61.5 (24.9)	63.6 (18.0)
KOOS-QOL	59.5 (15.3)	62.6 (17.0)	71.3 (17.9)	51.3 (13.7)	61.6 (14.8)	60.1 (13.4)
KOOS-PF††	54.5 (11.8)	65.2 (21.5)	70.2 (16.1)	47.2 (16.8)	61.6 (21.2)	60.2 (14.9)
AKPS‡‡	74.0 (8.6)	77.5 (12.4)	81.7 (11.5)	64.4 (14.3)	75.9 (12.3)	71.6 (11.9)
YQOL-SF§§	82.6 (14.9)	78.4 (25.4)	86.3 (14.5)	72.5 (18.9)	66.2 (22.6)	68.3 (21.1)

Values are mean (SD) unless otherwise indicated.
*n=12,
†n=12.
‡n=11.
§n=10.
¶Pain measured on 11-point numerical rating scale; 0=no pain, 10=worst pain imaginable.
**Knee injury and osteoarthritis outcome score—child version; 0–100 points with 0 indicating extreme knee problems and 100 indicating no knee problems.
††Knee injury and osteoarthritis outcome score—patellofemoral subscale; 0–100 points with 0 indicating extreme knee problems and 100 indicating no knee problems.
‡‡Anterior knee pain scale; 0–100 points; 0–100 with lower scores indicating greater knee pain and functional limitations.
§§Youth quality of life—short form; 0–100 points; 0–100 where higher scores indicate a better self-reported quality of life.
AKPS, Anterior Knee Pain Scale; KOOS, Knee Injury and Osteoarthritis Outcome Score; KOOS-ADL's, Knee Injury and Osteoarthritis Outcome Score- Activities of daily living; KOOS-PF, KOOS-Patellofemoral; KOOS-QOL, Knee Injury and Osteoarthritis Outcome Score - Quality of Life; YQOL-SF, Youth Quality of Life Short Form.

The improvement in worst pain over the past week was greater in those allocated to the flat, flexible shoe (1.8-point reduction) than those in the traditional school shoe (0.7-point reduction). The within-group improvement in the worst pain in those wearing the flat, flexible school shoe achieved the MCID as well as the between-group difference at 12 weeks (1.7 points).[25] The change in pain observed may result from reduced PFJ loading while wearing the flat, flexible shoe,[13] though this is uncertain. At baseline, those allocated to the traditional school shoe reported lower scores on the AKPS and the pain subscale of the KOOS-Child, indicating higher levels of knee pain

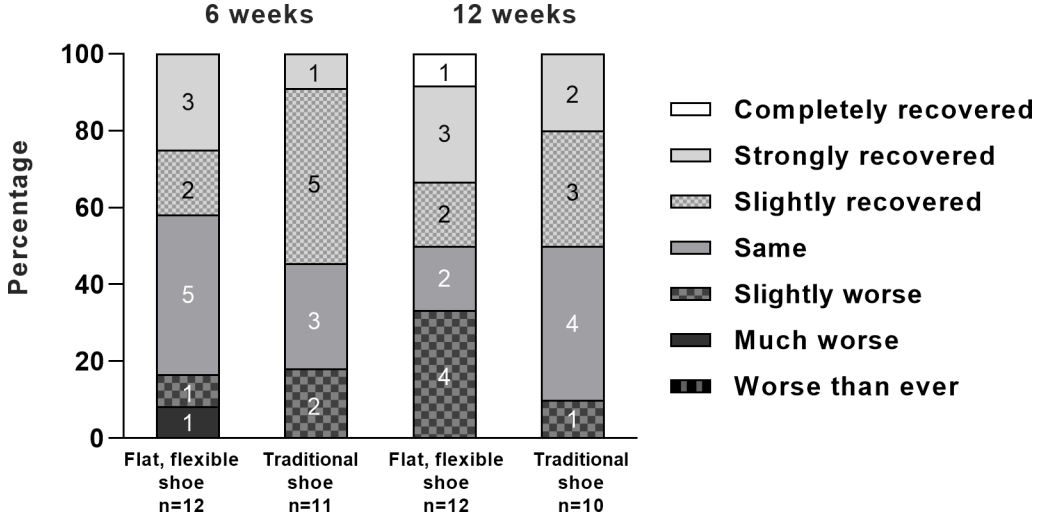

Figure 2 Percentage and number of participants' rating perceived global rating of change at 6 weeks and at trial conclusion (12 weeks).

and disability when compared with those allocated to the flat, flexible school shoe.[27] Those allocated to the traditional school shoe also reported a lower quality of life and longer duration of symptoms when compared with those allocated to the flat, flexible school shoe. As this was a feasibility trial with a small sample size, the differences between groups arose by chance during the randomisation process.

Strengths of this study include the blinding of assessors responsible for outcome assessment and the blinding of participants to the differences between the shoes. Our recruitment rate exceeded the *a priori* calculation for feasibility, and willingness to participate in the study was high. There were no differences between groups for credibility and treatment expectancy at baseline or 1 week after receiving their allocated shoe. This suggests that the traditional school shoe is an appropriate control for a trial investigating flat, flexible school footwear in adolescents with PFP. Only two participants (8%) were lost to follow-up, which was much less than the 20% dropout rate required for feasibility.

LIMITATIONS

Our feasibility trial showed that sex did not balance out on randomisation, and there was an imbalance in the duration of symptoms at baseline. Ninety-three per cent of those allocated to the flat, flexible shoe were male. Longer pain duration, female sex and a lower self-reported quality of life are most associated with a poor prognosis of adolescent knee pain after 5 years and this could have influenced the results of our clinical outcome measures.[36 37] Future large-scale clinical trials could consider stratifying by sex and use pain duration as a covariate in statistical analysis, which should mitigate some of the between-group differences observed in this study. We chose to use a standardised traditional school shoe as the comparator in this study to ensure outcomes were not confounded by variation in structural support or integrity associated with using "usual" footwear. We also did not intervene with participants' regular athletic footwear. All participants in this study wore an athletic shoe with an elevated heel for physical education at school. The effect of switching between these types of footwear on secondary outcome measures reported in this study is unclear.

Clinical implications

A large-scale RCT evaluating the efficacy of flat, flexible school shoes, compared with a traditional school shoe, for adolescents with PFP is feasible based on the results of this trial. The protocol used in the current study suggests that adherence to the intervention and recruitment strategies are effective in a cohort of adolescents with PFP. A full-scale RCT powered to detect treatment efficacy estimates using flat, flexible school shoes versus traditional school shoes will help guide evidence-based management of adolescent PFP.

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Contributors NM and JB were responsible for project conceptualisation. NM was responsible for all data collected and wrote the manuscript (review and editing). AF, DT and NS all provided critical revision of the manuscript. BV assisted with project conceptualisation and revision. JB analysed data and assisted with writing and revision of the manuscript and was the author responsible for the overall content.

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Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by Deakin University Human Ethics Committee (2021-135). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Access to the data will be subject to approvals by the Principal Investigator with a requirement to sign a data access agreement.

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