ISRCTN64482109 https://doi.org/10.1186/ISRCTN64482109

Is it possible to use home-based prehabilitation with added E-health in patients with colorectal cancer undergoing surgery?

Submission date
09/11/2021

Recruitment status
No longer recruiting

Registration date
11/11/2021

Overall study status
Completed

Last Edited
27/07/2022

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Colorectal cancer is the third most common type of cancer worldwide, with the majority of the patients being >70 years of age. The main treatment, surgery, is associated with a high number of complications. Furthermore, many patients experience loss of quality of life after surgical treatment.
Prehabilitation, optimization of a patient's health status between diagnosis and major surgical intervention, seems to be effective in improving fitness.
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 the 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.
The primary aim of this study is to investigate the feasibility of a home-based teleprehabilitation program in high-risk patients scheduled for cancer surgery.

Who can participate?
Adults over 18 years, with colorectal cancer requiring surgical treatment.

What does the study involve?
Participants are offered a teleprehabilitation program as part of their routine care in the weeks before surgery.

What are the possible benefits and risks of participating?
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.

Where is the study run from?
VieCuri Medisch Centrum (Netherlands)

When is the study starting and how long is it expected to run for?
March 2019 to September 2021

Who is funding the study?
VieCuri Medisch Centrum (Netherlands)
Nationaal Fonds tegen Kanker (National Fund angainst Cancer) (Netherlands)

Who is the main contact?
Ruud Franssen, rfranssen@viecuri.nl

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
METCZ20190150

Study information

Scientific Title
Feasibility of a tele-prehabilitation study in high-risk patients with colon or rectal cancer undergoing elective surgery: a pilot study

Acronym
E-health CRC

Study objectives
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 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).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/12/2019, Medical Ethics Committee of Zuyderland (METC Z Secretariaat, T3 Heerlen, Postbus 5500, 6130 MB Sittard, Netherlands; no telephone number provided; metc@zuyderland.nl), ref: METCZ20190150.

Study design
One-arm pre-post pilot observational longitudinal study

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prehabilitation of patients with colorectal cancer

Interventions
A multimodal tele-prehabilitation intervention was embedded within the existing colorectal cancer pathway of VieCuri Medical Center. Therefore, no additional hospital visits were required for study purposes. Baseline measurements were planned on the day of the appointment with the surgeon, approximately 2-5 days after final inclusion. Reassessment took place one or two

days prior to surgery. The tele-prehabilitation program consisted of a tele-monitored physical exercise module and a nutritional support module. Smoking cessation is part of usual care and therefore was not included in the tele-prehabilitation program.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility outcomes:
1. Study participation rates will be measured by calculating the number of participating patients as a proportion of potentially eligible patients that were referred for prehabilitation.
2. Reasons for non-willingness to participate measured during a telephone interview with the patient before the start of the study.
3. Number and severity of adverse events related to the physical exercise training program measured based on self-report of the participants and will be registered by the physiotherapist in the study management system.
4. 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.
5. Drop-out rates were calculated as the number and proportion of participating patients that are lost to follow up during the tele-prehabilitation program (i.e., between final inclusion and follow-up measurement). Reasons for drop-outs are registered by the principal investigator .

Key secondary outcome(s))
1. Participant experiences as measured by a patient appreciation questionnaire at the end of the tele-prehabilitation program (follow-up measurement 1 or 2 days before surgery)
2. User friendliness of the mobile phone application (HC@Home) that was used for tele-prehabilitation measured using the Systems Usability Questionnaire at the end of the tele-prehabilitation program (follow-up measurement 1 or 2 days before surgery)
3. Changes in physical fitness levels between baseline and follow up (approximately 4 weeks):
3.1 Change in aerobic fitness during teleprehabilitation, as measured by during the Constant Work rate test (CWT)
3.2 Change in functional performance, as measured by the 30-second chair stand test (30-sec CST)
3.3 Change in functional performance, as measured by the 4-meter gait speed (4-MGS) test

Completion date
01/09/2021

Eligibility

Key inclusion criteria
1. Diagnosed with colorectal cancer (stage I, II, or III) requiring elective colorectal resection
2. ≥18 years of age
3. Undergoing elective colorectal resection at VieCuri Medical Center, Venlo
4. Have a score ≤7 metabolic equivalents of task (METs) on the veterans-specific activity questionnaire (VSAQ)
5. Have a baseline VAT ≤11 mL/min/kg or an VO2peak ≤18 mL/kg/min, as measured during the

CPET
6. Sign written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
11

Key exclusion criteria
1. Not able to operate a mobile phone
2. Requiring acute (emergency) surgery
3. Contraindications for physical training of exercise testing as stated in the ATS/ACCP statement on cardiopulmonary exercise testing
4. Unable to cooperate with test procedures (e.g. physical complaints or insufficient knowledge of Dutch Language)

Date of first enrolment
01/02/2020

Date of final enrolment
01/09/2021

Locations

Countries of recruitment
Netherlands

Study participating centre
VieCuri Medical Center
Tegelseweg 210
Venlo
Netherlands
599512 BL

Sponsor information

Organisation
VieCuri Medisch Centrum

ROR
https://ror.org/02kjpb485

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
VieCuri Medisch Centrum

Funder Name
Nationaal Fonds tegen Kanker

Alternative Name(s)
National Cancer Fund, Stichting Nationaal Fonds tegen Kanker, Tegen Kanker, NFtK, SNFTK

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Ruud Franssen (rfranssen@viecuri.nl).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/07/2022	26/07/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file		01/11/2019	10/11/2021	No	No