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

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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…

| | |
|---|---|
| **Ethische beoordeling** | Niet van toepassing |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON29050

**Bron**
Nationaal Trial Register

**Verkorte titel**
COOA

**Aandoening**

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

### Ondersteuning

**Primaire sponsor:** VU medical centre, Amsterdam, the Netherlands
Reade, centrum voor Revalidatie en Reumatologie, Amsterdam, the Netherlands
**Overige ondersteuning:** The Royal Dutch Society for Physical Therapy (KNGF)

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

Physical functioning:<br>
1. Self reported physical functioning: The Western Ontario and MacMasters Universities Osteoarthritis Index, subscale physical functioning (WOMAC pf);<br>
2. Performance based test: Six Minute Walk Test (6MWT).

# Toelichting onderzoek

**Achtergrond van het onderzoek**

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.

**Doel van het onderzoek**

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.

**Onderzoeksopzet**

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).

**Onderzoeksproduct en/of interventie**

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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# Contactpersonen

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Enkelblind |
| Controle: | Actieve controle groep |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-12-2011 |
| Aantal proefpersonen: | 154 |
| Type: | Verwachte startdatum |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

# Ethische beoordeling

Niet van toepassing

| | |
|---|---|
| Soort: | Niet van toepassing |

# 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 | NL2881 |
| NTR-old | NTR3027 |
| Ander register | METC slotervaart-Reade : 37899 ABR |

# Resultaten

**Samenvatting resultaten**
N/A