

# Protocol for a randomised, assessor-blinded, parallel group feasibility trial of flat, flexible school shoes for adolescents with patellofemoral pain

Natalie Mazzella (✉ [nmazzella@deakin.edu.au](mailto:nmazzella@deakin.edu.au))

Deakin University Centre for Sport Research <https://orcid.org/0000-0002-4624-6896>

Aaron Fox

Deakin University Centre for Sport Research

Natalie Saunders

Deakin University Centre for Sport Research

Danielle Trowell

Deakin University Centre for Sport Research

Bill Vicenzino

The University of Queensland School of Health and Rehabilitation Sciences

Jason Bonacci

Deakin University Centre for Sport Research <https://orcid.org/0000-0002-4333-3214>

---

## Research Article

**Keywords:** Patellofemoral pain, adolescents, feasibility, footwear, shoes, knee

**Posted Date:** June 1st, 2022

**DOI:** <https://doi.org/10.21203/rs.3.rs-1667510/v1>

**License:** © ⓘ This work is licensed under a Creative Commons Attribution 4.0 International License.

[Read Full License](#)

---

# Abstract

## Background

There are limited evidence-based treatment options for adolescents with patellofemoral pain (PFP). Flat, flexible footwear have been shown to reduce patellofemoral joint loading and pain in adults with PFP. The efficacy of this intervention in adolescents with PFP is not established. The primary aim of this study is to determine the feasibility of conducting a large-scale randomised control trial (RCT) of the effect of flat, flexible school footwear, when compared to traditional school footwear, in adolescents with PFP. The secondary aim is to describe changes in self-reported outcome measures for adolescents with PFP while wearing flat, flexible footwear when compared to traditional school shoes.

## Methods

24 adolescents with PFP will be recruited from the community. Following baseline assessment, participants will be randomly allocated to receive either (i) flat, flexible school footwear or, (ii) traditional school footwear. Participants will wear the shoe as per school requirements throughout a 12-week intervention period. Feasibility will be assessed with (i)  $\geq 75\%$  adherence to allocated shoe wear of their total weekly school wear time, (ii) a recruitment rate of 1 participant per fortnight, and (iii) a dropout rate of  $\leq 20\%$ . Patient reported outcome measures will describe changes in knee pain, function, quality of life and global rating of change at 6 and 12 weeks. Descriptive statistics will be used for the primary outcomes of feasibility.

## Discussion

This study will determine the feasibility of conducting a large scale RCT evaluating the effect of flat, flexible school shoes for adolescents with PFP. A full-scale study will guide evidence-based management of adolescent PFP.

## Trial registration:

Australian New Zealand Clinical Trials Registry reference: ACTRN12621001525875, Date registered: 9th November 2021, <https://www.anzctr.org.au/ACTRN12621001525875.aspx>

## Background

There is a significant increase in the number of musculoskeletal injuries reported at the onset of and during adolescence (1). A quarter of adolescents aged 12–15 years' experience knee pain, with patellofemoral pain (PFP) the most prevalent diagnosis (2). PFP is characterized by pain in and around the patella that is aggravated by weightbearing activities such as running and stair ambulation (3). PFP

in adolescence has substantial implications on long-term physical and mental health (4). Seventy-percent of adolescents with PFP are likely to cease or reduce their participation in physical activity, compared to 50% of adolescents with other types of knee pain (5). Adolescents with PFP experience poorer mental health and they are twice as likely to use pain medication regularly when compared to other diagnoses of knee pain (6, 7). The long-term prognosis of adolescent PFP is poor, with symptoms persisting in up to 91% of adolescent cases after 4–18 years (8, 9).

Despite the burden of adolescent PFP, there is a paucity of literature examining treatment options within this cohort. Treatment of adolescent PFP is generally adopted from guidelines implemented in adult studies (10). As reported in the 'Best Practice Guide to Conservative Management of PFP' and an international consensus statement, exercise therapy has been shown to improve pain in the short, medium, and long-term in adults with PFP (10, 11). However, the efficacy of exercise therapy for adolescents with PFP is not as effective as that reported in adult studies (12). Matched studies examining exercise therapy in adults and adolescents with PFP reflect this, with 62% of adults reportedly recovering compared with only 38% of adolescents (13, 14). Several factors may underpin this. Exercise therapy is designed to address strength deficits that are observed in adults with PFP, such as reduced hip abduction and external rotation strength (15, 16). Adolescents with PFP do not demonstrate hip and knee strength deficits when compared to healthy controls (17, 18). Therefore, exercise therapy targeted to address strength deficits may be less efficacious in an adolescent cohort.

Poor adherence to exercise-based interventions are also reported in adolescents with PFP due to factors such as school commitments, time constraints and boredom with the program (12, 19, 20). Adolescents with PFP also typically report pain in both knees, with up to 79% reporting bilateral symptoms of PFP compared to 43% of adults with PFP (21). This bilateral nature may increase the time commitment of prescribed exercise therapy (12, 21). Given adolescents with PFP do not demonstrate reduced muscular capacity, and their adherence to prescribed exercise therapy may be reduced, alternative treatment options that focus on patellofemoral joint load reduction may be more advantageous within this population.

Flat, flexible footwear have been shown to reduce patellofemoral joint loading during running (22–24), stair descent (25) and jumping (26) in asymptomatic adults as well as adults with PFP (27). Improvements in PFP symptoms among adults have also been reported when flat, flexible footwear have been used in isolation (27) or when combined with gait retraining (28). The effectiveness of flat, flexible footwear within an adolescent cohort is unknown. Adolescents spend a large proportion of their weekdays attending school in school footwear (29). Activity data shows that adolescents participate in a range of sport and physical activity while at school and 23% meet their daily moderate-vigorous activity targets within school breaks alone (30). This suggests that a high percentage of total daily physical activity is performed in school footwear during school hours (31, 32). Wearing a flat, flexible shoe at school may be an alternative management option for adolescents with PFP as shoes address the bilateral nature of adolescent PFP; are likely to have greater adherence than exercise therapy; and are usually worn by adolescents for long periods of time while at school.

Investigating the feasibility of a flat, flexible school shoe for adolescents with PFP is a necessary step toward developing targeted evidence-based management. Early intervention is essential for minimising the potential for chronicity within this population, as well as reducing the significant long-term health-related behaviour changes associated with adolescent PFP (5, 9). A feasibility trial provides the first step to determining the requirements and potential application of a future large scale RCT (33). The primary objective of this study is to determine the feasibility of conducting a large scale RCT on the effect of a flat, flexible school shoe in adolescents with PFP. The secondary outcome is to describe changes in knee function and pain with the use of a flat, flexible school shoe compared to a traditional school shoe in adolescents with PFP.

## Methods

### Experimental/trial design

This study is an assessor blind, randomised, feasibility trial, with two parallel groups of adolescents with PFP. The research proposal has been developed in consultation with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 statement (34) and the Consolidated Standard of Reporting Trials (CONSORT) 2010 guidelines for randomised pilot and feasibility trials (35).

Ethical approval was granted through the Deakin University Human Research Ethics Committee (2021-135). The trial was prospectively registered on the Australian and New Zealand Clinical Trials Registry (ACTRN12621001525875, Date registered: 9<sup>th</sup> November 2021). Written informed consent will be obtained from all participants and their parents/guardians prior to participation within the study.

### Participants

Adolescent volunteers with a clinical diagnosis of PFP will be recruited from the community using a targeted comprehensive recruitment strategy with proven efficacy in previous studies of PFP (28, 36, 37). Recruitment strategies will include paid social media advertising, dissemination through social media networks and flyers displayed at local sports medicine clinics, footwear stores and sporting clubs/recreational facilities where PFP is likely to be prevalent. Eligibility criteria are based on previous high quality RCTs for PFP (13, 36).

Male and female adolescents will be eligible for inclusion if they meet the following criteria: (i) aged between 12-18 years, (ii) have been diagnosed clinically with PFP from a non-traumatic onset of at least 6 weeks duration, (iii) have pain  $\geq 30/100$ mm on a visual analogue scale (VAS), and (iv) have knee pain which is aggravated by activities that load the patellofemoral joint (e.g., squatting, stair ascent or descent, running).

Adolescents will be excluded if they (i) have a history of hip, knee or spine surgery, (ii) have pain at sites other than the anterior knee (e.g., menisci, patellar tendon, iliotibial band), (iii) have pain or injury in the hip, pelvis, or lumbar spine, (iv) have been diagnosed with other forms of knee pathology (e.g., Sinding

Larsen Syndrome, Osgood Schlatter's Disease etc), (v) have any condition which prevents them from wearing flat flexible footwear (e.g., calcaneal apophysitis) and/or if (vi) they are currently wearing flat flexible footwear for school.

To observe feasibility outcome of adherence, we plan to recruit 24 participants with PFP. A minimum of 23 participants are required to observe the feasibility outcome of adherence  $\geq 75\%$  allocated shoe wear, with  $\leq 50\%$  allocated shoe wear (i.e., 2 school days per week, excluding a sporting day) indicating a main trial is not feasible ( $\alpha < 0.05$ ,  $\beta 0.2$ ) (36, 38, 39).

## **Study Procedures**

Following contact with the research team, potential participants will be telephone screened for inclusion and exclusion criteria. Participants will then undergo a physical assessment at Deakin University to confirm diagnosis of PFP and the exclusion of other diagnoses of knee pain (e.g., Osgood Schlatter's disease). All participants will be screened for eligibility by an experienced Podiatrist (NM).

Eligible participants will provide written consent to participate along with their parent or guardian for those under 18 years of age. Following baseline data collection eligible participants will be randomised to receive either (i) a flat, flexible school shoe, or (ii) a traditional school shoe to be worn throughout the 12-week study period. Randomisation procedures will be performed by a staff member not involved in outcome assessment and measurement.

As the outcomes within this study are patient reported, this study is considered assessor-blinded which is consistent with other RCT's utilising footwear interventions (38). The research team processing the participant-reported data will be blinded to group allocation. Due to the inability to blind participants to the shoe they are wearing, participants will not be informed of the hypotheses of the study, nor of the differences between the shoes (38). They will simply be recommended to wear the shoe at all times they would usually wear their school shoe. Participants will be able to keep their allocated shoe at the cessation of the trial. Participant flow through the study is outlined in Figure 1.

**Figure 1:** Participant flow through the study

## **Randomisation**

Randomisation procedures will be performed by an external member of the research team via fixed concealed allocation. The randomisation sequence will be computer generated. All assessors responsible for measuring and analysing key outcomes will be blinded to participant allocation.

## **Interventions**

Participants will be fitted into both types of footwear at baseline by a Podiatrist (NM) with ten years of clinical and footwear fitting experience to ensure they are comfortable and correctly fitted. At this time, participants will be issued with an information sheet (see Additional file 1) outlining important

information about their shoes, the study, and the requirements of participation within the study. Participants will be advised to wear their allocated shoe for the duration of time per week they would normally wear their school footwear.

#### *Flat, flexible school shoe*

Participants randomised to flat, flexible school shoes will receive the Vivobarefoot Primus Lite and/or the Vivobarefoot RA II (Figure 2), which are both commercially available flat, flexible black lace up shoes (Vivobarefoot, Freiburg, Germany). The Primus Lite and the RA II are lightweight, have a 3mm outsole, zero heel-toe offset, a mass of 180grams, and no stability or motion control features. The Primus Lite and the RA II score 25/25 on the minimalist shoe index (40). Participants will receive either the RA II or the Primus Lite dependant on shoe size and stock availability. Participants will wear this shoe as per school requirements throughout the 12-week intervention period.

**Figure 2:** Flat, flexible footwear to be used within study, Vivobarefoot Primus Lite (left) & Vivobarefoot RA II (right) (Vivobarefoot, Freiburg, Germany).

#### *Traditional school shoe*

Participants randomised to the traditional school shoe will receive a pair of Clarks Daytona (Figure 3) (Clarks, Street, England). The Clarks Daytona has a stiff midsole and heel counter, a 12mm heel-toe offset, and mass of 350grams. The Clarks Daytona scores 2/25 on the minimalist shoe index indicating a low degree of minimalism and flexibility (40).

**Figure 3:** Traditional school shoe to be used within study, Clarks Daytona (Clarks, Street, England).

### **Concomitant care**

If participants are taking medication for their knee pain, they will be permitted to continue this throughout the study duration. This is consistent with other studies performed in adolescents with PFP (13, 36). At the time of entry within the study, participants will be asked to refrain from commencing new treatments for their knee pain for the duration of the study and to avoid using other assistive devices such as braces or orthotics for the study duration. Participants will be asked to report any use of co-interventions in the weekly log sheet (see Additional file 2).

### **Outcome assessment**

Once consent is provided, baseline testing will follow at the Deakin University 3D Gait Laboratory. The duration of testing will be approximately 1.5 hours. Baseline information will be obtained from participants including demographic data, body mass and height, sex, affected knee/s, duration of symptoms, previous treatments, and aggravating activities (41). To assess the stage of adolescence, participants will complete the modified Pubertal Maturational Observational Scale at baseline (42). This

scale has been used in other studies involving adolescents and can be used to reliably classify adolescent developmental stages (43-45).

Participants will complete self-reported outcome measures at baseline, 6 weeks, and 12 weeks. Data collection will be performed through self-reported questionnaires performed via Qualtrics™. Throughout the duration of the study participants will be asked to keep a weekly log (see Additional file 2) of the type of shoe worn that day; hours spent wearing that shoe; any adverse events associated with the allocated school shoe; use of co-interventions (e.g., pain medication, other footwear, taping); and any other comments. Participants will complete this in an online format distributed to them weekly via Qualtrics™. If participants do not have the equipment required to access the online format, a hard copy will be provided.

## **Outcomes measures**

**Primary outcome measures:** The primary outcome from this study is to determine the feasibility of conducting a full-scale RCT in adolescents with PFP. Feasibility will be assessed by the following outcome parameters; (i) adherence to allocated shoe wear of  $\geq 75\%$  of their total weekly school shoe wear time, (ii) a recruitment rate of 1 participant per fortnight, and (iii) a dropout rate of  $\leq 20\%$ . Success of blinding and participants' expectations of treatment will be evaluated using the Credibility and Expectancy Questionnaire (46). This will be completed at the end of the baseline assessment immediately after participants have been fitted into their shoes and then at the end of week one (36).

**Secondary outcome measures:** Secondary outcome measures will include the following patient reported outcomes taken at baseline, 6 weeks, and 12 weeks.

**Knee Pain Severity** will be assessed using a 100mm VAS, with 0mm indicating no pain and 100mm indicating the worst pain imaginable. Participants will be asked to report their worst pain and usual pain in the past week. The VAS for usual or worst pain has been shown to be reliable and valid in assessing treatment outcomes in PFP (47).

**Knee Injury and Osteoarthritis Outcome Score- Child Version (KOOS-Child)** - The KOOS-Child is a patient reported outcome measure assessing (i) pain; (ii) symptoms; (iii) difficulty during daily activity; (iv) function in sports and play; and (v) knee-related quality of life (48). Participants respond to each item using a 5-point Likert scale from 0 (no problem) to 4 (extreme problems). The scores are combined and displayed on a 0-100 scale with 0 indicating no problem and 100 indicating extreme knee problems. The KOOS-Child is recommended to evaluate knee function in adolescents and young people with a broad range of knee pain (49).

**Knee Injury and Osteoarthritis Outcome Score- Patellofemoral Pain (KOOS-PF)** - The KOOS-PF is a patient reported subscale of the KOOS for use in patients with PFP and patellofemoral osteoarthritis. This subscale of the KOOS is designed to be used in conjunction with the KOOS and/or KOOS-Child and has 11 items with the same response scales. The KOOS-PF has been shown to be valid and reliable when tested in adults but has yet to be assessed in adolescents and young people (50). The KOOS-PF has been

used by other RCTs conducted on adolescents, therefore it has been selected to ensure consistency of outcome measure assessments (36).

**Anterior Knee Pain Scale (AKPS)** - The AKPS is a patient reported assessment of 13 items related to symptoms and functional limitations. The AKPS is scored from 0 to 100 with lower scores indicating greater pain and functional limitations. The AKPS has been shown to be reliable and valid in assessing treatment outcomes in PFP (47).

**Youth Quality of Life Short Form (YQOL-SF)** - The YQOL-SF is a reliable tool used to assess the generic quality of life in adolescents aged 11-18 years with and without chronic conditions or disability (51). The short form, derived from the Youth Quality of Life- Research, measures four domains including sense of self, social relationships, environment, and general quality of life. Participants respond to several statements on a scale from 0 (not at all) to 10 (completely). The total participant score is then transformed with a higher score indicating a better self-reported quality of life.

**Global Rating of Change (GROC)** - A 7-point Likert scale will be used to evaluate GROC at 6 weeks and 12 weeks (52). Participants will be asked how their knee pain has changed since the start of the trial using the following responses: 'completely recovered', 'strongly recovered', 'slightly recovered', 'same', 'slightly worse', 'much worse', and 'worse than ever'. The GROC has been used as an outcome measure in previous RCTs of adolescents with PFP (13, 36).

**Biomechanical analysis** - Lower limb kinematics and kinetics will be measured while walking and running on an instrumented treadmill (Bertec, Ohio, USA) at baseline and 12 weeks. Participants walking and running biomechanics will be assessed while wearing the traditional school shoe; flat, flexible school shoe; and a standard athletic shoe (Asics Gel Cumulus) at baseline and their allocated school shoe and the standard athletic shoe at 12 weeks. Outcome measures will include: (i) hip, knee and ankle joint angles and torques in the sagittal, frontal, and transverse planes and (ii) patellofemoral joint forces.

### **Adverse events**

For the study duration participants will be advised to report information on adverse events and/or use of concomitant care within their weekly log sheet. Participants will be encouraged to report any discomfort they experience to the research team. If required, participants will attend an additional appointment with the research team to discuss any discomfort they may be experiencing. In this instance, standard clinical practice principles will be applied. The researcher may recommend strategies to improve the adaptation (e.g., a return to their regular footwear until pain settles). These events will be recorded as adverse events and if the discomfort cannot be reduced or tolerated, the participant will be encouraged to return to using their normal footwear and the individual's participation with the intervention will be ceased.

### **Use of co-interventions**

Participants will be asked to report any use of co-interventions within their logbook (e.g., pain medication, taping). This will be recorded in their logbooks over the three-month period. The reporting of co-

interventions is common in other trials of adolescent PFP (36).

## **Planned statistical analysis**

Data processing, data entry and data analysis will be performed by an assessor who is blinded to group allocation. All statistical analysis will be performed using SPSS version 24.0 (SPSS, Chicago, USA). Descriptive statistics will be used for the primary outcomes of feasibility and reported in relation to the pre-specified feasibility criteria. Patient reported outcome measures will be described with means and standard deviations for continuous data and counts and percentage for categorical data.

## **Data management**

Data gathered throughout the study will be coded in a re-identifiable format and stored on a separate database to group identifier to maintain blinding of the primary investigator. All electronic data will be stored on a shared drive of password protected computers.

## **Discussion**

PFP has substantial implications on long term health and physical activity behaviours in adolescents (3, 8). Adolescent knee pain is associated with significant health-related consequences, with PFP believed to carry the worst prognosis when compared to other diagnoses of adolescent knee pain (e.g., Osgood Schlatter's Disease, Sinding Larsen Syndrome) (5, 6, 9). Adolescents with PFP are likely to reduce or cease participation in recreational activity and report chronic pain that persists into adulthood, when compared to other diagnoses of adolescent knee pain (6). Current treatment for PFP is designed to address features of PFP that are seen in adults, such as reduced hip and knee strength (15, 16). However, these strength deficits are not seen in adolescents with PFP, and recommended treatment has shown less efficacy when compared to adults (13, 14).

Early intervention of adolescent PFP may provide a solution to addressing the poor long-term prognosis of this condition (9). Footwear provides an opportunity to explore a treatment option that may better suit an adolescent cohort. Shoes are a requisite for most school uniforms and adolescents spend a large percentage of their weekday time at school (29). Activity data shows that adolescents participate in a range of sport and physical activity while at school (30). A school shoe intervention for adolescents with PFP may help to address adherence issues commonly seen with exercise therapy (19, 20).

Flat, flexible shoes may be an appropriate alternative for school use, but the clinical effects of this footwear in an adolescent cohort are unknown. Studies in adults with PFP and medial tibiofemoral osteoarthritis demonstrate this style of footwear is safe to use and have little adverse effects (28, 38, 53). Within a RCT of 56 older women with medial tibiofemoral osteoarthritis, flat, flexible footwear were effective at reducing pain, improving function on activities of daily living, and reducing daily analgesic intake when compared to traditional footwear (53). Similarly, a 36% reduction in pain on the Western Ontario and McMaster Universities Osteoarthritis Index scale was seen when using flat, flexible footwear

compared to traditional stiff soled footwear (54). In contrast, a larger scale RCT in patients with medial tibiofemoral osteoarthritis reported improved knee pain during walking in stable supportive shoes compared to flat, flexible shoes (38). It is not appropriate to generalise findings from adults to adolescents with PFP and studies are needed in the target population to develop evidence-based clinical guidelines (12). Flat, flexible shoes are widely available, cost effective, easy to use and there is a minimal risk of adverse events associated with their use (53). Studies show that they have good compliance to daily wear of at least 6 hours over 6 months in adults (38). As footwear is regularly worn by adolescents to school, a footwear intervention may allow adolescents with PFP to self-manage their pain during activities of daily living and physical activity while at school.

The primary objective of this study is to determine the feasibility of conducting a large scale RCT on the effect of a flat, flexible school shoe in adolescents with PFP. Large scale RCTs are needed to allow the development of evidence-based guidelines specific to an adolescent PFP cohort. This study has been designed in consultation with the SPIRIT and CONSORT statements for randomized trials (34, 35). Strengths of this study include the planned randomization of participants, blinding of outcome assessors and a clear range of measurable feasibility outcomes (33, 39, 55). Investigating the feasibility of a flat, flexible school shoe for adolescents with PFP is a necessary step toward developing early and targeted evidence-based management. Secondary outcome measures have been selected based on their use in other studies of adolescents with PFP as well as their clinical applicability and reproducibility within an adolescent cohort (13, 36).

## List Of Abbreviations

AKPS	Anterior Knee Pain Scale
CONSORT	Consolidated Standards of Reporting Trials
GROC	Global Rating of Change
KOOS	Knee Injury and Osteoarthritis Outcome Score
KOOS-PF	Knee Injury and Osteoarthritis Outcome Score – Patellofemoral Subscale
PFP	Patellofemoral pain
RCT	Randomised control trial
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
VAS	Visual analogue scale
YQoL-SF	Youth Quality of Life- Short Form

# Declarations

## Ethics approval and consent to participate

Ethics approval was granted through the Deakin University Human Ethics Committee (2021-135). Written informed consent will be obtained from all participants and their parents prior to participation within the study.

## Consent for publication

Not applicable.

## Availability of data and materials

De-identified individual participant data will be collected during the trial. Access to the data will be subject to approvals by the Principal Investigator with a requirement to sign a data access agreement.

## Competing interests

The authors declare that they have no competing interests.

## Funding

This study is supported by PhD and internal Deakin Centre for Sports Research funding up to the value of \$15000.

## Author's contributions

JB conceptualised the study. JB and NM drafted the manuscript. All authors designed the trial protocol. All authors have read and approved the final manuscript.

## Authors information

1. Centre for Sport Research, Deakin University, Waurn Ponds Victoria 3215, Australia.
2. Centre for Sport Research, Deakin University, Waurn Ponds Victoria 3215, Australia.
3. Centre for Sport Research, Deakin University, Burwood Victoria 3125, Australia.
4. Centre for Sport Research, Deakin University, Burwood Victoria 3125, Australia
5. School of Health and Rehabilitation Sciences, The University of Queensland, St Lucia Queensland, 4072, Australia.
6. Centre for Sport Research, Deakin University, Waurn Ponds Victoria 3215, Australia.

# References

1. Straccolini A, Casciano R, Levey Friedman H, Meehan WP, 3rd, Micheli LJ. Pediatric sports injuries: An age comparison of children versus adolescents. *The American Journal of Sports Medicine*. 2013;41(8):1922-9.
2. Rathleff MS. Patellofemoral pain during adolescence: Much more prevalent than appreciated. *British Journal of Sports Medicine*. 2016;50(14):831-2.
3. Crossley KM, Stefanik JJ, Selfe J, Collins NJ, Davis IS, Powers CM, McConnell J, Vicenzino B, Bazett-Jones DM, Esculier J-F, Morrissey D, Callaghan MJ. 2016 Patellofemoral pain consensus statement from the 4th International Patellofemoral Pain Research Retreat, Manchester. Part 1: Terminology, definitions, clinical examination, natural history, patellofemoral osteoarthritis and patient-reported outcome measures. *British Journal of Sports Medicine*. 2016;50(14):839-43.
4. Rathleff CR, Olesen JL, Roos EM, Rasmussen S, Rathleff MS. Half of 12-15-year-olds with knee pain still have pain after one year. *Danish Medical Journal*. 2013;60(11):A4725.
5. Rathleff MS, Rathleff CR, Olesen JL, Rasmussen S, Roos EM. Is knee pain during adolescence a self-limiting condition? Prognosis of patellofemoral pain and other types of knee pain. *The American Journal of Sports Medicine*. 2016;44(5):1165-71.
6. Rathleff MS, Holden S, Straszek CL, Olesen JL, Jensen MB, Roos EM. Five-year prognosis and impact of adolescent knee pain: A prospective population-based cohort study of 504 adolescents in Denmark. *BMJ Open*. 2019;9(5):e024113.
7. Andreucci A, Roos EM, Rasmussen S, Olesen JL, Holmich P, Thorborg K, Rathleff MS. Analgesic use in adolescents with patellofemoral pain or Osgood-Schlatter Disease: a secondary cross-sectional analysis of 323 subjects. *Scandinavian Journal of Pain*. 2021; doi: 10.1515/sjpain-2021-0121.
8. Stathopulu E, Baildam E. Anterior knee pain: A long-term follow-up. *Rheumatology*. 2003;42(2):380-2.
9. Kastelein M, Luijsterburg PA, Heintjes EM, van Middelkoop M, Verhaar JA, Koes BW, Bierma-Seinstra SMA. The 6-year trajectory of non-traumatic knee symptoms (including patellofemoral pain) in adolescents and young adults in general practice: A study of clinical predictors. *British Journal of Sports Medicine*. 2015;49(6):400-5.
10. Collins NJ, Barton CJ, van Middelkoop M, Callaghan MJ, Rathleff MS, Vicenzino B, Davis IS, Powers CM, Macri EM, Hart HF, de Oliveira Silva D, Crossley KM. 2018 Consensus statement on exercise therapy and physical interventions (orthoses, taping and manual therapy) to treat patellofemoral pain: Recommendations from the 5th International Patellofemoral Pain Research Retreat, Gold Coast, Australia, 2017. *British Journal of Sports Medicine*. 2018;52(18):1170-8.
11. Barton CJ, Lack S, Hemmings S, Tufail S, Morrissey D. The 'Best Practice Guide to Conservative Management of Patellofemoral Pain': incorporating level 1 evidence with expert clinical reasoning. *British Journal of Sports Medicine*. 2015;49(14):923-34.
12. Rathleff MS, Vicenzino B, van Middelkoop M, Graven-Nielsen T, van Linschoten R, Hölmich P, Thorborg K. Patellofemoral pain in adolescence and adulthood: Same same, but different? *Sports Medicine*. 2015;45(11):1489-95.

13. Rathleff MS, Roos EM, Olesen JL, Rasmussen S. Exercise during school hours when added to patient education improves outcome for 2 years in adolescent patellofemoral pain: A cluster randomised trial. *British Journal of Sports Medicine*. 2015;49(6):406-12.
14. van Linschoten R, van Middelkoop M, Berger MY, Heintjes EM, Verhaar JA, Willemsen SP, Koes BW, Bierma-Zeinstra SM. Supervised exercise therapy versus usual care for patellofemoral pain syndrome: An open label randomised controlled trial. *British Medical Journal*. 2009;339:b4074.
15. Souza RB, Powers CM. Differences in hip kinematics, muscle strength, and muscle activation between subjects with and without patellofemoral pain. *Journal of Orthopaedic & Sports Physical Therapy*. 2009;39(1):12-9.
16. Bolgia LA, Earl-Boehm J, Emery C, Hamstra-Wright K, Ferber R. Comparison of hip and knee strength in males with and without patellofemoral pain. *Physical Therapy in Sport*. 2015;16(3):215-21.
17. Neal BS, Lack SD, Lankhorst NE, Raye A, Morrissey D, van Middelkoop M. Risk factors for patellofemoral pain: A systematic review and meta-analysis. *British Journal of Sports Medicine*. 2019;53(5):270-81.
18. Rathleff CR, Baird WN, Olesen JL, Roos EM, Rasmussen S, Rathleff MS. Hip and knee strength is not affected in 12-16 year old adolescents with patellofemoral pain - A cross-sectional population-based study. *PLoS One*. 2013;8(11):e79153.
19. Holt CJ, McKay CD, Truong LK, Le CY, Gross DP, Whittaker JL. Sticking to It: A scoping review of adherence to exercise therapy interventions in children and adolescents with musculoskeletal conditions. *Journal of Orthopaedic & Sports Physical Therapy*. 2020;50(9):503-15.
20. Rathleff MS, Rathleff CR, Holden S, Thorborg K, Olesen JL. Exercise therapy, patient education, and patellar taping in the treatment of adolescents with patellofemoral pain: A prospective pilot study with 6 months follow-up. *Pilot Feasibility Study*. 2018;4:73.
21. van Middelkoop M, van der Heijden MD, Bierma-Zeinstra SM. Characteristics and outcome of patellofemoral pain in adolescents: Do they differ from adults? *Journal of Orthopaedic & Sports Physical Therapy*. 2017;47(10):801-5.
22. Sinclair J. Effects of barefoot and barefoot inspired footwear on knee and ankle loading during running. *Clinical Biomechanics*. 2014;29(4):395-9.
23. Sinclair J, Richards J, Selfe J, Fau-Goodwin J, Shore H. The influence of minimalist and maximalist footwear on patellofemoral kinetics during running. *Journal of Applied Biomechanics*. 2016;32(4):359-64.
24. Yang C, Xiao S, Yang Y, Zhang X, Wang J, Fu W. Patellofemoral joint loads during running immediately changed by shoes with different minimalist indices: A cross-sectional study. *Applied Sciences*. 2019;9(19):4176.
25. Sacco IC, Trombini-Souza F, Butugan MK, Passaro AC, Arnone AC, Fuller R. Joint loading decreased by inexpensive and minimalist footwear in elderly women with knee osteoarthritis during stair descent. *Arthritis Care & Research* 2012;64(3):368-74.

26. Sinclair J, Hobbs SJ, Selfe J. The influence of minimalist footwear on knee and ankle load during depth jumping. *Research in Sports Medicine*. 2015;23(3):289-301.
27. Bonacci J, Hall M, Fox A, Saunders N, Shippides T, Vicenzino B. The influence of cadence and shoes on patellofemoral joint kinetics in runners with patellofemoral pain. *Journal of Science and Medicine in Sport*. 2018;21(6):574-8.
28. Bonacci J, Hall M, Saunders N, Vicenzino B. Gait retraining versus foot orthoses for patellofemoral pain: a pilot randomised clinical trial. *Journal of Science and Medicine in Sport*. 2018;21(5):457-61.
29. Arundell L, Salmon J, Koorts H, Contardo Ayala AM, Timperio A. Exploring when and how adolescents sit: cross-sectional analysis of activPAL-measured patterns of daily sitting time, bouts and breaks. *BMC Public Health*. 2019;19(1):653.
30. Ridgers ND, Timperio A, Crawford D, Salmon J. What factors are associated with adolescents' school break time physical activity and sedentary time? *PLoS One*. 2013;8(2):e56838.
31. Carson V, Cliff DP, Janssen X, Okely AD. Longitudinal levels and bouts of sedentary time among adolescent girls. *BMC Pediatrics*. 2013;13:173.
32. Tassitano RM, Weaver RG, Tenorio MCM, Brazendale K, Beets MW. Physical activity and sedentary time of youth in structured settings: A systematic review and meta-analysis. *International Journal of Behavioral Nutrition and Physical Activity*. 2020;17(1): 160.
33. Arain M, Campbell MJ, Cooper CL, Lancaster GA. What is a pilot or feasibility study? A review of current practice and editorial policy. *BMC Medical Research Methodology*. 2010;10:67.
34. Chan AW, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin JA, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WP, Krleza-Jeric K, Laupacis A, Moher, D. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *British Medical Journal*. 2013;346:e7586.
35. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, Lancaster GA, PAFS consensus group. CONSORT 2010 statement: Extension to randomised pilot and feasibility trials. *British Medical Journal*. 2016;355:i5239.
36. O'Sullivan IC, Crossley KM, Kamper SJ, van Middelkoop M, Vicenzino B, Franettovich Smith MM, Menz HB, Smith AJ, Tucker K, O'Leary KT, Costa N, Collins NJ. HAPPi Kneecaps! A double-blind, randomised, parallel group superiority trial investigating the effects of sHoe inserts for adolescents with patellofemoral Pain: phase II feasibility study. *Journal of Foot and Ankle Research*. 2021;14(1):64.
37. Matthews M, Rathleff MS, Claus A, McPoil T, Nee R, Crossley KM, Kasza J, Vicenzino B. Does foot mobility affect the outcome in the management of patellofemoral pain with foot orthoses versus hip exercises? A randomised clinical trial. *British Journal of Sports Medicine*. 2020;54:1416-22.
38. Paterson KL, Bennell KL, Campbell PK, Metcalf BR, Wrigley TV, Kasza J, Hinman RS. The Effect of Flat Flexible Versus Stable Supportive Shoes on Knee Osteoarthritis Symptoms : A Randomized Trial. *Annals of Internal Medicine*. 2021;174(4):462-71.
39. Lewis M, Bromley K, Sutton CJ, McCray G, Myers HL, Lancaster GA. Determining sample size for progression criteria for pragmatic pilot RCTs: the hypothesis test strikes back! *Pilot and Feasibility*

- Studies. 2021;7(1):40.
40. Esculier JF, Dubois B, Dionne CE, Leblond J, Roy JS. A consensus definition and rating scale for minimalist shoes. *Journal of Foot and Ankle Research*. 2015;8:42.
  41. Barton CJ, De Oliveira Silva D, Morton S, Collins NJ, Rathleff MS, Vicenzino B, van Middelkoop M, Crossley KM, Callaghan MJ, Selfe J, Holden S, Lack S, Macri EM, Bazett-Jones DM, Earl-Boehm JE, Riel H, Powers CM, Davis IS, Morrissey D. REPORT-PFP: a consensus from the International Patellofemoral Research Network to improve REPORTing of quantitative PatelloFemoral Pain studies. *British Journal of Sports Medicine*. 2021; 55; 1135-43.
  42. Davies PL, Rose JD. Motor Skills of Typically Developing Adolescents: Awkwardness or Improvement? *Physical and Occupational Therapy in Pediatrics*. 2000;20(1):19-42.
  43. Sigward SM, Pollard CD, Havens KL, Powers CM. Influence of sex and maturation on knee mechanics during side-step cutting. *Medicine & Science in Sports & Exercise*. 2012;44(8):1497-503.
  44. Taylor-Haas JA, Long JT, Garcia MC, Rauh MJ, Paterno MV, Brindle RA, Bazett-Jones DM, Ford KR. The influence of maturation and sex on pelvis and hip kinematics in youth distance runners. *Journal of Science and Medicine in Sport*. 2021; 25(3):272-8.
  45. Hewett TE, Myer GD, Ford KR. Decrease in Neuromuscular Control About the Knee with Maturation in Female Athletes. *The Journal of Bone and Joint Surgery*. 2004;86(8):1601-8.
  46. Borkovec TD, Nau SD. Credibility of analogue therapy rationales. *Journal of Behavior Therapy and Experimental Psychiatry*. 1972;3(4):257-60.
  47. Crossley KM, Bennell KL, Cowan SM, Green S. Analysis of outcome measures for persons with patellofemoral pain: Which are reliable and valid? *Archives of Physical Medicine and Rehabilitation*. 2004;85(5):815-22.
  48. Ortqvist M, Roos EM, Brostrom EW, Janarv PM, Iversen MD. Development of the Knee Injury and Osteoarthritis Outcome Score for children (KOOS-Child): Comprehensibility and content validity. *Acta Orthopaedica*. 2012;83(6):666-73.
  49. Ortqvist M, Iversen MD, Janarv PM, Brostrom EW, Roos EM. Psychometric properties of the Knee injury and Osteoarthritis Outcome Score for Children (KOOS-Child) in children with knee disorders. *British Journal of Sports Medicine*. 2014;48(19):1437-46.
  50. Crossley KM, Macri EM, Cowan SM, Collins NJ, Roos EM. The patellofemoral pain and osteoarthritis subscale of the KOOS (KOOS-PF): Development and validation using the COSMIN checklist. *British Journal of Sports Medicine*. 2018;52(17):1130-6.
  51. Edwards TC, Huebner CE, Connell FA, Patrick DL. Adolescent quality of life, Part 1: Conceptual and measurement model. *Journal of Adolescence*. 2002;25(3):275-86.
  52. Kamper SJ, Maher CG, Mackay G. Global rating of change scales: A review of strengths and weaknesses and considerations for design. *The Journal of Manual & Manipulative Therapy*. 2009;17(3):163-70.
  53. Trombini-Souza F, Matias AB, Yokota M, Butugan MK, Goldenstein-Schainberg C, Fuller R, Sacco ICN. Long-term use of minimal footwear on pain, self-reported function, analgesic intake, and joint

loading in elderly women with knee osteoarthritis: A randomized controlled trial. *Clinical Biomechanics*. 2015;30(10):1194-1201.

54. Shakoor N, Lidtke RH, Wimmer MA, Mikolaitis RA, Foucher KC, Thorp LE, Fogg LF, Block JA. Improvement in knee loading after use of specialized footwear for knee osteoarthritis: results of a six-month pilot investigation. *Arthritis & Rheumatology*. 2013;65(5):1282-89.
55. Thabane L, Ma J, Chu R, Cheng J, Ismaila A, Rios LP, Robson R, Thabane M, Giangregorio L, Goldsmith CH. A tutorial on pilot studies: the what, why and how. *BMC Medical Research Methodology*. 2010;10:1.

## Figures

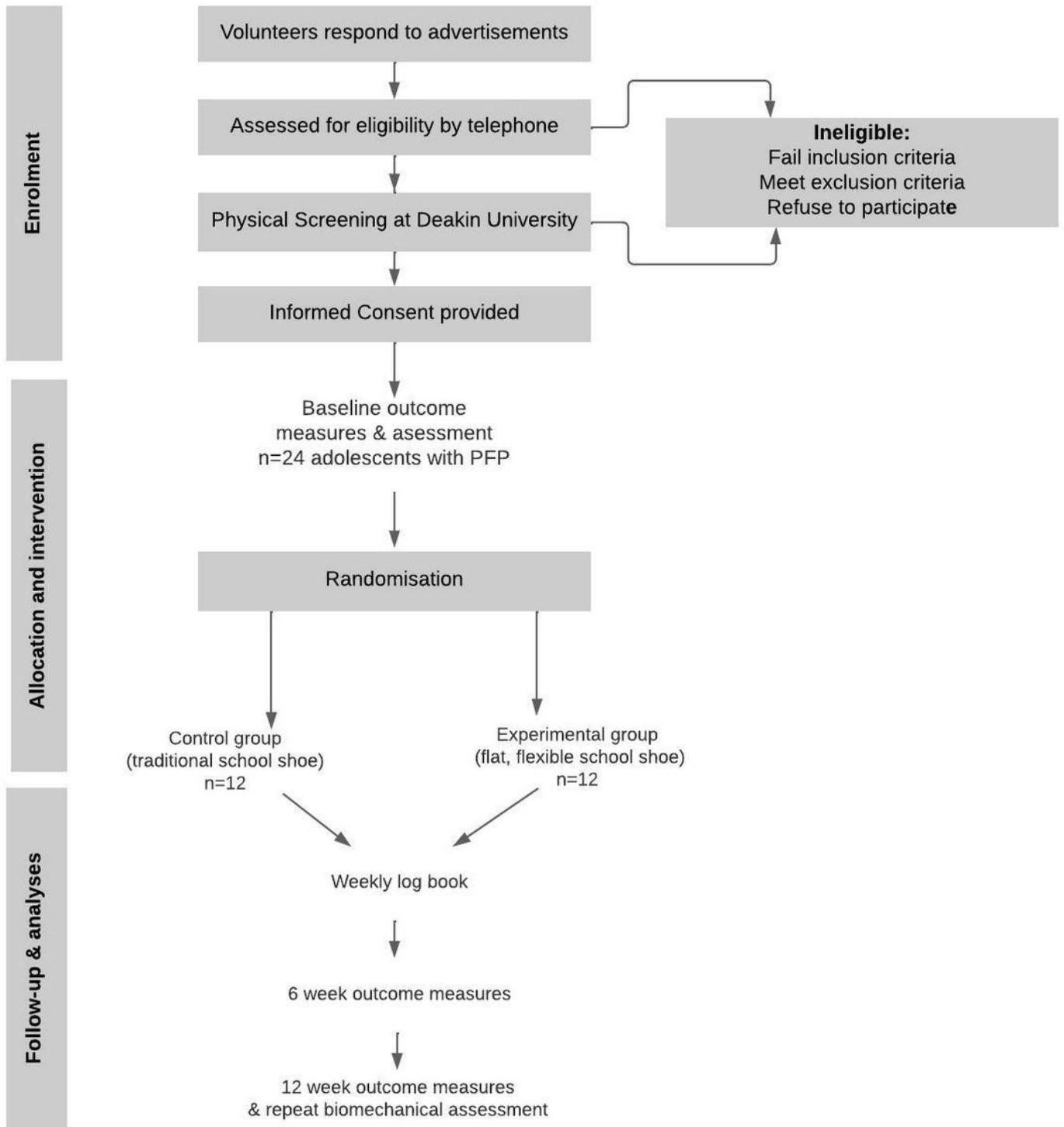


Figure 1

Participant flow through the study



**Figure 2**

Flat, flexible footwear to be used within study, Vivobarefoot Primus Lite (left) & Vivobarefoot RA II (right) (Vivobarefoot, Freiburg, Germany).



**Figure 3**

Traditional school shoe to be used within study, Clarks Daytona (Clarks, Street, England).

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Additionalfile1.pdf](#)
- [Additionalfile2.pdf](#)