Effectiveness of custom made insoles in athletes with patellofemoral pain; a randomized controlled trial.

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The aim of this study is to determine the clinical effectiveness of custom-made insoles on the general pain severity of patients with PFPS after 12 weeks from baseline.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON37189

Source
ToetsingOnline

Brief title
Effectiveness of insoles in athletes with patellofemoral pain

Condition

- Tendon, ligament and cartilage disorders

Synonym
anterior knee pain, chondromalacia patellae

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Athletes, Insoles, Orthoses, Patellofemoral pain syndrome

Outcome measures

Primary outcome

General pain severity over the preceding week after 12 weeks from baseline, measured on a numeric rating scale (NRS).

Secondary outcome

- experience of pain (using a NRS) and impairment (using a Likert scale) on activities of daily living, on work/study and on sporting activities over the preceding week

- self-reported recovery (using a Likert scale)

- functional disability (using the Anterior Knee Pain scale)

- participants pain experience (using two questionnaires: SCL-90 and POMS)

- satisfaction with the custom-made insoles based on comfort

Study description

Background summary

This study was designed after reviewing the literature on conservative therapy for patellofemoral pain syndrome (PFPS) in athletes. It was concluded that despite the wide prevalence and impact of PFPS there is a lack of high-quality research for the conservative management of PFPS in athletes. Insoles seem to play an important role in the general prevention and clinical management of PFPS, but again this is not studied in athletes. We investigate the effectiveness of insoles in athletes with patellofemoral pain on pain severity, perceived impairment, perceived recovery and functional disability. If custom-made insoles prove to be effective in athletes with patellofemoral pain syndrome, this may be helpful for optimizing treatment of those suffering from this condition.

Study objective

The aim of this study is to determine the clinical effectiveness of custom-made insoles on the general pain severity of patients with PFPS after 12 weeks from baseline.

Study design

The study involves a randomized controlled clinical trial with a 12-week follow-up from baseline. It will have two treatment arms: a home-based exercise program combined with custom-made insoles compared with a home-based exercise program with flat insoles.

Intervention

80 participants will be randomly assigned to the treatment or placebo group. Both groups will receive a home-based exercise program. In addition, the treatment group receives custom-made insoles and the placebo group flat insoles.

Study burden and risks

Participants have to come to Groningen one to four times, have to wear the insoles as often as possible, and accomplish the home-based exercise program 5 days a week for 25 minutes. They also have to fill in a questionnaire three times and keep up the logbook once a week, and will be called once. This study involves no risks associated with participation. Patients have to wear insoles that will fit their shoes comfortably as a primary goal to prevent wounds. The home-based exercise program is easy to accomplish and there are no dangerous exercises.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age 18-40 years
- athletes sporting at least three hours a week pre-injury
- clinical diagnosis of patellofemoral pain syndrome: insidious onset of anterior or retropatellar knee pain lasting longer than six weeks and provoked by at least two of the following activities: prolonged sitting or kneeling, squatting, running, hopping/jumping, climbing stairs; tenderness upon palpation of the patella, and worst pain over the previous week of at least 3 out of 10 on a 10-point numerical rating scale.

Exclusion criteria

- A traumatic origin
- Concomitant injury or pain form the hip, lumbar spine, or other knee structures (like intra-articular pathology of the knee, Osgood Schlatter*s disease, bursitis and patellar tendinopathy)
- Previous knee surgery
- Patellofemoral instability
- Knee joint effusion
- Previous treatment with insoles or physiotherapy in the preceding 12 months

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2012
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	24-01-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL41127.042.12
Other	TC 3430