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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28274

Source
NTR

Brief title
STABILO

Health condition

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

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

Sponsors and support

Primary sponsor: This study will be carried out by the VU University Medical Centre (VUmc) and Jan van Breemen Institute in Amsterdam
Source(s) of monetary or material Support: - Dutch Arthritis Association / Reumafonds
- VU University Medical Centre
- Jan van Breemen Institute

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

21-12-2011 Changes:
A number of secondary outcome measures are included in the study, reflecting both the assessment of disabilities in specific daily activities, the patient perspective, and relevant biomechanical factors.
These measures are:

- perceived global effect (7-point Likert scale)

- pain intensity (0-10 NRS)

- stiffness (WOMAC)

- fatigue (0-10 NRS)

- Fitzgerald’s self-reported knee joint instability scale

- proprioception

- laxity

- isokinetic muscle strength of the upper leg (BioDex)

- frontal plane alignment of the knee (goniometer)

- observed walking and transfer ability as assessed with the Get Up and Go (GUG) test

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

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

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

1. Co-morbidity which clearly affects functional ability.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2008
Enrollment:	120
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	03-10-2008
Application type:	First submission

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

Study results

Summary results
N/A