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Published in: American Journal of Physical Medicine and Rehabilitation

DOI: 10.1097/PHM.000000000001108

IMPORTANT NOTE: You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.

Document Version Final author's version (accepted by publisher, after peer review)

Publication date: 2019

Link to publication in University of Groningen/UMCG research database

Citation for published version (APA): Bruns, E. R. J., Argillander, T. E., Schuijt, H. J., van Duijvendijk, P., van der Zaag, E. S., Wassenaar, E., Gerhards, M. F., Consten, E. C., Buskens, CJ., van Munster, B. C., & Bemelman, W. A. (2019). Fit4SurgeryTV at-home prehabilitation for frail elderly planned for colorectal cancer surgery: a pilot study. American Journal of Physical Medicine and Rehabilitation, 98(5), 399-406. https://doi.org/10.1097/PHM.0000000000001108

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Fit4SurgeryTV at-home prehabilitation for frail elderly planned for colorectal cancer surgery: a pilot study

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Conflicts of interest and source of funding: None

Based on a previous communication to a society or meeting: Abstract presentation at the 2nd World Prehabilitation Congress in Eindhoven, The Netherlands, on June 29th 2018.

Abstract

Objective

The preoperative phase is a potential window of opportunity. Although frail elderly patients are known to be more prone to postoperative complications, they are often not considered capable of accomplishing a full prehabilitation program. The aim of this study was to assess the feasibility of Fit4SurgeryTV, an athome prehabilitation program specifically designed for frail elderly with colorectal cancer (CRC).

Design

The Fit4SurgeryTV program consisted of a daily elderly-adapted computer-supported strength training workout and two protein-rich meals. Frail patients \geq 70 years with CRC were included. The program was considered feasible if 80% of the patients would be able to complete 70% of the program.

Results

Fourteen patients (median age 79, 5 males) participated. At baseline, 86% patients were physically impaired and 64% were at risk for malnourishment. Median duration of the program was 26 days. The program was feasible as patients followed the exercises for 6/7 (86%) days and prepared the recipes 5/7 (71%) days per week. Patients specifically appreciated at-home exercises.

Conclusion

This study showed that at-home prehabilitation in frail elderly with CRC is feasible. As a result, patients might be fitter for surgery and might recover faster. The perioperative period could serve as a pivotal time point in reverting complications of immobility.

Keywords: prehabilitation, colorectal surgery, elderly, frailty

Introduction

Excellent results start with optimal preparation.¹ The ability to endure a surgical operation requires substantial physical and psychological resilience of the human body.² Older age is associated with age-dependent frailty which can substantially diminish the patient's perioperative resilience. As more than 50% of colorectal cancer patients are 70 years or older³, a large number of patients are at an increased risk for adverse outcomes and functional decline after the operation. In the past decades, great efforts have been made to improve outcomes in colorectal cancer patients scheduled for surgery. Regarding the perioperative and postoperative periods, the introduction of minimally invasive techniques and the implementation of fast track programs have increased the quality of care substantially.⁴

In the past years, the preoperative period has been increasingly recognized as a window of opportunity to further improve patient outcomes. Based on the identification of preoperative risk factors, prehabilitation programs that attempt to modify these risk factors have been developed.^{5,6} Decreased muscle mass (sarcopenia) has been shown to be an independent risk factor for postoperative complications such as anastomotic leakage, readmission and even mortality.⁷ This decreased physical state results from a combination of poor protein intake, physical inactivity and increased metabolic demands caused by the tumor.⁸ In order to increase muscle mass, strength training combined with enhanced protein intake has been shown to be effective also in frail older people.⁹

Previous studies have shown that current prehabilitation programs are often not applicable in the older patient leading to low compliance and disappointing results.¹⁰ It was the aim of this study to specifically target three challenges defined in literature. The first aim was to identify and target (pre-) frail patients as they might benefit the most from a prehabilitation program.^{7,11} The second aim was to adapt the program to the elderly patient as the content of the available prehabilitation programs is often not tailored for the older patient leading to low compliance.¹⁰ The third aim was to integrate the prehabilitation

program into the patient's daily life to further increase participation rates.¹² Based on these targets, an home-based digital Fit4SurgeryTV program was developed. The purpose of this pilot study was to assess the feasibility of the program for frail elderly undergoing surgery for colorectal cancer.

Methods

Study Design

The introduction of a prehabilitation program is a physical intervention aiming to introduce new habits of daily exercise and a protein-enhanced diet as has also been defined by Silver et al. as a process on the continuum of care between cancer diagnosis and acute treatment, providing targeted interventions that improve a patient's health to reduce future impairments.¹³ During the research phase, literature reviews were performed, patients were interviewed and experts were consulted about the introduction of new habits into the lives of older patients and how to motivate them.¹² The patient interviews consisted of five single interviews with frail elderly patients that had been operated for gastro-intestinal cancer about their exercise and eating habits. The most important adaptations compared to previous 'one-size-fits-all' prehabilitation programs were: 1) the possibility to execute the program at home (since transport is a major obstacle for frail elderly patients); 2) a feasible and safe exercise program requiring little time and no additional exercise material (since fall prevention is essential in this group and financial resources are limited); 3) an digital device that activates the user rather than waits for the user to switch it on (frail elderly patients often experience a threshold to initiate new things, especially concerning digital devices); 4) a social reward (since elderly patients tend to focus more on the positive events in the future as a motivation rather than the fear for complications during a surgical procedure). Based on the findings, a pilot study of elderly-adapted prehabilitation program combining physical training with a nutritional intervention was designed. Minimal duration of the program was 18 days, maximum duration was 32 days. This time framed was based upon previously described prehabilitation programs and the logistical planning capacity of the participating hospitals. Study approval was granted by the Medical

Ethics Committee of the Academic Medical Center, Amsterdam, the Netherlands, in June 2016. The study was performed in compliance with the Declaration of Helsinki and all patients gave written informed consent. This study conforms to all STROBE guidelines and reports the required information accordingly (see Supplementary Checklist, Supplemental Digital Content 1, http://links.lww.com/PHM/A713).

Physical Training

The goal of the physical training component was to create a daily strength-training program that is feasible for the frail elderly patients. An adapted form of the seven-minute-workout focusing on the movements needed to mobilize after the operation was created together with physiotherapists specialized in elderly care. The workout used bodyweight only and did not require any additional material. A description of the workout is shown in Table 1.

Nutritional Aid

The European Society of Parenteral and Enteral Nutrition (ESPEN) recommends a daily protein intake of 1.5–1.8g/kg/day for cancer patients. Five hospitalized elderly patients at the department of gastrointestinal surgery were interviewed about their daily diet and how to introduce new sources of protein-rich nutrition without disturbing the current diet drastically (Interviews in Appendix 1, Supplemental Digital Content 2, http://links.lww.com/PHM/A714). Together with dietary specialists, a 7-day menu consisting of two small meals per day (breakfast and snack, 20-30g protein in each) was developed. In order to prepare the meals, the ingredients were delivered at home prior to start of the program. An example of the daily menu is provided in Table 1.

Reward

Earlier research on the motivation of elderly has shown that positive prospects (e.g. attending the wedding of their children, maintaining residence) create a superior motivational trigger compared to the fear of

postoperative complications.^{12,14} Therefore, a system for collecting rewards was incorporated into the program. On a daily basis, digital awards could be collected according to whether the exercises and recipes had been completed. An additional screen showed day by day progress visualized by golden medals. At the end of the program and after the operation, the awards could be exchanged for a reward consisting of four day passes to the nearby zoo. In this pilot setting, all patients received the same award regardless of the amount of medals but this might be further developed in the future.

Fit4SurgeryTV

The introduction of a new habit requires abandoning existing routines. Psychological research concerning the motivation of elderly has shown that patients generally have strong adversity towards the introduction of new things, especially in emotionally stressful periods such as the preoperative period.^{12,14} At the same time, logistical challenges can pose an additional obstacle which can result in low compliance even if the patient would otherwise be motivated to participate. Furthermore, compliance to an at-home program without an activation trigger is low.^{10,15} Keeping these challenges in mind, an digital activating companion was developed (Fit4SurgeryTV, Figure 1). On a daily basis, the Fit4SurgeryTV created an activation trigger by alerting the patient to the exercises and the recipes. The patients had some degree of freedom when performing the exercises: at the beginning of the program, they could express their preference for when they would like to be alerted to the daily exercises. In addition, they could postpone or cancel individual exercises or recipes during the program. At the scheduled time, the device would make a sound like an old cuckoo clock followed by a voice indicating what type of activity would follow (exercise, breakfast or snack). The device was a prototype developed solely for the purposes of this study and is not commercially available. Upon onset of the program, the researcher would visit the home of a patient to perform baseline measurements and to deliver the device and the researcher would assess final measurements. The day prior to operation, patients would attend the hospital and return the device. In case of any technical problems or adverse events, the researcher could be reached by telephone.

Patients

From February 2017 until February 2018, all frail elderly patients (\geq 70 years) scheduled for elective colorectal cancer surgery in Gelre Hospitals, Apeldoorn (February 2017–February 2018), OLVG Hospital, Amsterdam (October 2017–February 2018) or Meander Hospital, Amersfoort (November 2017–February 2018)were eligible for inclusion. Frailty was defined according to the current Dutch guidelines stating either a VeiligheidsManagementSysteem (SafetyManagementSystem, VMS)–score \geq 1 or an Identification of Seniors at Risk–Hospitalized Patients (ISAR–HP) score \geq 2.^{16,17} Exclusion criteria were severe cognitive (e.g. dementia) or physical (e.g. bedridden) inability to join the program or being scheduled for surgery within two weeks of starting the program.

Baseline characteristics and measurements

Baseline demographics including the patient's age, height, weight, comorbidities, alcohol use and cigarette smoking, marital status and place of residence were recorded. Electronic patient files were consulted for preoperative hemoglobin levels, tumor stage, type of operation performed and postoperative outcomes including complications (graded according to severity with the Clavien-Dindo classification), mortality, length of hospital stay and readmissions.

At the start of the program, measurements and questionnaires on physical functioning, frailty, nutritional state, cognitive functioning and quality of life were performed.

Frailty and physical state were assessed with:

- Fried criteria¹⁸ (5 points, \geq 3 was considered frail)
 - Low hand grip strength (dominant hand) (HGS) (gender- and body mass index (BMI)specific cut-off points were used to determine low HGS)
 - Slow 4-meter gait speed (GS) (>6 seconds was considered slow)

- Low level of physical activity (sitting for more than four hours per day, less than one walk per month, and no biking or jogging)
- Self-reported exhaustion
- Weight loss (more than 4,5kg weight loss in the past year)
- Clinical Frailty Scale¹⁹ (9 points, ≤ 5 was defined as frail)
- Short Physical Performance Battery (SPPB)²⁰ (12 points, ≥ 5 was defined as physically impaired)
- KATZ- Independence of Activities of Daily Living (KATZ-ADL-6 questionnaire)²¹ (6 points, ≥2 was defined as ADL-dependent)

Nutritional state was assessed with:

- Mini Nutritional Assessment $(MNA)^{22}$ (14 points, <12 was indicative of malnourishment)

Cognitive functioning was assessed with:

- Mini Mental State Exam (MMSE)²³ (30 points, ≤24 was considered cognitive impairment)
- Geriatric Depression Scale (GDS-2/15)²⁴ (15 points, >2 was considered an increased risk for depression)

Quality of life was assessed with:

 European Organisation for Research and Treatment of Cancer Quality of Lfe Questionnaire (EORTC QLQ C29/30)²⁵

One day prior to operation, physical state (Fried criteria, Clinical Frailty Scale, HGS, GS, SPPB), and quality of life were assessed again.

Compliance & evaluation

One week after initiation of the program, the patient was contacted by phone to investigate any issues or questions relating to the program. Compliance to the program was assessed during this phone call and at the end of the program by asking the patients on how many days during the previous week they completed the exercises and followed the recipes. At the end of the program, an evaluation questionnaire was performed to assess the user experience concerning the exercise program, the diet and the digital device.

Outcomes

Previous research of adherence to at-home lifestyle interventions in other patients groups have shown a wide range of compliance rates (16-67%) and have defined success if an average of 70% adherence is obtained.^{26,27} This pilot study aimed to assess feasibility, defined as 80% of all patients completing at least 70% of the program. Compliance to the exercise program and the diet were assessed separately. Adverse events during the prehabilitation program were registered during the program. The patient was contacted after one week and at the end of the program.

Statistical methods

Normally distributed continuous data were presented with mean and standard deviation (SD), and skewed data were presented with median and interquartile range (IQR). The differences between baseline and end measurements were calculated and presented as percentage change. SPSS version 24.0 for Windows (IBM Corp. Armonk, NY) was used to perform all statistical analyses mentioned above.

Results

Patient inclusion

In total, 104 patients \geq 70 years underwent a resection for colorectal cancer at Gelre Hospitals, Meander Medical Center and OLVG Hospital during the inclusion periods. Of these, 24 patients were considered to be frail according to the inclusion criteria. Ten patients could not be included: six preferred to be scheduled for operation as soon as possible, two patients were already scheduled for operation within 14 days two patient refused participation for personal reasons. Fourteen patients participated in this pilot study. The flow chart of patient inclusion is presented in Figure 2.

Baseline characteristics

The median age of the patients was 79 years (IQR 74–86) and five (36%) were male. The patients had a median BMI of 25 kg/m² (IQR 21–28). Regarding comorbidities, ten patients (71%) suffered from cardiac diseases, one (7%) had a pulmonary disease and five (36%) were diagnosed with diabetes. Twelve (86%) patients used five or more medications. The median American Society of Anesthesiologists (ASA)– classification was 3 (IQR 2-3). The majority of the patients had stage I (n=6, 43%) or stage II (n=6, 43%) colorectal cancer. Their median preoperative hemoglobin level was 7.1 mmol/l (IQR 6.2–8.1). Four (29%) patients lived alone and none of the patients were institutionalized. Regarding frailty assessment, the patients had a median Fried score of 3 (IQR 2–3) and a median Clinical Frailty Score of 4 (IQR 3–5). A median HGS of 19kg (IQR 16–26) and a median 4–meter GS of 6.5 seconds (IQR 4.7–8.0) were recorded. Nine (64%) patients were at risk for malnourishment. Considering physical impairment measured with the KATZ-ADL-6 questionnaire, 12 (86%) patients were ADL-dependent. One (7%) patient was cognitively impaired and three (21%) patients were at risk for depression. The patients scored a median of 58% (IQR 48–69) for overall quality of life. All baseline characteristics are summarized in Table 2.

Peri- and postoperative characteristics

All patients were initially operated laparoscopically, and one (7%) patient had a conversion to open surgery due to extensive adhesions. Hemicolectomy was performed in eight (57%) patients, low anterior resection in five (36%) patients and one (7%) patient underwent transanal endoscopic microsurgery. Postoperatively, three (21%) patients had a minor complication (Clavien-Dindo grade I-II) and one (7%) patient had a major complication (Clavien-Dindo grade III-IV). The average length of hospital stay was seven days (IQR 4–8). Within 30 days, there was one (7%) readmission and no mortality.

Outcomes

Feasibility and compliancy

All patients finished the program with a median duration of 26 days (IQR 19–31). On average, patients performed the exercises 6 days (86%) per week. Thirteen patients did skip a training one to three times. If patients did not train, they were either tired (2, 15%), busy with other things (2, 15%) or forgot (3, 23%). Regarding the dietary component of the program, patients prepared the recipes 5 (71%) days per week. If recipes were not prepared, they were too difficult (1, 7%) or not tasty (4, 28%). All patients preferred an at-home program and nine (64%) patients had self-reported physical improvement. Twelve patients (86%) regarded the reward after the operation as an additional motivation. Regarding the Fit4SurgeryTV device, 12 (86%) patients evaluated the device as having a clear user interface. Two (14%) patients stated that it was difficult to use the touch screen and one patient (7%) experienced technical issues. Finally, the patients gave the program an overall grade of 8/10 (IQR 7–8). These results are summarized in Table 3.

Changes in functional performance and quality of life

Out of the five functional performance measurements performed at baseline and at the end of the program, only HGS declined (pre: median 19kg (IQR 16–25), post: median 18kg (IQR 18–24), difference: -1%) and Clinical Frailty Scale remained at the same level (pre: median 4 (IQR 3–5), post:

median 4 (IQR 3–4), difference 0%). Fried score (pre: median 3 (IQR 2–3), post: median 2 (IQR 1–4), difference: +20%), GS (pre: median 6.5 seconds (IQR 4.7–8.0), post: median 5.9 (IQR 4.6–7.6), difference +6%) and SPPB (pre: median 6 (IQR 5–10), post: median 9 (IQR 6–10), difference +25%) all increased. Overall quality of life also increased (pre: median 58% (IQR 48–69), post: median 75% (IQR 65-83), difference +17%). These results are summarized in Table 4.

Discussion

The results of this pilot study show that an at-home digital prehabilitation program for frail elderly undergoing surgery for colorectal cancer is feasible and has the potential to improve the patients' physical functioning and quality of life. Although the study was not powered to investigate the effects of the intervention on postoperative complications and recovery, the results suggest that it is possible to diminish the preoperative risk by reverting frailty. This study provides a base for further research in the development of prehabilitation programs, specifically for patients who are at an increased risk for adverse postoperative outcomes and delayed recovery.

In recent years, research into prehabilitation has received considerable attention which has resulted in a wide range of initiatives with mixed results.^{28,29} The current dogma states that interventions must be uniform so that their effects can be tested in the setting of a randomized controlled trial. However, this approach might not work when considering prehabilitation programs for the heterogeneous group of elderly patients with their varying needs and demands. For instance, some patients might benefit from strength training whereas others may only require a nutritional intervention. The need for personalized prehabilitation programs was emphasized by Wynter et al. in their statement: "Prehabilitation represents a shift away from the impairment driven, reactive model of care towards a proactive approach that enables patients to become active participants in their care".³⁰ Offering all patients a one-size-fits-all intervention fails to take individual preferences into account which can lead to

low compliance. Fortunately, the first steps towards tailor-made prehabilitation programs have already been taken. For example, Barberan et al. have published promising results of a personalized prehabilitation program that specifically targeted high-risk elderly patients undergoing major abdominal surgery showing both functional improvement and a significant decrease in postoperative complications.³¹

Performing prehabilitation research in elderly patients has additional barriers and obstacles including logistical challenges, technological inabilities and physical disabilities.¹⁵ The aim of this study was to focus on this group in particular and to involve them not only as patients but as a part of the team that developed the Fit4SurgeryTV. In order to obtain compliance with a digital prehabilitation device in this group, the introduction of a shared conversation at the beginning rather than a shared decision at the end was crucial. Therefore, the evaluation of the included patients of the program and the device can be considered as valuable as the numeric outcomes of their performance. A large number of patients stated that they would like to keep the device even after hospitalization. Prehabilitation offers the possibility to use a surgical intervention to pivot a frail lifestyle. By introduction of daily exercise, a Fit4SurgeryTV can be a promising method to ensure functional performance of elderly in the long term.

This study has some limitations. Clearly, a total of fourteen patients is a limited sample size. Its results serve primarily as a hypothesis forming stepping stone for a larger study. Since the study population consisted mainly of female patients, a more representative sample should also be studied in the future. Unfortunately, not all eligible patients were included creating the risk for selection bias. The fact that an operation may have to be delayed in order to complete a training program poses a mental challenge for many patients as a longer waiting period may be perceived to promote tumor growth and increase the risk of metastases. It demands an effort of surgeons to reframe the patient's expectations and to make prehabilitation an integral part of the treatment. Furthermore, although an at-home exercise program may be logistically and economically more suitable, the execution of the exercises in the program was unsupervised and may have been of lower quality compared to training in a supervised

setting. Additionally, despite the fact the workout and the recipes were developed together with patients, it was not possible to create a tailored program for each individual. Future research would benefit from the development of methodological frameworks for tailor-made lifestyle interventions. With the aid of technology such as Fit4SurgeryTV, it is possible to easily adapt the program according to the risk factors present and the patient's own preferences.

By the year of 2050, the world will be inhabited by over two billion people aged 60 years and older.³² This transition from "baby-" to "granny" -boom will create a tremendous challenge for our health care systems. Therefore, it is in the interest of all parties to target high-risk patients in order to revert their frailty to resilience, especially prior to a surgical and other clinical interventions. This study illustrates that at-home digital prehabilitation is feasible in frail elderly scheduled for colorectal cancer surgery. A suitable next step would be to evaluate the effects of Fit4Surgery prehabilitation in a randomized setting. In short term, prehabilitation could result in fewer complications and faster recovery. In the long run, the perioperative period could serve as a pivotal time point in reverting complications of immobility..

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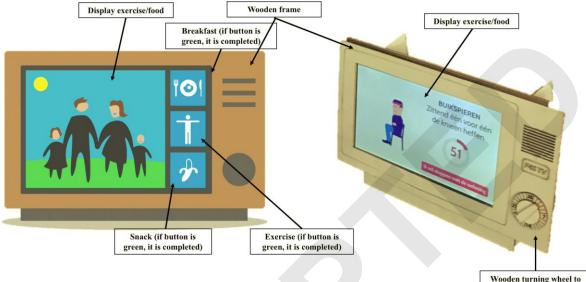
exercise, and muscle protein metabolism. *J Appl Physiol*. 2009;(106):2040-2048. doi:10.1152/japplphysiol.91551.2008.

Figure Legends

Figure 1. Fit4SurgeryTV digital device

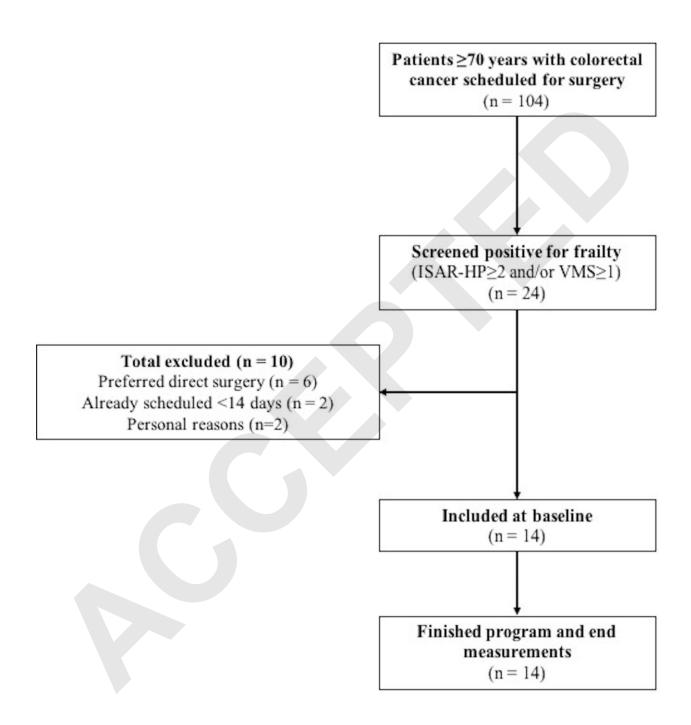
Figure 2. Flow chart of patient inclusion in the pilot study





Wooden turning wheel to track progress in days

Figure 2



22

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Table 1: Contents of the prehabilitation program

Physical Exercises (Senior 7-minute Workout)

Warming up:

- walking/dancing (1 minute)

Leg exercises:

- squats (40 seconds + 20 second break)
- lunges (40 seconds + 20 second break)

Arm exercises:

- moving arms in circles (40 seconds + 20 second break)
- arm lifting (40 seconds + 20 second break)

Core exercises:

- adapted plank (40 seconds + 20 second break)
- crunch (40 seconds + 20 second break)

Protein-rich meals (20-30g protein per meal)

Example breakfast:

- 200g low fat cottage cheese
- handful of blueberries
- 20g almonds

Example snack after workout:

- spelt bagel
- 2 slices of goat cheese
- 10g walnuts (optionally with honey)

Table 2. Baseline characteristics

	<i>n</i> =14	
Age (years), median (IQR)	79	74–86
Male, <i>n</i> (%)	5	36
BMI (kg/m ²), <i>median (IQR)</i>	25	21–28
ASA-classification, <i>n</i> (%)	3	2–3
Comorbidities		
Cardiac, n (%)	10	71
Pulmonary, <i>n</i> (%)	1	7
Diabetes, n (%)	5	36
Polypharmacy (\geq 5), <i>n</i> (%)	12	86
Intoxications		
Alcohol (>2 glasses/day), <i>n</i> (%)	2	14
Smoking (>10sig/day), <i>n</i> (%)	1	7
Cancer stage (AJCC)		
I, <i>n</i> (%)	6	43
II, <i>n</i> (%)	6	43
III, <i>n</i> (%)	2	14
Hemoglobin at diagnosis (mmol/l), median (IQR)	7.1	6.2-8.1
Living alone, <i>n</i> (%)	4	29
Institutionalized, n (%)	0	0
ADL-dependent (KATZ-ADL \geq 2), <i>n</i> (%)	12	86
KATZ-ADL, median (IQR)	6.5	3.7-8.0
Cognitive impairment (MMSE<24), n (%)	1	7
MMSE, median (IQR)	28	27-29
Depression (GDS>2), n (%)	3	21
At risk for malnutrition (MNA<12), n (%)	9	64
MNA, median (IQR)	11	10-12
Fried score (/5, \geq 3 is frail), <i>median</i> (<i>IQR</i>)	3	2-3
(z)		

Hand grip strength (kg), median (IQR)	19	16–25
4-meter gait speed (sec, >6s is slow), median (IQR)	6.5	4.7-8.0
Short Physical Performance Battery (/12, ≤ 5 is frail), median	6	5–10
(IQR)		
Quality of life (EORTC), median (IQR)	58	48–69

Notes: BMI= Body Mass Index, ASA= American Society of Anaesthesiologists, AJCC = American Joint Committee on Cancer, MMSE = Mini Mental State Exam, GDS = Geriatric Depression Score, MNA = Mini Nutritional Assessment, EORTC = European Organisation of Research and Treatment of Cancer

	n=14	
Overall		
Duration program (days), median (IQR)	26	19–31
Overall judgement of total program (1=worst,	8	7–8
10=best), median (IQR)		
Experienced progress, n (%)	9	64
Preferred at-home program, <i>n</i> (%)	14	100
Having a reward afterward was a strong motivation, n	12	86
(%)		
Physical training		
Number of days exercise completed (average per	6	86
week), <i>n</i> (%)	13	93
Total number of patients that skipped a training (1-3		
times)	2	15
Reasons for not completing	2	15
too tired, n (%)	3	23
busy with other things, n (%)		
forgot, <i>n</i> (%)		
Recipe preparation		
Number of days recipes prepared (average per week),	5	71
n (%)	14	100
Total number of patients that skipped a training (1-3		
times)	1	7
Reasons for not preparing	4	28
too difficult, <i>n</i> (%)		
not tasty, n (%)		
Fit4SurgeryTV		
Clear user interface, n (%)	12	86
Difficult to use touch screen, n (%)	2	14
Experienced technical issues, n (%)	1	7

Table 3. Compliancy registration and evaluation

Other comments

"I would like to keep device after operation to continue the daily exercises."

"I do not consider occasional sadness as bad quality of life."

"Hummus is not something our generation is willing to eat."

Table 4.	Functional	and	quality	of life	measurements
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	Before	After	Difference
	prehabilitation	prehabilitation	
	median (IQR)	median (IQR)	
Fried score (/5, \geq 3 is frail)	3 (2–3)	2 (1-4)	+20%
Clinical Frailty Scale (/9, ≥ 5 is frail)	4 (3–5)	4 (3–4)	0%
Hand grip strength (kg)	19 (16–25)	18 (18–24)	-1%
4-meter gait speed (sec, >6 is slow)	6.5 (4.7-8.0)	5.9 (4.6–7.6)	+6%
Short Physical Performance Battery (/12, ≥ 5 is	6 (5–10)	9 (6–10)	+25%
impaired)			
Overall quality of life (EORTC)	58 (48–69)	75 (65–83)	+17%

EORTC = European Organisation of Research and Treatment of Cancer