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

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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?

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28773

Bron
Nationaal Trial Register

Verkorte titel
STERK trial

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus MC
Department of General Practice
PO Box 2040
3000 CA Rotterdam, The Netherlands
Overige ondersteuning: ZonMW, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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?

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-02-2009
Aantal proefpersonen:	210
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-09-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1403
NTR-old	NTR1462
Ander register	: 17099.2402
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A