Improving knee joint stability in osteoarthritis with exercise therapy: does it work?

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Exercise therapy aimed at improving the knee joint stabilisation process, followed by muscle strengthening and functional training of daily activities, is more effective than muscle strengthening exercises followed by functional training in...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28274

Bron
NTR

Verkorte titel
STABILO

Aandoening

osteoarthritis, knee, joint instability, elderly, physical functioning, pain, laxity, proprioception, muscle strength, walking.

artrose, knie, gewrichtsinstabiliteit, ouderen, fysiek functioneren, pijn, laxiteit, propriocepsis, spierkracht, lopen.

Ondersteuning

Primaire sponsor: This study will be carried out by the VU University Medical Centre (VUmc) and Jan van Breemen Institute in Amsterdam
Overige ondersteuning: - Dutch Arthritis Association / Reumafonds
- VU University Medical Centre
- Jan van Breemen Institute

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

21-12-2011 Changes:
The primary outcome measure in this RCT is self-reported physical functioning as assessed with the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).

Toelichting onderzoek

Achtergrond van het onderzoek

This application concerns a study on the effectiveness of an exercise therapy programme aimed at improving knee joint stabilization in patients with osteoarthritis (OA) of the knee. Recent studies have shown that the process of knee joint stabilization is strongly related to the daily functioning of patients with OA. However, there are no treatments available that focus specifically on improving this process. Based on previous studies and a pilot study, it is expected that such a treatment programme will result in a considerable improvement in daily functioning. In the study featured in this application, two exercise therapy programs are compared. In the experimental group patients first receive therapy aimed at improving knee joint stabilization, followed muscle strengthening exercises and finally training of specific daily activities. In the control group, only muscle strengthening exercises and specific training of daily activities will be performed. Both groups receive 12 weeks of treatment.

In total 120 patients with OA and knee joint instability will participate (2x60), who will be randomized into one of the two treatment groups. Measurements will be taken prior to the start of the exercise therapy, and after 6, 12 and 38 weeks. Measurements include the assessment of daily functioning (Get Up and Go test, WOMAC questionnaire), biomechanical factors (muscle strength, laxity, joint proprioception), pain, fatigue and patient-perceived improvement.

It is expected that this study will show that the STABILO-training protocol is more effective in improving patient daily functioning than state-of-the-art exercise therapy.

Doel van het onderzoek

Exercise therapy aimed at improving the knee joint stabilisation process, followed by muscle strengthening and functional training of daily activities, is more effective than muscle strengthening exercises followed by functional training in improving physical functioning in daily activities in knee osteoarthritis patients with knee joint instability

Onderzoeksopzet

21-12-2011 Changes:
- December 1, 2008; official project start

- April 1, 2009: start of inclusion period, first baseline measurements

- June, 2009: first 6-week measurements

- August, 2009: first 12-week measurements

- February 2010: first 38-week measurements

- June 2011: end of inclusion period

- August 2011: final 6-week measurements

- October 2011: final 12-week measurements

- April 2012: final 38-week measurements

- March 31, 2013: end of project

Onderzoeksproduct en/of interventie

21-12-2011 Changes:
Experimental group:

The experimental intervention comprises a 12-week exercise therapy programme aimed at:

1) improving the knee joint stabilisation process

2) muscle strengthening

3) functional training of daily physical activities.

Patients will exercise twice a week in groups of 5-6 patients led by experienced physical

therapists specifically trained to provide this intervention.

In the first six weeks of exercise therapy, the focus is on improving knee joint stabilization. In the first week, low-intensity exercises with minimal joint loading are performed in the swimming pool. From the second week onwards, intensity of exercises and joint loading will be gradually increased during land-based exercise therapy sessions. These sessions comprise exercises specifically aimed at improving proprioceptive awareness (“feeling movements”), postural balance, and knee joint stability (actively minimizing the giving way, shifting or buckling of the knee) During these sessions, patients are also instructed to focus on neutral alignment of the knee (i.e., a linear alignment of hip, knee and ankle) while performing exercises. Starting in week 5, muscle strengthening exercises will be added to the programme and will gradually increase in frequency and intensity.

During the second six-week period, muscle strengthening exercises are initially dominant in the program. From week 8 onwards, the functional training of mobility-related daily activities is added to the program. Exercises will be individually tailored to specific activities indicated to be relevant and problematic by the patients themselves during a Patient Specific Complaint questionnaire at baseline.

Control group:
Patients in the control group will also receive a 12-week exercise therapy programme, aimed at muscle strengthening for the first seven weeks. Exercises will gradually increase in frequency and intensity. From week 8 onwards, the functional training of mobility-related daily activities is added to the programme using tailored exercises based on the information from the Patient Specific Complaint questionnaire

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

21-12-2011 Changes:
1. Diagnosis of knee OA according to the clinical ACR criteria, i.e.: knee pain and at least three of the following six: age > 50 years, morning stiffness <30 minutes, crepitus, bony tenderness, bony enlargement and no palpable warmth.

2. Age between 40 and 75 years.

3. Sufficient control of the Dutch language.

4. At least one of the following three criteria:

* self-reported instability of the knee joint affecting daily functioning, as assessed with Fitzgerald's knee stability questionnaire. A self-reported knee instability rating of 1 ("the symptom affects my activity mildly") or worse is regarded to reflect knee instability affecting daily functioning

* bodyweight-adjusted isokinetic hamstrings strength of 0.8 Nm/kg or less for men or 0.55 Nm/kg or less for women, in combination with a knee joint proprioception score of 4.3° or higher, as established with the instrumented knee proprioception test

* bodyweight-adjusted isokinetic hamstrings strength of 0.8 Nm/kg or less for men or 0.55 Nm/kg or less for women, in combination with a knee joint laxity score of 4.6° or higher for men or 7.7° or higher for women, as established with the instrumented knee laxity test

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Co-morbidity which clearly affects functional ability.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2008
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	03-10-2008
Soort:	Eerste indiening

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	NL1415
NTR-old	NTR1475
Ander register	Reumafonds : DAA 08-1-301
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A