Cost-effectiveness of exercise therapy added to general practitioner care for osteoarthritis of the hip.

No registrations found.

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

Summary

ID

NL-OMON28773

Source
Nationaal Trial Register

Brief title
STERK trial

Health condition

oefentherapie, fysiotherapie, heup, artrose, huisarts, exercise therapy, hip, osteoarthritis, physical therapy, general practitioner.

Sponsors and support

Primary sponsor: Erasmus MC
Department of General Practice
PO Box 2040
3000 CA Rotterdam, The Netherlands
Source(s) of monetary or material Support: ZonMW, The Netherlands

Intervention

Outcome measures

Primary outcome

Hip pain and hip function measured with the Hip Osteoarthritis disability Outcome Score (HOOS).

Secondary outcome

- Hip pain, Numeric Rating Scale score (NRS; 0-10 scale).

- Walking ability, 5-meter walking test (time in seconds).

- Functional mobility, timed Up and Go test.

- Perceived recovery (7-point Likert scale).

- Costs, EuroQol (EQ-5D) for the cost utility analysis and all direct medical and patient costs (TIC-P Questionnaire) and indirect costs (PRODISQ), such as referral to the orthopaedic specialist and subsequent treatment, including surgery.

Other parameters:

· Demographic data (including age, gender, height, weight, education, duration of complaints, previous hip pain, co-morbidity, scores from X-ray).

· Physical examination.

· Compliance to assigned treatment and implementation of home exercises.

· Co-interventions, including referral to physical therapy in the control group.

Study description

Background summary

1. Research question:
What is the cost-effectiveness of exercise therapy added to general practitioners (GP) care compared to general practitioners GP care alone over a period of 12 months in patients with a new episode of hip osteoarthritis (OA) in general practice?

2. Study design:
A prospective, multi-center, randomized clinical trial.

3. Study population:
Patients will be eligible for inclusion if they are 45 years or older and consulting for a new episode of hip OA in general practice.

4. Intervention:
The patients will be randomized into two groups, the intervention group, patients treated with exercise therapy (supervised by a physical therapist) added to GP care and the control group, patients managed by GP care only.

5. Outcome measures:
The primary outcomes are pain and function measured with the HOOS at baseline and at 3, 6, 9 and 12 months follow-up.

6. Sample size calculation/data analysis:
To detect a clinical relevant difference of 25% in pain (HOOS-pain) after one year with two-tailed testing, a power of 80%, an alpha 5%, cross-over 25%, 96 patients per group are needed. As we expect around 10% loss to follow-up, we need to include 210 patients. Data analysis will be based on the intention to treat principle. Additionally a per protocol analysis (patients receiving 80% or more of the maximum number of exercise therapy sessions) and subgroup analyses on age (45-65 years versus >65 years), pain intensity (NRS 3 or more), education,
joint space narrowing, gender and co-morbidity (Low back pain or knee pain) will be performed.

7. Economic evaluation:
Based on the HOOS (pain and function) and EuroQol (QALY during the first year) an incremental cost-effectiveness and cost-utility analysis will be conducted.

Study objective

What is the cost-effectiveness of exercise therapy added to general practitioners care compared to general practitioners care alone over a period of 12 months in patients with a new episode of hip osteoarthritis in general practice?

Study design

All outcome measures will be obtained by the research assistant at baseline and at 3, 6, 9 and 12 months after randomization, with the exception of the outcome measures from

physical examination, walking ability (walking test) and functional mobility (Up and Go test) which will only be obtained at baseline and at 12 months follow-up.

Intervention

Intervention group:

Fifteen consultations for exercise therapy will be prescribed and content, intensity, and frequency of treatment will be tailored to the patient's needs. A maximum of 12 sessions is allowed in the first 3 months.
Three additional booster sessions are planned in the fifth, seventh and ninth month. The physical therapy sessions in primary care will last about 30 minutes each. The exercise therapy will be discontinued if, according to the physical therapist and the patient, treatment goals have been achieved.

Control group:

In the GP only group the treatment is given by their own GP. The GPs will provide education and councelling including the advice to stay active and if possible return to work and/or resume leisure activities. If necessary, pain medication can be prescribed. Acetaminophen (paracetamol) is the first choice. If not effective, NSAID's (ibuprofen, diclofenac or naproxen) may be prescribed. When indicated the GPs can refer to physical therapy for patients allocated to the control group of the study.

The patients in both groups will receive an identical brochure with information and advice.

Contacts

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Eligibility criteria

Inclusion criteria

Patients will be eligible for inclusion in this trial if they:

1. Consult the GP for a new episode of non-traumatic hip complaints.

2. Are 45 years or older.

3. Comply with the clinical American College of Rheumatology (ACR) criteria for hip OA.

4. Complete the informed consent procedure.

Exclusion criteria

Patients will be excluded if they:

1. Are already treated with exercise therapy in the present episode of hip OA.

2. Have hip pain score of <2 on numeric rating score (0-10 scale).

3. Have a high level of physical function, a score of <2 on the walking ability and the physical function sections of the Algofunctional index.

4. Have undergone hip surgery or those on the waiting list for surgery.

5. Have severe disabling co-morbidity.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2009
Enrollment:	210
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-09-2008
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	NL1403

Register	ID
NTR-old	NTR1462
Other	: 17099.2402
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A