

# Six-week high-intensity exercise program for middle-aged patients with knee osteoarthritis: a randomized controlled trial

<b>Submission date</b> 15/08/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 16/08/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 20/12/2007	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Ingemar Petersson

**Contact details**  
Spenshult Hospital for Rheumatic Diseases  
Oskarström  
Sweden  
S-313 92  
ingemar.petersson@spenshult.se

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

# Study information

## Scientific Title

## Study objectives

Short-term high-intensity exercise improves self-reported pain, function and quality of life in middle-aged patients with moderate to severe knee osteoarthritis.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

The study was approved by the Research Ethics Committee at Lund University (Sweden) (ref: LU 99-98), and is in compliance with the Helsinki Declaration.

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Knee osteoarthritis

## Interventions

A six-week high-intensity supervised exercise session twice a week, or a non-intervention control group.

## Intervention Type

Other

## Phase

Not Specified

## Primary outcome measure

Knee injury and Osteoarthritis Outcome Score (KOOS, a disease specific questionnaire, assessing pain, other symptoms, activities of daily living, sport and recreation function and knee-related quality of life). Time points of interest were 6 weeks and 6 months.

## **Secondary outcome measures**

1. 36-item short form health survey (SF-36, a generic measure of general health status)
2. Five tests of functional performance:
  - 2.1. Åstrands bicycle-ergometre test
  - 2.2. Rising on one leg from sitting on lowest possible height
  - 2.3. One-leg hop
  - 2.4. Lateral step-up
  - 2.5. One-leg semi squatting
  - 2.6. Heel-rising on one leg

## **Overall study start date**

09/10/1998

## **Completion date**

08/10/2001

# **Eligibility**

## **Key inclusion criteria**

1. Aged 35 - 65 years
2. Living in a defined geographic area
3. Diagnosis of radiographic knee osteoarthritis according to Kellgren & Lawrence grade III or more (i.e joint space narrowing and definite osteophytes)

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Sex**

Both

## **Target number of participants**

61

## **Key exclusion criteria**

1. Inflammatory joint disease
2. Anterior cruciate ligament injury
3. Known symptomatic injury to the menisci
4. Hip symptoms more aggravating than the knee symptoms
5. About to have knee replacement surgery within 6 months
6. Co-morbidities not allowing exercise

## **Date of first enrolment**

09/10/1998

## **Date of final enrolment**

08/10/2001

# Locations

## Countries of recruitment

Sweden

## Study participating centre

**Spenshult Hospital for Rheumatic Diseases**

Oskarström

Sweden

S-313 92

# Sponsor information

## Organisation

The Swedish Rheumatism Association (Sweden)

## Sponsor details

Alströmergatan 39

Box 12851

Stockholm

Sweden

S-112 98

jan.bagge@reumatikerforbundet.se

## Sponsor type

Charity

## Website

<http://www.reumatikerforbundet.org>

## ROR

<https://ror.org/00zps9v98>

# Funder(s)

## Funder type

Research organisation

## Funder Name

The Vårdal Foundation (Sweden)

**Funder Name**

The Swedish Rheumatism Association in Stockholm (Sweden)

**Funder Name**

The Swedish Rheumatism Association in Gothenburgh (Sweden)

**Funder Name**

The Swedish Research Council (Sweden)

**Funder Name**

The Department of Research and Development at Spenshult Hospital for Rheumatic Diseases (Sweden)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Results	30/05/2005		Yes	No