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

Gepubliceerd: 13-01-2020 Laatst bijgewerkt: 18-08-2022

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

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

Samenvatting

ID

NL-OMON28555

Bron
NTR

Verkorte titel
ProActief

Aandoening

patients with osteoarthritis and sarcopenic obesity

Ondersteuning

Primaire sponsor: N/A
Overige ondersteuning: ZGV

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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:

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2020
Aantal proefpersonen:	34
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

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	NL8301
Ander register	METC-WU : ABR72249

Resultaten

Samenvatting resultaten
N/A