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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-