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

No registrations found.

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

Summary

ID

NL-OMON28555

Source
NTR

Brief title
ProActief

Health condition

patients with osteoarthritis and sarcopenic obesity

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: ZGV

Intervention

Outcome measures

Primary outcome

Feasibility is assessed by adherence to the treatment, inclusion and dropout rate, adverse events and the patient appreciation and motivation, as assessed by questionnaires.

Secondary outcome

Preliminary 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 (CRP, IL-6) before and after 6 weeks of intervention. In addition, postoperative inpatient complications, 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% 1. The poor skeletal muscle function, decreased physical func-tioning and increased inflammation associated with SO gives an additional risk of postoperative complications 1,2. The combination of exercise and dietary intervention seems the best strategy to counteract SO 3. 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).
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)
Study population: Thirty-four patients with sarcopenic obesity who are on the waiting list for a THA/TKA will be included.
Main study parameters/endpoints:

Study objective

The intervention is feasible for patients with osteoarthritis and sarcopenic obesity before total hip and knee surgery (and will improve physical functioning and outcome).

Study design

pre- (7 weeks and 2-4 days before) and postoperative (clinical period and 6 weeks after surgery)

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 ad-justed 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.
The control group will follow usual care.

Contacts

Public
Gelderse Vallei Hoispital
Ellen Oosting

+31318433799
Scientific
Gelderse Vallei Hoispital
Ellen Oosting

+31318433799

Eligibility criteria

Inclusion criteria

• scheduled for THA or TKA with a waiting period of minimal 6 weeks (which is the usual waiting period)
• OA as reason for THA or TKA
• 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) 12
• Adequate cognitive functioning (the patient is capable to understand instructions and to per-form the screening)
• Age 18 years or older

Exclusion criteria

• Unable to understand Dutch
• Patients diagnosed with dementia
• Patients who are unable to exercise due to comorbidities/ contra-indications. Absolute con-tra-indications for exercise are listed in the Dutch guideline for OA 13 and in the ACSM's Guidelines for Exercise Testing and Prescription 14. See appendix 1 for additional information

about contraindications and considerations when prescribing exercises to older people with comorbidity.
• Patients 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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2020
Enrollment:	34
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

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	NL8301
Other	METC-WU : ABR72249

Study results

Summary results
N/A