# Patellofemoral pain syndrome: long term follow-up outcomes of a randomized controlled trial

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To investigate the percentage of patients with persistent complaints and/or radiological abnormalities after 5 years follow-up after the first visit to the general practitioner or sport physician. 2. To investigate the long term effectiveness of...

**Ethical review** Approved WMO

**Status** Recruitment stopped

**Health condition type** Joint disorders

**Study type** Observational invasive

## **Summary**

#### ID

NL-OMON37666

#### Source

**ToetsingOnline** 

#### **Brief title**

Patellofemoral pain syndrome: long term outcomes

#### **Condition**

Joint disorders

#### **Synonym**

knee complaints

#### Research involving

Human

## **Sponsors and support**

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: KNGF-WCF

#### Intervention

**Keyword:** course, exercise therapy, general practice, knee

#### **Outcome measures**

#### **Primary outcome**

Primary outcomes are recovery (7-point Likert scale), semi-quantative features of the patellofemoral joint.

#### Secondary outcome

Pain, function, medical consumption, sport activity.

# **Study description**

#### **Background summary**

The patellofemoral painsyndrome (PFPS) is the most common overload injury in a relatively young and active population. A randomized trial (Pex-study) investigating the effectiveness of supervised exercise therapy, showed that exercise therapy is more effective compared to usual care in decreasing pain and improving function, at both short and long-term follow-up. However, 40% of the patients in the exercise therapy group indicated to have persistent complaints after 12 months follow-up.

#### Study objective

To investigate the percentage of patients with persistent complaints and/or radiological abnormalities after 5 years follow-up after the first visit to the general practitioner or sport physician. 2. To investigate the long term effectiveness of supervised exercise compared to usual care at long-term follow-up. 3. To investigate possible prognostic factors associated with persistent complaints after 5 years of follow-up.

#### Study design

The study concerns a long-term follow-up of 131 patients who participated in the Pex-study. Data will be collected with a questionnaire, physical examination and X-ray of the knee.

#### Study burden and risks

The risk to the subject will be minimal, because the research will exist of the usual care, except filling out an questionnaire. Burden for the subject will also be minimal, except X-ray radiation, and will be mainly exist of time for filling out a questionnaire, under wending a physical examination and an X-ray. There will be no direct benefits for the patients in this study.

## **Contacts**

#### **Public**

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#### **Scientific**

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## **Trial sites**

#### **Listed location countries**

**Netherlands** 

# **Eligibility criteria**

#### Age

Adults (18-64 years) Elderly (65 years and older)

#### Inclusion criteria

At baseline, patients with patellofemoral painsyndrome (the presence of at least three of the following symptoms: pain when walking up or down stairs; pain when squatting; pain when

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running; pain when cycling; pain when sitting with knees flexed for a prolonged period of time; grinding of the patella; and a positive clinical patellar test (such as Clarke\*s test or patellar femoral grinding test)) were included. All patients that had participated in the randomised clinical trail will be included in the follow-up study. These patients will be 18 years and older at the 6-year follow-up study.

#### **Exclusion criteria**

At baseline, patients were excluded if they had knee osteoarthritis, patellar tendinopathy, Osgood-Schlatter disease, or other defined pathological conditions of the knee, or had previous knee injuries or surgery. Patients who have indicated in the past that they wish not longer to participate in the

study will be excluded in this 6 year follow-up study

# Study design

## **Design**

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

#### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-03-2012

Enrollment: 131

Type: Anticipated

## **Ethics review**

Approved WMO

Date: 28-06-2012

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam

(Rotterdam)

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# **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

CCMO NL39666.078.12