# The effects of a combined lifestyle intervention in overweight patients with hip osteoarthritis: a pilot study

No registrations found.

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON26093

**Source**
NTR

**Brief title**
N/A

**Health condition**

Obese, overweight, osteoarthritis of the hip, exercise, weight loss, lifestyle intervention, combination therapy, pain, functional abilities.

### Sponsors and support

**Primary sponsor:** Department of Orthopaedic Surgery University Medical Center Groningen
**Source(s) of monetary or material Support:** Department of Orthopaedic Surgery University Medical Center Groningen

### Intervention

### Outcome measures

**Primary outcome**

Self-reported physical function as measured by the Western Ontario and McMaster

Universities Osteoarthritis Index (WOMAC) (Roorda et al., 2004).

### Secondary outcome

Body weight; height, objective functional abilities measured with use of a walking test of 20 meters, and the Timed Up and Go test (de Greef et al 2006); Pain measured by the WOMAC physical function scale and the health related Quality of Life measured by the SF-36 (Aaronson et al., 1998). The SQUASH (Wendel-Vos e.a. 2003) will be used to get an impression of the physical activity pattern.

## Study description

### Background summary

Osteoarthritis (OA) is a common musculoskeletal disorder and its prevalence increases with age. In the Netherlands every year a total of 200,000 people between twenty and sixty-five years of age visit the general practitioner because of OA. When considering people above the age of 65 an extra 450,000 persons are added to the previously mentioned number. Previous research has proven that even patients with severe OA can benefit from conservative treatment.
In this study the conservative treatment consists of a program which influences the lifestyle (exercise and eating habits). Until now this kind of treatment is applied and known to be effective in patients with knee OA (Messier 2004). Insufficient evidence is available of the positive effects of weight reduction and exercise in patients with hip OA.
Significant improvements of self reported and objectively measured functional abilities and pain after applying a combination program of exercise and weight loss as is seen with knee OA, is therefore also expected in patients with hip OA.
The combination program of exercise and weight loss will be implemented in a prospective cohort study. The patients will be overweight (BMI> 27), with clinical confirmed osteoarthritis of the hip and/or knee and not yet suitable for joint replacement. Primary outcome measurements are self reported physical function and pain, assessed with the Dutch-Womac. Measurements will be performed upon recruitment (T0, baseline), 3 months after recruitment (T1) and upon completion of the program, 6 months after recruitment (T2).

### Study objective

It is our hypothesis that a combined life style intervention of exercise and weight loss will result in a reduction of pain and improvement of function of the affected hip joint, which will postpone a chirurgical intervention.

### Intervention

The physical exercise therapy will be divided in an individual phase (2 to 3 months) and a group phase (3 months) (total of 6 months). Additionally the patients will be

stimulated to get active, or sustain being active, at home in order to satisfy the Dutch National Standard Healthy Movement (Kemper et al., 1999), during the group phase. Alongside the physical exercise therapy the dietary intervention will take place in 8 contact moments, executed by a certificated dietary therapist. In this intervention dietary advice and dietary problems will be discussed.

# Contacts

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# Eligibility criteria

## Inclusion criteria

Inclusion criteria:
Patients of 40 years and older with a calculated body mass index of 25 or more and radiographic and/or clinical evidence of hip osteoarthritis. The osteoarthritis presents with pain in combination with either (a) hip internal rotation equal or more than 15º, pain present on internal rotation of the hip, morning stiffness of the hip equal or less than 60 min or (b) hip internal rotation less than 15º, and hip flexion equal or less than 115º.

## Exclusion criteria

Patients with severe medical conditions that prevents safe participation in an exercise program (such as angina pectoris, peripheral vascular disease, stroke, congestive heart failure, chronic obstructive pulmonary disease, insulin-dependent diabetes, psychiatric disease, renal disease, renal disease, liver disease, active cancer other than skin cancer,

anaemia); symptoms of feet or ankle which could interfere with exercise programs; in case of rheumatic arthritis; an inability to walk without a cane or other assistive device; participation in another research study; inability to finish the study or unlikely to be compliant to the opinion of the clinical staff, because of frailty, illness, co morbidity or other reasons. Additionally patients who are not able to fill in a questionnaire as a result of language problems or dementia will be excluded.

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Other |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-10-2007 |
| Enrollment: | 25 |
| Type: | Anticipated |

# Ethics review

Positive opinion

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| Date: | 06-09-2007 |
| Application type: | First submission |

# 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 | NL1022 |
| NTR-old | NTR1053 |
| Other | : METc 2007/121 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

# Study results