

Effectiveness of insoles in athletes with patellofemoral pain.

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Our hypothesis is that custom made insoles and a home-based exercise program would be superior to a home-based exercise program alone at 12 weeks follow-up.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20854

Bron

NTR

Aandoening

- Patellofemoral pain syndrom
- Insoles, inlays, orthoses
- Athletes
- Patellofemoraal pijn syndroom
- PFPS
- Inlegzolen
- Sporters

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The participants fill in a (online) questionnaire before randomisation (baseline) and at 6 and 12 weeks after randomisation. The questionnaires contain questions regarding general pain and impairment, pain and impairment on general activities of daily living, during work/study activities and during sporting activities over the preceding week (10 point Likert scale), self

reported recovery (6 point Likert scale) and the Kujala score.

Toelichting onderzoek

Achtergrond van het onderzoek

This study had been designed after reviewing the literature on conservative therapy for patellofemoral pain syndrome in athletes. It was concluded despite the prevalence and the impact of PFPS is huge there is a lack of high quality research on the conservative management of PFPS in athletes. Insoles seem to play an important role in the prevention and clinical management of PFPS in the general, but again this is not studied in athletes. Based on available literature our research group expects to discover effectiveness of insoles in athletes with patellofemoral pain in perceived recovery, pain severity, impairment and functional disability. This study is a randomized clinical trial where customised insoles and a home based exercise program is compared to flat insoles and a home based exercise program.

Doel van het onderzoek

Our hypothesis is that custom made insoles and a home-based exercise program would be superior to a home-based exercise program alone at 12 weeks follow-up.

Onderzoeksopzet

Start inclusion: August 2012;

Start intervention: September 2012;

Follow-up: September 2012 till december 2012/ Februari 2013;

End of study: December 2013.

Onderzoeksproduct en/of interventie

The patiënt will be randomly assigned to the treatment or placebo group. Both the treatment and the placebo group will receive a home exercise program. In addition the treatment group receives custom made insoles and the placebo group flat insoles. They will have to wear the custom made insoles daily.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 18-40 years;
2. Athlete sporting at least 3 hours a week pre-injury;
3. Clinical diagnosis of patellofemoral pain syndrome: insidious onset of anterior or retropatellar knee pain of greater than six weeks duration and provoked by at least two of the following activities: prolonged sitting or kneeling, squatting, running, hopping/jumping, or stair walking;
4. Tenderness on palpation of the patella, or pain with step down or double leg squat;
5. Worst pain over the previous week of at least 3 out of 10 on a 10 point numerical rating scale.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. A traumatic origin;
2. Concomitant injury or pain from the hip, lumbar spine, or other knee structures;

3. Previous knee surgery;
4. Patellofemoral instability;
5. Knee joint effusion;
6. Any foot condition that precluded use of insoles;
7. Previous treatment with insoles or physiotherapy in the preceding 12 months.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2012
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3277
NTR-old	NTR3430
Ander register	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A