

# **\*Better Exercise and FOOd, better REcovery:**

## **\*Improving physical functioning and quality of life by preoperative training and nutritional supplementation in older patients undergoing colorectal cancer surgery. A pilot study.'**

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The aim of this randomized controlled pilot study is to investigate the feasibility and to improve the functional recovery of a patient, by providing them with a multimodal prehabilitation program consisting of supervised physical exercise and/or...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Gastrointestinal conditions NEC
<b>Study type</b>	Interventional

### **Summary**

#### **ID**

NL-OMON48140

#### **Source**

ToetsingOnline

#### **Brief title**

BEFORE - pilot study

#### **Condition**

- Gastrointestinal conditions NEC

#### **Synonym**

reduced muscle mass, under nutrition

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Zuyderland Medisch Centrum

**Source(s) of monetary or material Support:** Research & Innovatie Fonds Zuyderland;sponsorgelden van particulieren en eigen bijdrage Zuyderland Medisch Centrum.

## Intervention

**Keyword:** Exercise training, Nutrition, Prehabilitation, Protein rich

## Outcome measures

### Primary outcome

The primary outcome is functional capacity. This is measured with the validated 6-minute walking test (6MWT).

### Secondary outcome

- a. Postoperative complications within 30 days (Clavien Dindo)
- b. Time to functional recovery
- c. Health related quality of life (outpatient, EORTC QLQC-30)
- d. VAS score appetite (see appendix 4)
- e. VAS score food experience (see appendix 5)
- f. Handgrip strength test (according to the South Hampton protocol)
- g. Bioelectrical impedance analysis (BIA)
- h. Time Up and Go Test (TUGT)
- i. Maximal oxygen uptake (VO<sub>2</sub>max)
- j. Short Physical Performance Battery (SPPB)
- k. Sarcopenia (measured with preoperative abdominal CT-scan)

## Other outcomes

- a. Anthropomorphic and demographic parameters
- b. Disease related demographics
- c. Laboratory values: Hb, CRP, leukocytes, CEA, albumin, glucose, ferritin, vitamin D, liver- and kidney function test.
- d. Comorbidities
- e. Nutritional assessments (length, height, BMI, current weight)
- f. Short Nutritional Assessment Questionnaire (SNAQ)
- g. Groningen Frailty Index (GFI)

## Study description

### Background summary

Globally, the life expectancy has increased to 60 years of age and above. With increasing age of the population, more elderly patients are being admitted in the hospital for either chronic or acute treatment. The older patient requires a different approach when being treated. The functional and nutritional status of a patient has been proven to be important prognostic factors for recovery after surgery. Elderly patients are commonly frail, sarcopenic and undernourished. Standard dietary interventions seem to suffice, however do not tackle all contributing factors. We believe that by intervening with a prehabilitation program composed of supervised exercise training and/or protein-rich meals, we could improve the functional recovery of a patient.

### Study objective

The aim of this randomized controlled pilot study is to investigate the feasibility and to improve the functional recovery of a patient, by providing them with a multimodal prehabilitation program consisting of supervised physical exercise and/or protein-rich meals before surgery.

### Study design

This is prospective randomized controlled pilot study

## Intervention

This multimodal prehabilitation intervention is composed of a supervised exercise training program and/or provision of freshly prepared protein-rich meals supplied by Daily Fresh Food. The intervention takes place in the period leading up to colorectal cancer surgery.

## Study burden and risks

A benefit of participating in this study is, that it may provide an innovative way to improve physical functioning before colorectal cancer surgery. Furthermore, we expect an improved quality of life and satisfaction due to the exercise training program and freshly prepared meals. It is hypothesized, that this will build resistance against the trauma of surgery and reduce geriatric frailty. Very few risks are associated with the participation of this study, as patients who participate with the exercise training are continuously supervised by experienced professionals. We expect no adverse events due to this study. Though chances are very small, a food allergy may arise or a sprain during training.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Signed informed consent;
- Scheduled to undergo elective colorectal surgery with primary anastomosis for (pre)malignancy;
- 65 years or older;
- BMI < 35kg/m<sup>2</sup>;
- Physically and mentally capable of completing the exercise program & questionnaires;
- Capability to have a complete oral dietary intake.

### Exclusion criteria

- Participant is receiving parenteral nutrition or enteral nutrition via feeding tube in the preoperative phase;
- Participants who are scheduled to receive neoadjuvant therapy;
- BMI >35 kg/m<sup>2</sup>;
- A history of or an active inflammatory gastrointestinal disease;
- Distant metastasis at the time of diagnosis (TNM stage M1);
- Inability or contraindication to performing physical exercise;
- Complex dietary needs and/or dietary allergies;

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Other

## Recruitment

NL  
Recruitment status: Will not start  
Enrollment: 40  
Type: Anticipated

## Ethics review

Approved WMO  
Date: 19-08-2019  
Application type: First submission  
Review commission: METC Z: Zuyderland-Zuyd (Heerlen)  
Approved WMO  
Date: 28-04-2020  
Application type: Amendment  
Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

## 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	NL70836.096.19