Comorbidity and exercise therapy in patients with knee osteoarthritis: RCT.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29050

Source
Nationaal Trial Register

Brief title
COOA

Health condition

Knee Osteoarthritis, comorbidity:coronary diseases, heart failure, diabetes type 2, obesity, COPD)
knieartrose, comorbiditeit: coronairlijden, hartfalen, diabetes type 2, obesitas, COPD)

Sponsors and support

Primary sponsor: VU medical centre, Amsterdam, the Netherlands
Reade, centrum voor Revalidatie en Reumatologie, Amsterdam, the Netherlands
Source(s) of monetary or material Support: The Royal Dutch Society for Physical Therapy (KNGF)

Intervention

Outcome measures

Primary outcome

Physical functioning:

1. Self reported physical functioning: The Western Ontario and MacMasters Universities Osteoarthritis Index, subscale physical functioning (WOMAC pf);

2. Performance based test: Six Minute Walk Test (6MWT).

Secondary outcome

Secundary parameters in the treatment evaluation are the Time Get Up and Go Test, stair climbing test, knee joint proprioception, flexion and extension knee muscle strength, Range of motion of the knee (flexion and extension), perceived global effect (9-point Likert scale), pain (Numeric Rating Scale 0-10 (NRS)), pain (WOMAC), stiffness (WOMAC), fatigue (NRS 0-10), Patient Specific Functioning Scale (PSFS), Frailty Index, LASA Physical Activity Questionnaire (LAPAQ), Rand Short Form (SF36), HbAc1 mmol/mol, Medical Research Council (MRC) dyspnoea Scale, Body Mass Index (BMI).

Baseline descriptives:

Age, gender, marital status, educational level, medication use, year of diagnosis, comorbidity using the Cumulative Ilness Rating Scale (CIRS) and x-rays of the knee in standing position.

Study description

Background summary

Osteoarthritis (OA) is one of the diseases with the highest rate of comorbidity; rates between 68% to 85% have been reported. Comorbidity in patients with OA is associated with greater limitations in daily activities, more pain and a poor functional prognosis.

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.

As comorbidity is associated with physical and psychological limitations it is important to adapt exercise therapy to the comorbidity.

In clinical practice these complex patients are often not referred for exercise therapy, or dropped out in early stage of the treatment and /or are treated inadequately: Comorbidity may restrict the possibilities for exercise therapy. Therapists often reduce the intensity of treatment to the level where it is unlikely that the treatment is effective. In existing guidelines no advice is given how exercise therapy should be adapted to comorbidity.

The purpose of the study is evaluate the effect of the newly developed protocol in knee OA patients and comorbidity (coronary diseases, heart failure, diabetes type 2, obesity, COPD) on the outcome physical functioning in comparison to waiting list group.

This study is a single-blind randomized controlled trial. Eligible patients (N=154) will be randomized while using a minimisation procedure.

The experimental group will receive 20-week exercise therapy with the newly developed treatement strategy, explicitly taking into account the comorbidity. The control group is a waiting list group. Measurements will be made prior to the start of therapy (baseline), and at 10 weeks (intermediate), 20 weeks (end of intervention) and 32 weeks (follow-up).

Patients in the experimental group receive treatment according to the newly developed treatment strategy, explicitly taking into account the comorbidity.

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 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. The described adaptations in protocols are based on the decribed approach in the guidelines for the 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 a week, during an hour or twice a week during half an hour, depending on the complexity of the diseases.

By using the protocol, the therapist is able to tailor the exercise program to the individual capacity of the patient (on a save way).

Control group:

The control group is a waiting list group. If applicable patients can receive there current medical care related to the knee complaints and/or comorbidity. The medical care will be registered. After the follow up period of 32 weeks, the patients can ralso receive the treatment according to the newly developed treatment strategy.

Study objective

What is the effect of the newly developed protocol in knee OA patients and comorbidity (coronary diseases, heart failure, diabetes type 2, obesity, Chronic Obstructive Pulmonary Disease (COPD)) on the outcome physical functioning in comparison to a waiting list group.

Study design

Measurements will be made prior to the start of therapy (baseline), and at 10 weeks (intermediate), 20 weeks (end of intervention) and 32 weeks (follow-up).

Intervention

Patients in the experimental group receive treatment according to the newly developed treatmentstrategy, explicitly taking into account the comorbidity.

Prior to treatment, patients relevant goals for the treatment are established. Examples of frequently
established goals are:

1. Increasing walking distance;

2. Improving stair climbing.

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Contacts

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Eligibility criteria

Inclusion criteria

1. Diagnoses of knee OA according to the clinical ACR criteria, i.e: knee pain and at least htree of the following six: age > 50 years, morning stifness <30 minutes, crepitus, bony tenderness, bony enlargement and no palpable warmth;

2. At least one of the following comorbidities (diagosed by a physican), with a score ≥2 on the Cumulative Illness Rating Scale (ie influence of the comorbidity on daily functioning and treatment of the comorbifity is necessary): Coronary heart diseases, heart failure, diabetic type 2, obesity, chronic obstructive pulmonary diseases (COPD);

3. Focus of treatment is on OA- related diability (instead of comorbidity -related disability).

Exclusion criteria

1. Absolute contraindication for exercise therapy;

2. Indication of knee prothesis;

3. Refusal to sign informed consent;

4. Insufficient control over the Dutch language;

5. Patients with a high score of psychological distress (HADS score>11, SCL-90 score >150);

6. Dementia (MMSE score >26);

7. Suffering from significant physical limitations (possibly caused by co-morbidities) that would prohibit a patient from following the physiotherapy program;

8. Patients who are expected to be lost for follow-up (e.g. because of a planned change of residency.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2011
Enrollment:	154
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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	NL2881
NTR-old	NTR3027
Other	METC slotervaart-Reade : 37899 ABR

Study results

Summary results
N/A