

# Better Be on Top

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON25416

### Source

NTR

### Brief title

BEBOP

### Health condition

Coloncancer or rectal cancer

## Sponsors and support

**Primary sponsor:** Reinier de Graaf Gasthuis

**Source(s) of monetary or material Support:** Team Westland

## Intervention

## Outcome measures

### Primary outcome

One-year survival

### Secondary outcome

Rate of postoperative complications, quality of life and functional capacity (ADL)

## Study description

### Background summary

In this study, we will identify frailty in older colorectal cancer patients on six domains: physical performance, nutritional status, anemia, psychosocial, cognitive and smoking status. In case of frailty, patients will start with prehabilitation and rehabilitation to increase the preoperative and postoperative capacity and reduce the impact of surgery.

### Study objective

As the incidence of colorectal cancer (CRC) is increasing with age and several surgical developments have been made the past few years, the number of older patients receiving surgical treatment is increasing. However, the impact of surgery should not be underestimated in the older CRC patients. Especially the frail older CRC patients have higher mortality and postoperative complication rates in comparison to the non-frail patients. Identifying and modifying vulnerabilities before and after surgery may increase the capacity and decrease the impact of surgery. Evidence of prehabilitation with or without the combination of rehabilitation is limited and inconsistent due to studies with small sample sizes and the inclusion of non-frail patients. This means that a large cohort study is needed to establish the effect of prehabilitation and rehabilitation in frail older CRC patients.

### Study design

Inclusion, baseline measurements, preoperative frailty evaluation, postoperative physical test at 3, 6 and 12 months, postoperative evaluation of QoL and ADL at 6 and 12 months.

### Intervention

Included patients will be screened for frailty on physical performance, nutritional status, anaemia, psychosocial, cognitive and smoking status. The physiotherapist will screen for physical frailty, the dietician for nutritional frailty, the geriatrician for cognitive and psychosocial frailty and the surgeon for anaemia and smoking status. Only in case of frailty - defined by clear cut off points - interventions are initiated. Potential interventions are: four — six week exercise program, protein or energy supplements, iron infusion in case of proven iron deficiency anaemia, delirium preventing strategies, psychologic consultation and smoking cessation.

## Contacts

### Public

Reinier de Graaf Gasthuis  
Heleen van der Hulst

0152603830

**Scientific**

Reinier de Graaf Gasthuis

Heleen van der Hulst

0152603830

## Eligibility criteria

### Inclusion criteria

- diagnosis of colorectal cancer
- 70 years or older
- non-metastatic disease
- planned for elective surgery
- positive geriatric screening based on the G8 or 6CIT

### Exclusion criteria

- Need for surgery in acute setting
- No need for surgery due to complete tumour remission after chemo-radiation in rectal cancer patients
- Not willing to provide informed consent
- Not able to perform an exercise program; for instance wheelchair-dependent patients or paraplegic patients
- Patients in whom an exercise program is contra-indicated due to severe cardiopulmonary problems, diagnosed by a cardiologist and/or pulmonologist (for example COPD gold IV, unstable coronary artery disease, heart failure or poorly controlled arrhythmias).

## Study design

### Design

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

Control: Active

## Recruitment

NL  
Recruitment status: Pending  
Start date (anticipated): 01-03-2020  
Enrollment: 310  
Type: Anticipated

## IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Not applicable  
Application type: Not applicable

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 52663  
Bron: ToetsingOnline  
Titel:

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
NTR-new	NL8321
CCMO	NL72163.058.19
OMON	NL-OMON52663

## Study results