# Better Exercise and FOod, better REcovery: Is it feasible to enhance functional and nutritional status of elderly colorectal cancer patients before surgery to improve recovery?

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The aim of this study is to investigate feasibility of a prehabilitation program for colorectal cancer patients aged * 65 years before surgery.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Gastrointestinal conditions NEC |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON48054

**Source**
ToetsingOnline

**Brief title**
BEFORE - feasibility 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:** Daily Fresh Food ,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

Is it feasible to provide 80% of included colorectal cancer patients with

supervised exercise training and/or protein-rich meals before surgery? Yes or

no?

### Secondary outcome

Logistical feasibility

a. Success rate meal order and delivery

b. Success rate supervised exercise training and attendance

Feasibility of the interventions

c. Total protein-intake in grams and in grams/kilogram bodyweight

d. Total energy-intake in kilocalories and as percentage of the calculated

energy need (Harris Benedict)

e. Achievement of at least 80% of the calculated protein- and energy

requirement within the first week of the study

f. Amount of additional prescribed supplement drink according to usual care

based on the individually calculated needs

g. Distribution of protein and energy intake in one day

h. Compliance to exercise program of 80%

i. Success rate training program endurance

j. Average endured time of training program

k. Average achieved training intensity

l. Patient evaluation questionnaire: overall experience

Other study parameters (measurable outcomes)

m. Anthropomorphic and demographic parameters

n. Disease related demographics

o. Laboratory values: Hb, CRP, L, CEA, albumin, glucose, ferritin, vitamin D,

liver- and kidney function test.

p Comorbidities

q. Postoperative complications

r. Nutritional assessments (length, height, BMI, current weight)

s. Short Nutritional Assessment Questionnaire (SNAQ)

t. Groningen Frailty Index (GFI)

u. Health related quality of life (outpatient, EORTC QLQC-30)

v. VAS score appetite

w. VAS score food experience

x. Handgrip strength test (according to the South Hampton protocol)

y. Bioelectrical impedance analysis (BIA)

z. Maximal oxygen uptake (VO2max)

# 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 protein-rich meals, we could improve the functional capacity of a patient.

### Study objective

The aim of this study is to investigate feasibility of a prehabilitation program for colorectal cancer patients aged * 65 years before surgery.

### Study design

the study design is a prospective feasibility study.

### Intervention

this multimodal prehabilitation intervention is composed of a supervised exercise training program and provision of freshly prepared protein-rich meals supplied by Daily Fresh Food. The intervention takes place in the preoperative period between diagnosis and surgery for colorectal cancer.

### 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**
Zuyderland Medisch Centrum

Dr. H. van der Hoffplein 1
Sittard-Geleen 6162 BG
NL
**Scientific**
Zuyderland Medisch Centrum

Dr. H. van der Hoffplein 1
Sittard-Geleen 6162 BG
NL

# 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/m2;
- Physically and mentally capable of completing the exercise program;
- 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;
- BMI >35 kg/m²;
- A history of or an active inflammatory gastrointestinal disease;
- Patients with a palliative treatment course;
- Inability or contraindication to performing physical exercise;
- Complex dietary needs and/or dietary allergies;
- Mentally incompetent or challenged.

# Study design

## Design

**Study type:** Interventional

| | |
|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Other |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 19-11-2019 |
| Enrollment: | 10 |
| Type: | Actual |

# Ethics review

Approved WMO

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|---|---|
| Date: | 19-08-2019 |
| Application type: | First submission |
| Review commission: | METC Z: Zuyderland-Zuyd (Heerlen) |

Approved WMO

| | |
|---|---|
| Date: | 10-12-2019 |
| 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 | NL70834.096.19 |