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Original research

Foot exercises and foot orthoses are more effective than knee focused exercises in individuals with patellofemoral pain

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ABSTRACT

Objectives: To examine the effect of knee targeted exercises compared to knee targeted exercises combined with foot targeted exercises and foot orthoses in patients with patellofemoral pain.
Design: Forty adult individuals (28 women, 12 men) diagnosed with patellofemoral pain and screened for excessive calcaneal eversion were randomized to knee targeted exercises or knee targeted exercises combined with foot targeted exercise and orthoses.
Methods: The knee targeted exercises were prescribed during three supervised consultations. Individuals were instructed to perform the exercises 3 times per week during a 12-week period. The foot targeted exercises were prescribed for 2 times per week for 12 weeks with one session per week being supervised by a physiotherapist. The primary outcome was the subscale "pain" in the Knee Injury and Osteoarthritis Outcome Score (KOOS) at 4 months.
Results: Individuals randomized to knee targeted exercises combined with foot targeted exercises and foot orthoses had 8.9 points (95%CI: 0.4; 17.4) – NNT = 3 (2–16) larger improvement in KOOS pain at the primary endpoint.
Conclusions: The addition of foot targeted exercises and foot orthoses for 12 weeks was more effective than knee targeted exercises alone in individuals with patellofemoral pain. The effect was apparent after 4 months, but not significantly different after 12 months.

1. Introduction

Patellofemoral pain is a debilitating knee condition that affects up to 25% of active individuals.[1] The primary symptom is pain around the patella during activities that load the patellofemoral joint e.g., squatting, running and stair climbing. The long-term prognosis for patellofemoral pain is poor with only one-third being pain-free, 1 year after the initial diagnosis and as much as one-fourth will stop participating in sport as a result of their knee pain.[1,2]

Individuals with patellofemoral pain are a heterogeneous patient population reflecting the multifactorial causes leading to patellofemoral pain.[3] Research has identified both local factors and distal factors such as a large navicular drop which suggest that both local and distal factors may increase an individual risk of developing patellofemoral pain.[4] Various forms of exercise therapy have been shown in high quality trials to have a better effect on pain than wait-and-see or placebo treatment.[5] However, despite a prescription of evidence-based treatments, a 40% will continue to report knee pain 1 year after treatment.[1,2]

Different subgroups may respond differently to treatment.[6] As a result, recent endeavors have tried to elucidate the different subgroups that may exist within patellofemoral pain, to provide targeted interventions leading to better outcomes and higher rates of full return to sport.[3] Two previous reports suggest that individuals with a high midfoot mobility are more likely to respond favorably to distal intervention consisting of foot orthoses.[3,7] The reason for an increased effectiveness among this subgroup is unknown but the foot may be a key factor in the development of PFP and thus aiming the intervention at the foot may address one of the underlying factors of their knee pain. Foot orthoses may work by altering foot and lower limb biomechanics[8,9] and may theoreti-

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cally change patellofemoral joint function.[9,10] The clinical effects of foot orthoses has been supported by a randomised controlled trial where orthoses was associated with greater improvements after 6 weeks compared with a wait-and-see.[6] Although foot orthoses may improve lower limbs biomechanics they are unlikely to constitute an adequate management plan as a stand-alone intervention.[4] Combing exercises and foot orthoses have been investigated but the current evidence regarding the additional effects of exercises in the short term (4–8 weeks) is conflicting.[11,12]

At the time of the current trial, the recommended treatment was a knee-targeted treatment program inspired by the McConnell multimodal approach.[13] This was based on current evidence from a systematic review.[14] Treatment was administered for all individuals with patellofemoral pain, irrespective of patient characteristics. Distal strengthening has been suggested to be specifically important for some individuals with PFP but has so far received little attention in research.[4] The clinical question raised was if the subgroup with an excessive calcaneal eversion would be more effectively treated using distal interventions added to local interventions compared to local interventions alone? Thus the purpose of the randomised controlled trial was to compare the effect of standard knee targeted exercise therapy versus adding a distal intervention consisting of foot orthoses and foot strengthening exercises on pain among a subgroup of individuals with PFP with excessive calcaneal eversion. The primary hypothesis was that adding foot targeted exercises and foot orthoses would be associated with a larger reduction in pain, compared to the knee targeted treatment after four months.

2. Methods

The study was a randomised assessor-blinded controlled superiority trial with follow-up after 4 and 12 months.

The physiotherapist, responsible for collecting outcome measures at follow-up was blinded to the randomisation. The participants and the physiotherapists responsible for delivering the interventions were not blinded. The study was approved by the local ethics committee (Ref: 2005020). All individuals provided informed written consent.

Individuals were recruited from the orthopaedic Outpatient Clinic at Aalborg University Hospital and a private orthopaedic specialist in the Northern Region of Denmark. The diagnosis of PFP was determined by a skilled orthopaedic surgeon on the basis of the complaint of anterior knee pain and on physical examination findings.

Inclusion criteria were as follows: (a) anterior or retro patellar knee pain for more than twelve weeks; (b) excessive calcaneal eversion measured as calcaneal valgus in relaxed bilateral standing greater than 6°;[15] (c) pain elicited at least by two of the following four tests; (i) Isometric muscle contraction with slight bent knee, (ii) palpation of the patellofemoral joint line, (iii) patellar compression against the femoral bone (iv) active resisted knee extension (d) between 18 and 60 years of age; (e) able and motivated in completing the study. Exclusion criteria were; (I) previous knee surgery, except for diagnostic arthroscopy; (II) clinical suspicion of knee osteoarthritis or specific foot and/or knee pathologies (e.g. patellar tendinopathy, lesions of the menisci, cartilage, bone, collateral or cruciate ligaments); (III) and physically or mentally incapable of following the exercise protocol. This was a select group of individuals with PFP with a calcaneal eversion of more than 6°. Based on the data from our study this select group constitutes approximately 30% of the patients we screened for inclusion into the study.

The randomisation was managed by an independent secretary not involved in assessment of participants, who generated a simple randomisation sequence a priori. Allocation was sealed in opaque and consecutively numbered envelopes held in a central location. Envelopes were opened in sequence by a person not involved in the study after recruitment and baseline testing of participants.

Participants were randomly allocated to either the control group (CG) receiving the standard knee targeted exercises[13] which was standard practice at hospital at the time of the trial or to an intervention group (IG) receiving the standard knee targeted exercises combined with foot targeted exercises and foot orthoses. Experienced physiotherapists received education and training in the intervention protocol. Individuals were examined by the same outcome assessor at baseline and follow-up who was blinded to group allocation.

The CG and IG both received three sessions of physiotherapy during a three-month period after inclusion. The three sessions with an experienced physiotherapist were individually adjusted to educate, manual therapy treatment of the soft tissues around the patella, tibio-fibular joint, and soft tissue mobilisation of the iliotibial tract, patellar taping with medialisation of the patella with sports tape and a home exercise program which primarily targeted neuromuscular strength with repetition maximum of 15–20 reps. These home-based exercises included squats, semi squat, lunges, knee extensions with rubber band sitting.

The IG also received one weekly, supervised, session during the three-month period (a total of 12 sessions). The content of the foot exercise program is illustrated in Fig. 1. The standardised program was designed with the possibility of individual adjustments in relation to pain and functional level (see foot exercise program, Supplemental Digital Content).

Orthoses were individually manufactured by an orthopaedic shoemaker with more than 20 years of experience. The orthoses were made of ethylene-vinyl acetate (E.V.A.) with contouring and posting/wedging under the medial longitudinal arch and/or heel to increase the navicular height and reduce the calcaneal angle during loading. The orthoses were fitted to ensure a combination of neutral subtalar position and comfort, with comfort being the main priority. If necessary, individuals returned for fitting adjustments in the first couple of weeks to achieve a comfortable fit of the orthoses. Participants were instructed to wear orthoses for 2 h per day and then slowly increase wear time up to a full working day. They were instructed to wear them in all shoes possible

The a priori primary endpoint was thus 4 months follow-up after baseline measurements. This endpoint was chosen as it was very close to the time point where participants finished their exercise intervention. Measurements at twelve months were chosen to determine whether the effect was maintained. Each participant completed the Knee Injury and Osteoarthritis Outcomes Score self-reported questionnaire where the subscale "Pain" was chosen as the primary outcome (100 indicates no problems and 0 indicates extreme problems).[16] A 10 points difference has been suggested as a minimal relevant difference in KOOS score.[17]

Secondary outcomes included the four other subscales "ADL, Sport, QoL and Symptoms" in the Knee Injury and Osteoarthritis Outcomes Score.

The demographics of interest included sex, age, height, body mass. Subjective pain characteristics recorded were unilateral/bilateral pain, and years of symptoms. To explore which participants were most likely to respond to the prescribed treatments a range of foot measures were collected.

Foot posture was assessed as the navicular loading response (sagittal plane), navicular drift (frontal plane) and maximal calcaneal angle (frontal plane) in a standing position. Placement of the foot was always aligned and standardized in relation to a piece of tape on the floor. All patients were standing in a similar postion with the index fingers on the wall and the big toe of the opposite foot resting on the floor. The navicular height (Standing and sitting) and the corresponding calcaneal angles were quanti-

Fig. 1. Examples of weight-bearing exercises from the intervention program to improve strength and neuromuscular control in the foot and lower leg. From left to right, the exercises are: Tib. Posterior, Wobble board, Heel raise, Short foot.

fied photographically from two pictures taken in the sagittal plane and two pictures taken in the frontal plane (Canon EOS300D). A metal square of known dimensions (20 × 100 mm) was placed in the photographical field and in photographical plane for calibration purposes. The navicular tuberosity and caput of the first metatarsal bone were marked by pen before the pictures were taken. The navicular height was defined as the distance from the navicular tuberosity to the floor. The loading response of the navicular (Suppl. Fig. S1) was defined as the difference between the height between the unloaded (sitting) and loaded position (standing), measured in millimeters. The assessment of unloaded foot position was performed with the subject seated, the knee bent 90 degrees and the foot placed in a relaxed position. The loaded foots position was a relaxed one-legged standing position. The participants were instructed to stabilize this position by placing the opposite toe on the floor (Suppl. Fig. S1) and two fingers on a rigid support. The maximal Calcaneal angle was defined as the angle between the midline of the Calcaneus in the frontal plane and the bisection line of gastrocnemii as described earlier and was measured in degrees in a loaded one-legged position.[18] Navicular drift was measured as the horizontal movement of the navicular tuberosity in the frontal plane from unloaded to loaded position in millimeters. A plate with a groove, in which the measurement unit could be moved across a ruler, was used for navicular drift measurements (Suppl. Fig. S2). X-rays of the foot were taken in a loaded and unloaded position in the sagital plane as a baseline parameter. The Talus — first metatarsal angle was established as the angle between the talus and first metatarsal axes and the difference from unloaded to loaded was an indication of midfoot flexibility. Excellent relialibity of talus-first metatarsal angle has been shown previously, ICC 0.91 (0.78–0.97).[19] Intratester reliability was tested for measures of foot posture with 20 healthy subjects. Reliability were good to excellent with $ICC_{NavicularUnloaded} = 0.86$ (0.68–0.94), $ICC_{NavicularLoaded} = 0.89$ (0.74–0.95), $ICC_{Navicularloadingresponse} = 0.65$ (0.22–0.84), $ICC_{CAL} = 0.79$ (0.54–0.90) and $ICC_{drift} = 0.76$ (0.48–0.89).

The sample-size was based on detecting a difference between groups of at least 10 points on the KOOS subscale "pain". Using a common standard deviation of 10 points, power of 80%, and an alpha level of 5%, at least 16 individuals with PFP were needed in each group to detect a 10 point difference between groups. Therefore 20 individuals with PFP were included in each group to account for potential drop-outs.

All statistical analyses were defined a priori and took place after the 12 months follow-up and no intermediate analyses were performed. The first author and a statistician performed all analyses. They were not blinded to group allocation during data analyses. The statistical analysis was completed using SPSS software (version 16.0). Between-group comparison was analyzed on an intention-to-treat basis and included all individuals who responded to the self-report questionnaire at that time point. The primary outcome was analysed through a mixed ANOVA with time as the within subject variable and treatment as the between subject condition. Any baseline differences were included in an adjusted analysis. Normality was tested with QQ-plots. Explorative Spearman's or Pearson correlation tests were accordingly used to assess the effect of baseline participant characteristics and foot posture on the primary treatment outcome. Numbers Needed to Treat (NNT) was calculated based on a successful result with a pain reduction (KOOS) of 10 points or more.

3. Results

From January 2007 to February 2010, 122 volunteers were screened and forty participants were included at baseline, 28 women and 12 men. Mean age was 31.2 years (SD: 10.8 years), range 18–58 years. Eighty percent (n = 32) completed the 4 and 12 months follow up examination (Fig. 2). Reasons given by the participants for dropping out included; job situations, lack of time, lack of motivation for continuing in the project and illness (Fig. 2). No significant differences with regard to baseline characteristics were observed between the participants completing the trial and those dropping out of the trial. No serious adverse effects of the treatment were described. Two subjects in the IG reported 2–3 weeks of tenderness at the lateral border of calcaneus with no clear clinical differences compared to the rest of the IG.

At baseline, there were no differences in any of the self-reported outcomes between the two groups (Suppl. Table S1). The objective parameters were similar in the two groups apart from calcaneal angle (Suppl. Table S1). In the IG 17 individuals were assessed at 12 month follow up and had attended a mean of 10 (SD = 4, range 0–14) supervised exercise sessions during the trial. The CG attended an average of 2 sessions (range 1–3).

Individuals randomized to knee targeted exercises combined with foot targeted exercises and foot orthoses had 8.9 points (95%CI: 0.4; 17.4), NNT of 3 (2–16) larger improvement in KOOS pain at the primary endpoint (4 months) compared to individuals randomized to knee targeted exercises. Patients with successful outcome in the IG and CG were 12/20 and 5/20, respectively. The NNT suggest that you would get one extra successful outcome for every three patients treated with foot exercises and orthoses compared to general knee exercises. At 12 months the individuals receiving foot exercise and orthoses had 5.1 points (95%CI: −3.8; 14.1), non-significant larger difference in KOOS pain compared to the control group.

A similar trend for "Activities of Daily Living", "functional problems during Sports and recreational activities" and The Quality of Life score were also in favor of the IG although not significantly. A general trend of improvement with time was seen in both groups (Table 1).

The participants were asked at baseline if they had used painkillers 14 days prior to inclusion due to knee pain. Eleven in the IG compared to five in the CG did use painkillers. At 12 months follow-up three in each group continued using painkillers.

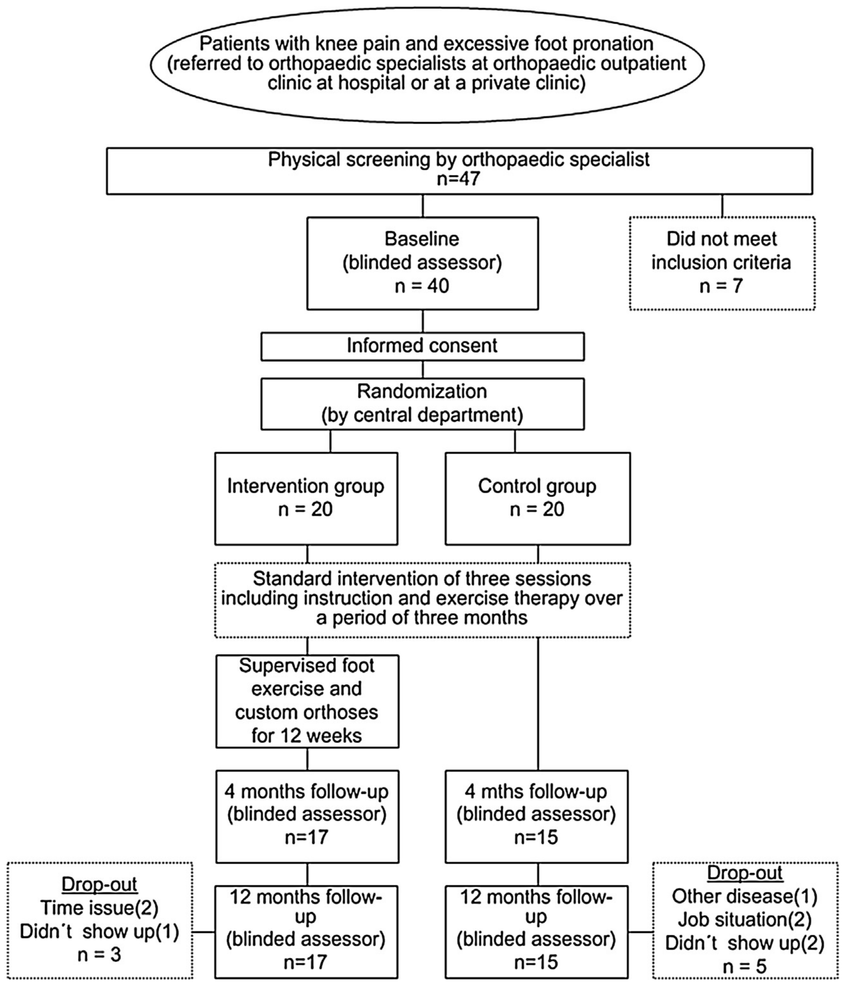

Fig. 2. Flow chart for patients in the randomized controlled design. The intervention group received foot targeted exercises and foot orthoses.

Table 1
Results of intension to treat analysis in Knee Osteoarthritis Outcome Scores from baseline to 4 and 12 months follow up.

	Baseline			Short term follow-up		4 months	Long term follow-up		12 months	
	n	CG Mean (SD)	IG Mean (SD)	CG Mean (SD)	IG Mean (SD)	Diff. (95% CI)	CG Mean (SD)	IG Mean (SD)	Diff. (95% CI)	Adjust.[b] ANOVA
Pain[K] (0–100)	20	68 (10)	64 (14)	69 (15)	78 (11)	8.9 (0.4;17)	74 (16)	79 (12)	5.1 (3.8;14)	0.015[a]
Symptom[K] (0–100)	20	72 (14)	69 (10)	76 (14)	79 (11)	2.9 (−5.3;11)	77 (12)	80 (13)	2.5 (−5.5;11)	0.228
ADL[K] (0–100)	20	78 (11)	76 (10)	78 (15)	83 (10)	5.5 (−2.6;14)	81 (15)	85 (12)	4.4 (−4.1;13)	0.071
Sport[K] (0–100)	20	47 (24)	46 (17)	48 (26)	59 (16)	11.3 (−2.3;25)	52 (27)	60 (24)	8.5 (−7.9;25)	0.058
QoL[K] (0–100)	20	46 (14)	45 (14)	50 (16)	54 (15)	4.4 (−5.2;14)	50 (13)	60 (17)	7.5 (−3.8;19)	0.124

CG = Control Group and IG = Intervention Group. K Indicate KOOS subscores. ADL = Activities of Daily Living. QoL = Quality of Life.
[a] Significant time*treatment interaction.
[b] Adjusted for baseline difference in calcaneal angle.

Improvement in KOOS pain was significantly correlated with a high midfoot flexibility at baseline. This was measured as the difference in Talus — first metatarsal angle (X-ray) from an unloaded to a loaded position (r = 0.43, P = 0.015 at 4 months; r = 0.39, P = 0.029 at 12 months). No other baseline parameter of foot posture was correlated to pain reduction from the explorative analysis. Individuals in the IG participated in an average of 10 sessions during the 12 weeks. Compliance to use of orthoses was not recorded. There was a significant difference in number of physiotherapy sessions between patients with or without treatment success (pain reduction >10 KOOS), 5 vs 9 visits, P = 0.05.

4. Discussion

Individuals randomized to knee targeted exercises combined with foot targeted exercises and foot orthoses had a significantly larger improvement in pain compared to individuals randomized to knee targeted exercises at 4 months follow-up. The difference did not exceed the clinically relevant difference for the KOOS. Still, this is important and suggests that a group of individuals with an excessive calcaneal eversion may benefit from a distally targeted treatment program and 12/20 (IG) and 5/20(CG) had a successful outcome.

The reason why foot orthoses and foot exercises reduce pain among individuals with PFP is currently unknown. However, it appears that orthoses may work by changing the biomechanics of the foot.[8] Furthermore, this may have kinematic effects on the entire lower extremity, possibly reducing internal tibial rotation, hip adduction, which may result in a reduction in internal femoral rotation thus decreasing lateral compressive forces on the patella and subsequently improve knee pain.[8,9,20] Furthermore, orthoses alter shock attenuation and reduce loading rate and vertical impact rate, which are believed to reduce load of the PFJ during walking and running.[20] We have previously shown that individuals with PFP have a 20–30% more medially directed foot-loading pattern compared to healthy individuals during high load activities.[21] Applying orthoses during high load activities can reduce medial to lateral peak load significantly.[22] The large forces imposed on the knee during these high load activities are transmitted from the foot and up through the kinetic chain to the knee. Loading of the knee and the patellofemoral joint is therefore dependent on force dissipation and loading patterns of the foot.[20,23] By using a distally focussed treatment consisting of both foot targeted exercises and foot orthoses may hypothetically lead to decreased forces acting on the patellofemoral joint and thereby improve pain.[20]

Foot orthoses has previously been shown to be effective (moderate effect size) in the short term in reducing pain in individuals with PFP.[6,7,24] The results of a meta-analysis showed that posted non-molded orthoses, as used in the present study, systematically reduced peak rearfoot eversion (2.12° (95% CI 0.72–3.53)) and tibial internal rotation (1.33° (0.12–2.53)) in non-injured cohorts.[20] Previous works suggest that individuals with a high midfoot mobility, high static navicular drop and large calcaneal eversion during overground gait were more likely to benefit from orthoses.[7,24,25] This suggests that individuals with excessive calcaneal eversion are more likely to benefit from orthoses, as a result of altered foot biomechanics.[26] So it is plausible that foot orthoses might have a mechanical effect on the patellofemoral joint.[26,27] Interestingly, a modelling study of foot orthoses on patellofemoral joint load indicated that while there was a significant effect, there was considerable inter-individual variation in the response[28] which further underpins the need to address who is most likely to benefit from foot orthoses.

The present study included patients with a long duration of PFP which has been associated with a poorer prognosis in previous research.[29] At 12 weeks follow-up Collins et al. found no significant difference between physiotherapy and physiotherapy plus orthoses (NNT = 7) despite a younger patient group with a much shorter duration of pain compared to the present study. The combination of foot targeted exercise and orthoses in the present study was effective — NNT of 3 (2–16). When comparing flat inserts and orthoses at 12 weeks the results were even less NNT = 50 in patients with PFP not selected based on foot posture.[24] The study design did however not allow distinguishing between foot targeted exercise and orthoses. The present study further supports the role of a distally oriented treatment program by showing that individuals with an excessive calcaneal eversion have larger improvements in pain if they are treated with foot orthoses and specific foot exercises. This also supports previous expert clinical experience, which indicates an effect of distal exercises.[4] Ideally the effect would also have manifested in the other domains of the KOOS. However a similar trend was published from the patellofemoral pain consensus statement. The appropriateness of each intervention was evaluated and there seems to be consensus that exercise is more certain to reduce pain than symptoms and function in the short term (<6 months).[30]

The difference in Talus — first metatarsal angle from an unloaded to a loaded position was the only static foot posture measured that was correlated with pain reduction. This is not surprising, as excessive calcaneal eversion was an inclusion criteria and has narrowed the opportunity for much spread in the foot measures. Nervertheless, Talus-first metatarsal mobility (X-ray) measured midfoot mobility. Others reported midfoot mobility as one of the clinical features that can predict success with foot orthoses intervention, including greater midfoot mobility.[6,7]

The relative small sample size and the highly selected population with excessive calcaneal eversion limit the generalizability of the study. Importantly, these results may only apply to individuals with PFP with a clinically verified everted foot posture. The selected sample of individuals with PFP and clinically verified eversion may also be a significant strength of the current study. This study is one of the first studies that try to target a specific treatment to a specific subgroup. As the study used combined treatments, it is not possible to elucidate which of the individual components were responsible for the improvements in pain or if it was the combined effect of all individual components. The intervention group received more exercise and contact with the physiotherapist, which is a potential intervention bias in favor of the intervention. A similar intervention could potentially be equally effective in patients with a neutral foot posture. None of the participant received specific hip strength training at the time of the study, which is now considered as best practice.

5. Conclusion

There are many different evidence-based treatment options available for individual with PFP. The addition of foot targeted exercises and foot orthoses to knee targeted interventions, for 12 weeks was more effective than knee targeted exercises alone in individuals with PFP and an everted foot posture. The effect was apparent after 4 months, but not significantly different after 12 months. The combination of orthoses and foot exercises may serve as an important additional treatment option for individuals with PFP in addition to existing hip and knee targeted treatment programs.

Contributors

CMM conceived the study, monitored data collection for the whole trial, wrote the statistical analysis plan, cleaned and analysed the data, and drafted and revised the paper. He is guarantor. JA analysed the data, and drafted and revised the paper. MC conducted the trial, analysed the data and revised the paper. SLC wrote the statistical analysis plan, and revised the draft paper. OS initiated the collaborative project, designed data collection tools, monitored data collection for the whole trial, and revised the draft paper. MSR analysed data, drafted and revised the paper. SK initiated the collaborative project, enrolled patients and revised the paper. All authors helped design the trial.

Practical implications

- Patients treated with a combination of foot orthoses and foot targeted exercises showed significantly greater improvement in pain compared to the control group.

- The combination of orthoses and foot exercises may serve as an important additional treatment for patients with patellofemoral pain syndrome in addition to knee and hip strength training protocols.
- Numbers needed to treat was 3 (2–16) at four months follow-up.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.jsams.2017.05.019.

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