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Gait retraining versus foot orthoses for patellofemoral pain: a pilot randomised clinical trial

Jason Bonacci[a,*], Michelle Hall[b], Natalie Saunders[a], Bill Vicenzino[c]

[a] Centre for Sports Research, School of Exercise and Nutrition Sciences, Deakin University, Australia
[b] Centre for Health, Exercise and Sports Medicine, Department of Physiotherapy, University of Melbourne, Australia
[c] School of Health and Rehabilitation Sciences, Physiotherapy, University of Queensland, Australia

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ABSTRACT

Objectives: To determine the feasibility of a clinical trial that compares a 6-week, physiotherapist-guided gait retraining program with a foot orthoses intervention in runners with patellofemoral pain.
Design: Pilot randomised controlled trial.
Methods: Runners aged 18–40 years with clinically diagnosed patellofemoral pain were randomly allocated to either a 6-week gait retraining intervention of increasing cadence and use of a minimalist shoe or prefabricated foot orthoses. Outcomes at baseline and 12-weeks included recruitment, retention, adherence, adverse events, global improvement, anterior knee pain scale, worst and average pain on a 100 mm visual analogue scale.
Results: Of the 16 randomised participants, two withdrew prior to commencing treatment due to non-trial related matters (n = 1 from each group) and 14 completed the pilot trial. Minor calf muscle soreness was reported by 3 participants in the gait retraining group while no adverse events were reported in the foot orthoses group. There were no deviations from the treatment protocols. There was a large between-group difference favouring gait retraining at 12-weeks in the anterior knee pain scale and the worst pain in the past week, which was reflected in the number needed-to-treat of 2.
Conclusions: This study supports the feasibility of a trial comparing gait retraining with foot orthoses and provides point estimates of effect that informs the design and planning of a larger clinical trial. It appears that a 6-week gait retraining program has a clinically meaningful effect on runners with patellofemoral pain when compared to an evidence-based treatment of foot orthoses.

1. Introduction

Patellofemoral pain affects up to 25% of individuals engaged in sporting activities that commonly involve running.[1,2] Gait retraining has been recommended as part of the 'Best Practice Guide' for treatment of patellofemoral pain.[3,4] For individuals with patellofemoral pain, the aim of gait retraining is often to reduce the mechanical load acting at the patellofemoral joint. Current evidence suggests that altering foot strike pattern during running is associated with improved patellofemoral pain[5,6] possibly through reduced impact loading and patellofemoral joint stress.[6] An improvement in symptoms in those with PFP has also been reported with gait retraining interventions focused on reducing frontal plane hip motion.[7,8] While these studies provide preliminary support for the use of gait retraining in the management of patellofemoral pain, all have used gait laboratories to facilitate gait retraining and only one has used a control group.[6]

Alternate approaches to reduce patellofemoral joint loads during running are to increase cadence,[9,10] run barefoot,[11] or wear a minimalist shoe.[12] Importantly, the combination of both a minimalist shoe and an increased cadence may reduce knee joint load more than either strategy in isolation.[13] While it is plausible that reducing patellofemoral joint loads via an increased running cadence, use of a minimalist shoe or a combination thereof may improve symptoms, there is little empirical evidence to support this. Studies evaluating the feasibility, safety profile and potential efficacy of these treatments for patellofemoral pain are required.[14] Two recent randomised controlled trials reported an increased risk of injury and greater calf pain when running in a minimalist shoe compared to a conventional shoe in previously healthy participants.[15,16] Increased calf pain when running in a minimalist shoe may be explained by the greater ankle plantarflexion muscle

* Corresponding author.
E-mail address: jason.bonacci@deakin.edu.au (J. Bonacci).

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work required.[17] It remains unclear if this biomechanical shift in strategy from the knee to the ankle[12,13,17] is safe and/or beneficial for individuals with patellofemoral pain.

Foot orthoses are an established therapy that have also been recommended as part of the 'Best Practice Guide' for management of patellofemoral pain.[3,4] Clinical trials demonstrate that foot orthoses are safe to use and superior to a wait-and-see-approach[18] and flat insoles[19] in the short term. Due to the established efficacy of foot orthoses, this treatment acts as a good comparator for other novel interventions such as gait retraining.

The objectives of this study were to compare a physiotherapist guided gait retraining intervention (increased cadence and use of a minimalist shoe) with foot orthoses to determine the: (i) feasibility (patient recruitment rates and retention); (ii) adherence (number of physiotherapy sessions attended and volume of weekly running); (iii) safety (number and nature of adverse events); and (iv) parameters of effect from which to perform power calculations.

2. Methods

This feasibility study was a randomised, parallel controlled trial that evaluated outcomes after gait retraining compared to foot orthoses over 12 weeks in participants with patellofemoral pain. The Deakin University Human Research Ethics Committee approved the trial and participants provided written informed consent.

All participants were recruited from the community via advertisements on social media and flyers at recreational facilities. Responders were initially telephone-screened and if eligible they were examined by a physiotherapist to confirm patellofemoral pain diagnosis. As per previous clinical trials[18–20] the inclusion criteria were: (i) aged 18–40 years; (ii) antero-patella or retro-patella pain that was non-traumatic, longer than six weeks duration and provoked by jogging/running or squatting, hopping/jumping or kneeling or prolonged sitting; (iii) worst pain over the previous week of at least 30/100 mm on a visual analogue scale (0 = no pain, 100 = worst pain imaginable); (iv) running at least 10 km per week; (v) tender over the patellar facet; and (vi) pain on step-down from a 25-cm step or during a double leg squat. All participants used a rearfoot footfall at the time of enrollment. The exclusion criteria were: (i) concomitant injury or pathology of other knee structures; (ii) a history of knee surgery; (iii) any foot condition that precludes the use of foot orthoses or running in a minimalist shoe; (iv) a history of use of foot orthoses or minimalist footwear; and (v) pain in and/or referred pain from the hip or lumbar spine.

Allocation to either gait retraining or foot orthoses without stratification was done according to a computer-generated randomisation schedule. Group allocation was sealed in opaque, consecutively numbered envelopes by an independent researcher and stored in a central locked location. Envelopes were opened in sequence of recruitment of participants by the independent researcher, who then subsequently disclosed the group allocation to the participant. Participants were not blinded to group allocation. The same blinded-assessor performed measures at baseline (week 0) and follow-up (week 12). Demographic information was collected at baseline.

Participants were randomly allocated to either gait retraining or to wear foot orthoses. Participants allocated to gait retraining underwent 10 supervised gait retraining sessions on a treadmill over the first six weeks. Participants attended a physiotherapy clinic twice in the first 4 weeks and once per week thereafter. Gait retraining included two key components: (i) running in a minimalist shoe (Vibram Seeya, Vibram, MA, USA); and (ii) a 10% increase in running cadence. Cadence was controlled by a metronome (Seiko DM51, Seiko Instruments Inc., Japan) and baseline self-selected running cadence was measured via digital video camera footage (Casio Exilim, Casio, Japan). Feedback of running cadence was provided via the metronome in all sessions during weeks 1–4, once in week 5 and removed in week 6. No instruction for foot strike was given, however participants were encouraged to land softly. The volume of gait retraining sessions each week comprised 20% of each participant's total weekly training volume. The remaining 80% of each participant's total weekly training volume was completed without supervision and in the participant's usual running shoe. A metronome was provided to each participant and they were instructed to use it while running in weeks 1–5 as required to achieve the targeted cadence. Within the 20% supervised training volume, a progressive walk/run program was implemented in order to minimize adverse effects at the foot and leg. During week 1 this was 50/50% walk/run, progressing to 40/60%, 30/70%, 20/80%, 10/90% in weeks 2, 3, 4 and 5, respectively. In week 6 the entire 20% of total weekly training volume was completed running. All running was completed at each participant's normal training pace.

Participants allocated to wear foot orthoses attended up to four orthoses fitting sessions. Participants received a prefabricated, commercially available full-length orthoses (Vasyli International, Brisbane, Australia), that were the same as those shown to be efficacious in previous randomised controlled trials.[18,19] The orthoses were fitted according to previous protocols,[19,21] which involved ensuring that the medial longitudinal arch of the orthoses did not interfere with first metatarsophalangeal joint motion. The orthoses were customized to optimize comfort through heat molding and by adding wedges or heel raises and participants were instructed to use them all times in their athletic footwear.

Feasibility was recorded as recruitment and retention rates and adherence to the gait retraining intervention while safety was recorded as the number of adverse events. Adverse events and co-interventions were assessed from physiotherapist treatment notes. Adherence to gait retraining was determined by the number of sessions completed with the physiotherapist and weekly running volume was recorded using an online log-book.

Self-reported pain during the past week was assessed on a visual analogue scale, assessing worst pain and average pain. A change score of 20 mm was considered a clinically meaningful change.[22] Patellofemoral pain was also assessed using the anterior knee pain scale which ranges from 0 to 100 points, where higher scores indicate less disability[23] and a 10-point change is considered clinically meaningful.[22] Global improvement was assessed using a 15-point global rating of change scale. The scale spans from −7 ('a very great deal worse') through 0 ('no change') to +7 ('a very great deal better'). We considered success to equate to $\geq$+4 (at least 'moderately better').[24,25]

All outcomes relating to feasibility, such as, rates of recruitment and retention, adherence to intervention and safety, are descriptively presented. Group data are presented as group means and standard deviation. Point estimates of effect are presented as between group mean differences and standardized mean differences (SMD) and their 95% confidence intervals. SMD >1.2 are considered large, 0.61–1.2 as medium, 0.2–0.6 as small and <0.2 as trivial.[26]

STATA software (version 14.0) was used for statistical analysis. We analyzed continuous outcome measures using univariate analysis of covariance and group allocation as a fixed factor. Participant characteristics that differed at baseline as well as the baseline measure for the outcome being analysed were included as covariates in the model. Significance was set at $\alpha < 0.05$. Statistical analyses were conducted on complete cases. The dichotomous measure of improvement 'success' was expressed as relative risk reduction and numbers needed to treat.

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