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

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Obtaining a first impression of the potential effect of a combined lifestyle intervention (exercise and weight loss), executed in patients with osteoarthritis of the hip.

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

Summary

ID

NL-OMON31407

Source ToetsingOnline

Brief title Lifestyle interventions in osteoarthritis of the hip: a pilotstudy

Condition

Joint disorders

Synonym arthritis, osteoarthritis

Research involving Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen Source(s) of monetary or material Support: Stimuleringsfonds;UMCG

Intervention

Keyword: diet, exercise, hip, Osteoarthritis

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

Osteoarthrosis (OA) especially within older adults is one of the most common chronically disorders. Patients with OA experience pain, stiffness and loss of joint function.

The incidence of OA in this group is increasing. This development is mainly a result of an increasing number of older adults and people on average getting older (Ostendorf e.a. 2002).

An additional reason for the above mentioned increase is the growing number of people with moderate overweight or obesities, which is considered a risk factor for OA (RIVM 2004).

Untill now there is no cure for osteoarthritis and to date, conservative treatment modalities have focused on pain relief and preservation of joint function (Bell 1999, O`Reilly 1999, Van Baar 1998). In osteoarthritis of the knee Messier et al. (2004) have shown that a combination therapy results in improvement of the symptoms. This combination therapy exists of weight loss and

exercise, and leads to a significant improvement of self-reported and objectively measured functional abilities and pain in patients with knee OA. Until now insufficient evidence exists of the beneficial effects of weight loss and therapeutic exercise in the treatment of OA of the hip (Voorlopig CBO rap/Programmeringstudie ZonMW (2006); Vignon et al., 2006). Similar reasoning raises the expectation to find a comparable effect to weight loss and exercise in osteoarthritis of the hip.

Study objective

Obtaining a first impression of the potential effect of a combined lifestyle intervention (exercise and weight loss), executed in patients with osteoarthritis of the hip.

Study design

A prospective cohort will be carried out at the department of orthopaedics of the UMCG in collaboration with the PCRR physiotherapy Hilberdink.

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.

Study burden and risks

There are no risks in participation in this pilot.

In respect of the safety of physical activity in people with osteoarthritis there is concluded (most recent review) healthy subjects as wel as patients with osteoarthritis in general can pursue a high level of physical activity, provided the activity is not painful and does not predispose to trauma (Vignon et al. 2006).

Radiographic or clinical osteoarthritis is not a contraindication to promoting activity in patients who have a sedentary lifestyle.

It is concluded with a high level of of scientific evidence that structured strengthening exercises have a favourable effect on pain and function in the sedentary patient with knee osteoarthritis (Vignon et. al. 2006).

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

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 $>= 15^{\circ}$, pain present on internal rotation of the hip, morning stiffness of the hip <= 60 min or (b) hip internal rotation $< 15^{\circ}$, and hip flexion $<= 115^{\circ}$.

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

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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. Dementia will be determined with use of the Mini-Mental State Examination score < 24 (Folstein et al., 1975)

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):	01-09-2007
Enrollment:	25
Туре:	Anticipated

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

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No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	
ССМО	
Other	

ID NL17162.042.07 nog niet bekend