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Effectiveness of exercise therapy in hip osteoarthritis

Submission date	Recruitment status	[ ] Prospectively registered
26/03/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/04/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/04/2009	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Effectiveness of exercise therapy in hip osteoarthritis: a randomised controlled trial in primary health care

Study objectives
1. Patients with hip osteoarthritis (OA) can undergo an exercise-training programme despite their pain and disability
2. Strength and range of motion exercises and general aerobic conditioning can reduce hip pain and improve physical function more effectively than general treatment alone
3. Compliance of exercise therapy improves by using exercise diaries and leads to better long-term results
4. The exercise-training programme reduces the need of drug treatments and medical care of patients with hip OA more than general treatment alone

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Mikkeli Central Hospital approved on the 6th June 2005. Amendments approved on the 27th August 2007.

Study design
Single centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Osteoarthritis of the hip

Interventions
The intervention group received 12 supervised, (once per week, sustaining 45 minutes), rehabilitation sessions at baseline and four additional booster sessions at a point one year later. A physiotherapist working in primary care led supervised rehabilitation sessions for exercise groups consisting of ten participants at any given time. Following supervision, participants were recommended to perform the exercises using the same protocol three times per week for 3 years.

The exercise programme was developed with common training principles as well as with the results of the other studies. It consisted of mainly strengthening exercises. The intensity of exercise training was not individually adjusted for each participant; they were recommended to perform strengthening exercise with maximum speed and power. Each training session started with a warm-up session with marching in place using arms as part of the movement for one minute. Stepping forward, backward, sideways in place for 2 minutes and finally cycling the legs in a supine position for 1 minute. The strengthening section included seven different exercises for hip and knee flexors, extensors, hip abductors and adductors and for pelvic and abdominal muscles for 30 - 35 minutes. The stretching section consisted of six different, analogues muscle flexibility exercises for hip, knee and ankle flexors and extensors and hip adductors, holding each position for 30 seconds with tailored intensity.

Participants in the GP-care group (no intervention) received standard care.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Self-reported pain and disease specific physical function were assessed by using the pain and functioning subscales of the WOMAC
2. Self-reported generic physical function was assessed by using the physical function score of the Finnish-validated SF-36 (36-item) Health Survey
3. Economic effectiveness was assessed by evaluating the number of doctor visits (associated with hip OA) and physiotherapy (sum score of using physiotherapy including exercise programme and/or inpatient rehabilitation associated with hip OA). The need of surgery (total hip replacement) and drug use (non-opioid analgesic (paracetamol, non steroidal anti-inflammatory drugs [NSAIDs]) and weak opioid (tramadol, codeine) concerning hip OA were also assessed.

Assesssed at the following timepoints: 0, 3, 6, 12, 18, 24 and 36 months.

Key secondary outcome(s))
Objective functional scores:
1. Passive internal rotation and flexion of the hip joint
2. Extensor power of lower limb
3. Six Minute Walk Test (6MWT)
4. Ten-Metre Walk Test
5. Timed Up & Go (TUG) test
6. Sock Test

Assessed at the following timepoints: 0, 3, 12, 24 and 36 months.

Completion date
07/04/2009

Eligibility

Key inclusion criteria
1. Both males and females, aged from 55 to 80 years
2. Unilateral or bilateral radiographic hip OA (X-ray less than 3 years old)
3. Pain experience in the hip region within the preceding month as indicated in the clinical criteria of the American College of Rheumatology

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Total hip replacement
2. Rheumatoid arthritis
3. Cognitive impairment
4. Major surgical operation within the preceding 6 months in the lower limb or lower back area
5. Acute or sub-acute lower back pain
6. Cardiovascular or pulmonary disease or some other chronic disease that would prevent full participation in the training programme

Date of first enrolment
04/07/2005

Date of final enrolment
07/04/2009

Locations

Countries of recruitment
Finland

Study participating centre
Department of Physical and Rehabilitation Medicine
Kuopio
Finland
70211

Sponsor information

Organisation
Mikkeli Central Hospital (Finland)

ROR
https://ror.org/00te55z70

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Mikkeli Central Hospital (Finland)

Funder Name
Kuopio University Hospital (Finland)

Alternative Name(s)
Kuopio University Hospital, KYS

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Finland

Funder Name
Kuopio University (Finland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration