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FEASIBILITY OF A TELEPREHABILITATION PROGRAM IN HIGH-RISK PATIENTS SCHEDULED FOR ELECTIVE COLORECTAL RESECTION: A PILOT STUDY

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Project leader and principal investigator	Prof.dr. Maryska Janssen-Heijnen Clinical epidemiologist VieCuri Medical Centre Tegelseweg 210, 6512 BL Venlo P: 077-320 5093, E: mjanssenheijnen@viecuri.nl Department of Epidemiology GROW School for Oncology and Developmental Biology Faculty of Health, Medicine and Life Sciences Maastricht University
Project team	Prof. Dr. Maryska Janssen Heijnen, clinical epidemiologist [1,2] Dr. Jeroen Vogelaar, surgical oncologist [1] Dr. Bart Bongers, medical physiologist [2] Drs. Ruud Franssen, physiotherapist, movement scientist /clinical exercise physiologist [1] Drs. Melissa Voorn, oncology physiotherapist [3] Ria Trepels, dietician [1] Drs. Marleen de Koning, sports physician [1] Prof.dr. Nico van Meeteren, physical therapist [2] *[1] Viecuri Medical Centre, Venlo* *[2] Maastricht University, Maastricht* *[3] Adelante, Venlo*
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LIST OF ABBREVIATIONS

30 sec-CST	30-Second Sit-to-Stand test
4-MGS	4-meter gait speed test
APP	Smartphone application
ASA score	American Society of Anesthesiologists score
ATS / ACCP	American Thoracic Society / American College of Chest Physicians
ATS / ERS	American Thoracic Society / European Respiratory Society
CPET	Cardiopulmonary exercise test
CRC	Colorectal carcinoma
CRC-day	Diagnostic day for colorectal cancer patients (usual care)
CRF	Case report form
CWT	Constant work rate test
GCP	Good Clinical Practice
HADS	Hospital anxiety and depression scale
IC	Informed consent
MET	Metabolic equivalent of task
NFtK	Nationaal Fonds tegen Kanker
PG-SGA-SF	Scored Patient-Generated Subjective Global Assessment – Short Form
PONS	Preoperative nutritional score
PET-CO_2	Partial pressure of End Tidal CO_2
RCP	Respiratory compensation point
RPE	Rating of perceived exertion
RPM	Revolutions per Minute
SUS	Systems usability scale

IBM-SPSS	International Business Machines Corporation - Statistical Package for the Social Sciences
VAT	Ventilatory anaerobic threshold
VO2peak	Oxygen uptake at peak exercise
VO2	Oxygen uptake
VSAQ	Veterans-specific activity questionnaire
WMO	Wet Medisch-wetenschappelijk Onderzoek met mensen

1. SUMMARY

Colorectal cancer is the third most common type of cancer worldwide, with the majority of the patients being >70 years of age. The main curative treatment, surgery, is associated with a high incidence of complications. Furthermore, many patients experience functional decline, loss of self-efficacy and loss of quality of life after surgical treatment. Especially patients with a low physiological reserve capacity (i.e. low aerobic fitness) have a high risk for postoperative complications and a delayed and often incomplete recovery post-surgery. Prehabilitation, optimization of a patient's health status between diagnosis and major surgical intervention, seems to be effective in improving aerobic fitness. The concept of prehabilitation in colorectal patients is already established, however it remains unclear what type of intervention is easiest to sustain. There are indications that a prehabilitation program that is personalized to the needs of a patient is most effective. Furthermore, a home-based prehabilitation program probably has least impact on the patient's life and is less demanding for high-risk patients (i.e. patients with low aerobic fitness), especially in the emotionally stressful period between diagnosis and surgery. On the other hand, supervision might be necessary to motivate and stimulate patients during their exercise routine. With modern technologies, already used in cardio-rehabilitation, such as teleprehabilitation, it is possible to monitor an exercise program remotely while the patient performs his training at home. To date, there are no studies investigating a prehabilitation program that is supervised by telemonitoring in cancer patients awaiting surgery. The aim of this study is to evaluate whether a home-based teleprehabilitation program is feasible and is able to increase aerobic fitness in high-risk patients who are scheduled for colorectal surgery. Secondary aim is to investigate experiences of patients with the proposed teleprehabilitation program and equipment.

2. PATIENT RELEVANCE

In Viecuri Medical Centre, 150 to 200 patients with colorectal cancer undergo surgical resection of the tumour annually. It is hypothesized that approximately (20%) of these patients have an increased risk for postoperative complications [1]. Postoperative complications are associated with worse short-term outcomes (i.e. increased length of stay, (permanent) loss of physical functioning and lower self-reliance) and long-term outcome (i.e. survival and cancer recurrence) [2-4]. Therefore, it is important to timely identify patients at risk for complications. Preoperative risk screening gives the opportunity to preoperatively optimize the at risk patient's psychophysiological status by means of a personalized prehabilitation program in anticipation of the surgical intervention and its associated period of hospitalization.

Previous prehabilitation programs were either unsupervised or relied on patients visiting healthcare providers at a medical centre several times a week [5]. Motivating patients to comply with an unsupervised program can be challenging for health care providers. Furthermore, from a patient's perspective, frequent visits to health care providers in a medical centre can be a major burden severely reducing the participation rate. By using E-health solutions in combination with deploying the social support system of the patient these barriers can be overcome, as the patient can carry out his personalized prehabilitation program at home using functional exercises of relevance to the patient,

while being monitored and coached by a professional via an online platform. Therefore, the patient is less reliant on fixed appointments and self-efficacy can be improved.

3. INTRODUCTION AND RATIONALE

The annual incidence of colorectal cancer (CRC) in the Netherlands is approximately 15,000 and is expected to rise as an effect of the aging population [6]. Over 40% of the patients diagnosed with CRC are aged 75 years or older [1]. The primary treatment of CRC is surgical resection of the tumour with or without (neo)adjuvant chemo(radiation)therapy, depending on tumour subsite and stage [7]. Despite advances in surgery and anaesthesia, such as minimally invasive approaches and enhanced recovery after surgery pathways, the incidence of postoperative complications after colorectal resection remains high, ranging between 20% and 50% in the general surgical population [1, 8-10] and up to 60% and over in high-risk populations [11, 12].

As postoperative complications have been associated with worse overall survival and higher tumour recurrence rates in CRC patients [2], it is important to identify patients at risk for complications. In the literature, preoperative aerobic fitness, measured formally by a progressive cardiorespiratory exercise test (CPET), has consistently been associated with an increased risk for postoperative complications and increased length of hospital stay (LOS) [13, 14], which might lead to a prolonged or even incomplete recovery of physical functioning. More specifically, optimal cut-off points for preoperative aerobic fitness to identify patient's with a higher risk for postoperative complications and an increased LOS are an oxygen uptake at the ventilatory anaerobic threshold (VAT) ≤11.0 mL/kg/min and/or an oxygen uptake at peak exercise (VO_{2peak}) ≤18.0 mL/kg/min [14]. Patients with a low aerobic fitness (e.g., VAT ≤11.0 mL/kg/min, VO_{2peak} ≤18.0 mL/kg/min) have a reduced physiological reserve capacity and might therefore be less resilient to cope with the increased perioperative metabolic demands caused by the surgical stress and possible complications. Additionally, even without complications, patients experience higher levels of fatigue and are less self-reliant during the postoperative period. It can take months before patients regain their preoperative level of physical functioning [3, 15].

The preoperative period provides a window of opportunity to increase the physiological reserve capacity (aerobic fitness) of patients in anticipation of their specific cancer treatment. Interventions aiming at optimizing the patient's health (e.g., aerobic fitness, nutritional support, psychological support) between the time of cancer diagnosis and the beginning of treatment in anticipation of an upcoming stressor (i.e. surgery) in order to reduce the incidence and the severity of current and future impairments are called prehabilitation [16]. Prehabilitation shows promising results in reducing postoperative complications in abdominal surgery when targeted at high-risk patients [4]; however, programs are heterogeneous in mode, intensity, duration, type of intervention [17] and therapeutic validity (i.e., adequate patient selection and program personalization) [5]. From a patient's perspective however, a personalized prehabilitation program that has a minimal disrupting impact on the patient's life is likely to be most feasible and cause minimal burden. In patients with a low aerobic fitness, mostly frail patients, it is of utmost importance that the prehabilitation program is feasible; not only concerning its content, but also concerning its context [18]. In a recent study on prehabilitation, inclusion was challenging because patients were not willing or not able to participate because of personal, logistic, and time-limitations (e.g. living too far away, no travel opportunities) [19]. Moreover, frequent hospital visits was one of the barriers mentioned by patients that prevented them from implementing an exercise routine [18]. Intuitively, an unsupervised home-based prehabilitation program will cause least disruption to the

patient's life. However when unsupervised, adherence can be problematic, as differences exist in adherence between supervised and unsupervised prehabilitation programs [17]. Adherence to prehabilitation programs is higher in supervised programs (on average 98%) [20-22] compared to unsupervised programs (on average 70%) [23-25]. Furthermore, although adherence and compliance to hospital-based programs is relatively easy to monitor, adherence and compliance to unsupervised home-based activities relies on self-report and therefore might overestimate or underestimate actual exercise frequency, intensity, and duration[26]. Also, although many patients prefer home-based exercise programs, they underline the need for regular supervision[18].

Technologies like telemonitoring can overcome these barriers, as compliance and adherence can be measured more objectively and accurately and patients can be coached and encouraged via telemonitoring while performing their home-based training sessions. Compared to unsupervised programs, telemonitoring can increase adherence and compliance by monitoring (although not real-time), patients from a distance while patients perform their training sessions at their own preferred location [27]. Tele-rehabilitation has already found his way into cardiac rehabilitation [28] but there is no evidence for the feasibility and effectiveness of tele-rehabilitation or teleprehabilitation in oncological patients. **The aim of this pilot study** is therefore to investigate whether a home-based and telemonitored prehabilitation program is feasible in high-risk patients scheduled for colorectal surgery. In addition, patient experiences and the preliminary effects on aerobic fitness will be evaluated.

4. OBJECTIVES

Primary objective

To investigate the feasibility of a home-based teleprehabilitation program in high-risk patients scheduled for elective colorectal resection.

Secondary objectives

To evaluate patient experiences with a teleprehabilitation program (measured by patient-reported experience measures) and to investigate to what extent preoperative physical fitness changes during the home-based teleprehabilitation program in high-risk patients scheduled for elective colorectal resection.

Hypotheses

We hypothesize that:

1) the majority (>60%) of the high-risk patients is willing to participate in the study, because the study is home-based, personalized and aims at optimizing the patient's physical fitness and health status in anticipation of the surgical intervention.

2) adherence and compliance to the teleprehabilitation program will be high (> 80%),there will be no dropout related to program content or context and there will be no program related adverse events as the program is personalized (i.e., tailored to the patient's needs and preferences), telemonitored, and delivered in the patient's home context.

3) the teleprehabilitation program will be experienced as valuable and well accepted in anticipation of the surgical intervention, because the teleprehabilitation program is home-based, personalized and supervised.

4) the equipment (i.e., telephone and heart rate monitor) is easy to use for all ages, as the telemonitoring equipment is specifically designed for elderly; however, some elderly might prefer face-to-face supervision instead of technology.

5) based on previous studies [11, 23] it is to be expected that preoperative physical fitness levels will increase as an effect of the prehabilitation intervention, which is likely to lower the risk for postoperative complications (although no endpoint of this study).

5. STUDY POPULATION

5.1 Inclusion criteria

Participants must meet the following criteria to be eligible for inclusion:

- Diagnosed with colorectal cancer (stage I, II, or III) requiring elective colorectal resection;
- ≥18 years of age;
- Undergoing elective colorectal resection at VieCuri Medical Center, Venlo;
- Have a score ≤7 metabolic equivalents of task (METs) on the veterans-specific activity questionnaire (VSAQ), appendix 1.
- Have a baseline VAT ≤11 mL/min/kg or an VO_{2peak} ≤18 mL/kg/min, as measured during the CPET
- Sign written informed consent.

5.2 Exclusion criteria

Participants meeting at least one of the following criteria will be excluded from participation:

- Not able to operate a mobile phone;
- Requiring acute (emergency) surgery;
- Contraindications for physical training of exercise testing as stated in the ATS/ACCP statement on cardiopulmonary exercise testing [29];
- Unable to cooperate with test procedures (e.g. physical complaints or insufficient knowledge of Dutch Language).

5.3 Sample size calculation

This is a pilot study primarily evaluating the feasibility of home-based teleprehabilitation in high-risk patients undergoing elective colorectal resection. Because the results of this study will be used to set up a larger study, the sample size calculation is based on the secondary outcome measure assessing the (preliminary) effect of the program on preoperative aerobic fitness. Based on a pre-post increase of the VAT of 1.5 mL/kg/min, with $\alpha = 0.05$ and $1-\beta = 0.80$, a sample size of 12 participants is needed. Taking into account a dropout rate of 20%, a sample size of 15 participants is needed.

6. METHODS

6.1 Study design

The current study is a non-randomised observational pilot study that will take place in Viecuri Medical Centre, Venlo.

6.2 Study parameters

6.2.1 Main study parameter

Feasibility of the home-based teleprehabilitation program will be determined by participation rate and reasons for non-participation, the registration of the number and severity of adverse events, adherence and compliance to the program, and drop-out rate and reasons for drop-out.

6.2.2 Secondary study parameters

Moreover, we will assess patient motivation, and appreciation.

1) Patient experiences:
- Patient experience measures as measured by a patient appreciation questionnaire based on Dronkers et al. [20, 30]: see Attachment 2;
- User friendliness as measured by the Systems Usability Questionnaire [31]: see Attachment 3;
- Experiences and preferences of patients with a teleprehabilitation program measured by a semi-structured interview.

2) Changes in physical fitness levels between baseline and follow up (approximately 4 weeks):
- Change in aerobic fitness during teleprehabilitation, as measured by during the Constant Work rate test (CWT)
- Change in functional performance, as measured by the 30-second chair stand test (30-sec CST)
- Change in functional performance, as measured by the 4-meter gait speed (4-MGS) test

6.2.3 Other study parameters

Age, sex, tumor subsite (right-sided colon, left-sided colon, rectal cancer), body mass index (BMI), co-morbidity (Charlson comorbidity index), surgical procedure (open/laparoscopic), neoadjuvant treatment (yes/no), adjuvant treatment (yes/no), American Society of Anesthesiologist (ASA) score, smoking status ("current smoker"/"ex-smoker"/"never smoker"), and other relevant information from medical records (i.e., length of hospital stay, postoperative complications, clinical and pathological TNM stage, tumor distance from anal verge (rectal cancer), lab results) will be recorded. Although this pilot study is not powered to adequately correct for all these parameters, this information is important to characterize our population. Furthermore, we would like to know how the study population relates to the general surgical population. These parameters can reveal trends that may be helpful for setting up future

research.

6.3 Randomization, blinding and treatment allocation

Randomization and blinding will not be applied in this non-randomized observational pilot study with a pre-post design. Based on results of previous studies, it would be unethical to withhold this preventive intervention in high-risk patients. Patients can participate in this study if eligibility criteria are met and informed consent is given.

6.4 Study procedures

6.4.1 Potential eligibility

Patients scheduled for elective colorectal resection who meet the eligibility criteria and are classified by a colon care nurse as potentially unfit by means of a VSAQ score [32] ≤7 METs will be asked to participate in the study. Patients with a VSAQ score >7 METs are not considered high-risk and will receive usual care, including information about the importance of physical activity and physical fitness before and after major surgery (see Figure 1).

6.4.2 Eligibility and informed consent

Patients with a VSAQ score ≤7 METs are considered as potentially unfit, and might be eligible for participation in the study. Potentially unfit patients will be informed by a colon care nurse about the study content and will receive an information letter regarding the aim, content, study burden, potential risks, possible benefits, and contact information. The informed consent form will also be provided. Patients will be contacted by the principal investigator a few days later to answer questions concerning the study and to ask for oral informed consent. Because of the short time-frame between screening and surgery the time to consider informed consent is only 2-3 days. When patients have provided oral informed consent, a CPET will be planned to verify final eligibility. Patients are considered eligible if their oxygen uptake at the VAT is ≤11.0 mL/kg/min or when their VO_{2peak} is ≤18.0 mL/kg/min [14]. As a part of usual care, all colorectal cancer patients will receive all preoperative measurements combined on a diagnostic day, the so-called “CRC-day”. The CPET will be scheduled during the CRC-day (no additional trip to the hospital is necessary). On the day of the CPET, written informed consent will be obtained before the start of any study procedures.

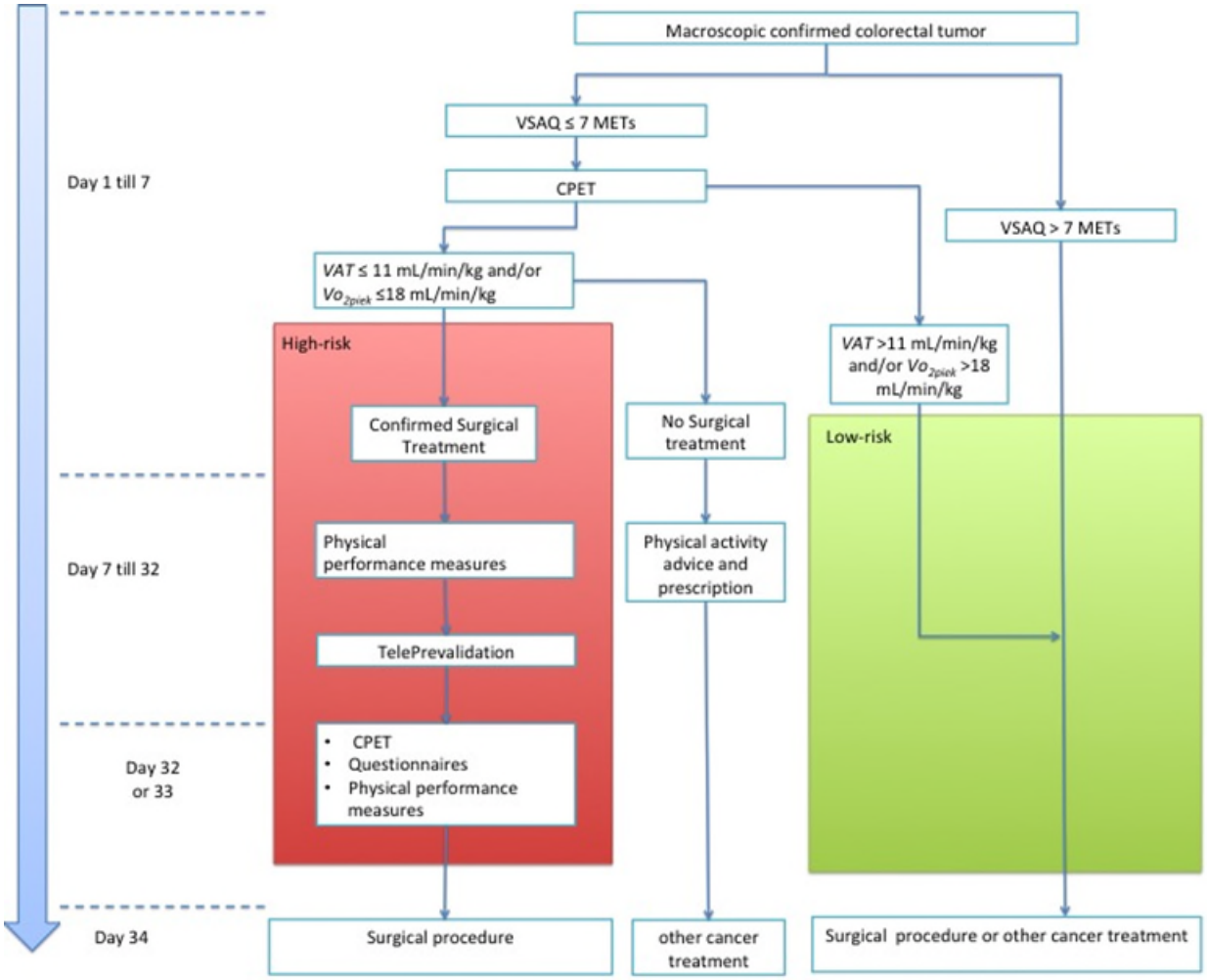

Figure 1. Study procedures.

6.4.3 Assessments

Adherence and compliance

Exercise adherence will be monitored with the app of HC@home and will be assessed as 1) completion of the recommended number training sessions per week and 2) as the ability to achieve the prescribed intensity and duration of exercise sessions. Successful exercise adherence involves achieving >80% of the prescribed exercise duration, intensity, and frequency of the training sessions during the study period but will be considered for each parameter separately.

Anthropometry

Body mass and body height will be measured, from which body mass index will be calculated. Before the CPET, the patient's body mass will be measured with patients wearing underwear only with an electronic scale (Seca delta 707,Seca, Hamburg, Germany) to the nearest 0.5 kg. Body height will be measured bare feet using a stadiometer (Seca, Hamburg, Germany) to the nearest 0.5 cm.

Cardiopulmonary exercise test
At baseline, a CPET will be done to stratify patients in having a low or high risk for complications. Only high-risk patients will be included in this study and will undergo the home-based teleprehabilitation program. At the end of the teleprehabilitation program, one or two days before surgery, included patients will undergo a second CPET to objectively measure if their aerobic fitness has improved.

Participants will perform an incremental CPET up to maximal exertion in upright position on an electronically braked cycle ergometer (Lode Corival, Lode BV, Groningen, the Netherlands). Prior to the test, participants will be asked to avoid exercise, caffeine and tobacco for 24 h, and food for 2 h, but to take all usual medications. Absolute and relative contra-indications for exercise testing will be checked according to ATS/ACCP statement [29] and a medical doctor will be stand-by in case of emergency/complications. Seat height will be adjusted to the participant's leg length. Before commencing the maximal CPET, forced vital capacity and forced expiratory volume in one second will be obtained from maximal flow-volume curves (Ergostik, Geratherm Respiratory, Bad Kissingen, Germany) according to ATS/ERS standards [29]. Subsequently, baseline cardiopulmonary values will be assessed during a three-minute rest period while seated at the cycle ergometer, where after the patient performs a three-minute warm-up phase that consist of unloaded cycling. After the warm-up, the work rate will be increased by constant increments of 5, 10, 15, 20, or 25 W/min in a ramp-like manner, depending on the patient's subjective physical fitness level and aimed at reaching a maximal effort within eight to twelve minutes. Throughout the CPET, patients have to maintain a pedaling frequency between 60 and 80 revolutions/min (rpm). The protocol continues until the patient's pedaling frequency falls definitely below 60 rpm, despite strong verbal encouragement, or when the patient meets the criteria for exercise termination before symptom limitation as proposed in the ATS/ACCP statement on cardiopulmonary exercise testing [29] indications for exercise termination.

During the cardiopulmonary exercise test, patients breath through a facemask (Hans Rudolph, Kansas City, MO, USA) connected to an ergospirometry system (Ergostik, Geratherm Respiratory, Bad Kissingen, Germany) that will be calibrated for respiratory gas analysis measurements (ambient air and a gas mixture of 16% oxygen and 5% carbon dioxide) and volume measurements (three-liter syringe). Expired gas will pass through a flow meter (Triple V volume transducer), an oxygen analyzer, and a carbon dioxide analyzer. The flow meter and gas analyzers will be connected to a computer, which calculates breath-by-breath minute ventilation, oxygen uptake, carbon dioxide production, and the respiratory exchange ratio averaged at ten-second intervals. Heart rate will be measured by continuous twelve-lead electrocardiography. A test will be considered to be at or near the maximal level when participants show clinical signs of intense effort (e.g., unsteady biking, sweating, and clear unwillingness to continue exercising despite strong encouragement), are unable to maintain the required pedaling speed (i.e., 60 rpm), and when at least one of the following criteria is met: a heart rate at peak exercise of >95% of predicted (predicted peak heart rate (beats/min) = 210 – (0.8 × age (years))) or a respiratory exchange ratio at peak exercise of >1.10.

Data interpretation will be performed by a trained clinical exercise physiologist. Absolute values at peak exercise will be calculated as the average value over the last 30 seconds prior to termination of the test. Peak heart rate is defined as the highest heart rate achieved during the cardiopulmonary exercise test. The VAT is identified by using a three-point discrimination technique as described extensively elsewhere by Levett et al. [33]. The Respiratory compensation point (RCP) is defined as the point where the VE – VCO_2 slope steepens because of a respiratory response to metabolic acidosis in combination with a fall

in partial pressure of end tidal CO2 (PET-CO_2) values [34]. The VAT, RCP and VO_{2peak} will be expressed as an absolute and relative VO_2 value (e.g. normalized for body mass).

Functional physical performance
In order to quantify to what extent the prehabilitation program had an effect on functional performance the following test are done. Physical performance measures will be done at baseline (during the physical therapy visit at home, 1 day after the CPET) and one or two days before surgery.

30-second chair stand test
The 30-second chair stand test (30-sec CST) is used to measures lower body muscle strength and functional mobility [35]. The test consists of standing up and sitting down from a chair (43-47 cm in height) as many times as possible within 30 seconds. It is not allowed to use the arm rests of the chair (patients are instructed to fold the arms across the chest during the test). The number of times standing up and sitting down is noted down.

4-meter gait speed test
Gait speed is reliable measure of functional capacity and has a good predictive value for major health related outcomes [36]. The 4-meter gait speed test (4MGS) is a test that requires the patient to walk 4 meters at their normal pace. After a one-meter acceleration zone the time is started when the first footfall enters the four-meter testing zone. The time stops at the first footfall after the four-meter line after which the patient enters the one-meter deceleration zone. The test is repeated three times with sufficient time for recuperation between trials. The mean of three trials is recorded.

Constant work rate test
A constant work rate test (CWT) is a responsive measure to quantify the effect of an intervention [37]. The CWT will be done at 80% of the work rate as accomplished during the baseline CPET [11]. Participants will cycle on a stationary bicycle until exhaustion. The total time that participants were able to cycle is recorded.

Questionnaires

Veterans-specific activity questionnaire
The veterans-specific activity questionnaire (see Appendix 1) is an easily applicable questionnaire developed for veterans that are referred to exercise testing for clinical reasons [32]. The questionnaire consists of a list of activities linked to a metabolic equivalent of task (MET) score. Patients are asked to draw a line below the activities that he or she was able to do routinely with minimal or no symptoms, such as fatigue, chest discomfort, or shortness of breath.

Anxiety and depression
Because anxiety and depressions symptoms can be related to both adherence and compliance, it is important to gain insight into the mental wellbeing of participants. The hospital anxiety and depression scale (HADS) is a self-reported questionnaire designed to identify mild mood disorders. The HADS consist of 14 items of which 7 are linked to depression and seven to anxiety. Each question has to be scored on four levels concerning frequency of symptoms of severity of symptoms. Previous research has shown that adherence and compliance rates to exercise are lower in patients with lower mental wellbeing [26]. The HADS will be measured at baseline (see appendix 4).

Rating of Perceived exertion
The Rating of Perceived exertion is a subjective scale for patients to rate how much effort an exercise takes. Patients rate their perceived exertion on a numeric scale between 6-20 in where 6 reflects no exertion and 20 maximal exertion (see appendix 5). Patients will rate their perceived exertion at the end of every training.

Screening for malnutrition
Suboptimal nutritional status is a strong independent predictor of poor postoperative outcomes [38]; therefore, all eligible patients will be screened by for malnutrition by a dietician using the Patient Generated Subjective Global Assessment Short form (PG-SGA-SF). (See appendix 6).

User friendliness
The system usability scale (SUS), a 10-item scale giving a global view of subjective assessments of usability of a wide variety of systems [31]. Answers are given on a 5-point Likert scale with anchors for "strongly agree" and "strongly disagree". The total score is between 0 and 100, with a score of 100 indicating best usability [31]. A score of ≥70 is considered acceptable usability [39]. In the current study the SUS is used to grade the uses-friendliness of the teleprehabilitation intervention. Participants will be asked to fill in the SUS at the end of the prehabilitation program, one or two days before surgery.

Patient appreciation
The patient appreciation of the home-based teleprehabilitation program will be recorded after completing the program with an appreciation questionnaire (see Appendix 2). The questionnaire consists of 11 questions that should be answered on a 5-point Likert scale (1=totally disagree, 5=totally agree). The higher the total score, the higher the appreciation of the prehabilitation program [20, 30]. Participants will be asked to fill in the "patient appreciation questionnaire" at the end of the prehabilitation program, one or two days prior to surgery.

Semi-structured interview
A semi-structured interview of approximately 30 minutes will take place at the patient's home or via telephone at the end of the teleprehabilitation program. The interviews will be recorded using an audio recorder. The topics of the interview will consist of;

1) Motivators and barriers concerning Teleprehabilitation; i.e. but not exclusively: what factors were helpful to comply and what barriers were experienced. What motivated patients.

2) Experiences and preferences regarding content and context; i.e. but not exclusively: How did patients experience the content of the teleprehabilitation program (duration, frequency, intensity, how challenging was it?)? How did they feel about telemonitoring? How did they feel about how formal caregivers treated them (in terms of, respectful, calm, lovingly etc.)?

3) Expectations of teleprehabilitation; i.e. but not exclusively: Beforehand, where the motives and goals clear?, Did the program fulfil the expectations? Did they feel well prepared for surgery?

Table 1. Schedule of assessments and interventions.

	Pre-prehabilitation			Prehabilitation				Post-prehabilitation	
Time point	Week 0			Week 1	Week 2	Week 3	Week 4	Week 5	
Eligibility screening	X								
VSAQ	X								
Informed consent		X							
CPET		X							
Baseline characteristics		X							
30-sec CST 4-MGS test			X X					X X	
PG-SGA-SF			X						
HADS			X						
Teleprehabilitation				X	X	X	X		
SUS								X	
Patient appreciation								X	
Constant work rate test			X					X	
Semi-structured interview									X

6.5 Teleprehabilitation program content

Physical fitness module

All eligible participants will receive a heart rate monitor that can be connected with the app of HC@Home (HC@Home B.V., Zwolle Nederland) on a dedicated smartphone. Based on the results of the CPET, personalized training zones are determined and defined as a percentage of the heart rate at the VAT and respiratory compensation point (RCP). Training sessions will take place every other day and will consist of aerobic interval training by a patient's preferred activity (walking, cycling, stair climbing, et cetera). Intervals will consist of 3 minutes low intensity exercise (≤ VAT or RPE score ≤11) followed by 3 minutes exercise of high intensity exercise (intensity just below RCP, approximately 70-85% of VO_{2peak} or RPE score 14-16) based on [40]. In-between training days, patients will be advised to retain relative rest but no absolute rest (e.g. >30 minutes of low intensity physical activity). Although a base training schedule will be provided as guidance, training duration and intensity will be adjusted according to a rating of perceived exertion scale (RPE-scale). The first training will be face-to-face, as the physical therapist will visit the participant at home to explain the use of the telemonitoring equipment of HC@Home and will execute the first trainings session together with the participant to ensure the participant is familiar with the equipment, comfortable with the training program, and has a safe environment for executing his training session. After the first training session, the participant will continue his home-based training sessions independently with his family or (informal) caregiver.

At the start of each training session, the participant attaches the optical heart rate monitor to the upper arm and connects the monitor to the dedicated smartphone. After the activity is terminated, data concerning type, duration and intensity of the activity are automatically uploaded to an online platform, at which they are accessible for the patient and physical therapist. The physical therapist can monitor the patient's achievements (however, not real-time) on the online platform and can motivate and coach the patient from a distance by sending messages. Once weekly, there will be a 15-minute video consult via the HC@Home App in which the patient can provide feedback on the training, ask questions and the training can be adjusted based on the RPE-scale. During this video consult, the physical therapist will also ask for any adverse effects and reasons for possible non-adherence or non-compliance via a semi-structured interview.

Nutritional support module

All eligible patients will be screened for malnutrition using the patient generated subjective global assessment short form (PG-SGA-SF) (see Appendix 6). Furthermore, all patients will undergo a preoperative nutritional screening by a registered dietician. Preoperative nutritional advice will include optimization of basic nutritional needs, as well intake of sufficient protein, stated as 1.2-2.0 g/kg [38]. After a face-to-face intake, follow-up meetings will be performed by a dietician via a weekly video consult using the app of HC@Home.

6.6 Withdrawal of individual subjects

Participants can leave the study at any time without indicating a reason. This will not have consequences for their standard cancer treatment. All study-related measurements will be terminated from the day of withdrawal. The investigator or other professionals involved in the study may decide to withdraw a participant in case of urgent medical reasons.

6.7 Replacement of individual subjects after withdrawal

This study will continue until the inclusion of 12 patients with full data collection. Considering a dropout rate of 20% we expect to include 15 patients.

6.8 Safety reporting

All adverse events reported by participants or observed by the investigator or healthcare providers involved in this study will be reported in the case report form (CRF). Serious adverse events are not expected in this study as no experimental study actions are executed. Nevertheless, all adverse events during study and during the execution of the prehabilitation program will be investigated extensively to determine whether they are treatment-related or related to the prehabilitation program. Moreover, it is expected that the prehablitation program can lower complications due to treatment (i.e. surgery).

6.8.1 Premature termination of the study

Given the nature of the study, no reasons for premature termination are expected. Previous studies have shown that performing a CPET is safe and feasible in oncology patients awaiting surgery [13] and that patients tolerate an exercise program well during the preoperative period [17]. Furthermore, as the patient chooses the mode of exercise and the exercise intensity is based on formal exercise testing, the prehabilitation program is adapted to the patients' needs and abilities. Regular (weekly) check-up video conferences are used to further tailor the program to the patient's needs and abilities. Additionally, effects and experiences will be collected and described more extensively than during normal clinical practice. Although this is not an experimental research field, when the suspicion arises that patient safety is harmed at any time during the study, the prehabilitation program will be stopped (temporarily) in order to investigate the potential risk. The study will not be continued until the project team unanimously agrees on the safety and continuation of the study.

7. STATISTICAL ANALYSES

All data will be analyzed by using IBM SPSS Statistics version 21.0 (IBM, Chicago, IL, USA). Relevant graphs will be created by using Graphpad (GraphPad Software, Inc.,CA, USA).

The percentage of patients that is eligible and not willing to cooperate will be described in combination with reasons for non-participation (only if a patient is willing to give a reason). Adherence and compliance with respect to frequency, duration, and intensity of the exercise program will be measured by the App of HC@Home and will be automatically uploaded to an online platform. Descriptive analyses will be performed to describe adherence and compliance and will be presented as follows. The observed average and total actual exercise duration of the attended sessions will be divided by the average and total prescribed exercise duration and will be presented as a percentage ± standard deviation (SD) of the average and total duration. Adherence to prescribed intensity of the attended exercise sessions (for Type I training session only) will be measured as follows, if in at least three high-intensity bouts per sessions the heart rate is within the prescribed zone this session is registered as a sessions in where the prescribed intensity is met. The number of attended sessions in where the prescribed intensity is met will be divided by the total number of attended sessions and will be presented as a percentage ± SD. The observed frequency of exercises will be divided by the prescribed frequency (maximum 16, 4 weeks 4x per week, but will be less if total duration is < 4 weeks) and will be presented as a percentage ± SD. A compliance and adherence rate of ≥70% is considered as acceptable, a compliance and adherence rate of is ≥ 80% considered good. All adherence and compliance parameters will be considered separately. Furthermore dropout rate will be expressed as a number and percentage of total number of participants. Patient appreciation and usability of the teleprehabilitation intervention will be presented by descriptive analyses.

A change in aerobic fitness will be measured by comparing baseline fitness test (CWT, 30-sec-CST and 4-MGS test) with the fitness test one or two days before surgery. Data will be checked for normality using the Shapiro-Wilk test in combination with checking the histograms for kurtosis or skewness. Data will be presented as mean ± SD or median and interquartile range (IQR) dependent on distribution. As appropriate, pre-post analysis of continuous variables will be performed with the parametric paired samples t-test or the non-parametric Wilcoxon signed rank test. Categorical variables will be analyzed using the Wilcoxon signed rank test. Differences between pre- and post-measurements will be considered statistically significant when $p<0.05$. Qualitative analysis of the interviews with a deductive approach will be done by listening to the audio files twice with the aim of the study in mind. Thereafter, transcription will take place of the parts of the interview that are relevant in relation to the study outcome. After transcription data will be analysed and open coding will take place according to the themes and questions that were drafted up beforehand. Furthermore, axial coding, checking fragments with the same code for consistency, and selective coding, translating the code into a theory, will be done.

8. COLLECTION, QUALITY AND VALIDITY OF DATA

8.1 Handling and storage of data and documents

Data will be handled confidentially. Study information will be stored/collected in a Good Clinical Practice (GCP) -proof data-management system. These data will be coded by a random combination of numbers which are not related to the patients and are not traceable. Participant codes will be linked to patient identifying information (patient code and birth date) by a secured additional file that is stored on a safe VieCuri computer. The key for the coded data will only be accessible for the investigator who is a caregiver of the patient. All data will be stored on a safe VieCuri computer until 15 years after the study. Afterwards, these data will be destroyed as required for confidential data. The results of the study with coded patient data will be used to present at international conferences and publications.

8.2 Loss to-follow up

Patients who withdraw from this study or are lost to follow-up still receive standard treatment. When patient contact during the study is lost without confirmation of withdrawing, the principal investigator asks the case manager to contact the patient during the regular check-up calls.

8.3 Monitoring and quality assurance

The principal investigators as well as most members of the project team are certified for Good Clinical Practice and will assure the quality of the study. External monitoring by a clinical trial centre will be arranged in case this study is deemed as a WMO-study.

8.4 Amendments

In case of critical alterations to the study protocol, amendments will be sent to the medical ethics committee that consented with this study. The study can only be executed according to the alterations after additional approval.

8.5 Annual progress report

It is aimed to complete all study procedures within two years. If this goal will not be reached, a progress report will be sent to the medical ethics committee (METC) after one year. After study closure, the METC will receive the end report of this study.

8.6 Public disclosure and publication policy

Data of the present study will be described anonymously and handled in confidentiality. Only anonymous results of this study will be presented at international conferences and published in

international journals.

9. ETHICAL CONSIDERATIONS

The principles of the Declaration of Helsinki will be handled during this study. The Zuyderland METC will judge this study for the so-called 'WMO' complicity. After approval of this METC and local approval in VieCuri Medical Centre, this study can start with participant recruitment.

9.1 Recruitment and consent

During the usual care visit for a colonoscopy, suspected CRC patients will be asked for their physical activity levels by a nurse using the VSAQ. If the diagnosis of CRC is confirmed by the colonoscopy and the VSAQ score is ≤7 METs, patients are classified as potentially unfit and will receive oral and written information about the study including the informed consent file. Three days after the colonoscopy, patients will be contacted by telephone by the principal investigator to give elaborate information about the study and answer questions regarding the study. Furthermore, patients are asked for oral informed consent. In oral informed consent is provided, a CPET will be scheduled for the "CRC day". Only after signing written informed consent, patients will undergo a CPET. Patients are definitely included in the study if they have a VAT ≤11.0 mL/kg/min and/or a VO_{2peak} ≤18.0 mL/kg/min. Patients that are excluded from the study (VAT ≥11.0 mL/kg/min and/or a VO_{2peak} ≥18.0 mL/kg/min on the CPET) will receive training advise based the CPET but will not be provided with telemonitoring equipment and guidance and if preferred can be advised to go to a community physical therapist.

9.2 Benefits and risk assessment, group relatedness

The measurements in this study pose no harm to participants. The performance tests used in this study are standard tests that are used in oncology rehabilitation, non-invasive, and considered safe and feasible for this population. If parts of the prehabilitation program are perceived as too intense for the patients, the regular check-up video consults can alter these shortcomings on a timely basis. It is thought that patients will benefit from this prehabilitation program without (additional) complications by increasing their physical fitness levels. The researchers realize that the prehabilitation intervention might be a burden to participants; however, the design of the study, being home-based and personalized to the patient's ability and preferences will reduce the burden to a minimum.

9.3 Foreseen barriers

- The success of the prehabilitation program depends largely on an active contribution of the patients (and informal caregivers) to the program. The program involves a, at least temporary, behaviour change of the patients with respect to his/her nutritional and physical-activity behaviour. Although there is a clear relation between preoperative aerobic fitness and long-term goals such as postoperative outcome, on the short-term basis the prehabilitation program imposes no clear benefits (apart from improving fitness levels), which might influence patients' willingness to participate, adherence and compliance.

Gaining insight into barriers and identifying areas for improvement are among the current study objectives.
- As the vast majority of the patients will be >70 years of age, there might be some barriers with the use of teleprehabilitation equipment (e.g., mobile phone and heart rate monitor). The app of HC@Home, however, is specifically designed for elderly people and feasibility of the program is the primary endpoint of this study. Furthermore, during the first training session the physiotherapist will explain and demonstrate the use of the equipment to the patient and his family or caregiver face-to-face.

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11. APPENDIX

11.1 Appendix 1. The Veteran Specific Activity Questionnaire (VSAQ)

Zet een streep onder de activiteiten die u regelmatig doet met minimale of geen klachten zoals kortademigheid, pijn op de borst of vermoeidheid.

MET's	Activiteit
1	• Eten, aankleden, werken achter een bureau • Rustig zitten
2	• Douchen • Acht treden van de trap af lopen • Wandelen 2,5 km/u
3	• Wandelen 3-4 km/u • Werkzaamheden met een gemiddelde inspanning in en om het huis zoals, stofzuigen, vloeren dweilen of het dragen van boodschappen
4	• Lichte tuinwerkzaamheden zoals bladeren harken, onkruid wieden of een elektrische grasmaaier duwen. • Fietsen 10 km/u en wandelen 5 km/u
5	• Stevig wandelen met een snelheid van 5,5 km/u • Fietsen 12 km/u
6	• Trap op lopen • Wandelen 6,5 km/u
7	• Zwaar werk buitenhuis verrichten zoals graven, aarde scheppen • Enkel potje tennis spelen of 25 kg dragen • Fietsen 15 km/u of Wandelen 7,5 km/u
8	• Snel de trap op lopen, de trap oplopen met een gewicht van 9 kg • Fietsen 19 km/u • Joggen 8 km/u
9	• Fietsen in een gemiddeld tempo, hout zagen, touwtje springen (langzaam).
10	• Stevig zwemmen, een heuvel op fietsen, stevig een heuvel op wandelen. • 9,5 km/u joggen • Fietsen 23 km/u
11	• Langlaufen, basketbalspelen op een volledig speelveld
12	• Stevig hardlopen zonder onderbreking (vlakke ondergrond, 12 km/u) • Fietsen 25 km/u
13	• Een wedstrijd spelen waarbij u zo nu en dan sprintjes trekt. • Stevig hardlopen zonder onderbreking (vlakke ondergrond, 15 km/u)
14	• Een hardloopwedstrijd, roeien, backpacken.

11.2 Appendix 2. Patient Appreciation Questionnaire

Geef aan in hoeverre u het Oneens of Eens bent met de onderstaande stellingen.

	Oneens				Eens
	1	2	3	4	5
Het doel van de behandeling ter voorbereiden op de operatie was duidelijk voor mij					
De ervaren mate van vermoeidheid, tijdens de fietstest was hoog					
Naar mijn mening was de fietstest zinvol					
De ervaren mate van vermoeidheid van de thuistrainingen was hoog					
Naar mijn mening waren de thuistrainingen nuttig					
Ik was gemotiveerd om de thuistrainingen uit te voeren					
Ik had plezier in het uitvoeren van de thuistrainingen					
De thuistrainingen kosten veel tijd					
Ik had voordeel van de wekelijkse contact momenten door middel van videobellen					
Ik vond het prettig dat ik de thuistrainingen zelfstandig thuis kon uitvoeren					
Ik denk dat de behandeling ter voorbereiding op de operatie me goed voorbereid heeft op de operatie					

11.3 Appendix 3. System Usability Scale (SUS)

Geef aan in hoeverre u het Oneens of Eens bent met de onderstaande stellingen over de App van HC@Home die u gebruikt heeft tijdens uw trainingen.

	Helemaal mee Oneens				Helemaal mee eens Eens
	1	2	3	4	5
Ik denk dat ik de App vaker zou willen gebruiken					
Ik vond de App onnodig complex					
Ik denk dat de App eenvoudig te gebruiken is					
Ik denk dat ik assistentie nodig heb van een technisch onderlegd persoon om de App te kunnen gebruiken					
Ik vond de verschillende onderdelen van de App goed op elkaar afgestemd					
Ik dacht dat er teveel inconsistentie in de App zit					
Ik kan me voorstellen dat de meeste mensen snel leren omgaan met deze App					
Ik vond de App erg omslachtig om mee om te gaan					
Ik voelde me erg bekwaam in het gebruik van de App					
Ik moest veel dingen leren voor ik om kon gaan met de App					

11.4 Appendix 4. Hospital Anxiety and Depression Scale (HADS)

Wij willen graag weten hoe u zich de laatste tijd heeft gevoeld. Wilt u bij elke vraag het cijfer voor het antwoord dat u het meest op u van toepassing is omcirkelen? Denk erom, het gaat bij deze vragen om hoe u zich de laatste tijd (in het bijzonder de afgelopen 4 weken) voelde, dus niet om hoe u zich in het verleden heeft gevoeld.

1. Ik voel me de laatste tijd gespannen	0 – meestal 1 – vaak 2 – af en toe, soms 3 – helemaal niet
2. Ik geniet nog steeds van de dingen waar ik vroeger van genoot.	0 – zeker zo veel 1 – wat minder 2 – duidelijk minder 3 – nauwelijks nog
3. Ik krijg de laatste tijd het angstige gevoel alsof er elk moment iets vreselijks zal gebeuren	0 – heel zeker en vrij erg 1 – ja, maar niet zo erg 2 – een beetje, maar ik maak me er geen zorgen over 3 – helemaal niet
4. Ik kan lachen en de dingen van de vrolijke kant zien.	0 – net zoveel als vroeger 1 – nu wat minder 2 – nu duidelijk minder 3 – helemaal niet meer
5. Ik maak me de laatste tijd ongerust.	0 – heel erg vaak 1 – vaak 2 – niet zo vaak 3 – heel soms
6. Ik voel me de laatste tijd opgewekt:	0 – helemaal niet 1 – niet vaak 2 – soms 3 – meestal
7. Ik kan de laatste tijd rustig zitten en me ontspannen:	0 – zeker 1 – meestal 2 – niet vaak 3 – helemaal niet
8. Ik voel me de laatste tijd alsof alles moeizamer gaat.	0 – bijna altijd 1 – heel vaak 2 – soms 3 – helemaal niet
9. Ik krijg de laatste tijd een soort benauwd, gespannen gevoel in mijn maag.	0 – helemaal niet 1 – soms 2 – vrij vaak 3 – heel vaak
10. Ik heb de laatste tijd geen interesse meer in mijn uiterlijk.	0 – zeker 1 – niet meer zoveel als ik zou moeten 2 – mogelijk wat minder 3 – evenveel interesse als voorheen
11. Ik voel me de laatste tijd rusteloos.	0 – heel erg 1 – tamelijk veel

	2 – niet erg veel 3 – helemaal niet
12. Ik verheug me van tevoren al op dingen.	0 – net zoveel als vroeger 1 – een beetje minder dan vroeger 2 – zeker minder dan vroeger 3 – bijna nooit
13. Ik krijg de laatste tijd plotseling gevoelens van angst of paniek.	0 – zeer vaak 1 – tamelijk vaak 2 – niet erg vaak 3 – helemaal niet
14. Ik kan van een goed boek genieten of een radio- of televisieprogramma.	0 – vaak 1 – soms 2 – niet vaak 3 – heel zelden

11.5 Appendix 5. Rating of Perceived exertion (RPE)

6		6
7	Zeer, Zéér licht	7
8		8
9	Zeer licht	9
10		10
11	Tamelijk licht	11
12		12
13	Redelijk zwaar	13
14		14
15	Zwaar	15
16		16
17	Zeer Zwaar	17
18		18
19	Zeer, Zéér Zwaar	19
20		20

11.6 Appendix 6. Patient Generated Subjective Global Assessment Short Form (PG-SGA-SF)

Scored Patient-Generated Subjective Global Assessment (PG-SGA)

Vak 1 t/m 4 worden ingevuld door de patiënt zelf
[Vak 1 t/m 4 worden aangeduid als de PG-SGA Short Form (SF)]

Patientgegevens:

1. Gewicht (zie werkblad 1)

Overzicht van mijn huidige en recente gewicht:

Op dit moment weeg ik ongeveer ____ kg

Ik ben ongeveer ____ cm lang

Eén maand geleden woog ik ongeveer ____ kg

Zes maanden geleden woog ik ongeveer ____ kg

De afgelopen twee weken is mijn gewicht:

- ◯ afgenomen (1)
- ◯ niet veranderd (0)
- ◯ toegenomen (0)

Cumulatieve score Vak 1:

2. Voedingsinname

Vergeleken met wat ik normaal eet, beoordeel ik mijn voedselinname van de afgelopen maand als *(noteer de maximale score)*:

- ◯ niet veranderd (0)
- ◯ meer dan gebruikelijk (0)
- ◯ minder dan gebruikelijk (1)

Ik gebruik nu:

- ◯ *normaal voedsel*, maar een kleinere hoeveelheid dan gebruikelijk (1)
- ◯ een beetje vast voedsel (2)
- ◯ alleen vloeibaar voedsel (3)
- ◯ alleen dieetvoeding (bijvoorbeeld drinkvoeding) (3)
- ◯ nauwelijks iets (4)
- ◯ alleen sondevoeding of parenterale voeding (TPN/TPV) (0)

Maximale score Vak 2:

3. Symptomen

Ik heb last gehad van de volgende problemen, waardoor ik niet genoeg kon eten de afgelopen twee weken (alles aankruisen wat van toepassing is):

- ◯ geen problemen bij eten (0)
- ◯ geen eetlust, had geen zin in eten (3)
- ◯ misselijkheid (1)
- ◯ verstopping (1)
- ◯ pijnlijke mond (2)
- ◯ eten smaakt vreemd/anders of heeft geen smaak (1)
- ◯ problemen met slikken (2)
- ◯ pijn, waar? (3) ____
- ◯ overige (1)*: ____
- ◯ overgeven (3)
- ◯ diarree (3)
- ◯ droge mond (1)
- ◯ ik heb last van de etenslucht (1)
- ◯ ik voel me snel vol (1)
- ◯ vermoeidheid (1)

* bv. depressie, geldzorgen, gebitsproblemen

Cumulatieve score Vak 3:

4. Activiteit en functioneren

Ik beoordeel mijn activiteiten van de afgelopen maand over het algemeen als:

- ◯ normaal zonder beperkingen (0)
- ◯ ik ben uit mijn gewone doen, maar ik hoef niet te rusten en ik ben wel bezig met redelijk normale bezigheden (1)
- ◯ ik heb geen zin in de meeste bezigheden, maar lig minder dan de helft van de dag in bed of op de bank (2)
- ◯ ik ben in staat tot weinig bezigheden en breng het grootste deel van de dag in bed of op de bank door (3)
- ◯ ik ben zo ongeveer gekluisterd aan bed, bijna niet uit bed (3)

Maximale score Vak 4:

Cumulatieve score Vak 1 t/m 4: A

De rest van dit formulier wordt ingevuld door de diëtist, arts, verpleegkundige of hulpverlener. Hartelijk dank voor uw medewerking!

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