Feasibility and preliminary effectiveness of a preoperative training and nutrition intervention in people with sarcopenic obesity who receive total hip or knee arthroplasty within the 'Actief Herstel' care pathway

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

Summary

ID

NL-OMON49062

Source
ToetsingOnline

Brief title
Preoperative training and nutrition in the 'Active Recovery' care pathway

Condition

- Other condition
- Joint disorders
- Bone and joint therapeutic procedures

Synonym
Sarcopenic obesity / Muscle weakness and overweight

Health condition

sarcopene obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuisvoorzieningen Gelderse Vallei
Source(s) of monetary or material Support: researchsubsidie Ziekenhuis Gelderse Vallei

Intervention

Keyword: exercise, nutrition, preoperative, sarcopenic obesity

Outcome measures

Primary outcome

Feasibility is assessed by adherence to treatment, inclusion rates, drop out

rates and adverse events and complications.

The amount of attended training sessions attended and the achieved intensity

are noted. The physical activity (accelerometer) and food intake (food diary)

are also measured.

The appreciation and motivation of the patient will be assessed with

questionnaires.

Secondary outcome

Effectiveness is assessed by measuring physical functioning (timed up and go

test, hand grip strength, walking speed/ six-minute walk test, chair rise time

test, questionnaires), body composition (BIA/ DEXA) and inflammation (IL-6),

before and after 6 weeks of intervention.

In addition, postoperative inpatient complications, CRP, recovery of physical

functioning and length of hospital stay will be assessed.

Furthermore, nutritional intake (3-day food diary) and physical activity (by

accelerometer) will be measured.

Study description

Background summary

The incidence of patients with sarcopenic obesity (SO) in orthopedic surgery is growing, with a reported prevalence of 3 up to 35%. The poor skeletal muscle function, decreased physical func-tioning and increased inflammation associated with SO gives an additional risk of postoperative complications. The combination of exercise and dietary intervention seems the best strategy to counteract SO. However, studies investigating the effect of a combined approach as a preoperative intervention in patients with SO have not been conducted yet. Therefore, we aim to evaluate, both in terms of feasibility and effectiveness, a combined preoperative nutrition and exercise intervention in patients who receive a total hip or knee arthroplasty (THA/TKA).

Study objective

The objective of this study is to evaluate the feasibility and to determine the preliminary effects on physical functioning, muscle function, body composition and postoperative recovery of a combined preoperative nutrition and exercise intervention in patients with sarcopenic obesity who receive a total hip or knee arthroplasty.

Study design

A pilot randomized controlled trial (RCT)

Intervention

The intervention group will follow a supervised (by a physiotherapist) exercise intervention of 6 weeks (twice a week) with progressive strength training and aerobic training. This will be combined with a nutritional intervention (by a dietician) focusing on optimal protein intake, i.e. 1.2 g / kg of adjusted body weight per day divided over the day. The dietary intervention will consist of a comprehensive screening, determining intake, and nutritional advice during 3 repeat consultations.
Usual care (control) group: Patients receive general exercise advice, a referral for *standard* physiotherapy and dietary guidelines only in case of

malnutrition. Furthermore, in the online program eZorg, patients can find information on the Dutch dietary guidelines and what they can do to make their food habits healthier.

Study burden and risks

• The patients in the both groups will be extensively examined pre-intervention (6 weeks before surgery) and post-intervention (about 2 days before surgery). This will take about 1,5 hours for each session. Postoperative examination is usual care (or data from patient files) and does not require extra visits to the hospital. Patients* appreciation and motivation will be investigated using a questionnaire based on a 10-point Likert scale.
• Taking blood samples will be done three times in both groups. Pre-intervention (usual care), post-intervention (2 days before surgery, additional moment) and 1 day after surgery (usual care).
• A DEXA scan and BIA measurement will be done twice preoperatively (six weeks and two days before surgery). DEXA is a simple, quick and noninvasive procedure. The amount of radiation used is extremely small*less than one-tenth the dose of a standard chest x-ray. No radiation remains in a patient's body after an x-ray examination.
• The intervention group will receive a supervised training (in the hospital or a physical therapy practice within out network in their home town) twice a week 60 minutes. Furthermore, they will have three sessions (30 minutes each) with a dietician to optimize their protein consumption to 1.2g/kg adjusted body weight and fill in three times a three-day food diary. Two of these sessions will be combined with measurements at T0 and T2 and one session can be done by phone. No extra supplements or compulsory food should be taken.
• Patients in both groups will be stimulated to be physically active at least 150 minutes per week. They will be asked to wear an accelerometer to check their adherence with this advice.
• The nature of effort is that the exercise program gives physical exertion (functional, strength and aerobic testing and training). Osteoarthritis, obesity or frailty are not contra indications to exercise. The therapeutic intervention will be tailored to each individual, based on guidelines and take into account limitations such as pain, comorbidity or obesity. The anesthesiologist will perform a medical clearance and exercises will be given by experienced physical ther-apists.
• The nutritional advice will be tailored to each individual, based on national guidelines and the experienced dietician will take into account specific needs or contraindications for the dietary advice (as usual) so therefore there are no additional risks.

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

• Scheduled for THA or TKA with a waiting period of minimal 6 weeks (which is the usual waiting period)
• Osteoarthritis as reason for surgery
• Having obesity (BMI >=30 kg/m2)
• Having muscle weakness (Men: Hand Grip Strength (HGS) <27kg; Women: HGS <16kg or Chair stand >15sec for five rises)
• Adequate cognitive functioning (the patient is capable to understand instructions and to per-form the screening)
• Age 18 years or older

Exclusion criteria

Patient
• unable to understand Dutch;

• diagnosed with dementia;
• who are unable to exercise due to comorbidities/ contra-indications. Absolute contra-indications for exercise are listed in the Dutch guideline for osteoarthritis and in the ACSM's Guidelines for Exercise Testing and Prescription;
• with severe renal insufficiency or an eGFR<30 (estimated Glomerular Filtration Rate)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-05-2021
Enrollment:	34
Type:	Actual

Ethics review

Approved WMO

Date:	02-04-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL72249.081.19

Study results

Date completed:	30-06-2023
Actual enrolment:	33