Exercise therapy and comorbidity in osteoarthritis of the hip or knee: case series

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON34798

Source
ToetsingOnline

Brief title
Comorbidity and exercise therapy in osteoarthritis: case studies

Condition

- Joint disorders

Synonym
osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Koningklijk Nederlands Genootschap Fysiotherapie (KNGF)
Source(s) of monetary or material Support: Koningklijk Nederlands Genootschap Fysiotherapie

Intervention

Keyword: comorbidity, exercise therapy, osteoarthritis

Outcome measures

Primary outcome

A process evaluation and treatment evaluation are performed in this study.

The process evaluation is based on the framework described by van Schenkman et al. 2006. We will evaluate which adaptations have been made to the standard treatment protocol due to co-morbidity. The form will be filled in by the therapist at the start and at the end of the treatment process. Additionally, after each treatment session, a registration form will be completed by the therapist, detailing specific changes that were made concerning that session. At the end of the treatment process, the therapist will be interviewed to identify strengths and weaknesses in the treatment protocol and possible areas of improvement. The patient will also be interviewed to obtain information about treatment satisfaction, as well as possible areas of improvement in the treatment process.

Primary outcome measures to evaluate treatment success are the Time Get Up and Go Test and the physical functioning scale of the Western Ontario and MacMasters Universities Osteoarthritis Index (WOMAC-pf).

Secondary outcome

Secundary parameters in the treatment evaluation are the 6-minute walking test, stair climbing test, knee joint proprioception, flexion and extension knee

muscle strength, perceived global effect (7-point Likert scale), pain (0-10

NRS), stiffness (WOMAC), fatigue (VAS) en patient specific complaints checklist

(PSK)

Study description

Background summary

Physical therapy has been proved to be an effective intervention for patients with knee and/or hip osteoarthritis in reducing pain and improving physical functioning. Physical therapy, e.g., exercise therapy, is recommended in existing guidelines.
Comorbidity is highly prevalent in patients with knee and/or hip osteoarthritis. As comorbidity is associated with physical and psychological limitations it is important to adapt exercise therapy to the comorbidity. For example, exercise therapy for a diabetis patient should be delayed when blood glucosis levels are equal or below 5 mmol/l. Another example is the adaptation of exercise therapy for a patient with chronic widespread pain by using behavioural principles.
In existing guidelines patiens with comorbidity are often excluded and no advice is given how exercise therapy should be adapted to comorbidity.

Study objective

The aim of this explorative study is to develop and evaluate an exercise protocol for patients with knee and/or hip osteoarthritis and comorbidity (e.g., coronary heart diseases, heart failure, hypertension, diabetes type 2, chronic obstructive pulmonary diseases (COPD), arthritis of the foot and hand, low back pain, chronic pain, depression, visual/hearing impairments and cystitis)

Study design

The present study is performed with case studies. At least 12 case studies (with a minimum of 1 case study per comorbidity) will be performed, including all relevant comorbidities.
Measurements for the evaluation of the treatmentprocess and the evaluation of the treatment itself will be performed.
Evaluation of the treatment process: weekly measurements and a pre- and posttreatment measurement.
Evaluation of the treatment itself: weekly measurements and three more extensive measurements which will be planned at baseline, in week 12 and

immediately after the treament.

Intervention

Prior to treatment, the goals for the treatment are established which have to be relevant for the patient. Examples of frequently established goals are: (1) increasing walking distance (2) improving stair climbing and (3) raising from a chair with less effort.
The following training modalities are used: aerobic exercise, strength training, training of coordination and stability, training of range of motion, training of daily activities such as walking and stair climbing. The training modalities have been advised in the guideline for knee an hip osteoarthritis (KNGF).

During the treatment of the case studies the exercise therapy will be adapted to the comorbidity in: intensity, duration and content of the therapy. This depends on present restrictions in exercise therapy, identified by the therapist during anamnesis and physical examination. A treatment protocol was developed for each comorbidity. In addition to exercise therapy, education will be given about the pathology and on how to cope with it. Therapy sessions will be given once or twice a week, during half an hour or one hour, depending on the complexity of the diseases. Treatment will be ended when the goals for treatment have been reached or no more improvements towards these goals can be expected.

Study burden and risks

This study will provide insight into how exercise therapy treatment can be adapted in the presence of comorbidity, in patients with knee or hip osteoarthritis. Patient burden is limited to the time and effort needed to participate in the therapeutic and measurement sessions. there are no specific risks associated with participation, as the patients will be exposed to a treatment that is regularly provided to osteoarthritis patients within the jan van Breemen Institute, with adaptations made specifically for the benefit of patients with present comorbidity.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- diagnosis of knee OA according to the clinical ACR criteria (33), i.e.: knee pain and at least three of the following six: age > 50 years, morning stiffness <30 minutes, crepitus, bony tenderness, bony enlargement and no palpable warmth
- diagnoses of hip OA according to the clinical ACR criteria:
Hip pain and hip internal roation < 15 degree and ESR (erythrocyte sedimentation rate (Westergren)* 45mm/hour (if ESR not available, substitute hip flexion * 115 degree) or hip internal rotation * 15 graden and pain on hip internal rotation and morning stiffness of the hip * 60 minutes and age > 50 years
- at least one of the following comorbidities (diagnosed by a physician): coronary heart diseases, heart failure, hypertension, diabetes type 2, obesitas, chronic obstructive pulmonary diseases (COPD), osteoarthritis of the foot and hand, chronic pain, chronic low back pain, depression, visual/hearing impairments and chronic cystitis

Exclusion criteria

- Indication for knee or hip prothesis
- Refusal to sign informed consent
- Not able to come to the centre for treatment
- Insufficient control over the Dutch language

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2010
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	25-03-2010
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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	NL30636.048.10