# STABILO: a randomised controlled trial of knee joint stabilisation therapy in osteoarthritis of the knee

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To establish the effectiveness of knee joint stabilisation exercise therapy in patients with knee osteoarthritis and knee joint instability, relative to usual-care exercise therapy

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Joint disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON33836

**Source**
ToetsingOnline

**Brief title**
STABILO

### Condition

- Joint disorders

**Synonym**
arthrosis, osteoarthritis

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum
**Source(s) of monetary or material Support:** Reumafonds

## Intervention

**Keyword:** Exercise therapy, Joint stability, Osteoarthritis, Randomized controlled trial

## Outcome measures

### Primary outcome

The primary outcome measure in this RCT is self-reported physical functioning as assessed with the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). The WOMAC-pf is a commonly used questionnaire to assess the physical functioning of patients with OA, and has been shown to be reliable, valid and sensitive to change.

### Secondary outcome

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), Irrgang*s and Felson*s self-reported knee joint instability scales, questionnaires on rising and sitting down, walking and stair climbing, proprioception, laxity, isokinetic muscle strength of the upper leg (BioDex) and frontal plane alignment of the knee (goniometer). Body length and weight will be collected at all time points to assess changes in Body Mass Index

# Study description

### Background summary

Based on a biomechanical model of physical functioning in patients with osteoarthritis of the knee, it is expected that an exercise program which initially focuses on knee joint stabilisation, followed by muscle strengthening and applied functional training of daily activities, is more effective in improving the functional status of patients with OA than current exercise programs, which are primarily aimed at muscle strengthening.

## Study objective

To establish the effectiveness of knee joint stabilisation exercise therapy in patients with knee osteoarthritis and knee joint instability, relative to usual-care exercise therapy

## Study design

This study is a single-blind randomized controlled trial. Eligible patients will be randomized into two treatment groups: the experimental group will receive a 12-week exercise therapy program aimed at improving the joint stabilization process, while the control group will receive a 12-week muscle strengthening program. Measurements will be made prior to the start of therapy (baseline), and at 6 weeks (intermediate), 12 weeks (end of intervention) and 38 weeks (6 month follow-up).

## Intervention

Experimental intervention
The experimental intervention comprises a 12-week exercise therapy program aimed at 1) improving the knee joint stabilisation process, 2) muscle strengthening and 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 program 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 MACTAR interview at baseline.

Control intervention
Patients in the control group will also receive a 12-week exercise therapy program, 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 program using tailored exercises based on the information from the MACTAR interview.

**Study burden and risks**

Both the experimental and control intervention comprise 24 1-hour therapeutic sessions, in which various body functions are trained in a physically active manner. Additionally, participants will be measured four times over a 38-week period. These measures include both questionnaires and physical tests. Fatigue and muscle pain may result from therapy and measurements.
During the inclusion, radiographs of the knees will be made once.
It is expected that participants in both the experimental and control group will experience considerable helath benefits from participating in this study.

Additional to the standard diagnostic tests, an MRI-scan of the most symptomatic knee will be made. In participants with increased risk of complications, this scan will not be made.

# 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

All potential participants* eligibility will first be assessed by a physiatrist, using the following inclusion criteria:
- 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.
- Age between 40 and 75 years
- Sufficient control of the Dutch language;Patients meeting these initial inclusion criteria will then be screened for symptoms of knee joint instability by a physical therapist. Patients are eligible for inclusion in the trial if they meet at least one of the following three criteria:
1. self-reported instability of the knee joint affecting daily functioning, as assessed with Irrgang*s knee stability questionnaire. A self-reported knee instability rating of 1 (*the symptom affects my activity slightly*) or worse is regarded to reflect knee instability affecting daily functioning
2. bodyweight-adjusted isokinetic quadriceps 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 (9;28)
3. bodyweight-adjusted isokinetic quadriceps 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 (8;27)}

## Exclusion criteria

Co-morbidity which affects functional ability

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

NL

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| Recruitment status: | Recruiting |
| Start date (anticipated): | 17-04-2009 |
| Enrollment: | 120 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 30-03-2009 |
| Application type: | First submission |
| Review commission: | METC Slotervaartziekenhuis en Reade (Amsterdam) |
| Approved WMO Date: | 26-08-2013 |
| Application type: | Amendment |
| Review commission: | METC Slotervaartziekenhuis, Jan van Breemen Instituut (Amsterdam) |

# 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 |
|---|---|
| Other | 1475 |
| CCMO | NL25349.048.08 |