

Optimizing Physical Recovery After Oncological Surgery

A blended physical activity and nutrition intervention

Marijke E. de Leeuwerk

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VRIJE UNIVERSITEIT

Optimizing physical recovery after oncological surgery

A blended physical activity and nutrition intervention

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Chapter 1

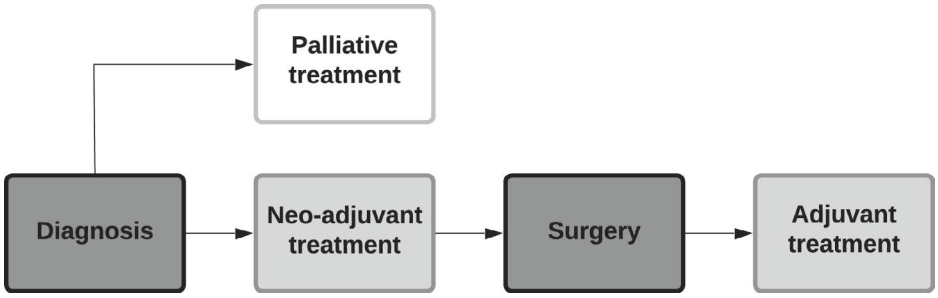
General introduction

Impact of cancer treatment

Cancer remains one of the most challenging health problems worldwide, with its treatment profoundly affecting patients' lives. In the Netherlands, gastrointestinal and lung cancer are among the most frequently diagnosed types [1]. In 2023, more than 22.000 patients were diagnosed with gastrointestinal cancers – including esophageal, gastric, colorectal, and hepato-pancreato-biliary cancers – while approximately 13.800 patients were diagnosed with lung cancer. Currently, the average one- and five-year survival rates for gastrointestinal cancers are 68% and 50%, respectively. Within this group, pancreatic cancer has the poorest prognosis, with survival rates of 23% and 4%, while rectal cancer has the highest, at 89% and 72% [2]. Fortunately, survival rates continue to improve due to ongoing advancements in oncological care [3-6]. Innovative therapies – including targeted therapies, immunotherapy and improved surgical techniques – have led to significant improvements in patient outcomes and overall prognosis.

In Figure 1, a schematic overview of the care pathway following diagnosis of gastrointestinal or lung cancer is presented. Following diagnosis, the medical team determines whether a patient is eligible for a curative treatment approach. If curative treatment is not feasible, a palliative treatment plan is initiated. In case of curative treatment, the treatment pathway may include neo-adjuvant therapy – such as chemotherapy and/or radiotherapy – prior to surgery, depending on the specific cancer type and protocol. For example, neoadjuvant treatment is standard in the clinical pathway for esophageal cancer, whereas the majority of patients with lung cancer proceed directly to surgery without prior systemic treatment. After completion of neoadjuvant therapy and an initial recovery period, patients are re-evaluated to determine eligibility for surgery. Following surgery, which is a key component of the treatment, patients enter another recovery phase. When indicated and approved by patients, adjuvant therapy is administered, typically involving chemotherapy or immunotherapy.

Figure 1: *Schematic overview of the care pathway following diagnosis of gastrointestinal or lung cancer.*



This thesis focuses on postoperative recovery within the curative care pathway for patients undergoing surgery for gastrointestinal or lung cancer. As part of this pathway, major oncological surgery is frequently associated with substantial physical decline, including loss of muscle mass, reduced strength, and impaired functional capacity [7-13]. In addition to these physical effects, patients often suffer from persistent symptoms such as fatigue and pain, as well as psychological distress, including fear of cancer recurrence and depressive symptoms [14-16]. Consequently, many patients experience delayed or incomplete functional recovery following major oncological surgery. Previous studies have shown that in more than half of the patients physical functioning is still diminished at three and six months postoperatively [17, 18]. In a study on recovery after lung cancer surgery, 76% of patients did not recover to pre-operative physical functioning at three months [14]. Furthermore, several studies have reported a long-term decline in health-related quality of life following oncological surgery [19-21].

Importance of physical functioning

Physical functioning is a critical determinant of overall quality of life. It refers to an individual's capacity to perform basic and instrumental activities in daily living (ADL) [22], including fundamental tasks such as self-care and home management, as well as instrumental activities, like grocery shopping. Physical functioning is influenced by two interrelated dimensions: physical capacity, defined as the individual's potential or what they are capable of doing, and physical performance, which reflects what the individual actually does in their daily environment [23]. Physical functioning represents a multidimensional construct within the framework of the International Classification of Functioning, Disability and Health (ICF), including body functions, activities and participation. Maintaining adequate physical functioning is essential not only for independence in daily life but also for participation in social, work-related, and recreational activities. When individuals are unable to meet the physical demands of these tasks, their quality of life is significantly reduced. Therefore, supportive care to minimize the loss in physical functioning during cancer treatment and supporting recovery afterwards are essential to preserving and enhancing patients' overall well-being.

Supportive care is defined as "*The prevention and management of the adverse effects of cancer and its treatment. This includes management of physical and psychological symptoms and side effects across the continuum of the cancer journey from diagnosis through treatment to post-treatment care. Supportive care aims to improve the quality of rehabilitation, secondary cancer prevention, survivorship, and end-of-life care*" [24]. Supportive care encompasses the whole cancer journey and therefore necessitates involvement of a multidisciplinary team, including allied healthcare professionals, such

as physiotherapists and dieticians. It is widely regarded as an "indispensable component" of modern oncology, due to its association with improved quality of life and significant health economic benefits [24].

The role of physical activity and protein intake in preventing muscle mass loss

Surgery-related muscle loss – skeletal muscle loss caused by increased catabolism due to surgical stress – is present in more than 50% of the patients after oncological surgery [25]. Skeletal muscles have both a functional and metabolic role [26]. Functionally, they support strength, balance, posture and movement. Metabolically, they serve as a source of amino acids for protein turnover, immune function, stress response, glucose regulation, and wound healing. Consequently, loss of muscle mass reduces the capacity to perform daily activities, thereby diminishing physical functioning [27]. Protein is the building block for muscles and has a high turn-over. In healthy balance, protein syntheses and breakdown are equal. When protein breakdown exceeds protein synthesis, anabolic resistance occurs, leading to muscle mass loss. Anabolic resistance is characterized by reduced capacity for protein synthesis due to factors such as inadequate nutritional intake, inactivity, illness and aging [28]. Insufficient protein intake leads to low amino acid concentrations in the bloodstream, weakening the anabolic stimulus – the biological signal that triggers muscle protein synthesis and supports muscle growth. In case of inactivity, the anabolic stimulus normally provided by activity is absent or significantly reduced. During illness, disruptions in the building process of muscles hinders muscle mass growth. Furthermore, aging increases the threshold of anabolic stimulation required to maintain muscle mass, necessitating a stronger stimulus to achieve comparable protein synthesis levels seen in younger individuals.

To minimize functional decline and enhancing recovery in physical functioning, preserving muscle mass is important [29, 30]. To prevent muscle mass loss, two key anabolic stimuli are essential: physical activity and nutrition [27]. Physical activity enhances muscle protein synthesis while reducing protein breakdown, thereby promoting a positive muscle protein balance. When combined with optimal protein intake, these effects on muscle protein synthesis are further amplified [31, 32]. Therefore, to limit muscle mass loss and associated decline in physical functioning, it is crucial for patients to increase their physical activity levels and meet protein intake requirements following oncological surgery. Beyond mitigating muscle loss, physical activity and adequate nutrition provide additional benefits, including the optimization of overall health outcomes, reduction of risk of cancer recurrence, and improvement in treatment efficacy and tolerance [33-37].

However, physical activity levels are low in patients after oncological surgery [17, 38]. This is often due to the impact of major oncological surgery causing physical symptoms, such as pain or fatigue, as well as problems related to motivation, social support and mental health (e.g. anxiety or depression). Also, patients often struggle to meet their protein intake requirements after surgery, despite the advice of a dietician [39]. In certain care pathways, such as following esophageal resection, patients may require tube feeding because oral intake is temporarily contraindicated due to surgical procedures. This supports patients in achieving their nutritional goals. However, eating difficulties frequently persist as one of the most significant long-term complaints in these patients [40]. In the current curative care pathways for patients undergoing oncological surgery, physiotherapy is not standard care after hospital discharge. While the physiotherapist may advise patients to continue physiotherapy in primary care, this is often not, or only partially, reimbursed by the health insurers. Dietitian care differs between patient groups. In Amsterdam UMC, the dietitian standard schedules postoperative consultations with patients who have undergone esophagus-, stomach-, pancreas-, biliair surgery at 2 and 4 weeks and 3 and 6 months after discharge. Post-discharge dietary care is not standard for patients after surgery for liver, colorectal or lung cancer.

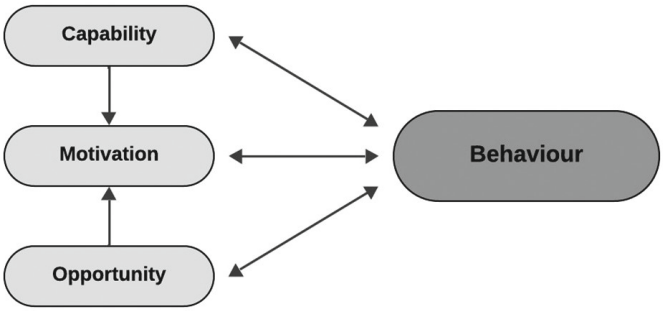
Patients emphasize the need for supportive care interventions after hospital discharge to improve physical activity levels and protein intake, thereby facilitating a return to normal activities after cancer surgery [41, 42]. However, the key question remains how to effectively support this vulnerable patient group in rebuilding their physical activity and protein intake once they have returned home after hospital discharge.

Factors influencing behavior after oncological surgery

Undergoing surgery is a significant life event for patients, which can be used as a "teachable moment": a time frame following a health event in which a patient is most conductive to behavioural change [43]. To identify barriers and facilitators for patients to increase their physical activity level and protein intake after hospital discharge, the Capability Opportunity and Motivation Behavior model (COM-B model) can be used (Figure 2). The COM-B model is a widely used framework for behavioural change, which identifies three key components necessary to influence behaviour: capability, motivation and opportunity. Capability refers to an individual's psychological and physical ability to perform a specific behaviour, which includes having the necessary knowledge and skills. Motivation encompasses as all mental processes that energize and direct behaviour, such as habitual responses, analytical decision making and emotional reactions. Opportunity refers to external factors that enable or prompt a specific behaviour. This model is often used for designing interventions aimed at promoting behaviour change. When designing

such interventions, it is important to clearly define the target behaviour and identify which components of the COM-B model need to be changed to achieve the desired outcome. By using the behaviour change wheel, a framework for designing behaviour change interventions, specific behavioural change techniques (BCT's) can be incorporated in the intervention [44]. Behavioural interventions that provide methods or materials to support behavioural change are most effective in improving physical activity and nutrition in cancer survivors [45, 46].

Figure 2: *The COM-B model*



Self-monitoring

Self-monitoring and feedback on behavior have been shown to be effective BCT's in improving physical activity and nutritional behavior [47, 48]. This can be facilitated through the use of activity trackers and mobile health applications, which allows individuals to monitor and manage health-related behaviors such as diet and physical activity. Activity trackers make it possible to track active minutes or steps throughout the day and can provide real-time feedback. By using self-monitoring, individuals can set targeted goals and receive personalized feedback on their behavior. It is hypothesized that by gaining insight into their own behavior and receiving feedback, individuals feel more in control of their health. This can empower them to take an active role in improving their behavior. Interventions using activity trackers are proven to be effective in enhancing physical activity in healthy adults [49, 50].

Blended rehabilitation interventions

While self-monitoring alone can already support behavior change, combining it with guidance from healthcare professionals might further enhance its effectiveness, especially in the context of complex care pathways, such as those following major oncological surgery [51]. In these cases, personalized support and advise is often essential to help patients navigate through their recovery. However, healthcare professionals face challenges in

delivering consistent support due to constraints in time, work structure, finances, and staffing. This highlights the need for scalable solutions that blend self-monitoring with tailored, yet low-threshold, professional support, i.e. blended interventions. Blended interventions enable more personalized care and provide data-driven feedback, which may ultimately lead to improved patient outcomes [52]. Blended interventions, combining self-monitoring with coaching by healthcare professionals, might be a promising solution to support recovery for patients after oncological surgery, by empowering patients and providing accessible support and continuity of care in patients' own environments.

Aim and outline of the thesis

The primary aim of this thesis is to develop and evaluate a blended intervention designed to enhance recovery in physical functioning following hospital discharge in patients who have undergone gastrointestinal or lung cancer surgery. Additionally, this thesis explores the potential for long-term implementation of the intervention within existing care pathways.

Chapter 2 evaluates if self-monitoring of physical activity using an activity tracker and smartphone app after hospital discharge is feasible in patients after gastrointestinal or lung cancer surgery. **Chapter 3** contains a systematic review and meta-analysis, evaluating the effectiveness of physical activity interventions using activity trackers during or after inpatient care.

Based on the results of chapter 2 and 3, the Optimal Physical Recovery After Hospitalization (OPRAH) intervention is developed. The OPRAH intervention combines self-monitoring of physical activity and protein intake, with remote coaching by a physiotherapist and dietitian after hospital discharge. **Chapter 4** evaluates the feasibility of the OPRAH intervention and the associated study procedures as a prelude to performing a randomized controlled trial. In **chapter 5** the protocol for the multicenter randomized controlled trial (RCT) to investigate the effectiveness of the OPRAH intervention compared to usual care is described and results of the multicenter RCT are presented in **chapter 6.**

For successful implementation in clinical practice, it is essential not only to assess the effectiveness of the intervention but also to understand how patients experience it. To address this, **chapter 7** presents qualitative data on patient's experiences with the OPRAH intervention. Furthermore, **chapter 8** evaluates the extent to which the OPRAH intervention is conducted as initially designed, by assessing the implementation fidelity. This evaluation also provides insight into the intervention's compatibility with the daily routines of healthcare professionals, as well as the opportunities and challenges associated with long-term implementation.

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Chapter 2

Self-monitoring of physical activity after hospital discharge in patients who have undergone gastrointestinal or lung cancer surgery: mixed methods feasibility study

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Abstract

Background: Self-monitoring of physical activity (PA) using an accelerometer is a promising intervention to stimulate PA after hospital discharge.

Objective: This study aimed to evaluate the feasibility of PA self-monitoring after discharge in patients who have undergone gastrointestinal or lung cancer surgery.

Methods: A mixed methods study was conducted in which 41 patients with cancer scheduled for lobectomy, esophageal resection, or hyperthermic intraperitoneal chemotherapy were included. Preoperatively, patients received an ankle-worn accelerometer and the corresponding mobile health app to familiarize themselves with its use. The use was continued for up to 6 weeks after surgery. Feasibility criteria related to the study procedures, the System Usability Scale, and user experiences were established. In addition, 6 patients were selected to participate in semistructured interviews.

Results: The percentage of patients willing to participate in the study (68/90, 76%) and the final participation rate (57/90, 63%) were considered good. The retention rate was acceptable (41/57, 72%), whereas the rate of missing accelerometer data was relatively high (31%). The mean System Usability Scale score was good (77.3). Interviewed patients mentioned that the accelerometer and app were easy to use, motivated them to be more physically active, and provided postdischarge support. The technical shortcomings and comfort of the ankle straps should be improved.

Conclusions: Self-monitoring of PA after discharge appears to be feasible based on good system usability and predominantly positive user experiences in patients with cancer after lobectomy, esophageal resection, or hyperthermic intraperitoneal chemotherapy. Solving technical problems and improving the comfort of the ankle strap may reduce the number of dropouts and missing data in clinical use and follow-up studies.

Introduction

Surgery is an essential curative treatment option for patients diagnosed with gastrointestinal or lung cancer; however, it has a major impact on daily functioning and quality of life [1-3]. Most patients experience incomplete or delayed recovery of physical functioning after major thoracic or abdominal surgery [2-4].

During hospitalization, stimulation of physical activity (PA) has been shown to enhance the recovery of physical functioning [2,4-6], reduce the postoperative risk of readmission, and shorten the length of hospital stay [7,8]. Therefore, PA promotion is integrated into Enhanced Recovery After Surgery (ERAS) programs [9]. The aim of ERAS programs is to reduce postoperative complications and improve postoperative recovery. However, ERAS programs are mainly limited to the period of hospitalization, whereas encouraging PA after hospital discharge is also important for improving functional recovery [10,11].

In their own environments, increasing PA levels and resuming daily activities can be challenging for patients. They may experience barriers such as physical symptoms, insecurity, lack of motivation, or social support in doing so [12]. The use of body-worn accelerometers can support patients in resuming their daily activities after cancer surgery [10,13]. Such devices enable self-monitoring of and feedback on PAs by quantifying the frequency and intensity of human movement [14].

Adequate use of accelerometers for PA self-monitoring is an important prerequisite for its potential positive effect on functional recovery. Several studies have shown the feasibility of PA self-monitoring in patients who have undergone major (oncological) surgery, each using a different device [15,16]. Qualitative data on experiences with PA self-monitoring in these patients are largely unknown [17], and these experiences may add to the knowledge about potential barriers to the use of this technology and may help resolve them [18].

Therefore, this study aimed to collect both quantitative and qualitative data to investigate the feasibility of self-monitoring of PA using accelerometers after hospital discharge in patients with cancer who have undergone gastrointestinal or lung cancer surgery.

Methods

Ethics Approval

The study was approved by the medical research ethics committee of the Amsterdam University Medical Center, location Vrije Universiteit Medical Center (registration number 2018/112). All patients provided written informed consent.

Study Design

A feasibility study with a mixed methods design was performed between April 2019 and April 2020 in patients with gastrointestinal or lung cancer scheduled for surgery. The formal sample size was not calculated. Instead, a convenience sample with a 1-year inclusion period was chosen. Self-monitoring of PA after hospital discharge was evaluated using a questionnaire and interviews conducted in April 2020, and the study procedures were evaluated using administrative data during the course of the study.

Participants

The inclusion criteria were adult patients with gastrointestinal or lung cancer who were invited for preoperative physiotherapy screening between April 2019 and April 2020 at the outpatient clinic of our tertiary teaching hospital (Amsterdam University Medical Center, location Vrije Universiteit Medical Center), which included patients scheduled for a lobectomy, esophageal resection, or hyperthermic intraperitoneal chemotherapy (HIPEC). Exclusion criteria were <7 days between inclusion and surgery, emergency procedures, patients who are nonambulatory, and no access to or not able to use a smartphone or tablet.

Intervention

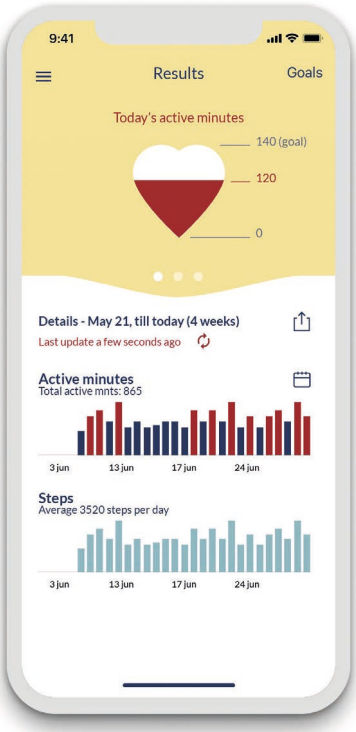
Potentially eligible patients were informed about the study by the treating physiotherapist during the preoperative consultation. Patients who were willing and eligible to participate received the Physical Activity Monitor (PAM) AM400 3-axis accelerometer (Pam BV Doorwerth) and were given access to the corresponding smartphone app called *Atris* (Peercode BV, Geldermalsen; Figures 1 and 2). The PAM was selected for this study as (1) the PAM AM400 was found to be a suitable movement sensor to validly measure activity minutes [19]; (2) the battery of the PAM lasts for approximately 1 year, eliminating the need for patients to recharge the device; (3) the data of the PAM can be synced directly to a web-based application, enabling remote monitoring by clinicians; and (4) the PAM can be worn around the ankle and is waterproof to allow 24/7 wearing. The PAM measures PA continuously and provides the total PA every 15 minutes. With the *Atris app*, patients were able to self-monitor their daily PA levels and received feedback on the number of

active minutes per day. Patients were able to set personal activity goals in the app by themselves.

Figure 1. *The Physical Activity Monitor.*



Figure 2. *Atris app.*



All patients received the usual pre- and postoperative physiotherapy care. During the standard preoperative consultation, potential risk factors (eg, smoking or sedentary lifestyle) for delayed postoperative recovery were identified, leading to personalized advice for improving preoperative physical fitness. In addition, the patients were given instructions about the PAM and *Atris* app. The physiotherapist informed the patient that the app provided insights into the recovery of PA and advised them to use the app to resume their daily activities after surgery. Patients were asked to start wearing the PAM 24 hours a day in a strap around the ankle for at least 7 days before surgery to familiarize themselves with its use.

During hospitalization, patients received standard physiotherapy consultations and were stimulated to mobilize according to a daily mobilization goal following the ERAS protocol [20]. In addition, the physiotherapist guided the patients in using the PAM and *Atris* app.

Personalized rehabilitation recommendations were provided at discharge. If indicated by the physiotherapist, the patients were advised to continue physiotherapy in primary care after discharge. For this study, the patients were asked to wear the PAM 24 hours a day for 6 weeks. A period of 6 weeks was chosen as it was expected that patients would be able to gain sufficient experience using the PAM and *Atris* app to assess feasibility. A hospital physiotherapist provided insights into the activity levels of the patient on the corresponding web application and monitored the activity data of the patients weekly. In case the activity levels decreased or no data were available, the physiotherapist contacted the patient. In the case of technical problems, the physiotherapist helped resolve them if possible. In cases where patients had problems resuming their PA level by themselves, the physiotherapist advised them to contact a physiotherapist in primary care. The patients also had the opportunity to contact the physiotherapist themselves.

Outcome Measures

Study Procedures

Patients who were willing to participate (out of potentially eligible patients invited to the study), those who ultimately participated, and those who completed the study were recorded and described as percentages. Furthermore, the amount, type, and reasons for missing PAM data were identified. For exploration purposes, the PAM data were described as the number of active minutes per day (24 hours) from 1 week before surgery (baseline) to 6 weeks after surgery.

System Usability

System usability was assessed using the Dutch translation of the System Usability Scale (SUS). The SUS contains 10 statements about efficiency, learnability, and satisfaction and has been validated to assess the usability of electronic systems [21]. Patients can indicate the degree of agreement with each statement on a 5-point Likert scale. The total SUS score ranges from 0 to 100, with a score of ≥70 considered good. The patients received an email in April 2020 to complete the questionnaire on a secured web-based system (Castor Electronic Data Capture).

User Experiences

In addition to the SUS, the patients received 13 additional questions about the acceptability, satisfaction, and added value of the PAM and *Atris* app that was experienced (see Appendix 1 for the questionnaire). In addition, the user experiences of the patients were assessed using semi structured qualitative interviews (see Appendix 2 for the topic list). The responses to the SUS and additional questions were used as supplemental topics to the topic list. All patients were asked if they were willing to participate in the interviews.

There were 2 groups, patients who did and patients who did not experience additional value. Of both groups, 3 patients were randomly selected for the interview. Interviews were conducted by VvV and MEdL via telephone and recorded using a voice recorder. Interviews were transcribed verbatim.

Descriptive Data

Demographic and clinical data were collected retrospectively from electronic medical records.

Feasibility Criteria

To evaluate the feasibility of self-monitoring of PA using the PAM and *Atris* app, we set feasibility criteria a priori based on cutoff points described in previous studies (Textbox 1) [22-25].

To better understand the feasibility, additional qualitative data on acceptability, satisfaction, and experienced additional value were collected to explore user experiences.

Textbox 1. *Feasibility criteria based on cutoff points described in previous studies.*

Willingness to participate

- Percentage of invited, potentially eligible, patients who were willing to participate in the study; a percentage of >70% was considered feasible

Participation rate

- Percentage of willing and eligible patients who intended to participate in the study; a percentage of >60% was considered feasible

Retention rate

- Percentage of included patients who completed the study (ie, these patients did not explicitly indicate their decision to stop); a retention rate of 80% was considered feasible

Data collection

- Percentage of missing Physical Activity Monitor data was determined to investigate whether physical activity data collection using the Physical Activity Monitor was feasible; complete data in at least 70% of all participants were considered feasible

System usability

- Measured with the System Usability Scale; a score of ≥70 was considered good

Data Analysis

SPSS (version 26; IBM Corporation) was used for quantitative data analysis. Study population characteristics were presented descriptively as mean (SD), median (IQR), and percentage. Quantitative data were analyzed descriptively. The study procedures were presented as percentages. PAM data were considered missing if they were not available for ≥3 days in a given week. The available PAM data are presented as the median (IQR) of the total active minutes per day of each week and as a percentage of the preoperative PA baseline level. The mean (SD) SUS was calculated using the method described in the study by Brooke [21]. Additional questions about user experience are presented as percentages.

The research software ATLAS.ti (version 8) was used for qualitative analysis. Qualitative data analysis was performed following the steps of thematic analysis by 2 researchers (MvdL and MB) [26]. The interviews were read several times to familiarize with the data. Data were open coded line by line to segment them into the initial codes. Axial coding was used to define the definitive codes. Definitive codes were classified and described under different themes [26].

Results

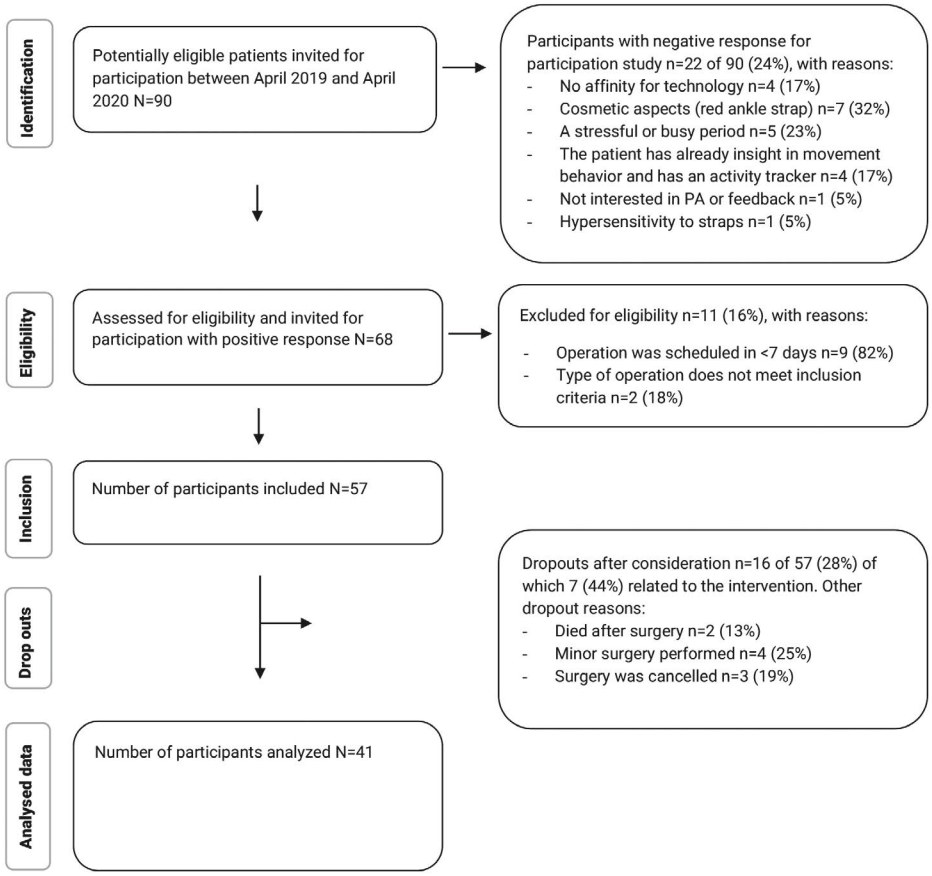
Overview

A total of 90 potentially eligible patients were invited to participate between April 2019 and April 2020, of whom 68 (76%) were willing to participate. After the final eligibility check, of the 90 patients, 57 (63%) were included in the study, resulting in a participation rate of 63%. The retention rate was 72% (41/57); 28% (16/57) of patients dropped out during the study, of whom 44% (7/16) were related to the intervention. The reasons for nonparticipation, exclusion, and dropout are presented in the flowchart (Figure 3). Ultimately, 41 patients were included in the analysis. The median age of the patients in this study was 68 (IQR 60-73) years, and 58% (25/41) were male. The most common types of surgery were lobectomy (23/41, 56%) and HIPEC (10/41, 24%). The median length of hospital stay was 7 (IQR 6-11) days. Other relevant demographic and clinical data are presented in Table 1.

Approximately, 31% of the PAM data were missing. Missing value analysis suggested that the data were missing at random, as missing data increased during the time blocks of the postoperative phase. The amount of missing data increased during the 6 postoperative weeks: 27% of the PAM data were missing in the first postoperative week and 44% in the sixth postoperative week. Figure 4 shows an overview of the reasons for the missing data. The most common reasons for missing data were technical problems or withdrawal of wearing the PAM. Table 2 shows the median preoperative and postoperative PA levels

in minutes per day and the median percentage of recovery in PA compared with the preoperative levels.

Figure 3. *Flow of participants through the study.*



PA: physical activity

Table 1. *Patient characteristics (N=41).*

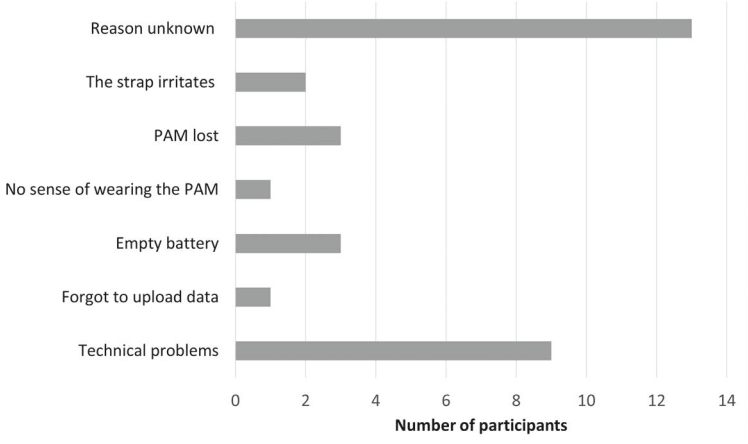
Variable	Results
Patient characteristics	
Sex (male), n (%)	25 (58)
Age (years), median (IQR)	68 (60-73)
BMI, mean (SD)	26.1 (4.2)
Smoke status, n (%)	
Current	5 (12)
Past	24 (59)
Never	12 (29)
Primary diagnosis, n (%)	
Rectum cancer	1 (2)
Lung cancer	21 (51)
Esophagus cancer	8 (20)
Peritonitis carcinomatosa	8 (20)
Schwannoma	2 (5)
Thymoma	1 (2)
Tumor stage, n (%)	
1	7 (17)
2	8 (20)
3	6 (15)
4	18 (44)
Schwannoma	2 (5)
Comorbidities (ASA[a] score), n (%)	
Grade I	3 (7)
Grade II	27 (66)
Grade III	10 (24)
Grade IV	1 (2)
Type of treatment before surgery, n (%)	
Neoadjuvant chemotherapy	3 (7)
Neoadjuvant chemoradiotherapy	9 (22)
Neoadjuvant immunotherapy	1 (2)
Neoadjuvant hormone therapy	1 (2)
Sports ≥1 time per week, n (%)	15 (37)
Missing	1 (2)
Perioperative characteristics	
Type of surgery, n (%)	
Lobectomy	23 (56)
Esophagus resection	7 (17)

Table 1. *Continued*

Variable	Results
Perioperative characteristics	
HIPEC[b] procedure	10 (24)
Schwannoma resection	1 (2)
Surgical approach, n (%)	
Video-assisted thoracic surgery	6 (15)
Open surgery	35 (85)
Type of treatment after surgery, n (%)	
Adjuvant chemoradiotherapy	2 (5)
Adjuvant chemotherapy	3 (7)
Adjuvant radiotherapy	1 (2)
Adjuvant hormonotherapy	1 (2)
Length of stay (days), median (IQR)	7 (6-11)
Complications (Clavien Dindo score), n (%)	
Grade I	26 (63)
Grade II	5 (12)
Grade IIIa	2 (5)
Grade IIIb	5 (12)
Grade IVa	3 (7)
Hospital readmission, n (%)	5 (12)
Duration of operation (minutes), median (IQR)	200 (128-336)

[a]ASA: American Society of Anesthesiologists.
[b]HIPEC: hyperthermic intraperitoneal chemotherapy.

Figure 4. *Reasons for missing data*



PAM: Physical Activity Monitor

Table 2. *Median PAa (minutes per week) and percentage of PA compared with preoperative levels of PA (N=41)b.*

PA level	Preoperative	1 week[c]	2 weeks	3 weeks	4 weeks	5 weeks	6 weeks
PA (minutes)							
Values, median (IQR)	172 (114-213)	51(26-82)	87(54-138.5)	96(68.5-171.5)	108(78.3-170.5)	118.5 (80-196.5)	139(81-184)
Values, n (%)	38 (93)	30 (73)	29 (71)	29 (71)	28 (68)	28 (68)	27 (66)
PA compared with preoperative level of PA (%)							
Values, median (IQR)	N/A[d]	29.4 (17.9-47.4)	55.7 (34.1-77.0)	65.0 (44.9-84.3)	67.2 (52.1-93.5)	78.0 (49.6-101.9)	80.3 (57.6-99.7)
Values, n (%)	N/A	29 (71)	27 (66)	26 (63)	25 (61)	25 (61)	25 (61)

[a]PA: physical activity. [b]PA at baseline (preoperative; time point 0) and 1 to 6 weeks postoperative (time point 1 to time point 6). [c]After surgery. [d]N/A: not applicable.

Feasibility

Overview

The results of the feasibility criteria are presented in Table 3.

Table 3. *Summary of results of feasibility criteria.*

Study procedures	Targets	Results	Conclusions
Willingness to participate	Percentage of willing patients >70%	76% of the invited patients were willing to participate	Feasible
Participation rate	Participation rate >60%	The participation rate was 63%	Feasible
Retention rate	A retention rate of >80%	The number of dropouts during the study was 16; this resulted in a retention rate of 72%	Marginally feasible
Data collection	Complete outcome data of PA[a] in at least 70% of all participants at follow-up	Approximately 31% of the PA data were missing; the number of complete cases was 9, and 8 cases had <10% missing data	Not feasible
System usability			
Efficiency	SUS[b] score ≥70	Mean 79.6 (SD 24.2)	Feasible
Learnability	SUS score ≥70	Mean 74.0 (SD 27.5)	Feasible
Satisfaction	SUS score ≥70	Mean 75.0 (SD 25.2)	Feasible
User experience			
Study patients	Qualitative data about acceptability, satisfaction, and experienced added value	Wearing the PAM[c] was acceptable, patients were largely positive about the PAM and Atris app, and most patients experienced an added value; technical problems and the comfort of the ankle strap need to be improved	Feasible

[a]PA: physical activity.
[b]SUS: System Usability Score.
[c]PAM: Physical Activity Monitor.

SUS and Additional Questions

Of the 41 patients, the SUS and additional questionnaires were sent to 39 (95%) patients (n=2, 5% of patients died before April 2020). The mean number of weeks between the end of the self-monitoring period and receiving the questionnaire was 21.6 (SD 17.0). Approximately 85% (33/39) of patients responded to the questionnaire, of whom 5% (2/39) did not complete the entire questionnaire. System usability was feasible, with a mean SUS score of 77.3 (SD 20.7). Of all responding patients, 75% would recommend other patients to use the PAM and *Atris* app after surgery. Most patients (84%) indicated that they wore the PAM all day during the study period. The reasons for not wearing the PAM

were poor comfort with the ankle strap or technical problems (eg, connection problems between the PAM and app). The other outcomes of the questionnaire are presented in Multimedia Appendix 3.

Interviews

Overview

Of the 39 patients, 8 (21%) patients did not respond to the interview invitation, and 4 (10%) were unwilling to participate in additional interviews. Of the remaining 27 patients who were willing to participate, 8 (30%) patients did not, and 19 (70%) patients found that the use of the PAM and *Atris* app added value. Approximately 15% (6/39) of patients were selected. The characteristics of the interviewed patients are shown in Table 4. The results are described by themes in the following paragraphs and supported by quotes (Table 5). The code tree is shown in Figure 5.

Table 4. *Characteristics of interviewed patients.*

Interviewee number	Gender	Age (years)	Type of surgery	ASA[a]	Length of hospital stay (days)	Missing data (%)	SUS[b] score
1	Male	69	HIPEC[c] (open)	1	11	69.4 (reason unknown)	70
2	Female	61	Lobectomy (VATS[d])	2	3	63.3 (PAM[e] lost)	90
3	Male	66	Lobectomy (VATS)	2	11	0	85
4	Male	77	Lobectomy (VATS)	2	4	34 (connection lost between PAM and smartphone)	97.5
5	Male	56	Lobectomy (open)	2	7	34.7 (no connection between PAM and smartphone)	67.5
6	Male	73	Lobectomy (open)	2	5	26.5 (low battery)	92.5

[a]ASA: American Society of Anesthesiologists; [b]SUS: System Usability Scale; [c]HIPEC: hyperthermic intraperitoneal chemotherapy; [d]VATS: video-assisted thoracic surgery; [e]PAM: Physical Activity Monitor.

Table 5. *Quotations of interviewed participants.*

Quotation	Code	Interviewed participant number
User adherence		
"By the way, that bracelet was awful. Especially the closure. You have to invest a bit more in that. I don't know much else to improve. It weights nothing. You even forget it once in a while." (quote 1)	Comfort of the ankle strap	2
"Every morning and during the day I had to put the bracelet back on again, because it would be loose for a while, but that wasn't that bad...I don't have any complaints about it, that bracelet is a simple but good solution for wearing the sensor." (quote 2)	Comfort of the ankle strap	6
"In the beginning I had some trouble with updating. The connection wasn't always good. I have a certain brand of phone and apparently it doesn't work as well as other phones. Later I did a new update and then it worked better. I also had some contact with the VUmc about this." (quote 3)	Technical problems	4
"It didn't work well at all times. Then I called for a new battery. Then it worked again." (quote 4)	Technical problems	5
"And again about the technical problems. That really frustrated me. I called with the VUmc for help. They could often improve it remotely and the new battery helped in the end." (quote 5)	Technical problems	5
"I found the use of the app very friendly. Very easy, absolutely not unnecessarily complicated." (quote 6)	Easy to use	2
"It was a new experience for me. But I had no problems at all with it. It all went well." (quote 7)	Easy to use	6
"I have not thought for a moment of not using it because of my privacy. Only my active minutes were registered and I did not see any reason not to use it." (quote 8)	No privacy concerns	6
Experienced added value		
"I thought it was a phenominal item...You keep track of your active minutes in the app during the day. I do not use cell phones very often, because I am 63 years old, but this was a very nice challenge." (quote 9)	Provided insights into recovery	2
"I found it a nice application, I watched it every day." (quote 10)	Provided insights into recovery	6
"It had really became part of my lifestyle. When I went to sleep I took it off and put it on the bedside table. Before I took a shower I put it o, so every active minute would count. I had the feeling that the health professionals from the Vumc did everything they could, so I wanted to do that myself. This device helped me a lot with that." (quote 11)	Provided support	5

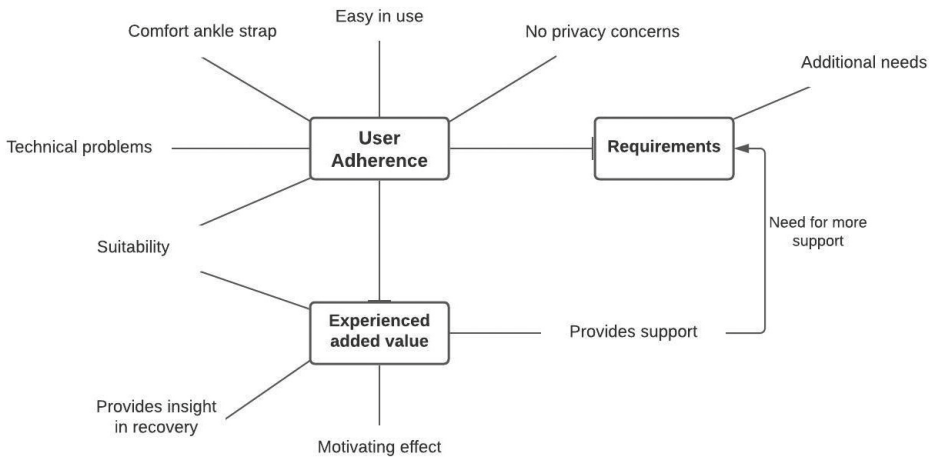
Table 5. *Continued*

Quotation	Code	Interviewed participant number
"Well if we look at the operation, especially my recovery, then it's very important to me that I have insight in and influence on my recovery. That you are able to see if you're making progress. When I just started I was 30 minutes active per day and at the end I was 4 to 5 hours active. It is very nice and important to have that insight." (quote 12)	Provided insights into recovery	3
"Well it worked really stimulating for me. Making movement goals gives direction in the rehabilitation proces. You can work towards that. It has really helped me and that's why I would recommend it to others." (quote 13)	Motivating effect	5
"You feel more co-responsible. Well then it's nice that you can show you are dowing well and that you try your best." (quote 14)	Motivating effect	3
"It's an addition to you health and life. It makes rehabilitation a little easier and more challenging. It focuses more on recovery than on your problems." (quote 15)	Provided support	2
"It's all very frightening and scary. What is going to happen? Will I wake up after the operation? Can I still do the same as I did? There is a lot going through you head and it's pretty scary, to be honest. At that moment, health profesionnals and such a motion sensor around you ankle helps enormously. You get feedback and it gives you something to hold on to." (quote 16)	Provided support	5
"I think it is a very good remedy. Only for myself it had not been necessary. For someone who has more difficulty with being active this is a completely different story. Then it can be a very nice support. If I speak for myself, it was just that I was curious about how much I walked that day." (quote 17)	Suitability	4
"I already moved a lot: I go to the gym twice a week and I also walk a lot and cycle a bit. Therefore, the PAM wasn't the reason I started being more active. But it was nice to see how active I was during the day." (quote 18)	Suitability	6
Requirements		
"I would like to get a signal if I don't show good or abnormal activity behavior. Starting a conversation. That's also possible by telephone. I don't necessarily have to come to the VUmc more often. But such a conversation would be very nice." (quote 19)	Need for more support	1
"A sort of alarm or stimulating message. I think that also helps in creating awareness. People need to become aware of their activity behavior. A message when things are not going that well can help with that. It triggers you to think about it." (quote 20)	Need for more support	2
"I would like to get some more information as well. So besides the activity data. For example, about the heartrate and blood pressure. But anyway, it might also be difficult to integrate that into one application." (quote 21)	Additional needs	4

Table 5. *Continued*

Quotation	Code	Interviewed participant number
"Activity data should be more clearly displayed. Now you have a graph, but the activity data is only presented per day. You actually want to be able to see data and differences during the day. For example my difference in activity between an evening shift and day shift at work. I would have found that interesting to be able to see." (quote 22)	Additional needs	5
"I think it might work better if the goals are better tailored to the person." (quote 22)	Additional needs	5

Figure 5. *Code Tree.*



User Adherence

Topics that may have had a negative impact on user adherence included problems experienced with the ankle straps and technical problems. All the interviewed patients experienced problems with the closure of the strap. They mentioned occasional loosening of the strap, as the closure did not function properly (quote 1; Table 5). Despite this problem, wearing the bracelet was an obstacle for none of the patients (quote 2; Table 5). In total, 67% (4/6) of patients mentioned technical problems; sometimes the connection between the sensor and the app did not work, disabling the update of the activity data (quote 3; Table 5). Of these 4 patients, 2 (50%) received a new sensor as the battery was depleted prematurely (quote 4; Table 5). One of the participants mentioned that the technical problems were frustrating (quote 5; Table 5).

Topics that may have had a positive effect on user adherence were ease of use of the *Atris* app (quotes 6 and 7; Table 5) and absence of privacy concerns (quote 8; Table 5).

Experienced Added Value

Most of the interviewed patients were positive about the use of the PAM and *Atris* app (quotes 9 and 10; Table 5). One of the participants mentioned that the use of the PAM had become a part of his lifestyle (quote 11; Table 5). All patients experienced having more insight into their recovery with the use of the PAM and *Atris* app as they were able to see if they were making progress (quote 12; Table 5). In addition, they mentioned that the PAM and *Atris* app had a motivating effect. They stimulated them to be more physically active as they were able to set goals and they felt more coresponsible for their recovery (quotes 13 and 14; Table 5). Moreover, patients experienced the PAM and *Atris* app as support during their recovery process. They mentioned that they provided more focus on recovery and provided something to hold on to (quotes 15 and 16; Table 5).

Approximately 33% (2/6) of patients did not experience additional values but were positive about the concept. They mentioned that they were already motivated to be physically active regardless of the PAM. They thought it would be more suitable for patients who needed more motivation to be physically active (quotes 17 and 18; Table 5).

Requirements

Overall, 67% (4/6) of patients highlighted the need for more support. They mentioned that it would be of additional value if they received messages or calls in situations of insufficient or abnormal activity behavior (quote 19; Table 5). Moreover, 33% (2/6) of patients also mentioned that motivational messages might serve as additional incentives (quote 20, Table 5). Additional requirements mentioned by 4 patients were the possibility to add additional measurements of data, such as heart rate or blood pressure (quote 21; Table 5). In addition, 33% (2/6) of patients wanted to gain more insight into the activity pattern during the day (quote 22; Table 5); 33% (2/6) of patients highlighted the need for more personalization (quote 23; Table 5).

Discussion

Principal Findings

Self-monitoring of PA after discharge appears to be feasible based on good system usability and predominantly positive user experiences in patients with cancer after lobectomy, esophageal resection, or HIPEC. These findings are consistent with those of other studies [15-17, 22]. Wu et al [15] found good feasibility of self-monitoring using a

wrist-worn accelerometer and an app in patients after gastric cancer surgery. Low et al [17] reported good usability of a real-time mobile technology–based sedentary behavior intervention for patients with abdominal cancer in the perioperative period using a smartwatch. However, feasibility was considered moderate in that study as adherence to wearing the smartwatch decreased significantly from before to after the surgery. In our study, adherence also seemed to decrease based on an increase in missing data during the intervention period. Solving technical problems and improving the comfort of the ankle strap may reduce the number of dropouts and missing data in clinical use and follow-up studies. In addition, improving self-efficacy and self-motivation and engaging in more social support could enhance user adherence, as suggested in a systematic review of predictors of adherence in home-based physical rehabilitation [27].

The system usability of the PAM and *Atris* app is similar to that of devices used in other studies [17, 25]. Jonker et al [25] reported good system usability (mean SUS 73.1) for a wrist-worn activity tracker and mobile app in older adult patients after oncological surgery. In a study by Low et al [17], the system usability of a Fitbit smartwatch with an accompanying smartphone app during the perioperative period in patients scheduled for abdominal cancer surgery was also found to be good (mean SUS 83.8). The qualitative data, in addition to the quantitative data, provided insights into the facilitators of and barriers to the use of the *Atris* app and PAM. The user experiences were largely positive. The interviewed patients mentioned that the PAM and *Atris* app were easy to use, motivated them to be more physically active, and provided support after discharge. However, most of the patients recommended the design of a more comfortable ankle strap, and some were annoyed about technical problems. Only a few patients did not experience the added value of the PAM and *Atris* app as, in their opinion, they were already sufficiently active and, therefore, did not feel the need for additional support. In contrast, some other patients indicated the need for more support, such as through occasional telephone contact with a physiotherapist or motivational messages. Therefore, the tailoring of interventions to individual needs and preferences should be considered.

In this study, we explored the course of recovery in PA in the first 6 weeks after surgery. These results may be supportive in clinical practice to gain more objective insights into patient recovery and identify which patients may need more support in improving their PA levels. We found that most (19/25, 76%) of our study population did not return to baseline PA levels 6 weeks after surgery, although these results should be interpreted with caution, given the relatively large amount of missing PA data. In previous observational pilot studies using objective PA data after (cancer) surgery, most patients did not reach preoperative PA levels even at 3 months after surgery [28, 29]. Similarly, a study using questionnaires

to investigate the course of recovery in physical functioning 6 and 12 weeks after lung cancer surgery showed that patients were still recovering between 6 and 12 weeks after surgery [4]. The patients in our study underwent major surgeries, including HIPEC and major lung resections. These procedures are both associated with prolonged functional recovery compared with less invasive procedures such as minimally invasive segmental colectomies or video-assisted small lung resections. Therefore, it is suggested that for most of these patients, the period of supportive care to improve PA should be >6 weeks after surgery. However, to increase user adherence for longer-term use, the previously mentioned improvements to the ankle bracelet and resolution of technical problems are necessary. In addition, to better understand all dimensions of user adherence, an in-depth analysis of adherence to ambulant monitoring in this patient population should be performed, taking into account the 5 dimensions of adherence as described by the World Health Organization [30].

By conducting this feasibility study, barriers and enablers were identified for the use of the PAM and *Atris* app after hospital discharge in patients after cancer surgery. However, proper technical functioning and comfort in wearing are important prerequisites for all activity trackers. Moreover, the enablers found in our study, for example, that it motivates patients to be more physically active and that it provides more insight into PA recovery, are also generalizable to other activity trackers. The cost-effectiveness and effectiveness of interventions using PA self-monitoring during cancer treatment is largely unknown, and the conduct of randomized clinical trials is warranted [31]. In addition, not all patients seem to require the same amount of postoperative support. Further research should take into account the risk of functional decline after surgery, as well as the needs and preferences of individual patients.

Limitations

This study had some limitations. First, this feasibility study was conducted in a single hospital setting. In addition, not all diagnoses within gastrointestinal and lung cancer surgery were represented in our study population as preoperative physiotherapy screening was not part of the care pathway for all patients in our hospital. Therefore, the results of this study cannot be generalized to other diagnoses. Second, all patients were contacted to ask whether they were willing to participate in an interview after PA data collection had already ended. However, some patients did not respond or were unwilling to participate in the interviews. This could have caused a selection bias. To reduce selection bias among the patients interviewed, they were selected based on whether they perceived the PAM and *Atris* app as adding value. However, the selected interviewees had a somewhat higher mean SUS score than that of the entire study population (83.8 vs 77.3). Thus, this approach

probably did not sufficiently eliminate the selection bias. To gain a full understanding of feasibility, future studies should also interview nonparticipants. In addition, data saturation may not have been achieved as the interviews were conducted in a small and partly selective sample. Third, for some patients, there was a period of several months between the end of the self-monitoring period and the completion of the questionnaires (and interviews), which may have led to recall bias. Finally, as the study was conducted in the usual care setting, the perioperative instructions from the physiotherapist were not strictly followed as per protocol, which hindered reproducibility. Our research group is currently working on a protocol to guide physiotherapists in using this intervention.

Conclusions

The results of our study showed good system usability and predominantly positive user experiences in patients with cancer after lobectomy, esophageal resection, or HIPEC. Most patients mentioned that the PAM and *Atris* app motivated them to be more physically active after discharge. The retention rate and amount of missing data need to be improved in follow-up studies. Solving technical problems and improving the comfort of ankle straps may enhance user adherence, thereby reducing the number of dropouts and missing data. Randomized clinical trials should be conducted to investigate whether interventions using accelerometers indeed improve the recovery of PA and physical functioning after surgery in this population.

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Authors' Contributions

EG, VvV, EEHvW, CD, JBT, MvdL, and MvdS conceived the study. EG included the patients for this study. EG, VvV, and MEdL collected the data. MEdL and MB analyzed the quantitative and qualitative data. MEdL and MB drafted the manuscript. MEdL, MB, MvdL, MvdS, and VdG drafted the final version of the manuscript. All authors reviewed, revised, and approved the final manuscript.

Conflicts of Interest

None declared.

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Supplementary Files

Supplementary File 1: Additional feasibility questions



Scan QR code

Supplementary File 2: Topic list interviews



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Supplementary File 3: Outcomes feasibility questionnaire



Scan QR code



Chapter 3

The effectiveness of physical activity interventions using activity trackers during or after inpatient care: a systematic review and meta-analysis of randomized controlled trials

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Abstract

Background: Promoting physical activity (PA) in patients during and/or after an inpatient stay appears important but challenging. Interventions using activity trackers seem promising to increase PA and enhance recovery of physical functioning.

Objective: To review the effectiveness of physical activity interventions using activity trackers on improving PA and physical functioning, compared to usual care in patients during and/or after inpatient care. In addition, it was determined whether the following intervention characteristics increase the effectiveness of these interventions: the number of Behaviour change techniques (BCTs) used, the use of a theoretical model or the addition of coaching by a health professional.

Design: Systematic review and meta-analysis.

Data Sources: PubMed, EMBASE, Cinahl, SportDiscus and Web of Science databases were searched in March 2020 and updated in March 2021.

Eligibility criteria for selecting studies: Randomized controlled trials (RCTs) including interventions using activity trackers and feedback on PA in adult patients during, or less than 3 months after, hospitalization or inpatient rehabilitation.

Methods: Following database search and title and abstract screening, articles were screened on full text for eligibility and then assessed for risk of bias by using the Physiotherapy Evidence Database (PEDro) scale. Meta-analyses, including subgroup analysis on intervention characteristics, were conducted for the outcomes PA and physical functioning.

Results: Overall, 21 RCTs totalling 2355 patients were included. The trials covered a variety of clinical areas. There was considerable heterogeneity between studies. For the 13 studies that measured PA as an outcome variable(N= 1435), a significant small positive effect in favour of the intervention was found (standardized mean difference (SMD)=0.34; 95%CI 0.12 - 0.56). For the 13 studies that measured physical functioning as an outcome variable (N= 1415) no significant effect was found (SMD=0.09; 95%CI -0.02 - 0.19). Effectiveness on PA seems to improve by providing the intervention both during and after the inpatient period and by using a theoretical model, multiple BCTs and coaching by a health professional.

Conclusion: Interventions using activity trackers during and/or after an inpatient period can be effective in increasing the level of PA. However, these improvements did not necessarily translate into improvements in physical functioning. Several intervention characteristics were found to increase the effectiveness of PA interventions.

Introduction

Admission to a hospital or rehabilitation centre often leads to a decline in physical functioning.[1-4] This may be caused by the initial disease or medical treatment, but also by a reduction in physical activity (PA). It has been shown that increasing PA during or after an inpatient period is effective in improving recovery in physical functioning.[2, 5-8] However, stimulating PA in patients during and after an inpatient stay appears to be challenging because healthcare professionals may have insufficient time and patients may experience physical discomfort or lack of motivation.[9-12] Therefore, extra support to increase PA levels is desired.[13]

Activity trackers are wearable devices to monitor PA and are commonly used in interventions to stimulate PA.[14-18] In various patient populations, for example in patients with COPD or with rheumatic and musculoskeletal diseases, the use of activity trackers was found effective in increasing PA.[14-18] The evidence of effectiveness of interventions with activity trackers on physical functioning has been studied less and is conflicting.[16, 17]

The use of interventions with activity trackers during or after an inpatient period is expected to be effective, because an inpatient period, for example after oncological surgery or after a neurological event, can be considered as a "teachable moment": a time frame following a health event which a patients is most conducive to behavioural change.[19, 20] However, the effectiveness of PA interventions with activity trackers during or after admission to a hospital or rehabilitation centre has not been summarized systematically to date.

There is a wide variation in interventions with activity trackers. It is therefore important to identify which intervention characteristics have the highest effect on increasing patients' PA. To systematically describe, develop and test active elements of behavioural health interventions a taxonomy of behaviour change techniques (BCTs) has been developed.[21] BCTs are "observable, replicable and irreducible components of an intervention designed to alter or redirect causal processes that regulate behaviour".[21] Interventions with activity trackers often contain several BCTs.[22] However, there is insufficient evidence about the potential for the use of BCTs to improve the effectiveness of an intervention in patients during or after an inpatient period.

Besides BCTs, there is evidence for the use of a theoretical model, e.g. the Trans theoretical Model (TTM), the Social Cognitive Theory (SCT) or the self-efficacy theory.[23-26] Theory-based interventions are expected to be more effective because they tend to be better substantiated and more carefully described and carried out. In addition, the engagement

of coaching from a health professional during the intervention may also influence the impact on the targeted behaviour (PA).[27] It is expected that a health professional having insight into the level of PA will be more motivating to the patient and PA goals can be better adjusted by the health professional during the intervention.

The primary aim of this study was to review the effectiveness of physical activity interventions using activity trackers on PA and physical functioning, compared to usual care in patients during or after inpatient care. The secondary aim was to determine whether the following intervention characteristics increase the effectiveness of these interventions: the number of BCTs used, the use of a theoretical model or the addition of coaching by a health professional.

Methods

Protocol and registration

The review protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO) at https://www.crd.york.ac.uk/prospero/ (registration number CRD42020175977, submitted on March 23th, 2020). This review applies a systematic approach according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) updated guideline.[28]

Search strategy

A systematic literature search was conducted in March 2020 and updated on 3 March 2021, using the databases PubMed, EMbase.com, Ebsco/CINAHL, Ebsco/SportDiscus and Clarivate Analytics/Web of Science Core Collection (by MEL and JCFK). The search strategy included the following search terms and their synonyms: [1] inpatient period, [2] activity trackers and [3] adult patients. The full search string is presented in Electronic Supplementary Material Table S1. The reference lists of the included studies were checked to detect additional articles.

Study selection

The software program 'Rayyan' was used for the study selection. The studies were independently screened by two reviewers (ML and PB), first on title and abstract and second on full text, to assess eligibility for inclusion. The reviewers were blinded to each other's decisions. If necessary, final judgement about the eligibility was made by a third reviewer (MvdL).

Eligibility criteria

Type of studies

Randomized controlled trials about interventions with the use of activity trackers and feedback on PA level were included. No restrictions concerning the language or year of publication were used.

Type of participants

The target population for this review were adults during or less than 3 months after hospitalization or inpatient rehabilitation. No restrictions were made for the medical reason of the inpatient period.

Type of intervention

All studies with an intervention that included [1] an objective measurement of PA with the use of an activity tracker (e.g. accelerometer or pedometer) and [2] feedback on PA level for the participant (e.g. visual feedback from the activity tracker or feedback from a therapist), alone, or in combination with other interventions, were included. Studies that only used activity trackers to measure activity of the upper body were excluded from this review.

Type of control group

Usual care or an intervention with activity trackers without any form of feedback on PA level.

Type of outcomes

The main outcomes of this review were PA and physical functioning. For this study, we used the definition of physical activity defined by the World Health Organization (WHO), i.e. any bodily movement produced by skeletal muscles that requires energy expenditure.[29] Up until now there is no consensus on the definition of physical functioning. For this study, physical functioning was defined as the ability to perform both basic and instrumental activities of daily living, this definition is more often used in other studies.[30] Studies were eligible if they had included an objectively measured outcome of PA (i.e. steps per day or active minutes per day) or if they had measured physical functioning by means of performance-based measures or by patient-reported measures (PROM) of function.

Data extraction

The following study characteristics were extracted from the included RCTs: author, year of publication, study population, group characteristics, setting, description of the intervention, intervention characteristics, description of the control group and outcome measures of the primary outcomes for this review. The following intervention characteristics were

extracted: duration, coaching by a health professional during the intervention (yes/no), theory mentioned (e.g. social cognitive theory)(yes/no) and type of activity tracker. If an article reported multiple comparisons, we only extracted data from the groups of interest. For the outcome PA, we extracted steps per day if available. We had chosen for steps/day because this is the most common used outcome for PA and is currently the most convenient to interpret. When this data was not available, we extracted another outcome measured with the accelerometer (e.g. active minutes per day). For the outcome physical functioning, we had chosen to extract the most task-specific test (e.g. Short Physical Performance Battery rather than a muscle strength test), because task-specific tests are more indicative of patients ADL-functioning. The data was extracted by one reviewer and verified by a second reviewer. Disagreements were resolved by discussion.

Coding of behaviour change techniques

The BCT taxonomy (v1) of 93 hierarchically cluster techniques from Michie et al. was used to identify and code the BCTs reported in the intervention.[21] The most comprehensive description of the intervention was used (e.g. study protocol). Coding was carried out by one reviewer (ML) and a second independent reviewer (PB) double coded a random 20% of all descriptions to check for reliability. Disagreements were resolved via discussion. Cohen's kappa was used to measure the agreement between the reviewers. Both reviewers completed the BCT taxonomy v1 Online Training. The BCTs in the intervention and control group were identified separately and only the BCTs exclusively used in the intervention group were extracted. In addition, the total number of BCTs used in the intervention were recorded.

Evaluation of the methodological quality

The Physiotherapy Evidence Database (PEDro) scale was used to assess the methodological quality of the individual studies. The PEDro scale is a valid and reliable tool for assessing methodological quality of clinical trials and randomized controlled trials.[31, 32] The PEDro scale consists of 11 items; eight items (item 2-9) are used to asses internal validity and two (item 10-11) items are used to assess interpretability of the results. The first item, which assesses the external validity, is excluded in calculating the total score (following the methods of the PEDro score). [33] Therefore, the score ranges from 0 to 10 points. A higher score indicates a lower risk of bias. Trials with a score of ≥ 6 were considered as 'low risk' of bias. Trials were considered as 'high risk' of bias if they had a score < 6.[32] Quality assessment was independently conducted by two reviewers. Disagreement between the reviewers was discusses with a third reviewer (MvdL). Cohen's kappa was used to measure the agreement between the reviewers.

Data Analysis

Outcomes of the studies were collected at baseline, during the intervention, post-intervention (within one month after the end of the intervention period) and long term follow up if available. Outcomes not included in the meta-analyses were presented descriptively.

Meta-analysis

A meta-analysis was conducted for the post-intervention outcomes of PA and physical functioning. The studies varied in the use of statistics and reporting of the effect sizes. The mean difference and standard deviation (SD) between baseline and post-intervention were extracted. If not reported in the study results, the mean difference and SD were calculated. In case data was missing to calculate the mean difference, authors were contacted. If only median and interquartile ranges (IQR) were reported, the sample mean and standard deviation were estimated following the method of Wan et al.[34]

The software program Review Manager (version 5.3.5) was used to conduct the meta-analysis. Included studies were assessed on statistical and clinical heterogeneity by inspection of the forest plots and the I^2 statistics. If no considerable between-group statistical or clinical heterogeneity was detected, the fixed effects model was used; otherwise, a random effects model was used. Meta-analysis was performed to calculate the pooled treatment effect size with a 95% confidence interval for both outcomes. Results were visually presented using forest plots. An effect size of 0.2 was considered as small, 0.5 as moderate and 0.8 or higher as large.[35] A funnel plot and Egger's regression test was used to assess the presence of publication bias. If Egger's regression test shows a significance level ≤ 0.05, there is a high probability of publication bias. Leave-one-out sensitivity analysis was conducted in order to confirm that the results were not driven by any single study.

Subgroup-analyses

For this review a broad population has been included, therefore the different study populations were expected to be heterogeneous. To explore the contribution of different study characteristics on the overall outcome, pre-specified subgroup analyses were conducted for the following possible moderators: (1) setting (hospitalization vs rehabilitation), (2) period of intervention (during and/or after the inpatient period), (3) duration of the intervention (≤3 months or > 3 months) and the age group of the participants (mean age ≤ 60 years or mean age > 60 years). In addition, subgroup analyses were performed on methodological quality (low risk of bias vs. high risk of bias) to explore if the methodological quality has affected the overall effect size. Cochrane's Q test was performed to test whether there was a significant moderation effect ($p < 0.05$).

Given the small number of included studies and the large variety in combination of coded BCTs, it was not possible to determine the effect of combinations of different BCTs using meta-regression. It was decided not to perform sub-analysis of individual BCTs, because it is suggested that a combination of different BCTs is more important than the effect of a single BCT. [36] Therefore, subgroup analyses were conducted in the following intervention characteristics: (1) number of BCTs used in the intervention, theory-based interventions (yes/no) and (3) coaching by a health professional (yes/no). The cut-off value for the subgroup analysis of the number BCTs was determined by the mean number of BCTs used in the included studies. In addition, it was investigated how the use of BCTs differed between these subgroups.

Results

Study selection

After removing duplicates from the initial search, a total of 7457 articles were screened on title and abstract. Of the 128 articles screened on full-text, 107 articles were excluded. Reasons for exclusion are shown in the flow diagram (Figure 1). A total of 21 RCTs were included in this review, totalling 2355 patients.

Study characteristics

With the exception of the study of Izawa et al. (2005) [37], all trials were published between 2011 and 2020. The number of participants per study ranged from 30 to 344. The following patient populations were present in the included studies: patients with neurological diseases[38-42], patients with cardiovascular diseases[37, 43-45], patients after orthopaedic surgery[46-50], patients after abdominal surgery [51, 52], oncological patients [53], patients with COPD [54], patients after bariatric surgery [55], older patients admitted to post-acute care rehabilitation [56] and patients with low functional independence[57]. Eight trials were performed during the inpatient period, eight after the inpatient period and five trials both during and after the inpatient period. Eleven trials were performed during and/or after hospitalization, ten trials were performed during and/or after inpatient rehabilitation. Other study characteristics are presented in Table 1.

Figure 1. *Flow diagram of selected studies (PRISMA)*

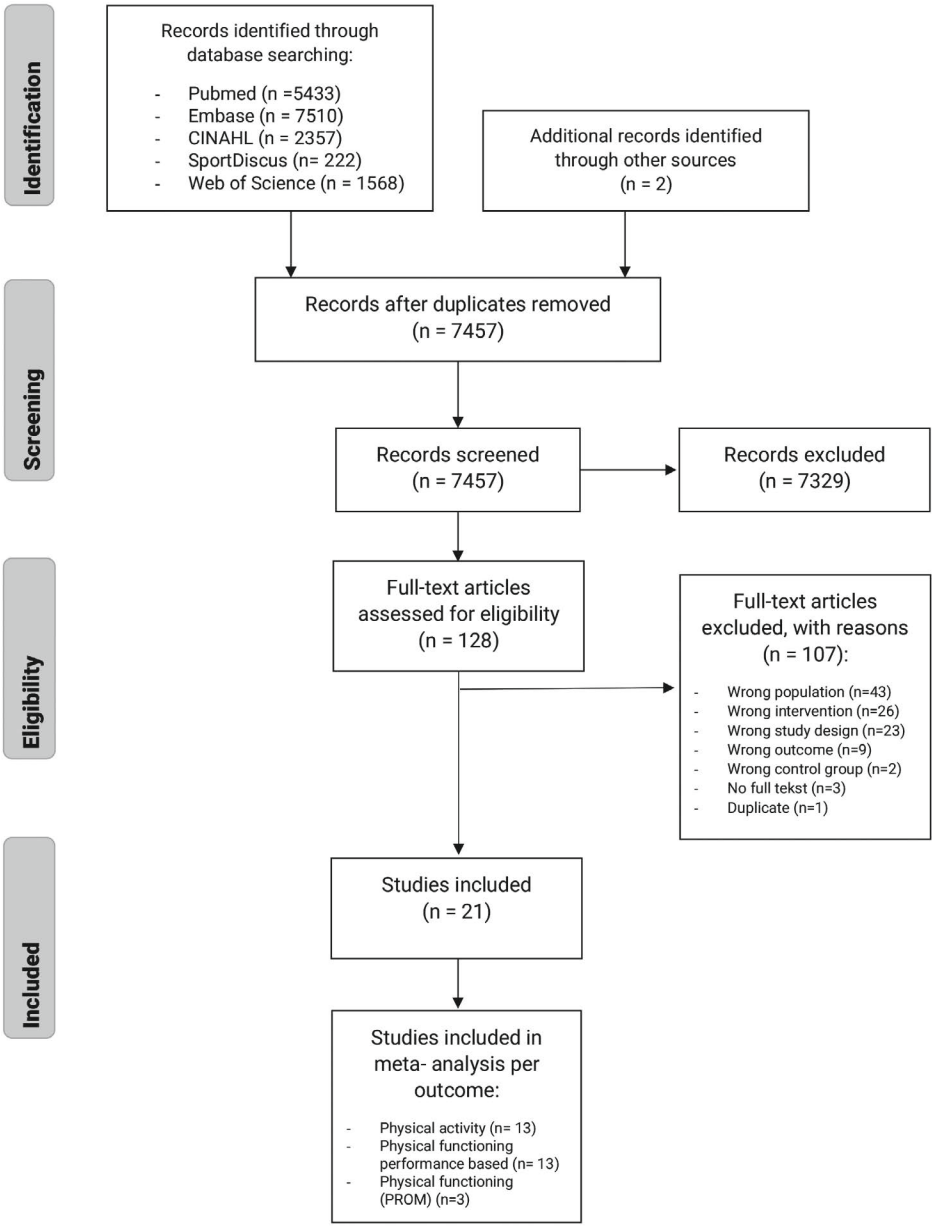


Table 1 – *Characteristics of included RCT's*

See end of Chapter 3

BCT coding

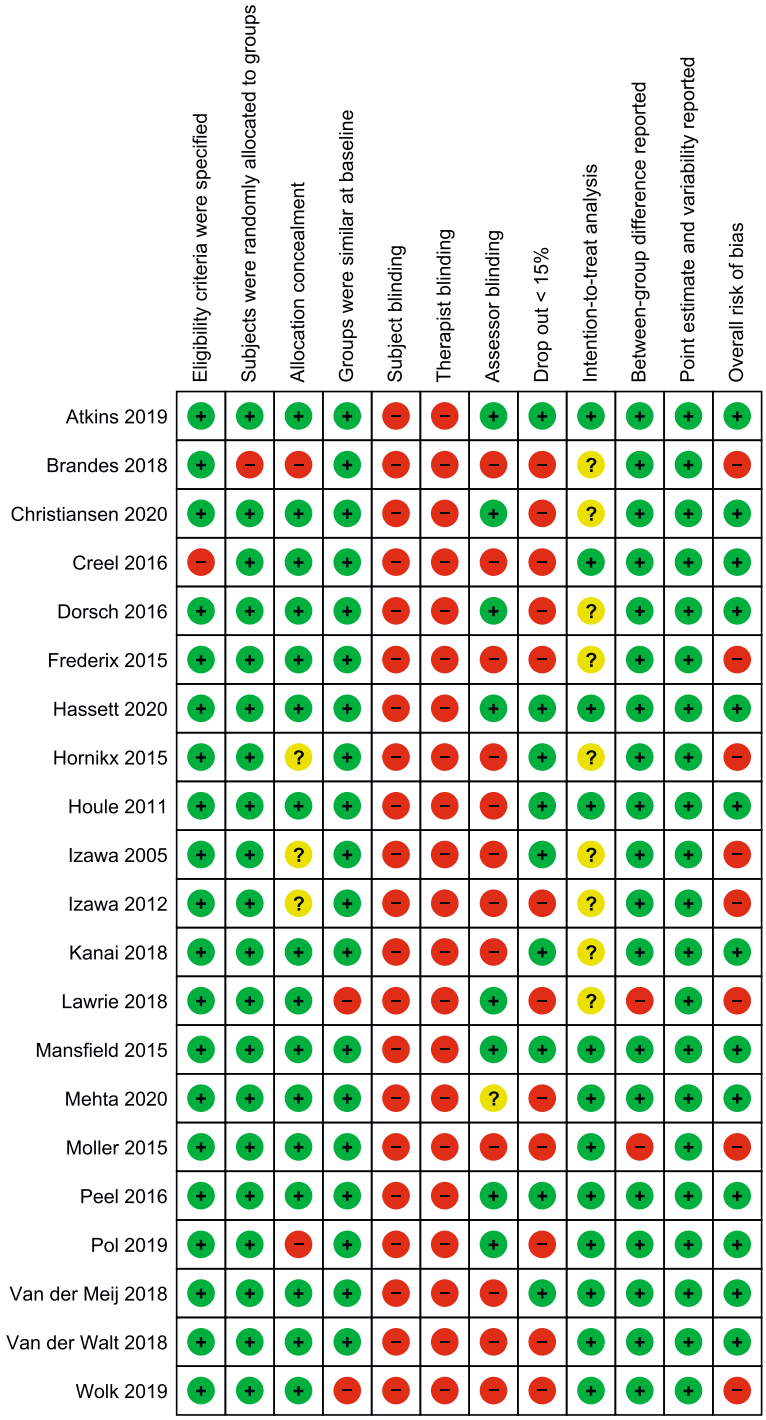
Overall, 20 of the 93 BCTs were coded exclusively in the intervention group compared to the control group. In two studies, two different interventions were included in the analyses; these interventions were coded on BCTs separately.[50, 55] Cohen's kappa between both reviewers (ML & PB) was 0.93. One BCT was coded by the second reviewer, who checked 20% of the trials, which was not coded by the first reviewer. Therefore, all other trials were checked again for that specific BCT. Overall, an agreement between the reviewers was reached.

The amount of BCTs used in the included interventions ranged from 1 to 12, with a mean of 6.2 (SD = 2.96). The BCT feedback on behaviour was used in all interventions (n=23). Other commonly used BCTs were goal setting (behaviour)(n=15), action planning (n=12), self-monitoring of behaviour (n=15), graded tasks (n=12) and adding objects to the environment (n=15). An overview of the coded BCT per intervention is presented in Electronic Supplementary Material Table S2.

Methodological quality

The results of the Risk of Bias assessment are presented in Table 2. Cohen's kappa between both reviewers was 0.79 (ML & PB). After discussion, full consensus was reached between both reviewers. The PEDro score of the included trials ranged from 3 to 8. Thirteen trials were judged as low risk of bias and eight trials as high risk of bias. With the exception of one trial [55], all studies had clearly specified the eligibility criteria. The study of Brandes et al. (2018) performed a pseudo-randomization and was therefore negatively assessed on the randomization procedure. Blinding of participants and therapists was not possible in any study due to the intervention setting.

Table 2. *Risk of bias assessment of included studies (n=21)*



Primary outcomes

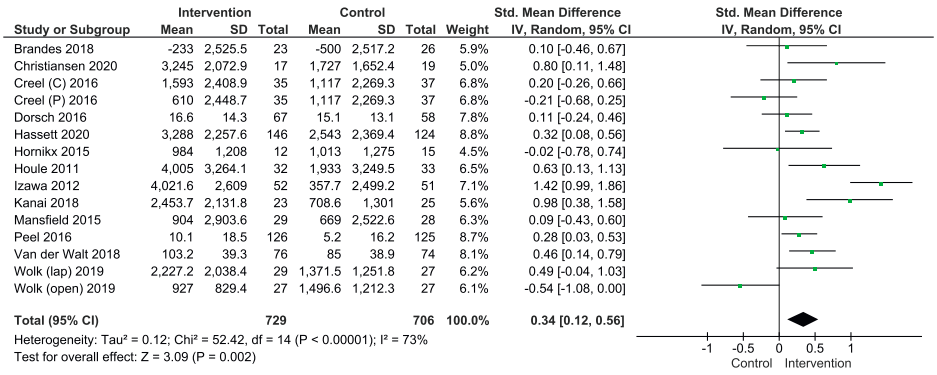
Physical activity

Of the 21 included studies, 15 studies measured the effect of the intervention on objectively measured PA.[37-39, 41, 42, 44-46, 48, 49, 52, 54-57] The most frequent outcome measure of PA was steps per day, which was used in eleven studies.[37, 39, 41, 42, 44-46, 49, 54, 55, 57] Other outcome measures of PA were time spent walking [38], non-therapy walking time [56], percentage of preoperative step count at follow up [48] and mean step count during the first five postoperative days [52]. Six studies reported PA during the intervention of which five studies showed a significant positive effect in favour of the intervention group compared to the control group.[48, 55-58] The post-intervention outcome was reported in 13 studies; seven studies showed a significant positive effect in favour of the intervention group [39, 44, 45, 48, 49, 55, 56] and one study showed a significant positive effect in favour of the control group [52]. Four studies reported a long-term follow up of 6 months after intervention: three studies reported a significant positive effect in favour of the intervention group.[37, 48, 49]

Meta-analysis was conducted for the mean difference between baseline and post-intervention comparing the intervention and control group, for which 13 studies provided data. Of these, only four studies reported the mean difference between baseline and post-intervention [38, 48, 52, 54], therefore the mean difference had to be calculated for the other studies. Three authors were contacted with success, because data to measure the mean difference was not available.[48, 55, 56] In the study of Creel et al. [55] and the study of Wolk et al. [52], data analysis was performed in two different population groups: these groups have been included separate in the meta-analysis.

Data was pooled in a random effects meta-analysis using data from 1435 participants (729 intervention/706 control). The model resulted in an overall estimated effect size in terms of standardized mean difference (SMD) of 0.34 (95%CI 0.12; 0.56) indicating a significant effect in favour of the intervention group (p = 0.002). The level of heterogeneity (I^2) was 73% (Figure 2). The Funnel plot is presented in Electronic Supplementary Material Figure S1. Egger's regression test indicated no significant asymmetry of the funnel plot (Egger's Test = 0.205 p = 0.373). The SMD of Izawa et al. (2012) and Wolk et al. (open surgery) deviated the most from the overall effect size (SMD 1.42 and -0.54, respectively). However, leave-one-out sensitivity analysis showed that the effect sizes remained within the 95%CI after iteratively removing both studies from analysis (SMD 0.26, 95%CI 0.09;0.43, p = 0.003 resp. SMD 0.40, 95%CI 0.19; 0.60, p =0.0002).

Figure 2: *Forest plot for the outcome physical activity*

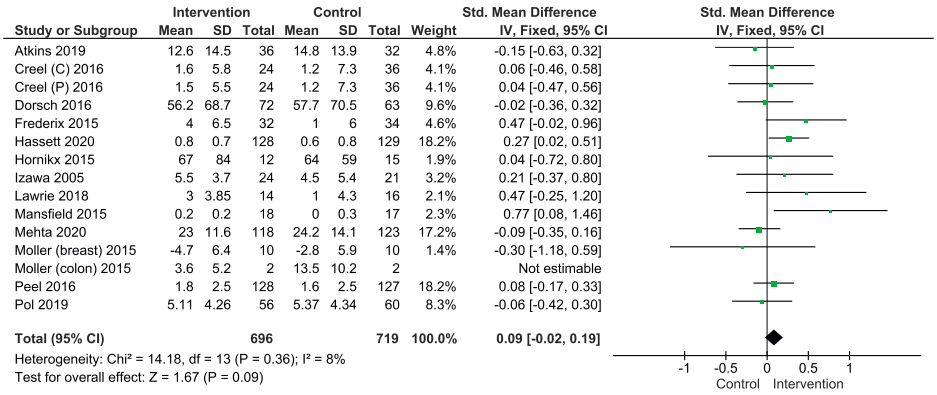


Physical functioning (performance based)

A total of 13 trials reported a performance based outcome of physical functioning.[37, 38, 40-43, 47, 50, 53-57] The most common used outcome measure was peak oxygen uptake (peak VO_2) measured during an cardiopulmonary exercise test and was reported in three studies.[37, 43, 53] Other outcome measures were the Short Physical Performance Battery [42, 56], three or six minutes walking distance [38, 54], the Morton Mobility Index [57], exercise tolerance (MET's) [55], the Barthel Index [40], walking speed [41], the Performance-Oriented Mobility Assessment [47] and the Timed Up and Go test [50]. All studies reported post-intervention outcome of which three reported a significant positive effect in favour of the intervention group.[41-43] Only the study of Pol et al. reported a long term follow-up, but did not found a significant effect.[47]

The mean difference was reported in two studies and had to be calculated for the other ten studies. The study of Creel et al. [55] included two different intervention groups (see Table 1), therefore these groups have been included separate in the meta-analysis. In the study of Moller et al. [53] data analysis was performed in two different population groups (colon and breast cancer). However, one group has been excluded for meta-analysis due to the low number of participants in both intervention and control group (n=4). In the study of Mehta et al., only the median and IQR were reported, therefore the sample mean and SD were estimated as described in the method section. Data was pooled in a random effects model meta-analysis including 1415 participants (696 intervention/719 control). The model resulted in an overall estimated effect size in terms of standardized mean difference of 0.09 (95%CI -0.02; 0.20, I^2 = 8%). No significant effect was found between groups (P = 0.11) (Figure 3). Funnel plot (Electronic Supplementary Material Figure S2) and Egger's regression test indicated that publication bias was unlikely to have influenced de results (Egger's Test = -0,063; p = 0.914).

Figure 3. *Forest plot for outcome performance based physical functioning*

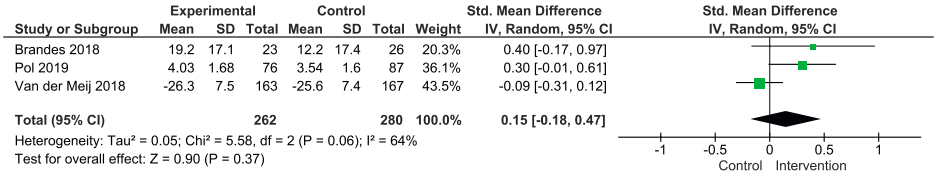


Physical functioning (patient reported)

Four studies reported a PROM of physical functioning.[46-48, 51] The study of Brandes et al. used the Oxford knee/hip score as outcome, but did not find a significant difference between the intervention and control group post-intervention or at 6 months follow up.[46] Also in the study of Van der Walt et al., no significant effect was found at six months follow up on the Knee Injury and Osteoarthritis Outcome Score.[48] On the other hand, a significant positive treatment effect was found on the Canadian Occupational Performance Measure (COPM) post intervention and at six months follow-up in the study of Pol et al. [47] In the study of van der Meij et al, a significant positive effect on the median days return to normal activities, measured with the Patient Reported Outcomes Measurement Information System – Physical Functioning (PROMIS-PF), was found in favour of the intervention group.[51] However, no significant difference between groups was found in the PROMIS-PF post-intervention compared to baseline.

Overall, meta-analysis of patient reported outcome of physical functioning post-intervention using a random effects model resulted in an overall estimated effect size of 0.15 (95% CI -0.18; 0.47) (Figure 4). A funnel plot and Eggers test was not performed because of the low number of included studies.

Figure 4. *Forest plot for patient reported outcome measure of physical functioning*



Subgroup analysis study characteristics

Meta-analysis for PA presented high heterogeneity (73%, see Figure 2), therefore subgroup analyses were conducted to explore the contribution of different study characteristics on the overall effect. No significant differences were found between subgroups (Table 3). However, interventions that took place both during and after the inpatient period showed a high significant effect in favour of the intervention group (SMD = 0.71, 95%CI 0.13;1.29), whereas interventions that only took place during or after the inpatient period did not reveal significant effects (SMD = 0.21, 95%CI -0.07; 0.48 resp. SMD = 0.26, 95%CI -0.11; 0.64). This also applies for the age group, however differences in effect sizes were less in these groups (Table 3). Methodological quality had no significant effect on effect size (p = 0.97): studies with a higher risk of bias did not result in different effect sizes.

Subgroup analysis for the outcome performance based and patient reported physical functioning were not conducted, because the meta-analysis either presented low heterogeneity (I^2 = 8%) or included a low number of studies.

Table 3. *Subgroup analysis study characteristics*

Study characteristics	Outcome PA (n=15)				
	n	Combined sample size	Pooled mean SMD (95% CI)	Q	p
Setting				0.88	0.35
Hospitalization	10	683	0.43 (0.06; 0.79)*		
Rehabilitation	5	752	0.24 (0.10; 0.38)*		
Period				2.38	0.30
During	7	640	0.21 (-0.07; 0.48)		
After	5	272	0.26 (-0.11; 0.64)		
During and after	3	523	0.71 (0.13; 1.29)*		
Duration of the intervention				0.04	0.84
≤3 months	10	920	0.35 (0.04; 0.66)*		
>3 months	5	515	0.31 (0.02; 0.60)*		
Age group				0.00	0.95
Mean age ≤ 60 years	6	422	0.34 (-0.23; 0.91)		
Mean age > 60 years	9	1013	0.32 (0.16; 0.48)*		
Risk of Bias				0.00	0.97
Low risk	10	1146	0.32 (0.15; 0.49)*		
High risk	5	289	0.31 (-0.42; 1.04)		

*p<0.05, Q = cochrane's Q

Subgroup analysis intervention characteristics

The mean number of BCTs in the included interventions was 6.4. Therefore, subgroup analysis was conducted for interventions with ≥ 7 BCTs and < 7 BCTs. Interventions with ≥ 7 BCTs showed an significant effect on PA (SMD = 0.60, 95%CI 0.18;1.02, p = 0.005), whereas interventions with < 7 BCTs did not (SMD = 0.18, 95%CI -0.04;0.39, p = 0.11). The forest plot is presented in Electronic Supplementary Material Figure S3. The following BCTs were only used in the subgroup with ≥ 7 BCTs: problem solving (n=5), instructions on how to perform a behavior (n=3), information about health consequences (n=1), information about social and environmental consequences (n=1), social comparison (n=1), prompts/cues (n=3) and social reward (n=2).

The SMD of theory-based interventions with activity trackers was higher (SMD = 0.66, 95%CI 0.14; 1.18, p = 0.01) compared to interventions without a theoretical model (SMD = 0.20. 95%CI -0.00; 0.40, p = 0.04)(Electronic Supplementary Material Figure S4). The mean number of BCTs used in theory-based interventions was higher: 8.4 compared to 5.3. The BCTs that were exclusively coded in the subgroup with theory-based interventions were: information about health consequences (n=1), information about social and environmental consequences (n=1), social comparison (n=1) and social reward (n=2).

Interventions with coaching by a health professional showed a larger effect on PA (SMD = 0.44, 95%CI 0.19; 0.69, p = 0.0004) compared to interventions without coaching by a health professional (SMD = 0.07, 95%CI -0.42; 0.56, p = 0.78) (Electronic Supplementary Material Figure S5). In the interventions with supervision by a health professional more different BCTs were used: the mean number of BCTs was 6.8 compared to 4.8. The following BCTs were exclusively coded in interventions with coaching by a health professional: problem solving (n=5), review behaviour goals (n=4), instructions on how to perform a behaviour (n=3), information about health consequences (n=1), information about social and environmental consequences (n=1), social comparison (n=1), prompts/cues (n=3) and social reward (n=3).

Discussion

The results of this systematic review and meta-analysis showed that interventions using activity trackers during and/or after an inpatient period are heterogeneous, but are generally more effective in increasing the level of PA compared to usual care. However, this does not necessarily translate into an improvement in physical functioning. There was high variability of study populations, characteristics and intervention strategies across the included studies. Subgroup analysis of study characteristics suggest that

interventions taking place both during and after an inpatient period may be more effective in stimulating PA compared to interventions only during or only after inpatient treatment. In addition, interventions using more BCTs, theory based interventions and interventions in combination with coaching by a health professional also seem to increase the effect on the level of PA.

A small positive effect on PA in favour of the intervention group was found. These results are in line with the results of meta-analyses in other patient populations.[15-18] In the review of Braakhuis et al, a small positive effect of healthcare interventions using objective feedback on PA was found (SMD = 0.34, p<0.01) in a heterogeneous patient population (patients with COPD, stroke, cardio-vascular diseases, Parkinson's disease and geriatric patients).[18] A moderate positive effect on PA was found in a meta-analysis in people with type 2 diabetes (SMD 0.57, p<0.01) and in a meta-analysis in patients with COPD using step counters (SMD 0.57, p<0.05).[15, 17] A high positive effect on daily step count was found in a meta-analysis in patients with rheumatic and musculoskeletal diseases (SMD 0.83, p<0.01).[16] The lower effect in our study compared to these studies may be caused by patients experiencing more barriers to increase their level of PA during or after an inpatient period due to impact of the 'acute event' (e.g. having symptoms, such as pain or fatigue or due to overall reduced strength and condition as result of the acute event) compared to patients with chronic conditions in a daily life setting.[10, 11, 13]

Although a positive effect was found on PA in favour of the intervention group, no effect was found on the outcome physical functioning in our meta-analysis. In other patient populations, previous reviews have found conflicting results on the effectiveness of activity tracker interventions on physical functioning. A small significant positive effect was found on physical functioning in patients with COPD (SMD = 0.32, p < 0.05) [17], whereas no significant effect was found in patients with rheumatic and musculoskeletal diseases (SMD = 0.09, p > 0.05). [16] Of the individual included studies in our meta-analysis, two studies supported the effect that increased PA contributes to recovery in physical functioning.[42, 43] In contrast, no significant effect on physical functioning was found in four studies reporting a significant effect on PA in favour of the intervention group.[48, 55-57] One possible explanation for these differences in effectiveness is the timing of physical functioning measurements, as PA-interventions may have more effect on the rate than on the level of functional recovery. In other words, patients in the intervention group may have a physical functioning level similar to that of the control group after a certain time, but it may take them less time to reach that level. This could be particularly true in patient populations that fully recover to their pre-treatment physical functioning levels. Another explanation could be the very low number of studies that used a patient-reported

outcome measure of physical functioning. Patient-reported outcomes are important because they can provide unique information on the impact of a medical condition and its intervention from the patient's perspective. Finally, high variability in outcome measures and small sample sizes in our review lead to low certainty of evidence of the results for both performance-based and patient-reported physical functioning, according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach.[59] To gain a better understanding of the effect of interventions using activity trackers during and/or after an inpatient period, conducting clinical trials measuring both patient-reported and performance-based outcomes of physical functioning at multiple follow-up times is warranted.

Subgroup analysis of study characteristics suggested that interventions conducted both during and after an inpatient period may be more effective in increasing the level of PA. This may be explained by the fact that in the interventions during the inpatient period, activity trackers were often added to standard interventions aimed at improving PA, whereas in the interventions after discharge, the activity tracker was often the only component aimed at improving PA. Three studies that conducted the intervention only during inpatient rehabilitation also mentioned the high load of usual rehabilitation care in the control group as possible explanation that no significant effect on PA was found.[38, 41, 46] In most cases priority was even given in the intervention group to the rehabilitation goals of usual care instead of the experimental intervention goals (daily step count). Also, if the intervention starts during inpatient stay and continues after discharge, patients might be more aware of their PA behaviour being back at home. Therefore, it is suggested that these interventions may be more effective when implemented both during and after discharge.

Our results support previous studies suggesting that theory-based interventions are generally more effective in promoting PA.[23-26] It is assumed that in theory-based interventions, the active ingredients of the interventions are more carefully described and implemented. This is supported by our results of coded BCTs in both subgroups, as the mean number of coded BCTs was higher in theory-based interventions (8.4 vs. 5.7).

Interventions using a higher number of BCTs were found to be more effective in improving PA, as also found in other studies.[60, 61] This is in line with the finding that interventions with coaching by a health professional are more effective, because more different BCTs can be used if interventions are supported by a health professional (e.g. problem solving, social reward). Besides that, it is suggested that activity trackers as standalone intervention might not be sufficient for special patient populations, because most activity trackers do

not include BCTs that are specific to a certain population.[22, 62] Incorporating coaching by a health professional to the intervention gives the opportunity to provide targeted advice and interventions for a specific population group with a more personal touch. These findings are also supported by earlier research.[27, 63]

Results suggest that interventions using activity trackers increase PA levels of surgical and non-surgical patients during and/or after an inpatient period. The advantage of activity trackers is the minimal burden on the user in relation to the data that can be produced, and the ability to provide real-time feedback on PA. Activity trackers can thereby motivate and support patients and reduce the time and resources required for traditional methods of ongoing support.

Strengths and limitations

To our knowledge, this is the first meta-analysis investigating the effect of interventions with activity trackers in patients during and/or after an inpatient period. The study provides insight into which intervention characteristics may improve the effectiveness, which can be helpful in the development of interventions with activity trackers in this population. An internationally validated taxonomy was used to identify BCTs in these interventions. Two trained researchers coded BCTs individually and agreement was received through discussion. Other strengths of this study are that only objective data of PA was used as outcome measurement for PA and that the outcome measurements were corrected for baseline status.

This study has also several limitations. First, there was considerable heterogeneity among the included studies in terms of study populations, duration of intervention and intensity of intervention. Because the high level of heterogeneity, standardized mean difference (SMD) was used. However, using SMD only partly resolves the problem of comparing different outcomes. Therefore, results should be interpreted carefully. Second, heterogeneity in the terminology and insufficient description of the active ingredients of the interventions impaired the coding of BCTs. As a result, it is likely that BCTs are underreported. Unfortunately, this problem is common in research on the effect of different BCTs.[64] Third, not all studies reported the mean difference between the post-intervention and baseline measurement. In these studies, the mean difference was calculated based on available or requested data. In the study of Hassett et al., this has led to a difference in significance of the outcome due to a different analysis method.[42] Our calculation of the mean difference in the study of Hassett et al. resulted in a significant effect on PA, whereas Hassett et al. reported a non-significance effect (p=0.09). However, the estimated effect was roughly similar to our result. Finally, the meta-analysis could only be conducted

for short-term outcomes (post-intervention), due to the lack of long-term outcomes (e.g., three or six months of follow-up). However, it is likely that the effect of interventions and the role of BCTs differ between short- and long-term outcome assessments[65], so intervention studies are encouraged to include long-term outcome assessments.

Conclusion

Interventions using activity trackers during and/or after an inpatient period have the potential to increase the level of PA across a wide range of surgical and non-surgical populations. Despite the expectation that higher levels of PA have a positive effect on physical functioning, no significant effect on physical functioning was found. The intensity and quality of the interventions seem to improve by providing the intervention both during and after the inpatient period, by using more BCTs, integrating a theoretical model, and providing coaching by a healthcare professional, as a greater effect on PA increase has been found in studies using these intervention characteristics. Thus, interventions using activity trackers have the potential to be included as an effective tool to motivate patients and to assist health professionals to provide ongoing monitoring and support with minimal resource expenditure. However, results of this review should be interpreted carefully due to the high heterogeneity between studies. Future RCTs investigating the use of activity trackers should investigate the effect on the course of recovery in physical functioning and should pay attention to a sufficient description of the active ingredients of both the intervention and control conditions, enabling the comparison of different BCTs on outcomes of these interventions.

Trial registration

Registered in PROSPERO (CRD42020175977) on March 23th, 2020

List of abbreviations

- BCT: Behavioral change technique
- IQR: Interquartile range
- PA: Physical activity
- RCT: Randomized Controlled Trial
- SD: Standard Deviation
- SMD: Standardized Mean Difference

Availability of data and materials

The datasets generated during and analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

MEL, PB, MvdS, MvdL conceived the study. MEL, PB, MvdS and MvdL registrated the protocol in PROSPERO. JCF and MEL conducted the search strategy and completed database searches and extraction. MEL, PB and MvdL compleded screening on title and abstract and full text screening. MEL, PB and MvdL completed risk of bias assessment. MEL and PB completed data extraction. MEL, MvdL and MvdS completed data-analysis. MEL drafted the manuscript. PB, MvdL, MvdS, HvdP and VdG reviewed the draft version of the manuscript. All authors reviewed, revised and approved the final manuscript.

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Supplementary Files

Electronic Supplementary Material (S1 t/m S5)



Scan QR code

Table 1. *Characteristics of included RCT's*

Author (year)	Population	Group characteristics, sample size; n, male; n(%), age; mean ±SD	Setting	Intervention	
				Descriptive	Duration
Atkins (2019) [57]	Patients with lower initial function independence measure scores and longer anticipated length of stay.	Intervention: n = 39, 20 (51), 74 ± 17 Control: n = 39, 12 (31), 78 ± 18	During inpatient rehabilitation	Usual care + pedometer with feedback on step count	1 month*
Brandes (2018) [46]	Patients after primary, unilateral joint replacement due to knee or hip osteoarthritis	Intervention: n = 23, 11 (48), 71 ± NA Control: n = 26, 12 (46), 70 ± NA	During inpatient rehabilitation	Usual care + activity tracker with physical activity counselling with tailored approach by adding +5% in daily steps compared to the previous days	3 weeks*
Christiansen (2020) [49]	Patients after a unilateral total knee replacement	Intervention: n=20, 12 (60), 66.5 ± 6.9 Control: n=23, 8 (35), 67.5 ± 7.2	After hospital discharge	Usual outpatient physiotherapy care + activity tracker with weekly steps/day goal and monthly follow-up calls	10 weeks outpatient physiotherapy* + 6 months follow up
Creel (2016) [55]	Patients after bariatric surgery	Intervention 1: n = 52, 8 (15), 42 ± 11 Intervention 2: n = 48, 8 (17), 44 ± 12 Control: n = 50, 8 (16), 44 ± 11	After hospital discharge	1)Pedometer intervention: Usual care + Pedometer + information sheet to increase PA to 10.000 steps/day 2)Counseling intervention: Usual care + Pedometer + exercise counseling with Motivational Interviewing (MI)	6 months
Dorsch (2015) [38]	Patients with stroke	Intervention: n = 78, 31 (40), 62 ± 16 Control: n = 73, 28 (38), 65 ± 13	During inpatient rehabilitation	Speed feedback + results and feedback on their summary activity graphs with a therapist	21 days*
Frederix (2015) [43]	Patients with acute coronary syndrome after a percutaneous coronary intervention or coronary artery bypass graft	Intervention: n = 32, 26 (81), 58 ± 9 Control: n = 34, 29 (85), 63 ± 10	During phase II cardiac rehabilitation.	Exercise training at home with telemonitoring support with accelerometers to encourage patients to increase his/her daily amount of steps wit 10% each week from baseline.	18 weeks

Coaching by a health professional	Theory used	Type of activity tracker	Control	PA outcome measure(s)**	PF performance-based outcome measure(s)**	PF patient reported outcome measure**	Short conclusion
No	NA	Yamax Digiwalker SW200 pedometer	Usual care + pedometer without feedback on step count.	**Steps/day (D)** Daily upright time	**Morton mobility index (DEMMI) (P)**	NA	Pedometers without targets do not improve functional mobility
Yes (RL)	NA	Step Activity Monitor 3.0	Usual care	**Steps/day (P, FU)** Active minutes/day Inactive time	NA	**Oxford hip/knee score (P, FU)**	PA counselling during inpatient rehabilitation did not improve PA or functional outcomes
Yes (RL+OD)	NA	Fitbit Zip	Usual outpatient physiotherapy care	**Steps/day (P, FU)** Minutes in moderate – vigorous PA	NA	NA	A PA intervention with supervision is feasible and may increase PA
1)No 2)Yes (RL)	1)NA 2)Self-determination theory	Omron HJ 113 pedometer	Usual care	**Steps/day (D, P)** % time spent in sedentary activity	**Submaximal graded exercise test (P)**	NA	A counselling intervention using pedometers increased PA in the perioperative period
Yes (RL)	NA	Tri-axial accelerometer (Gulf Coast Data Concepts)	Speed feedback only: verbal feedback about walking speed after 10m walking test.	**Time spent walking (P)**	**3-minute walking test (P)** 150m walking speed test	NA	Augmented feedback did not improve walking outcomes
No	NA	Triaxial accelerometer (Yorbody company)	Exercise training in the hospital's rehabilitation centre	NA	**Maximal cardio-pulmonary exercise test (P)**	NA	PA monitoring might be effective to maintain exercise tolerance

Table 1. *Continued*

Author (year)	Population	Group characteristics, sample size; n, male; n(%), age; mean ±SD	Setting	Intervention	
				Descriptive	Duration
Hassett (2020) [42]	Adults with mobility limitations undertaking aged care and neurological inpatient rehabilitation	Intervention: n = 149, 77 (52), 70 ± 18 Control: n = 151, 74 (49), 73 ± 15	During and after inpatient rehabilitation	Usual care + activity monitor, virtual reality video games and handheld computer devices with support by a physiotherapist	6 months
Hornikx (2015) [54]	Patients with COPD, hospitalized for an exacerbation of COPD	Intervention: n = 15, 8 (53), 66 ± 7 Control: n = 15, 9 (60), 68 ± 6	After hospital discharge	Pedometer + physical activity counselling with personalized goals	1 month
Houle (2011) [44]	Patients < 80 years hospitalized for an acute coronary syndrome	Intervention: n = 32, 26 (81), 58 ± 8 Control: n = 33, 25 (76), 59 ± 9	After hospital discharge	Home based cardiac rehabilitation program + pedometer + exercise counseling by clinical nurse specialist with a target of 3000 steps per day increment in physical activity	12 months
Izawa (2005) [37]	Patients after completion of an acute-phase inpatient cardiac rehabilitation program	Intervention: n = 24, 21 (88), 64 ± 10 Control: n = 21, 17 (81), 65 ± 10	After inpatient rehabilitation	Usual care + self-monitoring of physical activity with feedback from a physical therapist	5 months
Izawa (2012) [45]	Consecutive cardiovascular patients	Intervention: n = 52, 41 (79), 59 ± 8 Control: n = 51, 42 (82), 59 ± 13	During hospitalization until the first outpatient contact with a physician after discharge.	Usual care + self-monitoring of physical activity with feedback from a physical therapist	7 weeks*
Kanai (2018) [39]	Patients with acute ischemic stroke	Intervention: n = 23, 15 (65), 67 ± 10 Control: n = 25, 13 (52), 63 ± 9	During hospitalization	Usual care + self-monitoring of physical activity with feedback from a physical therapist	12 days*

Coaching by a health professional	Theory used	Type of activity tracker	Control	PA outcome measure(s)**	PF performance-based outcome measure(s)**	PF patient reported outcome measure**	Short conclusion
Yes (RL+OD)	NA	Fitbit Zip, One and Alta	Usual care	**Steps/day (D,P)** Time spent walking/day % of the day spent upright	**Short Physical Performance Battery (SPPB) (P)** DEMMI Step test	NA	The use of digitally enabled rehabilitation improved mobility
Yes (OD)	NA	Fitbit Ultra pedometer	Usual care	**Steps/day (P)** Time spent walking/day	**Six minutes walking test (P)** Quadriceps muscle strength	NA	PA counselling with pedometer feedback did not improve PA or clinical outcomes
Yes (RL+OD)	Social Cognitive theory	Yamax Digiwalker SW-200	Usual care	**Steps/day (D, P)**	NA	NA	A pedometer intervention was useful to improve average steps/day
Yes (RL)	Bandura's self-efficacy theory	Kenz Liferecorder pedometer	Usual care	Steps/day (FU)	**Cardio-pulmonary exercise test (P)** Hand grip strength Quadriceps muscle strength	NA	Self-monitoring of PA may effectively increase PA
Yes (RL)	Self-efficacy theory of Bandura and Oka	Kenz Lifecorder EX 1-axial accelerometer	Usual care	**Steps/day (P)**	NA	NA	Self-monitoring of PA might effectively increase PA
Yes (RL)	Self-efficacy theory of Bandura	Fitbit One	Usual care	**Steps/day (P)**	NA	NA	Exercise training with accelerometer-based feedback effectively increased PA

Table 1. *Continued*

Author (year)	Population	Group characteristics, sample size; n, male; n(%), age; mean ±SD	Setting	Intervention	
				Descriptive	Duration
Lawrie (2018) [40]	Patients with recent stroke during rehabilitation	Intervention: n = 14, 10 (71), 53 ± 12 Control: n = 16, 13 (81), 62 ± 12	During inpatient rehabilitation	Usual care + smartwatch with visual feedback and a set goals based on a 5% increase in the total activity.	3 weeks*
Mansfield (2015) [41]	Patients with sub-acute stroke attending inpatient rehabilitation	Intervention: n =29, 20 (69), 64 ± 19 Control: n = 28, 16 (57), 62 ± 13	During inpatient rehabilitation	Usual care + accelerometer-based daily walking activity reports with feedback from a physical therapist	2 weeks*
Mehta (2020) [50]	Patients after hip or knee arthroplasty	Intervention: n=118, 38 (24), median age 66 (IQR 60-73) Control: n=124, 25 (20), median age 66 (IQR 57-73)	After hospital discharge	1) Intervention A: Usual care + remote monitoring alone 2)Intervention B: Usual care + remote monitoring with gamification and social support	45 days
Moller (2015) [53]	Inactive patients with breast or colon cancer referred to adjuvant chemotherapy	Intervention: n = 14, 1 (7), 48 ± 8 Control: n = 16, 2 (13), 47 ± 9	After surgery, during adjuvant chemotherapy	Usual care + Home-based individual progressive pedometer intervention with health promotion counselling and symptom management by a clinical nurse specialist	12 weeks
Peel (2016) [56]	Patients admitted to post-acute care rehabilitation (aged 60 years and older)	Intervention: n = 128, 50 (39), 81 ± 9 Control: n = 127, 57 (45), 82 ± 8	During inpatient rehabilitation	Usual care + accelerometer based feedback and goal setting on daily walking time by therapist	4 weeks
Pol (2019) [47]	Patients > 65 years old after hip fracture	Intervention: n =76, 11 (14), 84 ± 7 Control: n =87, 21 (24), 83 ± 7	During and after institutional-ization in a skilled nursing facility	Usual occupational care + Cognitive Behavioural Treatment (CBT) + sensor monitoring	4 months

Coaching by a health professional	Theory used	Type of activity tracker	Control	PA outcome measure(s)**	PF performance-based outcome measure(s)**	PF patient reported outcome measure**	Short conclusion
No	NA	ZGPAX S8 Android smartwatch	Usual care + smartwatch with limited visual feedback without goal setting.	NA	**Barthel Index (P)** 10m walk test Hand grip strength	NA	No effect was found on functional outcome
Yes (RL)	NA	Two tri-axial accelerometers (Gulf Data Concepts)	Usual care	**Steps/day (P)** Time spent walking/day	**6-meter walk test (P)**	NA	Feedback did not increase the amount of walking
1)No 2)No	NA	Withings physical activity monitor	Usual care	NA	**Timed up and Go test (P)**	NA	PA monitoring did not improve functional outcomes
Yes (RL)	NA	Omron Walking Style Pro pedometer	Usual care	NA	**Cardio-respiratory fitness test (P)** Muscle strength (leg press and chest press)	NA	No effect was found on functional outcomes
Yes (RL)	NA	Triaxial ALIVE Heart and Activity Monitors and ActivPAL	Usual care	**Non-therapy walking time (D, P)**	**Short Physical Performance Battery (SPPB) (P)**	NA	Daily feedback on PA using accelerometers increased walking time
Yes (RL)	Self-efficacy theory of Bandura	PAM AM300	Usual occupational care + CBT	NA	**Performed-Oriented Mobility Assessment (POMA) (P, FU)** Timed up and Go test	**Canadian Occupational Performance Measure (COPM) – performance scale (P, FU)**	Sensor monitoring occupation therapy was more effective in improving patient reported daily functioning than usual care

Table 1. *Continued*

Author (year)	Population	Group characteristics, sample size; n, male; n(%), age; mean ±SD	Setting	Intervention	
				Descriptive	Duration
Van der Meij (2018) [51]	Adult patients scheduled for laparoscopic adnexal surgery, laparoscopic or open hernia inguinal surgery or laparoscopic cholecystectomy	Intervention: n = 173, 78 (45), 52 ± NA Control: n = 171, 79 (46), 51 ± NA	During and after hospitalization	Usual care + Personalized E-health program including self-monitoring on PA	6 weeks
Van der Walt (2018) [48]	Adults undergoing primary elective hip or knee arthroplasty	Intervention: n = 81, 45 (56), 67 ± 9 Control: n = 82, 36 (44), 66 ± 9	During and after hospitalization	Usual care + activity tracker with daily step goals	6 weeks
Wolk (2019) [52]	Patients scheduled for elective open and laparoscopic surgery of the colon, rectum, stomach, pancreas or liver.	Intervention: n = 27, 16 (59), 61 ± 10 Control: n = 27, 19 (70), 56 ± 11.1	During the first 5 postoperative days	Usual care + activity trackers with daily step goals	5 days

NA = not applicable, *dependent on admission time, RL = real life, OD = on distance, D=during the intervention, P=post-intervention, FU = long term follow up, ****Bold** = included in meta-analysis

	Coaching by a health professional	Theory used	Type of activity tracker	Control	PA outcome measure(s)**	PF performance-based outcome measure(s)**	PF patient reported outcome measure**	Short conclusion
	Yes (OD)	NA	UP MOVE, Jawbone	Usual care	NA	NA	**Patient Reported Outcomes Measurement Information System (PROMIS) – Physical Functioning (P)**	A personalised e-health program speeds up the return to normal activities compared to usual care
	No	NA	Garmin Vivofit 2	Usual care + activity tracker with obscured display	**% of preoperative step count (D, P, FU)**	NA	Knee Injury and osteoarthritis outcome score (KOOS) (FU)	Patients who received feedback from a activity tracker had significant higher activity levels
	No	NA	Polar Loop activity tracker	Usual care + activity tracker with obscured display	**Steps/day (P)**			



Chapter 4

The Optimal Physical Recovery After Hospitalization (OPRAH) intervention to improve physical activity and protein intake after oncological surgery: a feasibility study

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Abstract

Aim

1)To assess the feasibility of a blended intervention, combining a smartphone app for self-monitoring of physical activity and protein intake with coaching from a physiotherapist and dietician after hospitalization and 2) to evaluate the associated study procedures.

Methods

A single-arm feasibility study was performed with adult patients scheduled for curative intent gastrointestinal or lung cancer surgery. Patients were provided with a smartphone app and accelerometer one week before surgery, which they used for six weeks following discharge. In addition, patients received coaching from a physiotherapist and dietician. Feasibility was assessed by evaluating participation and completion rates, user adherence, system usability score (SUS), as well as experiences and safety, based on predefined criteria.

Results

In total, 32 patients were included, with participation and completion rates of 69% and 75%, respectively. User adherence to wearing the accelerometer was deemed satisfactory (91%), while user adherence to protein intake was suboptimal (59%). The mean SUS was acceptable (73.5). Patient experiences were predominantly positive, although some patients mentioned a lack of options in the protein registration tool.

Conclusion

The intervention is feasible for implementation in a larger study. To improve adherence, modifications are needed regarding self-recording of protein intake. Study procedures require minor modifications.

Introduction

The surgical treatment of patients with gastrointestinal (GI) or lung cancer has a substantial impact on their physical functioning and quality of life. [1-4] Research has shown that improvements in physical activity and adequate nutritional intake play an important role in enhancing both quality of life and physical functioning after surgery. [5-7] However, reduced physical activity and nutritional challenges are common in these patients. [8, 9] This is often due to the impact of major oncological surgery on patients' daily lives, with physical symptoms such as pain or fatigue and problems related to motivation or social support contributing to reduced physical activity. [10, 11] Moreover, many surgical patients struggle to meet their post-surgery protein requirements despite dietary guidance, which, when combined with inadequate physical activity, increases the risk of muscle loss and reduces one-year survival. [12, 13]

Many studies highlight the need for supportive care interventions to improve physical activity and nutritional status in patients after oncological surgery. [2, 3, 5, 14-17] However, given the increasing strain on healthcare resources, providing intensive individualized guidance to every patient is not feasible. Interventions using smartphone apps and activity trackers could offer a promising solution as they integrate various behavioural change techniques, such as self-monitoring, which can increase patient engagement and support improvements in physical activity and nutritional intake.[18, 19] Moreover, these interventions often require less direct time investment from healthcare professionals. As a result, they can provide a scalable and efficient approach to supporting adherence to rehabilitation strategies, offering patients personalised and easy accessible tools to manage their recovery. [20-22]

Despite the promising potential of interventions using apps and activity trackers, previous studies have shown that stand-alone app-based interventions are often less effective and feasible [23-25]. A blended approach, combining E-health with additional guidance from healthcare professionals might be more effective.[26] This combination harnesses the benefits of digital tools while providing the essential support and personalised care needed to address barriers in recovery.

To our knowledge, there is a lack of blended interventions that focus on self-monitoring of physical activity and protein intake for patients after oncological surgery. To address this gap, we developed the Optimal Physical Recovery After Hospitalization (OPRAH) intervention. Following the Medical Research Council (MRC) framework for developing and evaluating complex interventions, it is essential to evaluate the usability and feasibility

of the OPRAH intervention prior to conducting a randomized controlled trial (RCT). [27] In addition, as these patients undergo an extensive postoperative care pathway, it is important to evaluate the feasibility of the study procedures within this pathway. The results will guide improvements for the definitive RCT.

The study objectives were (1) to determine the feasibility of the OPRAH intervention (i.e. adherence to the intervention, intervention acceptability and safety) and (2) to determine the feasibility of study procedures.

Materials and methods

Design

This feasibility study was conducted as a non-randomized, single-institution, prospective, one-arm intervention study at Amsterdam UMC, location VUmc, from September 2021 to April 2022. The hospital was chosen for the study due to its status as one of the largest oncology surgery centers in the Netherlands, and the planned randomized controlled trial (RCT) will also take place at this location. Baseline measurements (T0) were conducted prior to surgery and follow-up measurements took place at one week (T1) and six weeks (T2) after hospital discharge. The study was approved by the Medical Research Ethics Committee of the Amsterdam University Medical Centre, Location VU medical Centre (VUmc) (registration number 2021.0112). All patients provided written informed consent. The extension of CONSORT 2010 checklist specifically for pilot and feasibility trials was used for reporting of the study. [28] The corresponding checklist can be found in Appendix 1.

Participants

Patients were eligible to participate if they were scheduled for oncologic GI or lung cancer surgery at Amsterdam UMC (location VUmc), were 18 years of age or older, the surgery had a curative intent, there was an indication for postoperative hospital stay ≥ 2 nights, and they were able to complete online questionnaires in Dutch and provide informed consent. Exclusion criteria were: wedge excision lung, surgery with open/close procedure, no access to a mobile device compatible for applications, less than 5 days between inclusion and surgery, patients who were wheelchair dependent, Mini-Mental State Examination (MMSE) ≤ 24 and already participating in a conflicting study.

Recruitment

Potentially eligible patients were informed about the study by the treating dietician, physiotherapist or nurse specialist during a preoperative consultation. If the patient was interested in participating, the researcher contacted the patient after 24 hours to

further explain the study procedures and answer the patient's questions. If the patient was eligible and willing to participate, the baseline measurements were scheduled. The informed consent letter was signed before the start of the baseline measurements. In case there were doubts about the patients' cognition, the Mini Mental State Examination (MMSE) was administered before the baseline measurements. The patient received a copy of the signed informed consent.

OPRAH Intervention

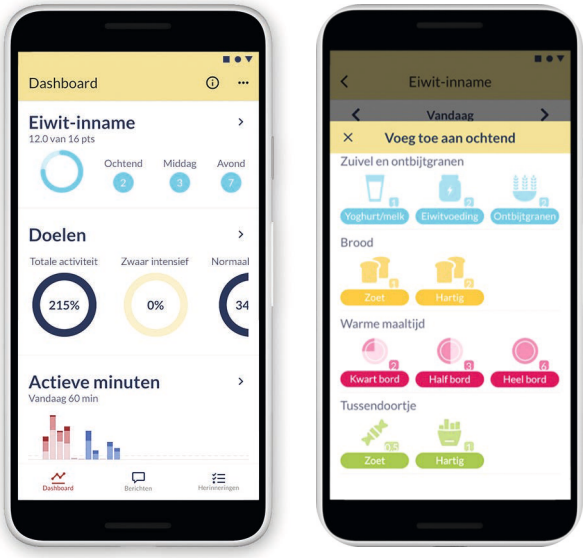
The intervention consisted of the use of the Atris app (Peercode B.V. Geldermalsen, the Netherlands) in combination with remote coaching by a physiotherapist and dietician from Amsterdam UMC (location VUmc), during 6 weeks after hospital discharge. A description of the intervention was written according to the Tidier checklist and is presented in Appendix 2. The following behaviour change techniques were used to develop the intervention: goal setting, problem solving, action planning, review of behaviour goals, discrepancy between current behaviour and goal, feedback on behaviour, self-monitoring of behaviour, social support, instructions on how to perform the behaviour, prompts and cues, graded tasks, social reward, social incentive and adding objects to the environment. [29]

The Atris app was used to self-monitor physical activity and protein intake. In combination with the Physical Activity Monitor (PAM) AM400 three-axis accelerometer (PAM B.V. Doorwerth, the Netherlands), the Atris app allowed patients to self-monitor their daily physical activity. In addition, patients were able to self-monitor their protein intake by using an in-app self-registration system. This self-registration system is based on a validated method developed by the Dutch Committee on Malnutrition. [30] It uses a point system to provide an overall estimate of protein intake. See Figure 1 for screenshots of the app and Appendix 3 for a corresponding subscript for the screenshots. Physical activity was represented in active minutes per day, with a distinction made between low (1.4–2.99 metabolic equivalents of energy expenditure (METs)), moderate (3-7 METs) and vigorous activity (>7 METs). The protein intake was expressed in points, with 1 point representing approximately 5 grams of protein. The Atris app provided feedback on progress towards their goals. In addition, patients could ask questions through the app's chat feature and receive answers and information from the physiotherapist or dietician. Through the corresponding Atris backend website, the physiotherapist and dietician could interactively view patient data, send messages to the patient and could access Atris (triggers) through the patient monitor.

Approximately one week before surgery, patients received the PAM and were given access to and instructions about the Atris app to familiarize themselves with the application.

Patients were instructed by means of a flyer and a telephone consultation with a researcher. Patients were asked to wear the PAM in a strap around their ankle, from at least 5 days prior to surgery until six weeks after surgery. During hospitalization, the treating physiotherapist and dietician guided the patients in the use of the app during their standard consultations. As discharge approached, the physiotherapist and dietician together with the patient set goals on active minutes and protein intake for after discharge. After discharge to home, patients were coached remotely (by telephone and chat) by a physiotherapist and dietician about their physical activity and protein intake. The goals and intensity of the coaching were based on personal needs and recovery progress. Initiative for contact between the patient and the physiotherapist or dietician may originate from either party. The physiotherapist or dietician could contact the patient if, for example, goals had not been met for several days. Alternatively, the patient could send a message to the physiotherapist or dietician via de the app with any question or problem related to physical activity or nutritional intake. The physiotherapist and dietician aimed to respond to the patients messages within two working days. In addition, as part of usual care, the dietician has standard scheduled postoperative telephonic consultations with patients after oesophagus, stomach and pancreas cancer surgery at two and four weeks after hospital discharge.

Figure 1. *Screenshots of the Atris app.*



Two screenshots of the Atris app, the first screen provides an overview of the dashboard of the app. The second screen shows the tool to record the protein intake.

Outcome measures

Feasibility of the study procedures

Participation rate was defined as the percentage of invited potentially eligible patients who were willing to participate in the study. A percentage of 70% was considered feasible. [24] Completion rate was defined as the proportion of consenting patients who completed follow-up assessments. A completion rate of 70% was considered feasible. [31]

Feasibility of the OPRAH intervention

Adherence to the intervention was defined as the percentage of days PAM data was available and the percentage of days the protein intake was registered in the app. An adherence of 80% was considered feasible. In addition, the mean course in recovery of physical activity measured with the PAM was measured. The percentage of physical activity and protein intake goals achieved during the intervention period were also measured. To obtain information on the fidelity of the coaching component of the intervention, the number of telephone consultations with the physiotherapist and dietician was recorded. The number of chat messages from the physiotherapist, dieticians and patients was also collected.

The usability of the Atris app was assessed with the System Usability Scale (SUS); a validated questionnaire including ten statements regarding the usability of an electronic device or system that patients can rate on a 5-point Likert scale. [32, 33] A SUS score higher than 70% was considered feasible. Acceptability was assessed with additional questionnaires about their general impressions and the added value of using the app. In addition, patients were asked whether they would recommend the Atris app to other patients who are scheduled for surgery. The SUS and additional questions were administered via the digital platform OnlinePROMS (appendix 4). Also, patients were asked to share their experiences through a telephone evaluation at the end of the intervention period. Experiences of the physiotherapists and dieticians were obtained through feedback gained during the evaluation sessions about the intervention. The physiotherapists and dietician provided oral informed consent to share their experiences. A narrative summary was written about the experiences of patients, physiotherapists and dieticians.

Study and intervention safety were monitored by examining Serious Adverse Events (SAE's) and Adverse Events (AE) related to the intervention. Adverse events were defined as any undesirable experience occurring to a subject during the study, whether or not considered related to experimental intervention. All adverse events with a direct or possible link to the intervention (e.g. AE's occurring during intervention related activities) reported spontaneously by the subject or observed by the investigator or his staff were

recorded. No intervention-related SAE's must have occurred for the intervention to be considered feasible.

Data collection and course of functional recovery up to six weeks after hospital discharge

Participants were asked to wear the ActivPAL accelerometer for 5 days at the baseline and follow-up measurements to investigate if it is feasible to use the ActivPAL as one of the main outcome measures in the planned RCT. The response rates at all follow-up measurements and the compliance with wearing the ActivPAL was investigated. The response rates were considered good if more than 80% of the data is available at each measurement. The compliance of wearing the ActivPAL was good if more than 80% of the patients had at least 3 valid days of the ActivPAL during each measurement. The most important outcome was patient reported physical functioning, measured with the Computer Adaptive Testing Dutch-Flemish Patient Reported Outcome Measure Information System for Physical Functioning (CAT PROMIS-PF). The CAT PROMIS PF measures a person's ability to perform activities requiring physical action, ranging from general daily activities to more complex activities requiring a combination of skills. The most important secondary outcomes were physical activity and protein intake. Other secondary outcomes were lean body mass, pain, fatigue, physical performance, self-efficacy, participation in social roles and activities, generic quality of life, global perceived effect, hospital readmission and adverse events. See Table 1 for a detailed description of the outcome measures with the corresponding follow-up time points.

Table 1. *Outcome measures.*

Construct	Measure	Abbrev.	description	Time points
Primary outcome				
Physical functioning	Computer Adaptive Testing (CAT) Dutch-Flemish Patient Reported Outcome Measure Information System for Physical Functioning	CAT PROMIS-PF	The CAT PROMIS-PF is a digital questionnaire. [34] A CAT is a computer-administered measure in which a computer algorithm is used to select successive items based on responses to previous items. Using a 5-point Likert scale the questionnaire reflects the participant' functioning in the past 7 days. The items cover a wide range of activities, from activities of daily living to more complex activities [35]. The CAT PROMIS-PF has sufficient psychometric properties in measuring the level of physical function of physiotherapy patients [36] and has been shown to be reliable and sensitive to change in surgical patients. [37, 38]	T0, T1, T2
Most important secondary outcomes				
Physical activity	ActivPAL™		The ActivPAL (PAL Technologies Ltd., Glasgow, UK) is a thigh-worn tri-axial accelerometer and uses proprietary analysis algorithms to determine posture (sedentary time, upright time) and stepping (stepping time and steps). The Activpal will be affixed to the skin with hydrogel pads on the thigh. The ActivPAL is one of the most frequently used activity trackers in clinical research and has been shown to be a valid measure of posture and stepping. [39-41] Patients in both the intervention and control group will wear the ActivPAL for 5 days.	T0, T1, T2
Protein and energy intake	48-h dietary recall		A 48-h dietary recall will be performed by trained interviewers, dietician researchers or graduate students, following a standard protocol. The intake of food items will be registered, including details of preparation methods, recipes, quantities and the size of portions, and the brands of products. The calculation of total energy intake and protein intake will be based on the database of 'The Netherlands Nutrition Centre'. Protein intake will be calculated in gram per day. Energy intake will be calculated in kcal per day. Earlier studies suggested that a 48-h recall is superior to a single 24-h recall. [42, 43]	T0, T1, T2

Table 1. *Continued*

Construct	Measure	Abbrev.	description	Time points
Other secondary outcomes				
Lean body mass	Bioelectrical Impedance Analysis	BIA	A single frequency bio electric impedance meter (50kHz) will be used for the BIA. These impedance meters uses 4 electrodes to measures the impedance, resistance, reactance and phase angle. A BIA is a non-invasive validated method to assess body composition, fat-free mass (FFM) and appendicular skeletal muscle mass (ASSM) patients with cancer. [44] FFM is one of the factors the dietician uses to determine patients' personal protein requirements. FFM will be measured with the formula of Kyle [45]	T0, T2
Physical performance	1) Hand grip strength 2) 30 second chair stand test 3) 2 minute step test	1) - 2) 30SCST 3) TMST	1) Handgrip strength will be measured using the Jamar grip strength dynamometer as a measure of generalized muscle strength. The Jamar grip strength shows good reliability and can be used to measure changes in strength over time. [46, 47] The normative data of Dodds. et al will be used as reference. [48] 2) The 30SCST will be used to measure functional lower extremity muscle functioning. The 30CST measures extremity strength in relation to demanding functional daily activities such as stair climbing. [49] The patient is seated in a chair and will be asked to complete as many full stands as possible in 30 seconds. The 30CST shows good reliability and criterion validity.[50] 3) The TMST will be used to measure exercise capacity. [51] The test requires the patients to march in place as fast as possible for 2 minutes while lifting the knees to a height midway between their patella and iliac crest when standing. Performance is defined as the number of steps completed in 2 minutes. These performance tests are easy to perform at the patient's home. The physical performance tests will be performed by trained (student) allied healthcare professionals. Standard operating procedures will be used for all tests. [52]	T0, T2

Table 1. *Continued*

Construct	Measure	Abbrev.	description	Time points
Pain	Numeric Pain Rating Scale	NPRS	The NPRS is a measure of subjective intensity of pain in adult patients. The 11-point numeric scale ranges from '0' (no pain) to '10' (worst pain imaginable). The NPRS is a valid, reliable and usual tool to measure pain in postoperative patients. [53, 54]	T0, T1, T2
Fatigue	Dutch-Flemish Patient Reported Outcome Measure Information System for Fatigue – Short Form	PROMIS F-SF	The PROMIS F-SF consists of seven items that measure both the experience of fatigue and the interference of fatigue on daily activities over the past week. The response scale is a 5-point Likert scale, ranging from 1 (never) to 5 (always). Total scores range from 7 to 35: a higher score indicating greater fatigue. The PROMIS F-SF showed acceptable reliability and validity and is suitable to measure fatigue across a diverse clinical population. [55]	T0, T1, T2
Participation in social roles and activities	CAT Dutch-Flemish Patient Reported Outcome Measure Information System for participation	CAT PROMIS participation	the CAT PROMIS participation item bank including the item banks 'Ability to participate in Social Roles and Activities' and 'Satisfaction with Social Roles and Activities'. The response scale is a 5-point Likert scale; a higher score indicates better participation. The CAT PROMIS item bank is an reliable and valid measurement of participation with limited administration time. [56]	T0, T1, T2
Self-efficacy	General self-efficacy scale	GSES	The questionnaire contains 10 items with a 4-point response scale (1=completely wrong, 4 = completely true). Total scores range from 10 to 40: a higher score indicating more self-efficacy. The GSES Is a valid tool to measure self-efficacy. [57]	T0, T1, T2
Global perceived effect	Global Perceived Effect questionnaire	GPE	The Dutch version of the GPE will be used to measure the patients opinion of their recovery. [58] The questionnaire consists of two questions with a 7 point Likert scale. Patients will be asked to indicate to which extent they are recovered since the beginning of their recovery after surgery (1 = much better, 7 = much worse). In addition, patients will be asked how satisfied they are with their treatment since the beginning of their recovery after surgery (1=very satisfied, 7 = very unsatisfied).	T0, T1, T2

Table 1. *Continued*

Construct	Measure	Abbrev.	description	Time points
Generic Quality of Life	The 5-level EuroQol five-demensional questionnaire	EQ-5D-5L	This EQ-5D-5L consists of five questions representing five health dimensions; mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The EQ-5D-5L is added in order to carry out cost-effectiveness analysis. The EQ-5D-5L shows good psychometric properties and is suitable for economic evaluation studies in oncological patients. [59]	T0, T1, T2
Hospital readmission	Medical Record Data		Unplanned *hospital readmissions* within 30 days after discharge will be reported.	T3
Adverse event	Medical record data and self-reported		All adverse events with a direct or possible link to the OPRAH trial (e.g. AE's occurring during intervention related activities) reported spontaneously by the subject or observed by the investigator or his staff will be recorded. This study will include patients undergoing oncological lung or GI surgery. These types of surgery are associated with a certain risk of postoperative complications. Our intervention starts after hospital discharge, therefore, all complications during hospitalization will not be reported as SAE. We expect that our, low risk, post-discharge intervention will not have any negative influence on the occurrence complications after discharge. Therefore, all complications after discharge which are unmistakably caused by the surgery and/or medical treatment will not be reported as SAE. When there are doubts about the relation between the intervention and the occurrence of an SAE, these SAE's will be discussed with the surgeons involved in this study.	T1, T2
Other study parameters				
Patient characteristics	Self-reported and Medical Record Data		age (years), gender (male/female), Body Mass Index (BMI), marital status (living together/alone), comorbidities, The American Society of Anaesthesiologists Classification of physical health (ASA classification), Tumour location (lung, upper GI, HPB, colorectal), stage of cancer (1-4), unintentional weight loss (% over de last 6 months), nutritional intake (% of nutritional requirements).	T0

Table 1. *Continued*

Construct	Measure	Abbrev.	description	Time points
Perioperative characteristics	Medical Record Data		Operation technique (open/laparoscopic), pre- or post-treatment with chemotherapy or radiotherapy, length of hospital stay (days) and complications.	T1
Self-management Skills	Self-Management Screening tool	SeMaS	The SeMaS is a short tool that can signal potential barriers for self-management that need to be addressed in the dialogue with the patients and can facilitate personalized counselling. The following items of the SeMaS will be measured: level of education, experienced burden of disease, digital skills, locus of control, self-efficacy, social support, coping style, anxiety and depression. Based on the outcome factors of the SeMaS tool, the physiotherapist will give specific advice to the patients for the tailored intervention. The SeMaS is validated in patients with chronic condition in primary care. [60] However, this tool contains patient characteristics that are generally important in self-management and the questionnaire is not specific to a particular condition.	T0

T0 = baseline (pre-operative), T1= one week after discharge, T2 = six weeks after hospital discharge

Statistical analysis

A sample size of at least 30 participants was required to evaluate feasibility goals. [61] The Statistical package for the Social Sciences (SPSS version 26) was used for the data analysis. Study population characteristics were presented descriptively by mean (SD), median (IQR) and percentage.

To determine the feasibility of the OPRAH intervention, the adherence to the intervention was presented in percentage of available physical activity and protein data, recorded with the Atris app, from hospital discharge until six weeks after discharge. The total mean (SD) SUS was calculated following the method of Brooke. [33] The additional questions about the user experiences were presented by percentages. Qualitative experiences from the patients, physiotherapists and dietician were narratively described. To determine the feasibility of study procedures for an RCT the participation rate, completion rate and adherence rate were shown by percentages. For each outcome measure, the percentages of complete data were presented. To investigate the course of recovery in

physical functioning, physical activity and protein intake during the first six weeks after hospital discharge, differences in baseline outcomes and one and six weeks after hospital discharge were determined using a paired samples t-test or a Wilcoxon matched-pairs signed rank test in case of skewed date.

Results

Feasibility of the study procedures

A total of 81 potentially eligible patients were invited to participate between September 2021 and January 2022. Of these patients, 31% were not interested in participating, resulting in a participation rate of 69%. Of the remaining 56 patients, 24 (42%) were not eligible to participate in this study. The reasons are shown in the flow chart, Figure 2. Finally, 32 patients were included in this study. After enrolment, eight patients withdrew from the study for various reasons. Reasons for withdrawal are presented in Figure 2. A total of 24 patients completed the intervention period and follow-up measurements, which resulted in a completion rate of 75%.

The mean age of patients in this study was 63 years (SD 9.1) and 55.2% (16/29) were male. The different tumour locations were lung (31%), oesophagus (31%), pancreas (31%), stomach (3.4%) and colorectal (3.4%). The median (IQR) length of hospital stay in days was 6 (4). Of all patients, 51.7% (15/29) had comorbidities. The most common comorbidities were Diabetes mellitus type 2 (20.7%), COPD (13.8%) and cardiovascular diseases (13.8%). Other relevant and clinical data are presented in Table 2.

Feasibility of the intervention

User adherence

The mean percentage of PAM data available from discharge until six weeks after hospital discharge was 91%. The most common reason for missing data of the PAM were technical problems with the sensor, i.e. low batteries or disconnection with the app. The mean percentage of protein available was 59%. One patient did not use the protein self-registration tool because their entire intake consisted of tube feeding. Seven patients did not register their protein intake during the intervention period. The reasons for this can be attributed to two primary factors. First, patients omitted entries because they forgot to log their protein intake using the application. Second, patients consciously chose not to do so. The main reason for patients' reluctance to enter their intake was the fact that they felt they were unable to provide sufficiently detailed information on individual foods, which led them to consider the activity valueless. Therefore, the user adherence to the

PAM is deemed satisfactory, while the user adherence to protein intake is evaluated as suboptimal.

Figure 2. *Flow of participants through the study.*

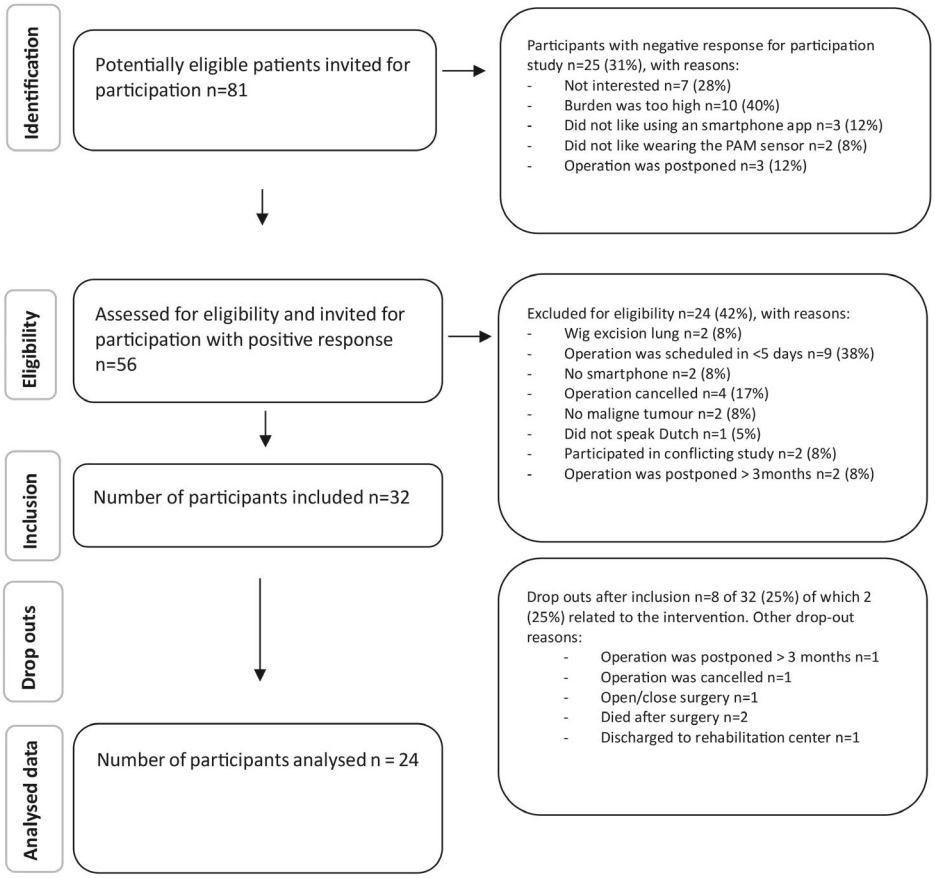


Table 2. *Patient and perioperative characteristics.*

	Variable	Results
Patient characteristics	**Sex (male), n (%)**	16 (55.2%)
	Age (years), mean ± SD	63 ± 9.1
	BMI, mean ± SD	27.1 ± 3.8
	Tumour location, n (%)	
	Lung	9 (31.0%)
	Oesophagus	9 (31.0%)
	Pancreas	9 (31.0%)
	Stomach	1 (3.4%)
	Colorectal	1 (3.4%)
	Tumour size, n (%)	
	0	6 (20.7%)
	1	5 (17.2%)
	2	3 (10.3%)
	3	12 (41.4%)
	4	2 (6.9%)
	ASA classification, n (%)	
	1	1 (3.4%)
	2	18 (62.1%)
	3	10 (34.5%)
	Comorbidities, n (%)	
	No comorbidities	14 (48.3%)
	Diabetes mellitus type 2	6 (20.7%)
	COPD	4 (13.8%)
	Cardiovascular disease	4 (13.8%)
	Renal insufficiency	2 (6.9%)
	Rheumatism	2 (6.9%)
	Multiple sclerosis	1 (3.4%)
	N. Waldenström	1 (3.4%)
	Hypothyroidism	1 (3.4%)
Perioperative characteristics	**Type of surgery, n (%)**	
	Laparoscopic	21 (72.4%)
	Open	8 (27.6%)
	Length of hospital stay (days), median (IQR)	6 (4)
	Complications n (%)	12 (41.4%)
	Hospital readmission n (%)	4 (13.8%)
	Tube feeding pre-operative	2 (6.3%)
	Tube feeding until 6 weeks post-discharge	8 (29.6%)

ASA = The American Society of Anesthesiologists Classification of physical health; BMI = body mass index; COPD = chronic obstructive pulmonary disease;

In figure 3 an example of the course of recovery in physical activity of a random patient from one week prior to surgery until six weeks after surgery is presented. This data was measured with the PAM and visible for the patient via the app and for the physiotherapist

via the corresponding dashboard. At hospital discharge, a goal was discussed with the patient (red dotted line) and was adjusted during the follow-up period. In this specific case, the patient's physical activity level was higher than before surgery. However, for the majority of patients, pre-operative physical activity levels were not reached at six weeks after surgery, as shown in figure 4. This figure present the mean (SD) course of physical activity of all patients measured with the PAM from one week prior to surgery until six weeks after surgery. Table 3 presents the mean number of activity goals that were set during the intervention period, the percentage of these goals achieved, and the mean percentage of the protein target reached.

Of the 24 patients who completed the intervention period, 19 (79 %) had telephone consultations with a physiotherapist. The mean number (range) of telephone consultations was 2 (0 – 3). All patients were in contact with the physiotherapist via the chat. The mean number (range) of chat messages sent by physiotherapists was 5 (2 – 13).

The number of patients who had a telephone consultation with a dietician was 19 (79%), of which in 15 patients this was part of usual care. In three cases, telephone contact was made earlier than usual care due to a question in the chat or referral from the physiotherapist. Eight patients received chat messages from a dietician (33%), with a mean (range) of 2 (1 – 4). Four patients had no contact with the dietician during the intervention period.

Figure 3. *Course of recovery in physical activity of a random patient. The light colour represents low intensity physical activity and the darker colour represents medium intensity physical activity. The red dotted line represents the activity goal.*

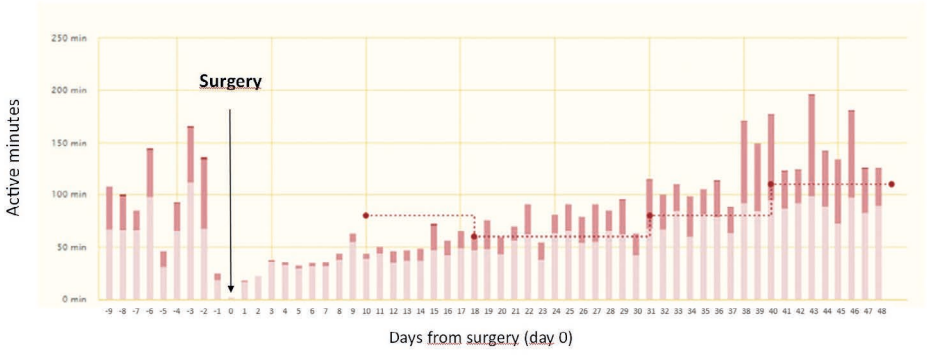


Figure 4. *Mean (SD) course of recovery in physical activity measured with the PAM. The course in mean active minutes per day from one week before surgery to six weeks after hospital discharge, measured with a physical activity monitor.*

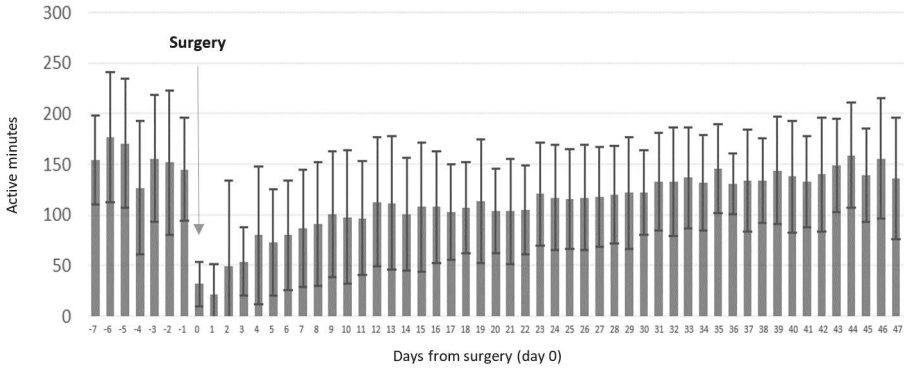


Table 3. *Goals on physical activity and protein intake.*

	Mean	Min – Max
Physical activity (N=24)		
Number of goals	2.5	1 – 4
Percentage of goals reached	94 %	50% - 100%
Protein intake (N=16)	**Number of patients (%)**	
0-50% of protein target reached	2 (12.5%)	
50-75% of protein target reached	5 (31%)	
75-125% of protein target reached	7 (44%)	
>125% of protein target reached	2 (12.5%)	

System usability and additional questions

The evaluation questionnaire was sent to 24 patients. Three patients did not respond, resulting in 21 completed questionnaires. The system usability was acceptable with a mean SUS of 73.5 (SD 19.3). The efficiency and learnability of the Atris app was acceptable (SUS 77.8 and 76.6 respectively), while satisfaction was moderate (67.9). Of all responding patients, 81% stated that the Atris app had motivated them to improve their physical activity and 61.9% stated that the Atris app stimulated them to improve their daily protein intake. The majority of patients (66.9%) stated that the Atris app had added value to their recovery. Almost all patients (95%) recommend using the Atris app to other patients after surgery.

Patients' experiences

A total of 19 patients were interviewed about their experiences. Patients mentioned that the Atris app was easy to use. It motivated them to be more physically active when they did not reach their daily goal. They mentioned that it gave them insight into their recovery

by visualizing the progression of physical activity over time. The protein tool made them aware of the importance of protein intake alongside exercise and they mentioned that it was useful to see if protein intake was sufficient. They also indicated it was very helpful to be able to contact the physiotherapist and dietician via the app's chat function. A point for improvement is that the connection between the PAM sensor and the app sometimes did not work, which caused some inconvenience. Some patients also mentioned that there were insufficient options in the protein registration tool, which gave them the feeling that they were unable to provide sufficiently detailed information about individual foods.

Experiences of physiotherapists and dieticians

The intervention was delivered by three physiotherapists and three dieticians. A total of three evaluation sessions were organized in which they all gave feedback on the intervention. The physiotherapists appreciated the added value of being able to monitor the patient remotely, as this is not possible in usual care. They also mentioned that goal setting motivated patients to be more physically active. Both the physiotherapists and dietician mentioned that the Atris dashboard was easy to use. They also mentioned that through the use of the OPRAH intervention, there was an improved collaboration between the physiotherapist and dietician, but both indicated that there should be even more focus on the synergy between protein intake and physical activity.

Similar to the patients, the dieticians also indicated that there are too few categories in the app's protein tool. They mentioned that there should be more instructions for the patients about the use of the protein tool. Finally, both physiotherapists and dietician mentioned that it was not visible in the dashboard whether a notification was addressed to the physiotherapist or the dietician. They mentioned that this would be a good improvement to the dashboard.

Study and intervention safety

The study and intervention are considered safe, because no intervention or study related AE's or SAE's have occurred during the study period.

Feasibility of the data collection

In table 4 the percentages of complete data per outcome measure are described. The most important outcome measure, physical functioning, was 100% complete at baseline and 92% at follow-up. At baseline and T2 the compliance with wearing the ActivPAL was good, as the percentage of complete data was respectively 81% and 85%. At T1, compliance was moderate (69%). Reasons for missing ActivPAL data are presented in Table 4.

Table 4. *Completion rate of outcome measurements.*

Outcome	Baseline N=32	T1 N=26	T2 N=26
Physical functioning	32/32 (100%)	24/26 (92%)	24/26 (92%)
Physical activity	26/32 (81%) Missings: - Technical problems (n=3) - Sensor lost (n=2) - Empty battery (n=1)	18/26 (69%) Missings: - Sensor lost (n=4) - Technical problems (n=2) - Forgot to put it on (n=1) - Hospital readmission (n=1)	22/26 (85%) Missings: - Lost to follow up (n=2) - Technical problems (n=1) - Forgot to put it on (n=1)
Protein intake	25/32 (78%)	23/26 (88%)	23/26 (88%)
Lean body mass	27/32 (84%)	NA	21/26 (81%)
Hand grip strength	27/32 (84%)	NA	23/26 (88%)
Physical performance	27/32 (84%)	NA	23/26 (88%)
Participation (capability)	32/32 (100%)	24/26 (92%)	23/26 (88%)
Participation (satisfaction)	32/32 (100%)	24/26 (92%)	23/26 (88%)
Fatigue	32/32 (100%)	24/26 (92%)	23/26 (88%)
Pain	32/32 (100%)	24/26 (92%)	23/26 (88%)
Self-efficacy	32/32 (100%)	24/26 (92%)	23/26 (88%)
Global Perceived Effect	NA	24/26 (92%)	23/26 (88%)
Quality of life	32/32 (100%)	24/26 (92%)	23/26 (88%)

Course of functional recovery up to six weeks after hospital discharge

Results of the outcome measures at baseline and at one and six week after hospital discharge are presented in Table 5. The mean difference in physical functioning between baseline and one week after discharge was -13.1 with a 95% Confidence Interval (CI) ranging from -15.9 to -10.2. The mean difference (95% CI) between one and six weeks after hospital discharge was 10.1 (8.0; 12.1). Four patients (17%) were back at their baseline levels of physical functioning at six weeks after hospital discharge. For physical activity, the mean difference (95% CI) in total active minutes a day between baseline and one week after hospital discharge was -41.2 (-52.7; -29.8). The mean difference (95% CI) between one and six weeks after hospital discharge was 30.9 (21.5; 40.4). The mean difference in protein intake per kg Fat Free Mass (FFM) increased with 0.19g (95%CI from -0.1 to 0.5) between baseline and one week after hospital discharge. Between one and six weeks after hospital discharge, the mean difference (95%CI) decreased by 0.11g (-0.37;0.15).

Table 5. *Outcome measures.*

Outcome		Baseline mean (SD)	Mean at 1 weeks after hospital discharge (SD)	Mean at 6 weeks after hospital discharge (SD)
Physical functioning		46.25 (7.09) (N=32)	33.56 (6.40) (N=24)	43.43 (7.36) N=24
Physical activity (active minutes per day)		94.15 (33.07) N=27	44.88 (23.34) N=19	80.82 (26.66) N=22
Protein intake (g per kg FFM)		1.7 (0.5) N=23	1.9 (0.5) N=21	1.8 (0.4) N=21
Lean body mass index	Low Average Good Missing	6 (19%) 13 (40%) 7 (22%) 6 (19%)	N.A.	6 (25%) 9 (38%) 6 (25%) 3 (12%)
Hand grip strength (kg)		39 (12)	N.A.	36 (10)
Physical performance TMST 30secCST		 78 (23) 13 (3)	 N.A. N.A.	 74 (24) 13 (4)
Participation (capability)		51.45 (11.15)	41.78(7.32)	45.99 (7.95)
Participation (satisfaction)		50.62 (11.43)	40.38 (5.86)	47.53 (13.05)
Fatigue		49.53 (10.27)	60.17 (8.19)	53.97 (7.22)
Pain		1.48 (1.99)	5.29 (2.18)	2.00 (1.83)
Self-efficacy		32.59 (5.29)	29.42 (5.91)	31.70 (4.67)
GPE		N.A.	3.13 (1.15)	2.61 (1.03)
Quality of life		0.84 (0.17)	0.64 (0.23)	0.79 (0.13)

Discussion

Based on the results of this feasibility study, the OPRAH intervention, combining a smartphone app for self-monitoring of physical activity and protein intake with coaching from a physiotherapist and dietician, is deemed feasible for implementation in a larger RCT in patients following GI or lung cancer surgery. Patients were predominantly positive about the intervention, and physiotherapists and dieticians mentioned that monitoring the patient was of added value. To improve user adherence to reporting protein intake, modifications to the app are required. The study procedures are feasible; however, the sample size for the RCT should be increased to allow for a higher drop-out rate. Most patients did not return to pre-operative levels at six weeks after hospital discharge. However, since there was a substantial increase in physical activity and most patients achieved their protein requirements, extending the duration of the intervention and follow-up may prove beneficial in enhancing functioning recovery.

To our knowledge, a few studies have combined self-monitoring of physical activity and protein intake in interventions after oncological surgery. A study by van der Linden et al (2022) assessed the feasibility of personal devices for monitoring physical activity and nutritional intake after colorectal cancer surgery. [62] However, this study used separate apps for both physical activity and nutritional intake, potentially increasing complexity for the patient. User compliance with recording nutritional intake was similar to our results (54%). In contrast, the available postoperative data from the activity tracker was much less (50%). Patients reported that recording their nutritional intake was time-consuming and complex. Our self-registration tool for protein intake has fewer options, making it less time-consuming and complex. However, in our study patients were reluctant to record their intake because they felt unable to provide sufficient information on individual foods. The challenge is to find the optimal number of options in terms of complexity and the time required to register protein intake. Therefore, changes have been made to the protein intake section of the app to improve compliance. First, based on patient feedback, the number of protein intake options in the app has been expanded, allowing patients to better record their products and experience more added value. Second, to better inform and guide patients in their dietary choices, the amount of information available on protein intake has been expanded. This includes a flyer with information on the importance of protein intake and more explanation on which products fall under which categories in the self-registration tool in the app. Patient adherence to wearing the PAM was high, with 91% available data. To minimize data loss due to low batteries, a newer version of the PAM will be utilized in the RCT, which allows for battery replacement. This feature was not available in the PAM used in this feasibility trial.

Based on our results, the study procedures seem feasible for conducting a larger RCT. However, the drop-out rate is relatively high. Most reasons for dropout are difficult to avoid, such as patient death, cancelled operations or discharge to a rehabilitation centre. This is also observed in other studies involving patients with cancer. [63] To ensure sufficient statistical power, the sample size for the RCT should be increased to allow for a higher drop-out rate.

To prevent muscle mass loss, patients with cancer should consume 1.5-1.9 g/kg FFM/day, as recommended by the ESPEN guideline. [64] This is particularly important before and after surgery, as surgery can increase muscle mass loss, which is associated with higher mortality and tumour recurrence. [65] Unlike other observational studies in patients with cancer, the majority of patients in our study met this guideline, as the mean protein intake at one and six weeks after hospital discharge was 1.9 g/kg FFM/day and 1.8 g/kg FFM/day, respectively. [66, 67] This could be attributed to the fact that 29% of the

patients were supported by post-operative tube feeding until six weeks after hospital discharge. Additionally, patients were encouraged to increase their protein intake through self-monitoring, which could have contributed to these results. However, to examine the effect of our intervention on these outcomes, an RCT must be conducted. The duration of the intervention in our RCT will be 3 months after discharge, rather than 6 weeks, because the majority of patients have not yet recovered to their pre-operative level of physical functioning and most patients feel that the intervention should have lasted longer than the first six weeks after discharge from the hospital. Our study protocol describes the final intervention and study procedures for the RCT. [68]

A strength of the OPRAH intervention is the combination of self-monitoring of both physical activity and protein intake, contributing to the important synergy between protein intake and physical activity to minimise muscle mass loss. In addition, this study monitored patients from before surgery until six weeks after hospital discharge, allowing return to preoperative levels to be investigated. This study also has limitations. First, there was a risk of selection bias, as only Dutch speaking patients who were familiar with and open to using smartphone apps were likely to participate in this study. Also, patients who did not consider nutrition and exercise important were less likely to participate in this study, even though this is an important group to reach. Combined with the fact that this is a single-institution study, restricts the generalizability of the findings. To improve the generalizability, the planned RCT will be multi-centre. Second, the results are preliminary and limited to usability and acceptability due to a limited sample size and the lack of a control group. Third, the data collection and analysis of the experiences of patients, physiotherapists and dieticians lacked robustness. Despite this limitation, the insights gathered were considered valuable and were, therefore, included in the results. A more rigorous approach will be ensured for the planned RCT. Also important to note is that patients may experience symptoms due to their surgery that negatively affect their ability to increase their physical activity or protein intake, such as pain, fever or difficulty swallowing. These symptoms may result in a delay in recovery of physical activity and protein intake while they cannot directly be influenced by coaching from a physiotherapist or dietician. Discussing symptoms that hinder recovery with the medical doctor or specialized nurse may lead to timely measures to prevent serious adverse events.

In conclusion, this study suggests that self-monitoring of physical activity and protein intake, in combination with remote coaching by a healthcare professional, is feasible in patients after oncological surgery. However, adjustments to the protein self-registration tool are needed to improve user adherence. When conducting an RCT, the sample size must take into account a higher drop-out rate. To improve the generalizability of the

results, the RCT will be multi-centre. Other study procedures were feasible. Preliminary outcome measures show an increase in physical activity after hospital discharge. In addition, the majority of patients consumed the daily recommended amount of protein, according to the ESPEN guideline. To investigate whether these results are due to the OPRAH intervention, an RCT will be conducted.

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Declaration of interest statement

The authors declare that they have no competing interests.

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Supplementary Files

Appendix 1: CONSORT 2010 checklist



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Appendix 2: Intervention description and replication



Scan QR code

Appendix 3: Subscript screenshots Figure 1



Scan QR code

Appendix 4: Questionnaire



Scan QR code



Chapter 5

The efficacy of a blended intervention to improve physical activity and protein intake for optimal physical recovery after oncological gastrointestinal and lung cancer surgery, the Optimal Physical Recovery After Hospitalization (OPRAH) trial: study protocol for a randomized controlled multicenter trial

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Abstract

Background: Improving physical activity, especially in combination with optimizing protein intake, after surgery has a potential positive effect on recovery of physical functioning in patients after gastrointestinal and lung cancer surgery. The aim of this randomized controlled trial is to evaluate the efficacy of a blended intervention to improve physical activity and protein intake after hospital discharge on recovery of physical functioning in these patients.

Methods: In this multicenter single-blinded randomized controlled trial, 161 adult patients scheduled for elective gastrointestinal or lung cancer surgery will be randomly assigned to the intervention or control group. The purpose of the Optimal Physical Recovery After Hospitalization (OPRAH) intervention is to encourage self-management of patients in their functional recovery, by using a smartphone application and corresponding accelerometer in combination with coaching by a physiotherapist and dietician during three months after hospital discharge. Study outcomes will be measured prior to surgery (baseline) and one, four, eight, and twelve weeks and six months after hospital discharge. The primary outcome is recovery in physical functioning six months after surgery, and the most important secondary outcome is physical activity. Other outcomes include lean body mass, muscle mass, protein intake, symptoms, physical performance, self-reported limitations in activities and participation, self-efficacy, hospital readmissions and adverse events.

Discussion: The results of this study will demonstrate whether a blended intervention to support patients increasing their level of physical activity and protein intake after hospital discharge improves recovery in physical functioning in patients after gastrointestinal and lung cancer surgery.

Trial registration: The trial has been registered at the International Clinical Trials Registry Platform at 14-10-2021 with registration number NL9793. Trial registration data are presented in table 1.

Key words: cancer, surgery, supportive care, physical functioning, physical activity, protein intake

Table 1. *Trial registration data set.*

Data category	Information
Primary registry and trial identifying number	International Clinical Trials Registry Platform NL9793
Date of registration in primary registry	14 October, 2021
Secondary identifying numbers	NL78840.029.21
Source(s) of monetary or material support	Amsterdam UMC, location VUmc, department of Rehabilitation
Primary sponsor	Amsterdam UMC, location VUmc, department of Rehabilitation
Secondary sponsor(s)	Amsterdam Movement Sciences Institute
Public title	Optimal Physical Recovery After Hospitalization (OPRAH study)
Scientific title	The efficacy of a blended intervention to improve physical activity and protein intake for optimal physical recovery after oncological gastrointestinal and lung cancer surgery: study protocol for a randomized controlled multicenter trial
Countries of recruitment	The Netherlands
Health condition(s) or problem(s) studied	Rehabilitation after oncological surgery
Intervention(s)	Intervention: Smartphone application and corresponding accelerometer in combination with coaching by a physiotherapist and dietician during three months after hospital discharge
	Control: Usual care
Key inclusion and exclusion criteria	Ages eligible for study: ≥18 years; Sexes eligible for study: both; Accepts healthy volunteers: no
	Inclusion criteria: adult patient (≥ 18 years), scheduled for curative intent surgery for gastrointestinal cancer, including esophageal and stomach cancer (upper GI), colorectal and hepato-pancreato-biliary (HPB) cancer, or lung cancer with a planned hospital stay of ≥ 2 nights, able to fill in online questionnaires in Dutch and give informed consent
	Exclusion criteria: pulmonary wedge resection, surgery with open/close procedure, having no access to a mobile device compatible for applications, less than 5 days between inclusion and surgery, patients who are wheelchair dependent, a Mini-Mental State Examination (MMSE) ≤ 24 and already participating in a conflicting study.
Study type	Multicentre randomised controlled intervention trial with allocation at level of the individual
	Allocation: randomised
	Primary purpose: treatment
	Phase III trial
Date of first enrolment	June 2022
Target sample size	161
Primary outcome(s)	Recovery in physical functioning six months after hospital discharge
Key secondary outcomes	Physical activity, lean body mass, pain, fatigue, muscle mass, protein intake, physical performance, patient specific activity limitations, self-efficacy, participation in social roles and activities, generic quality of life, global perceived effect, hospital readmission and adverse events.

Introduction

Major surgical procedures for gastro-intestinal (GI) and lung cancer frequently result in significant loss of muscle mass, caused by increased catabolism due to the surgical stress response. This has major implications for postoperative physical function, and has been associated with postoperative morbidity, mortality and quality of life. [1-6] Adequate physical activity and nutrition are important to prevent loss of muscle mass. [7-10] A combination of both is even more important, as adequate protein intake is needed to optimally benefit from the physical training stimuli. [11] This has also been reflected in the results from a systematic review showing that a combination of adequate protein intake and sufficient physical activity facilitates muscle gain in sarcopenia. [12] Therefore, to minimise the postoperative loss of muscle mass and restore physical function, it is important for patients with cancer undergoing surgery to maintain or enhance their physical activity and nutritional status in the postoperative phase.

However, patients often experience barriers to being physically active after surgery, e.g. due to physical symptoms, such as pain and fatigue, and lack of motivation or social support. [13-16] In addition, previous studies found that many surgical patients were unable to meet their protein requirements after surgery despite the advices of a dietician, e.g. due to a loss of appetite or feelings of worry.[17] Patients emphasize the need for more supportive care interventions after discharge to facilitate return to normal activities after cancer surgery.[18, 19] Therefore, additional support in promoting physical activity and protein intake is needed to improve recovery of physical functioning after surgery in these patients. [20]

Self-monitoring of physical activity with the use of accelerometers is an often used strategy to increase physical activity in patients, by giving patients insight in their daily physical activity level.[21] A recent meta-analysis showed that interventions combining accelerometers with feedback using different behavioral change techniques (BCT's) and coaching by a health care professional are more effective in increasing physical activity than the use of an accelerometer alone. [22] In this study it is suggested that this is due to the fact that incorporating coaching by a health professional to the intervention gives the opportunity to provide targeted advice and interventions for a specific population group with a more personal touch. Also, more BCT's can be used when a health care professional is involved, e.g. problem solving, social reward. In addition, findings of a review on patients with a colorectal adenoma indicate that behavioral interventions can encourage these patients to improve their diet. [23] The effect of a combined intervention,

using eHealth and remote coaching by a dietician and physiotherapist in patients after GI or lung cancer is unknown.

We therefore developed a blended intervention to support patients in increasing their level of physical activity and protein intake after hospital discharge: The Optimal Physical Recovery After Hospitalization (OPRAH) intervention. The purpose of the OPRAH intervention is to encourage self-management of patients in their recovery in physical functioning, by using a smartphone application and corresponding accelerometer in combination with coaching by a physiotherapist and dietician. To investigate the potential effect of providing ongoing support on physical activity and protein intake after hospital discharge on recovery in physical functioning, the intervention will be compared to usual care. Therefore, the aim of this randomized controlled multicenter trial is to investigate the effectiveness of the OPRAH intervention on recovery of physical functioning, compared to usual care, in patients who have undergone elective GI and lung cancer surgery.

Objective and hypothesis

Objective: to evaluate the efficacy of the OPRAH intervention on recovery of physical functioning (compared with usual care) in patients who have undergone elective GI and lung cancer surgery.

Hypothesis: The aim of the intervention is to encourage self-management of patients by the use of self-monitoring on physical activity and protein intake. Patients will also be monitored in their recovery of physical activity and protein intake by a physiotherapist and dietician. If this recovery stagnates and goals are not achieved, the physiotherapist or dietician can contact the patient to identify barriers in their recovery. The use of multiple BCT's can help to reduce or eliminate these barriers and to increase the patients level of physical activity and protein intake. Higher levels of physical activity and achieving protein requirements are expected to have a positive effect on the recovery in physical functioning after discharge. Therefore, it is hypothesized that patients in the intervention group will have a faster and better recovery in physical functioning during the first 6 months after hospital discharge compared to patients receiving usual care.

Methods

Study design

The proposed study is a multi-center, single-blinded two-arm randomized controlled study comparing a blended intervention delivered alongside usual care, with a control arm (usual care) in patients after hospital discharge who have undergone GI or lung

cancer surgery. Baseline measurements (T_0) will be conducted prior to surgery and follow-up measurements take place at hospital discharge (T_1) and one (T_2), four (T_3), eight(T_4) and twelve(T_5) weeks and six months(T_6) after hospital discharge. The trial will be conducted at two hospitals in the Netherlands: Amsterdam UMC, location VUmc and St. Antonius, location Nieuwegein. The OPRAH trial has been designed in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement.[24] The Standard Protocol Items Recommendations for Interventional Trial (SPIRIT) checklist is provided as additional file. See figure 1 for the flow-chart of the study and figure 2 for the SPIRIT schedule of enrollment, intervention and assessments.

Participants

Eligibility criteria

Patients are eligible to participate when scheduled for curative intent surgery for gastrointestinal cancer, including esophageal and stomach cancer (upper GI), colorectal and hepato-pancreato-biliary (HPB) cancer, or lung cancer with a planned hospital stay of ≥ 2 nights, are aged 18 years or older, and whether they are able to fill in online questionnaires in Dutch and give informed consent.

Exclusion criteria are the following: pulmonary wedge resection, surgery with open/close procedure, having no access to a mobile device compatible for applications, less than 5 days between inclusion and surgery, patients who are wheelchair dependent, a Mini-Mental State Examination (MMSE) ≤ 24 and already participating in a conflicting study.

Recruitment

Potentially eligible patients will be informed about the study by the treating dietician, physiotherapist, nurse specialist or case-manager during a preoperative consultation. When the patient is interested in participation, the researcher will contact the patient after 24 hours to further explain the study procedures and to answer questions of the patient. If the patient is eligible and willing to participate, the informed consent letter will be signed before the start of the baseline measurements. During the informed consent procedure, participants are also asked to confirm if their data may be used to support other research in the future. Participants will also indicate whether they would be willing to be contacted about future related research and if they give consent to the making, use and retention of audio recordings of conversations with the dietitian and physiotherapist. In case there are doubts about the patients' cognition, the MMSE will be administered before final inclusion. The patient receives a copy of the signed informed consent. The recruitment period is 18 months, with a target of approximately 10 included participants per month.

Figure 1. *Flow chart.*

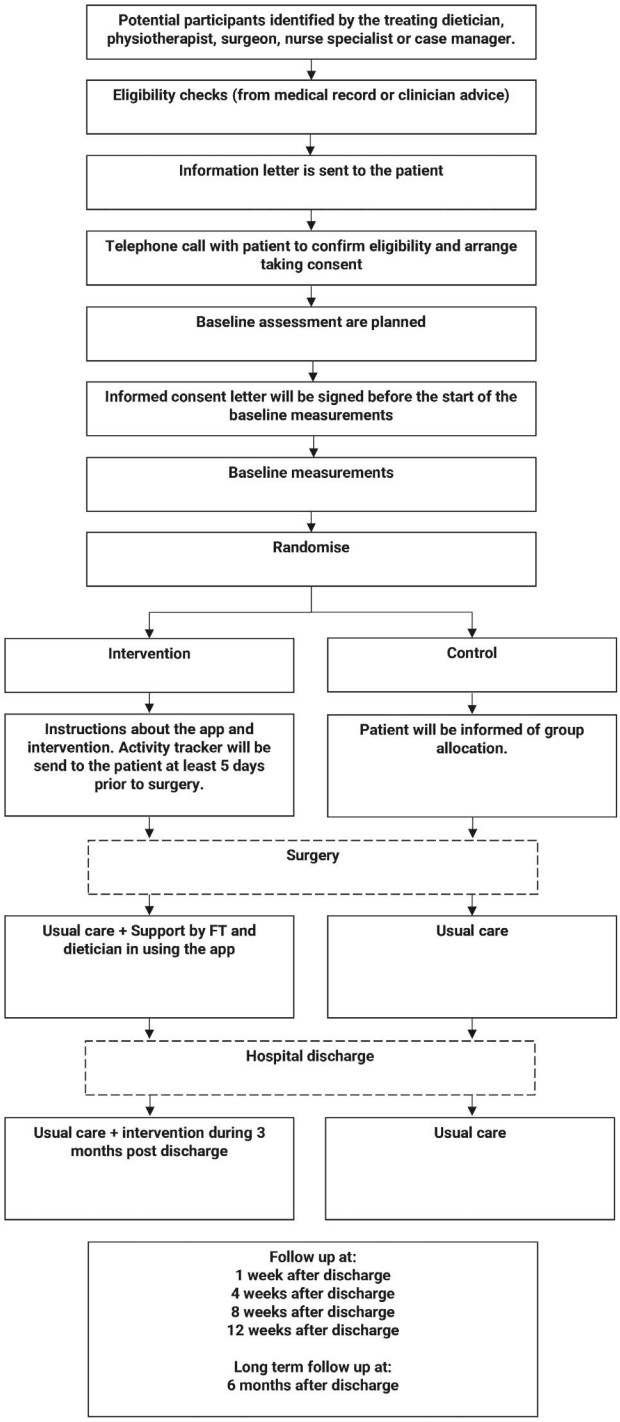


Figure 2. *SPIRIT schedule of enrolment, intervention, and assessments.*

	STUDY PERIOD							
	Enrolment	Allocation	Post-allocation					Close-out
TIMEPOINT**	T_0		T_1	T_2	T_3	T_4	T_5	T_6
ENROLMENT:								
Eligibility screen	X							
Informed consent	X							
Allocation		X						
INTERVENTIONS:								
Intervention			←	—	—	—	→	
Control								
ASSESSMENTS:								
Physical functioning	X			X	X	X	X	X
Physical activity	X		X	X	X	X	X	X
Lean body mass	X				X		X	
Pain	X			X	X	X	X	X
Fatigue	X			X	X	X	X	X
Muscle mass	X							X
Protein intake	X			X	X		X	X
Physical performance	X				X		X	
Patient specific outcome limitations				X	X	X	X	X
Self-efficacy	X			X	X	X	X	X
Participation	X			X	X	X	X	X
Generic quality of life	X			X	X	X	X	X
Global perceived effect				X	X	X	X	X
Hospital readmission					X			
Adverse events			X	X	X	X	X	X
OTHER STUDY PARAMETERS								
Patient characteristics	X							
Perioperative characteristics	X		X					
Self-management skills	X			X				
Treatment fidelity				X	X	X	X	
Treatment adherence				X	X	X	X	
Process evaluation							X	
Healthcare use				X	X	X	X	X

Randomisation and blinding

After the baseline measurements, patients will be randomly assigned to the control or intervention group with a 1:1 allocation ratio using the randomisation tool of Castor Electronic Data Capture (EDC). [25] Randomisation will be stratified per centre by: type of

surgery (lung, HPB, upper GI, colorectal) and ASA score (1-2 or ≥ 3). The randomisation tool of Castor ensures concealment of allocation. The researcher informs the participant by e-mail which group he has been assigned to. Assessments will be conducted by a blinded research assistant. Neither the patient nor the therapist will be blinded.

Sample size

For the present sample size analysis, a conservative estimate of 0.40 as the between-group effect size on the outcome physical functioning is used. This estimate is based on reported effect sizes on patient reported outcomes of physical functioning in other studies using technology and coaching on physical activity. [26, 27] Based on alpha =0.05, power (1-β) =0.80, a two-sided test for repeated measures with an expected within-subject correlation coefficient of 0.6 and 5 follow-up measurements the minimum number of 67 subjects per group is required, with a total sample size of 134 (see Formula 1). Allowing for a drop-out rate of 20% during the study, this study should include 161 patients.

The most important secondary outcome of this study is objectively measured physical activity. Therefore, a sample size calculation was also made on this outcome measure. Based on the effect sizes found in our recent systematic review and meta-analysis of interventions using activity trackers in patients during or after inpatient stay on the outcome physical activity, an effect size on physical activity of 0.50 is expected. [22] Based on alpha = 0.05, power (1-beta) = 0.80 and a two sided test the minimum number of subjects required is n=128 (64 in each group). Allowing a drop-out rate of 20% during the study, a total of 154 patients should be included.

Formula 1:

$$N = \frac{(Z(1-\text{alpha}/2) + Z(1-B))^2 \times \sigma^2 \times (r+1) \times [1 + (T-1) \times \rho]}{v^2 \times r \times T}$$

Intervention

The intervention is described according to the template for intervention description and replication (TIDIER) checklist (See Supplementary File 1). The main purpose of the OPRAH intervention is to facilitate faster and better recovery in physical functioning by stimulating patients' self-management regarding their level of physical activity and protein intake after hospital discharge.

Development of the intervention

The Medical Research Council (MRC) framework for the development and evaluation of complex intervention was used.[28] Supplementary File 3 shows the stages of the MRC

framework alongside with our activities of the development process and the activities that are described in this paper. The intervention development process was guided by findings from a feasibility study [29], systematic review of literature on the effectiveness of intervention components [22], a literature search about barriers and facilitators to the targeted behavior and expert meetings with researchers and health professionals (OPRAH consortium, consisting of physiotherapists, dieticians, surgeons, researchers and a specialist in behavioral change). The behavioral change wheel was used as theoretical underpinning of the intervention [30]; with the use of this theory we have been able to substantiate how the intervention causes change, what the active ingredients of the intervention are and how they can exert their effect. A feasibility study was conducted to evaluate the practical effectiveness.

The basis of the intervention was an existing app with a self-monitoring function of physical activity, which had been investigated in the postoperative period of oncological patients through a feasibility study.[29] Self-monitoring appeared to be feasible in this population. However, some patients emphasized the need for more support in addition to self-monitoring. This finding was strengthened by the results from our systematic review, because interventions with activity trackers in combination with coaching by a health professional seemed to be more effective in increasing physical activity during and after hospitalization.[22] In addition, the use of more Behavioral Change Techniques (BCT's) within the intervention was also suggested to be more effective.

Because of the important synergy between protein intake and physical activity after major oncological surgery, the app has been expanded with a self-monitoring tool for protein intake. By conducting a comprehensive literature search, barriers and facilitators to the targeted behaviors, improving physical activity and protein intake, were identified. Based on the behavioral change wheel and with input from the OPRAH consortium, a total of 15 behavioral change techniques, following the BCT taxonomy of Michie et al.[31], were identified and linked to a mode of delivery in order to target the desired behavior. (See table 2) In Supplementary File 4, the BCT's are linked to the Capability, Opportunity, Motivation and Behavior (COM-B) model [30], intervention functions and mode of delivery. In order to improve the motivation of patients for behavioral change, Motivational Interviewing (MI) and Shared decision making (SDM) was incorporated in the intervention. Based on initial feedback from the OPRAH consortium, the intervention was refined in preparation for evaluation.

Table 2. *Intervention components based on the BCT taxonomy (v1) of 93 hierarchically cluster techniques from Michie et al.[31]*

Behavioral change technique	Description
1.1 Goal setting (behavior)	Patients are able to set goals on the amount of physical activity per day. Patients will be supported by the physiotherapist to set realistic goals Goals on requirements of protein intake will be set based on advice of the dietician.
1.2 Problem solving	The physiotherapist/dietician analysis factors influencing the behavior and select strategies for overcoming barriers/ increasing facilitator to perform behavior
1.4 Action planning	Patients are able to set in-app tasks. Patients will be encouraged by the physiotherapist/dietician to plan the performance (when, what time etc.)
1.5 Review behavioral goals	The physiotherapist/dietician will review the behavioral goals and consider modifying goals based on their achievement.
1.6 Discrepancy between current behavior and goal	Visual in-app presentation of behavior and targeted goals
2.2 Feedback on behavior	The amount of minutes patients have to be active to achieve their goal is presented in the app. The number of points remaining to achieve protein requirements is shown. In addition, the physiotherapist/dietician will give the patient feedback about their activity/intake.
2.3 Self-monitoring of behavior	Patients are able to monitor their daily level of physical activity and protein intake via the app
3.1 Social support	Patients are able to request contact with the physiotherapist/dietician via the app The physiotherapist/dietician will contact the patient (how often is determined in consultation with the patient)
4.1 Instructions on how to perform the behavior	Tailored in-app information and personalized instructions by physiotherapist/dietician
5.1 Instructions about health consequences	Tailored in-app information and personalized instructions by physiotherapist/dietician
7.1 Prompts/cues	Patients can have the opportunity to receive in-app reminders to reach their daily goal
8.7 Graded tasks	The physiotherapists stimulate patients to set easy-to-perform tasks.
10.4 Social reward	Physiotherapist/dietician reward the patients if there has been effort in performing the behavior
10.5 Social incentive	Patients receive in-app rewards if they achieved their goal.
12.5 Adding objects to the environment	Wearing the PAM sensor

Coaching by health professionals

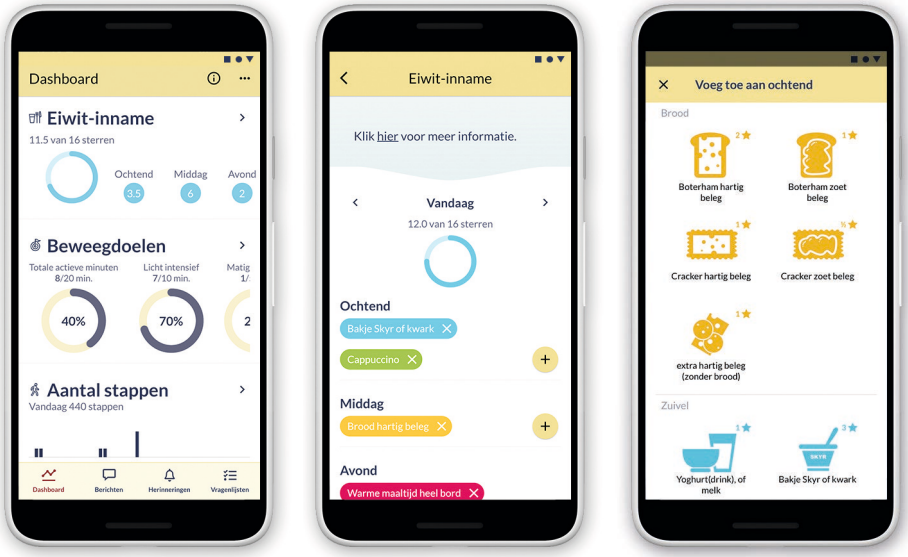
Coaching is an important part of the intervention, as the use of self-monitoring has proven to be more effective when combined with coaching by a healthcare professional and is considered important to improve the synergy and collaboration between physiotherapy and dietetics. Through the use of coaching, the intervention can be tailored to the clinical status of the patient. In addition, potential barriers to the desired behavior can be identified and, if they are within the scope of physiotherapist and dietician, addressed in collaboration with the patient. To support the physiotherapists and dieticians in coaching, the choice has been made to use Motivational Interviewing (MI) and Shared Decision Making (SDM). MI increases patient autonomy, enhances intrinsic motivation and supports the patients self-efficacy all of which contributes to increasing the patients self-management.[32] A recent review indicated that MI is a powerful intervention in combination with self-monitoring using activity trackers to improve autonomous motivation and to reduce a-motivation for physical activity.[33] Furthermore, it was indicated that the delivery of the intervention can vary from telephone to real life coaching and can still be effective in impacting motivation, regardless of the delivery method.[33] SDM provides an opportunity to integrate evidence and patient preferences into a health related decision.[34, 35] The physiotherapist and dieticians involved in this study have received a training about MI and SDM prior to the start of the study. The main purpose of this 3-day training course was to teach strategies according to the principles of MI to encourage patients to adopt healthy behavior, especially focused on physical activity and protein intake. In the first session, attention was paid to reflective listening; i.e. listening carefully to what the patient says and giving it back to the patient in different words in order to create understanding and clarity. Next, it was discussed what ambivalence is and how it can be recognized. Ambivalence means being pulled back and forth between the disadvantages and advantages of the current situation and the new situation. In the second session, the recognition of ambivalence was continued and conversation techniques were applied in order to guide the patient towards healthy behavior. During the last training day all techniques were practiced with the help of a trained actor. Between the training days, the physiotherapists an dieticians applied the learned techniques in practice and reflected on this in duo sessions. To keep their knowledge and skills up to date during the study period, peer review meetings will be organised.

E-health technology

The Atris software (Peercode B.V. Geldermalsen, the Netherlands) is the investigational software used in the intervention. In combination with the ankle-worn PAM AM400 three-axis accelerometer (PAM B.V. Doorwerth, the Netherlands), the Atris software is used for self-monitoring of physical activity and protein intake. The Atris software consists

of a Atris app for patients, Atris backend website for health professionals and the Atris (triggers) software. The Atris app allows patients to self-monitor their daily physical activity and protein intake through wearing the PAM and tracking daily protein intake by using a simple in-app self-registration system. See figure 3 for screenshots of the app and Supplementary File 2 for a subscript of the screenshots. Physical activity is represented in active minutes per day, with a distinction in low (1.4–2.99 metabolic equivalents of energy expenditure (METs)), moderate (3-7 METs) and vigorous activity (>7 METs). The protein intake is represented in stars (★), where 1 star represents approximately 5 grams of protein. The Atris app provides feedback on progress related to their goals. In addition, patients can ask questions through the app's chat feature and receive response and information by the physiotherapist or dietician. Via the Atris backend website, the physiotherapist and dietician can interactively view patient data, send messages to the patient and can access Atris (triggers) through the patient monitor. The software Atris (triggers) enables personalized goal setting and threshold values per patient.

Figure 3. *Screenshots of the Atris app*



Intervention description and procedures

One week prior to planned surgery, patients receive the PAM and will receive access to, and get instructions about the Atris app to get familiarized with the application. Patients are asked to wear the PAM 24-hours a day in a strap around the ankle, from at least 5 days prior to surgery until 3 months after surgery. During hospitalization, the treating physiotherapist and dietician guide the patients in the use of the app during their

standard consultations. As the day of hospital discharge approaches, the patient will be supported by the physiotherapists and dietician using the SDM process to set goals on active minutes and protein intake for after discharge. After discharge to home, patients are coached remotely (by telephone and chat) by a physiotherapist and dietician about physical activity and protein intake during 3 months after discharge. Through a chat function in the app, patients can ask questions to the physiotherapist or dietician, the physiotherapist and dietician can also send information through the chat. The ultimate goal for physical activity is to return to pre-surgery level of physical activity. The ultimate goal for protein intake is to achieve the personal daily requirements. If the recovery stagnates and goals are not achieved, the physiotherapist or dietician will contact the patient to identify barriers in their recovery. The sub goals and the degree of coaching will be tailored using a SDM process to the personal needs and preferences of the patient. To support patients self-management, MI techniques will be applied during the coaching sessions with the physiotherapist and dietician by telephone and chat. [32]

Criteria for discontinuing the intervention

Patients may discontinue the intervention in the following cases:

- Completion of the intervention period: Patients may discontinue the intervention once they have completed the predetermined duration of the OPRAH intervention (3 months after hospital discharge).
- Adverse effects or complications: If patients experience any adverse effects or complications directly related to the intervention, it may be necessary to discontinue their participation for safety reasons.
- Lack of adherence: If patients consistently fail to comply with the requirements or recommendations of the intervention, discontinuation will be considered. This can include non-engagement with wearing the PAM sensor or registration of their protein intake.
- Patient's request or withdrawal: Patients have the right to choose whether they want to continue or discontinue the intervention. If a patient decides to withdraw from the program, their participation will be discontinued.

Usual care

Both participants in the intervention and the control group receive usual care.
During hospitalization, patients are treated according to the Early Recovery After Surgery (ERAS) protocol. [36] This includes early mobilisation and (nutritional) intake supported by the entire (para)medical team. In the daily consultations by the medical doctor and nursing staff, attention is paid to the improvement of mobilisation and intake. The amount

of consultation by the physiotherapist and dietician is determined based on the clinical assessment of the physiotherapist and dietician.

After hospital discharge, there is no usual physiotherapy care. The physiotherapist may advise the patient to continue physiotherapy in primary care, based on the clinical assessment of the physiotherapist. The usual care of the dietician differs between patient groups. In Amsterdam UMC, the dietician standard schedules postoperative consultations with patients after oesophagus-, stomach-, pancreas-, biliair and Hypertherme Intraperitoneale Chemotherapy (HIPEC) cancer surgery at two and four weeks and three and six months after discharge. At St. Antonius, the dietician only schedules a standard postoperative consultations at two weeks after discharge for patients after pancreas surgery. When necessary, more consultations can be planned. Patients after hepatic, colorectal (excl. HIPEC) or lung cancer surgery receive post-operative consultations by the dietician only on indication or the dietician may advise the patient to continue dietetic treatment in primary care. All participants are permitted to engage any form of (para) medical care during the study period.

Adverse event reporting

Adverse events(AEs)

Adverse events are defined as any undesirable experience occurring to a subject during the study, whether or not considered related to experimental intervention. All adverse events with a direct or possible link to the OPRAH trial (e.g. AE's occurring during intervention related activities) reported spontaneously by the subject or observed by the investigator or his staff will be recorded.

Serious adverse events (SAE)

This study includes patients undergoing oncological lung or GI surgery. These types of surgery are associated with a certain risk of postoperative complications. Our intervention starts after hospital discharge, therefore, all complications during hospitalization will not be reported as SAE. We expect that our, low risk, post-discharge intervention will not have any negative influence on the occurrence complications after discharge. Therefore, all complications after discharge which are unmistakably caused by the surgery and/or medical treatment will not be reported as SAE. When there are doubts about the relation between the intervention and the occurrence of an SAE, these SAE's will be discussed with the surgeons involved in this study per patient group. If, after discussion, there is still any doubt about the relation between the intervention and the occurrence of an SAE, the SAE will be reported.

The participating hospitals will report SAE's within 24 hours to the sponsor. The sponsor will report the SAEs to the accredited medical ethical committee that approved the protocol, within 7 days of first knowledge for SAEs that result in death or are life threatening followed by a period of maximum of 8 days to complete the initial preliminary report. All other SAEs will be reported within a period of maximum 15 days after the sponsor has first knowledge of the serious adverse events.

Outcomes

The primary outcome is recovery in physical functioning six months after hospital discharge and the most important secondary outcome is physical activity. Other secondary outcomes are lean body mass, pain, fatigue, muscle mass, protein and energy intake, physical performance, patient specific activity limitations, self-efficacy, participation in social roles and activities, generic quality of life, global perceived effect, hospital readmission and adverse events. See Table 3 for a detailed description of the outcome measures with the corresponding follow-up time points.

Table 3. *Outcome measures.*

Construct	Measure	Abbrev.	Description	Time points
Primary outcome				
Physical functioning	Computer Adaptive Testing (CAT) Dutch-Flemish Patient Reported Outcome Measure Information System for Physical Functioning	CAT PROMIS-PF	The CAT PROMIS-PF is a digital questionnaire. [40] A CAT is a computer-administered measure in which a computer algorithm is used to select successive items based on responses to previous items. Using a 5-point Likert scale the questionnaire reflects the participant' functioning in the past 7 days. The items cover a wide range of activities, from activities of daily living to more complex activities [41]. The CAT PROMIS-PF has sufficient psychometric properties in measuring the level of physical function of physiotherapy patients [42] and has been shown to be reliable and sensitive to change in surgical patients. [43, 44]	T0, T2, T3, T4, T5, T6
Most important secondary outcome				
Physical activity	ActivPAL™		The ActivPAL (PAL Technologies Ltd., Glasgow, UK) is a thigh-worn tri-axial accelerometer and uses proprietary analysis algorithms to determine posture (sedentary time, upright time) and stepping (stepping time and steps). The Activpal will be affixed to the skin with hydrogel pads on the thigh. The ActivPAL is one of the most frequently used activity trackers in clinical research and has been shown to be a valid measure of posture and stepping. [45-47] Patients in both the intervention and control group will wear the ActivPAL for 5 days.	T0, T1, T3, T5, T6
Other secondary outcomes				
Lean body mass	Bioelectrical Impedance Analysis	BIA	A single frequency bio electric impedance meter (50kHz) will be used for the BIA. These impedance meters uses 4 electrodes to measures the impedance, resistance, reactance and phase angle. A BIA is a non-invasive validated method to assess body composition, fat-free mass (FFM) and appendicular skeletal muscle mass (ASSM) patients with cancer. [48] FFM is one of the factors the dietician uses to determine patients' personal protein requirements. FFM will be measured with the formula of Kyle [49]	T0, T3, T5

Table 3. *Continued*

Construct	Measure	Abbrev.	Description	Time points
Pain	Numeric Pain Rating Scale	NPRS	The NPRS is a measure of subjective intensity of pain in adult patients. The 11-point numeric scale ranges from '0' (no pain) to '10' (worst pain imaginable). The NPRS is a valid, reliable and usual tool to measure pain in postoperative patients. [50, 51]	T0, T2, T3, T4, T5, T6
Fatigue	Dutch-Flemish Patient Reported Outcome Measure Information System for Fatigue – Short Form	PROMIS F-SF	The PROMIS F-SF consists of seven items that measure both the experience of fatigue and the interference of fatigue on daily activities over the past week. The response scale is a 5-point Likert scale, ranging from 1 (never) to 5 (always). Total scores range from 7 to 35: a higher score indicating greater fatigue. The PROMIS F-SF showed acceptable reliability and validity and is suitable to measure fatigue across a diverse clinical population. [52]	T0, T2, T3, T4, T5, T6
Muscle mass	Analyses of Computer Tomography	CT-analyses	CT images are routinely obtained in the oncological workup of lung and GI cancer patients, both pre- and postoperative. CT images obtained from whole-body PET/CT scans will be analyzed by a validated computer program AMUSE (acronym for Automatic MUscle and visceral/subcutaneous fat SEgmentor). The landmarks for the assessment of muscle mass will be the third lumbar vertebra (L3) and the fourth thoracic vertebra (Th4).	T0, T6
Protein and energy intake	48-h dietary recall		A 48-h dietary recall will be performed by trained interviewers, dietician researchers or graduate students, following a standard protocol. The intake of food items will be registered, including details of preparation methods, recipes, quantities and the size of portions, and the brands of products. The calculation of total energy intake and protein intake will be based on the database of 'The Netherlands Nutrition Centre'. Protein intake will be calculated in gram per day. Energy intake will be calculated in kcal per day. Earlier studies suggested that a 48-h recall is superior to a single 24-h recall. [53, 54]	T0, T2, T3, T5, T6

Table 3. *Continued*

Construct	Measure	Abbrev.	Description	Time points
Physical performance	1) Hand grip strength 2) 30 second chair stand test 3) 2 minute step test	1) - 2) 30SCST 3) TMST	1) Handgrip strength will be measured using the Jamar grip strength dynamometer as a measure of generalized muscle strength. The Jamar grip strength shows good reliability and can be used to measure changes in strength over time. [55, 56] The normative data of Dodds. et al will be used as reference. [57] 2) The 30SCST will be used to measure functional lower extremity muscle functioning. The 30CST measures extremity strength in relation to demanding functional daily activities such as stair climbing. [58] The patient is seated in a chair and will be asked to complete as many full stands as possible in 30 seconds. The 30CST shows good reliability and criterion validity.[59] 3) The TMST will be used to measure exercise capacity. [60] The test requires the patients to march in place as fast as possible for 2 minutes while lifting the knees to a height midway between their patella and iliac crest when standing. Performance is defined as the number of steps completed in 2 minutes. These performance tests are easy to perform at the patient's home. The physical performance tests will be performed by trained (student) allied health professionals. Standard operating procedures will be used for all tests. [61]	T0, T3, T5

Table 3. *Continued*

Construct	Measure	Abbrev.	Description	Time points
Patient specific activity limitations	Patient-specific Functional Scale	PSFS	The Dutch PSFS includes a list of 24 activities adapted from the activity list for patients with heart failure by Beurskens et al. and patients will be asked to indicate all activities that he or she was limited in performing within the previous week.[62] Patients have also the possibility to indicate any additional activities in the "other" section. The patient will be asked to prioritize their three most important activity limitations. Patients will then be asked to rate these activities on a numeric rating scale ranging from 0 to 10, where 0 indicates no limitations in performing the activity and 10 indicates that performing the activity is impossible. The PSFS is an appropriate measure for statistical comparisons in clinical research.	T0, T2, T3, T4, T5, T6
Self-efficacy	General self-efficacy scale	GSES	The questionnaire contains 10 items with a 4-point response scale (1=completely wrong, 4 = completely true). Total scores range from 10 to 40: a higher score indicating more self-efficacy. The GSES Is a valid tool to measure self-efficacy. [63]	T0, T2, T3, T4, T5, T6
Participation in social roles and activities	CAT Dutch-Flemish Patient Reported Outcome Measure Information System for participation	CAT PROMIS participation	the CAT PROMIS participation item bank including the item banks 'Ability to participate in Social Roles and Activities' and 'Satisfaction with Social Roles and Activities'. The response scale is a 5-point Likert scale; a higher score indicates better participation. The CAT PROMIS item bank is an reliable and valid measurement of participation with limited administration time. [64]	T0, T2, T3, T4, T5, T6
Generic Quality of Life	The 5-level EuroQol five-demensional questionnaire	EQ-5D-5L	This EQ-5D-5L consists of five questions representing five health dimensions; mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The EQ-5D-5L is added in order to carry out cost-effectiveness analysis. The EQ-5D-5L shows good psychometric properties and is suitable for economic evaluation studies in oncological patients. [65]	T0, T2, T3, T4, T5, T6

Table 3. *Continued*

Construct	Measure	Abbrev.	Description	Time points
Global perceived effect	Global Perceived Effect questionnaire	GPE	The Dutch version of the GPE will be used to measure the patients opinion of their recovery. [66] The questionnaire consists of two questions with a 7 point Likert scale. Patients will be asked to indicate to which extent they are recovered since the beginning of their recovery after surgery (1 = much better, 7 = much worse). In addition, patients will be asked how satisfied they are with their treatment since the beginning of their recovery after surgery (1=very satisfied, 7 = very unsatisfied).	T0, T2, T3, T4, T5, T6
Hospital readmission	Medical Record Data		Unplanned *hospital readmissions* within 30 days after discharge will be reported.	T3
Adverse event	Medical record data and self-reported		All adverse events with a direct or possible link to the OPRAH trial (e.g. AE's occurring during intervention related activities) reported spontaneously by the subject or observed by the investigator or his staff will be recorded. This study will include patients undergoing oncological lung or GI surgery. These types of surgery are associated with a certain risk of postoperative complications. Our intervention starts after hospital discharge, therefore, all complications during hospitalization will not be reported as SAE. We expect that our, low risk, post-discharge intervention will not have any negative influence on the occurrence complications after discharge. Therefore, all complications after discharge which are unmistakably caused by the surgery and/or medical treatment will not be reported as SAE. When there are doubts about the relation between the intervention and the occurrence of an SAE, these SAE's will be discussed with the surgeons involved in this study.	T1 t/m T6

Table 3. *Continued*

Construct	Measure	Abbrev.	Description	Time points
Other study parameters				
Patient characteristics	Self-reported and Medical Record Data		age (years), gender (male/female), Body Mass Index (BMI), marital status (living together/alone), comorbidities, Mini-Mental State examination (MMSE)*, The American Society of Anaesthesiologists Classification of physical health (ASA classification), Tumor location (lung, upper GI, HPB, colorectal), stage of cancer (1-4), unintentional weight loss (% over de last 6 months), nutritional intake (% of nutritional requirements). *The MMSE will only be measured when there are doubts about the patients cognition. The MMSE is an instrument used for cognitive impairment in the elderly.[67] A low score on the MMSE corresponds to a low cognitive level. A score < 24 (out of 30) is usually considered deviant.[68]	T0
Perioperative characteristics	Medical Record Data		Operation technique (open/laparoscopic), pre- or post-treatment with chemotherapy or radiotherapy, length of hospital stay (days).	T1
Self-management Skills	Self-Management Screening tool	SeMaS	The SeMaS is a short tool that can signal potential barriers for self-management that need to be addressed in the dialogue with the patients and can facilitate personalized counselling. The following items of the SeMaS will be measured: level of education, experienced burden of disease, digital skills, locus of control, self-efficacy, social support, coping style, anxiety and depression. Based on the outcome factors of the SeMaS tool, the physiotherapist will give specific advice to the patients for the tailored intervention. The SeMaS is validated in patients with chronic condition in primary care. [69] However, this tool contains patient characteristics that are generally important in self-management and the questionnaire is not specific to a particular condition.	T0

Table 3. *Continued*

Construct	Measure	Abbrev.	Description	Time points
Treatment fidelity	Audio records		To investigate whether the intervention techniques used in the intervention (MI and SDM) have been implemented properly, some consultations with the physiotherapist and dietician will be audio-recorded. The audio records will be made with professional recording equipment and in no case with a telephone. The consultations will only be recorded if the patients has given his or her specific consent to record their consultations. Researchers trained in the use of MI and SDM will listen to these consultation to determine if the techniques have been used appropriately. The recordings will be made at multiple times during the study as a learning effect of the health professionals is expected.	T1 t/m T5
Treatment adherence	Intervention data		*Treatment adherence* will be measured to determine the extent to which the patients complied with the intervention. The following outcomes will be considered to determine treatment adherence: • Number of days of wearing the PAM sensor • Number of days of for which protein intake is recorded • Number of contact moments with the physiotherapist and dietician	T1 t/m T5
Process evaluation	Focus groups		A qualitative process evaluation will be performed to evaluate the implementation of the intervention in order to identify possible barriers and facilitators for further implementation. Focus groups will be conducted with patients from the intervention group, involved healthcare professionals and members of the research team to evaluate the intervention and implementation process. In addition, user adherence of the smartphone application and web application will be measured during the study.	NA

Table 3. *Continued*

Construct	Measure	Abbrev.	Description	Time points
Healthcare use	Self-reported and Medical Record Data		The number of consultations with a healthcare provider will be registered by asking the patients about their use of paramedic consultations in primary care and by screening the Medical Record data. This can be used to determine the difference in healthcare use and costs between the intervention and control group	

T0 = baseline (pre-operative), T1= at hospital discharge, T2 = one week after discharge, T3 = four weeks after hospital discharge, T4 = eight weeks after hospital discharge, T5 = twelve weeks after hospital discharge, T6 = six months after hospital discharge, NA = not applicable

Data collection

At baseline, the questionnaires will be send by the researcher via the OnlinePROMS platform. After registration of the date of hospital discharge, the questionnaires will be automatically send at one week, four weeks, eight weeks, twelfth weeks and six months after hospital discharge. To improve the retention rate, patients will receive a reminder automatically after 2 and 5 days.

Standard operating procedures have been established for performing the physical measurements. All research assistants are trained to perform these measurements accurately and consistently. To ensure a higher follow-up rate, researchers have the flexibility to visit patients at home to perform the physical measurements. This approach aims to enhance convenience for participants and increase the likelihood of their continued participation in the study.

Data management

Data obtained from the medical record and collected during baseline and follow-up measurements will be manually entered into Castor EDC. Castor EDC incorporates protection for data entry and validation to reduce data entry errors, and management features to facilitate audits and data quality assurance. Data from the online questionnaires will be saved at the OnlinePROMS database.

Both databases have been specifically developed to ensure the safeguarding of participant information in accordance with data protection regulations. Participants will be identified solely by a unique patient ID number, ensuring their anonymity. Trial-related documents

will be securely stored and restricted to trial staff and authorized personnel only. Data will be anonymized promptly whenever feasible. All essential data that contains identifiable information will be retained for a period of 10 years, while anonymized digital data will be stored indefinitely. The Chief Investigator holds the role of the data manager, overseeing the management and security of the data.

Cleaned data sets will be made available to all Principal Investigators. These data sets will be securely stored on the research drive of Amsterdam UMC, VUmc location, and protected by passwords. Each Project Principal Investigator will have direct access to the data sets from their respective site, and access to data from other sites can be obtained upon request. To ensure confidentiality and privacy, any identifying participant information will be removed from the data sets if possible, when shared with project team members. Access to the full protocol, participant-level dataset and statistical code for non-commercial researchers outside the project team will be available from the corresponding author upon reasonable request.

Statistical analysis

Missing data will be handled using longitudinal data analysis. The differences in course of recovery between groups, measured with the CAT PROMIS PF, will be analysed using linear mixed model analysis, with group as independent variable and the PROMIS PF at all post-operative measurement points (T_1 – T_6) as dependent variable, adjusting for baseline PROMIS PF (T_0). The primary analysis will be conducted based on the full analysis set according to the intention to treat method.

Descriptive statistics will be calculated for all parameters, include mean, median, standard deviation, standard error of the mean and the interquartile range. In addition, per-protocol analysis will be performed among all participants with sufficient protocol adherence (> 80%). Continuous secondary outcomes are analyzed using linear mixed model, with group as the independent variable and outcome at all postoperative measurement points as dependent variable, adjusting for baseline scores. Dichotomous outcomes are analyzed using generalized mixed model with the same multilevel structure. A mediation analyses will be performed on the longitudinal trial data to determine if the relationship between the intervention and the primary outcome (PROMIS-PF) can be explained by improvement of PA and protein intake.

Qualitative data-analysis of the focus groups will be conducted following the steps of thematic analysis by two researchers.

Dissemination policy

Research findings will be shared through publication in leading international peer-reviewed journals and through presentations at both national and international conferences. We are committed to disseminating the findings to all relevant stakeholders. In addition, a summary of the research findings will be sent to participants who have indicated that they would like to receive such information once the research findings are published. Standard authorship eligibility guidelines will be followed and professional writers will not be used.

Discussion

The aim of this RCT is to evaluate the efficacy of a blended intervention to improve physical activity and protein intake on recovery of physical functioning in patients after gastrointestinal and lung cancer surgery. The OPRAH intervention, investigated in this RCT, aims to increase the patient's self-management in physical recovery, by using a smartphone application, accelerometer and coaching by a physiotherapist and dietician to improve the patients level of physical activity and protein intake after hospital discharge. In addition, the OPRAH intervention aims to improve the collaboration between physiotherapy and dietetics in order to achieve an optimal synergy between nutrition and physical activity in patients after oncological GI and lung surgery. With this RCT, the short and longer term changes in physical functioning, physical activity and protein intake will be determined with the hypothesis that a higher level of physical activity and protein intake will improve the recovery in physical functioning.

To improve recovery in physical functioning after oncological surgery, multiple studies have focused on prehabilitation, i.e. the process to enhance the patients functional capacity prior to major surgery, in order to enhance clinical outcomes and therefore reduce postoperative complications.[37, 38] However, surgery causes surgery-related muscle loss: muscle loss caused by increased catabolism due to surgical stress. [7] A recent study showed that more than 50% of the patients had surgery-related muscle loss. [39] Important risk factors that contributes to loss of muscle mass after oncological surgery are inactivity and malnutrition. [9, 39] To counteract the adverse effects of surgery, it is important that interventions also focus on encouraging physical activity and protein intake in the period after surgery.

This study has several strengths. First, the theoretical underpinnings of the intervention, by conducting a systematic review on the use of activity trackers and by using the Behavioral Change Wheel. Second, the tailored approach, by personalizing physical activity and protein goals for each patient and allowing the health professional to monitor the patient

remotely. Third, an app that combines self-monitoring of physical activity and protein. This combination is unique and can facilitate collaboration between the physical therapist and dietitian. Fourth, a strength of the trial design is the use of blinded assessors.

A limitation of the study is that the intervention is only accessible for patients who are able to understand the Dutch language and have their own smartphone. However, based on our experiences with the feasibility studies, we have found that currently very few patients do not own a smartphone. In addition, a study is ongoing to make the Atris app more inclusive and therefore more accessible to patients with low health literacy or who do not speak the Dutch language. If our RCT shows effectiveness, the adapted app can be implemented in the OPRAH intervention.

To our knowledge, this is the first multicentre, assessor-blind RCT testing the effect of a blended intervention focused on improving physical activity and protein intake after discharge in patients who have undergone elective GI, HPB or lung cancer surgery on the outcome recovery in physical functioning. The results of this research will reveal whether the OPRAH intervention, aiming to motivate patients and to assist health professionals to provide ongoing monitoring and support after hospital discharge, is an effective intervention to increase physical activity and protein intake and improve physical functioning recovery in these patients.

Trial status

The most recent version of the protocol is version 3, updated on 5 July 2022. The recruitment started at 24 June 2022. Recruitment is expected to be completed by December 2023.

List of abbreviations

BCT:	Behavioral Change Technique
CAT:	Computer Adaptive Testing
CONSORT:	Consolidated Standards of Reporting Trials
EDC:	Electronic Data Capture
ERAS:	Early Recovery After Surgery
GI:	Gastro-intestinal
HPB:	Hepato-pancreato-biliary
HIPEC:	Hypertherme Intraperitoneale Chemotherapy
MET:	Metabolic equivalents of energy expenditure
MI:	Motivational Interviewing
MMSE:	Mini-Mental State Examination

MRC: Medical Research Council
OPRAH: Optimal Physical Recovery After Hospitalization
PROMIS: Patient reported outcome measure information System
RCT: Randomized Controlled Trial
SDM: Shared Decision Making

Declarations

Ethical approval and consent to participate: The trial protocol has been approved by the Medical Ethical Research Committee (METC) of Amsterdam UMC, location VUmc (METC 2021.0627). This study will be conducted according to the principles of the Declaration of Helsinki (version 9, October 2013), in accordance with the Dutch Medical Research Involving Human Subjects Act (WMO) and the Dutch Personal Data Protection Act (General Data Protection Regulation (GDPR)). The trial has been registered at the International Clinical Trials Registry Platform (NL9793) and the study description is available at the following web link: https://trialsearch.who.int/Trial2.aspx?TrialID=NL9793. All amendments of the protocol will be notified to the METC and the competent authority. Non-substantial amendments will not be notified to the accredited METC and the competent authority, but will be recorded and filed by the sponsor. Participating sites in the study will be notified of any changes to the study protocols. This will enable them to make the necessary arrangements to incorporate the changes, if necessary, and to confirm their continued support for the study after the implementation of the changes.

All patients will sign informed consent prior to participation in the trial. All participants will be informed that they are under no obligation to enter the trial and that they can withdraw at any time during the trial without having to give a reason, and that this will not affect the medical care they receive.

Consent for publication*:* Not Applicable

Availability of data and materials: The datasets generated and/or analyzed are available from the corresponding author upon reasonable request.

Competing interests: The authors declare that they have no competing interests.

Funding*:* A research grant of the Amsterdam Movement Sciences Institute was received for financing 50% of a PhD project aiming to develop and evaluate an accelerometer-based feedback and coaching intervention for patients at risk for functional decline admitted to the hospital. A copy of the original funding documentation is presented in supplementary

file 2. This current RCT was conducted in support of this project. The funder had no role in the study design, the data collection, analysis, writing of the article or in the decision to submit the paper for publication.

Authors' contribution: MvdL and MvdS are the principal investigators; they conceived the study. MdL is the executive investigator; she led the proposal and protocol development and drafted the work. SD, HK, PW and EG contributed in the development of the intervention and study design. VdG substantially revised the protocol. All authors, including the authors of the OPRAH consortium, read and approved the final manuscript.

Acknowledgements:

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Supplementary information

Composition, roles and responsibilities of the coordinating centre, OPRAH consortium, Medical Ethics Committee and ORPAH research group.

Coordinating centre

Amsterdam UMC, location VUmc, is the coordinating centre of this trial. Therefore, they are responsible for the participant recruitment, data-collection and data-analysis. Amsterdam UMC, location VUmc, is also the owner of the medical devices used in this trial (movement sensors and associated software) and therefore maintains the management of this devices. MdL is mainly responsible for this.

OPRAH consortium

The OPRAH consortium is a multidisciplinary group that aims to provide expert advice and monitor the progress during the preparation and execution of the trial. Please refer to the acknowledgments for the members of the OPRAH consortium. Meetings are held twice a year, and more frequently if deemed necessary.

Medical Ethics Committee (MEC)

The MEC of Amsterdam UMC, VUmc location, is an independent multidisciplinary group that monitors the safety and effectiveness of the trial and oversees the overall conduct of the study. The Data Monitoring Center (DMC) supports clinical researchers in ensuring compliance with relevant laws and regulatory requirements, such as WMO, ICH-GCP, and/or ISO14155. During the trial, there will be four on-site monitoring visits at Amsterdam UMC, VUmc location, and three monitoring visits at St. Antonius Hospital, Nieuwegein. Both sites will have a close-out visit after the last subject visit.

OPRAH research group

The OPRAH research group is responsible for the management of the trial and will be led by MdL, the executive researcher of the OPRAH study. Other members of the Trial management group include MvdL (principal investigator), MvdS (principal investigator), EG (innovator and physiotherapist), StD (dietician-researcher), and HK (dietician-researcher). The OPRAH research group will meet approximately once a month to oversee the day-to-day management of the trial.

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Supplementary Files

Supplementary File 1: Intervention description and replication (TiDieR)



Scan QR code

Supplementary File 2: Subscript screenshots Figure 3



Scan QR code

Supplementary File 3: Mapping activities to MRC Framework



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Supplementary File 4: The Behavioural Change Wheel



Scan QR code



Chapter 6

Optimal physical recovery after hospitalization for patients after oncological surgery (OPRAH): a multicenter, single-blind, randomized controlled trial

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Submitted

Abstract

Purpose: Effective post-discharge interventions to improve recovery in physical functioning after oncological surgery are limited. The aim of this study is to evaluate the efficacy of the Optimal Physical Recovery After Hospitalization (OPRAH) intervention to improve physical activity and protein intake after hospital discharge on recovery of physical functioning in patients after oncological gastrointestinal and pulmonary surgery.

Methods: A multicenter single-blinded randomized controlled trial was performed in adults undergoing curative intent oncological gastrointestinal and pulmonary surgery. Patients were assigned to usual care (control) or usual care plus a three-month post-discharge intervention comprising a smartphone app, activity tracker, and remote coaching from a physiotherapist and dietitian. Assessments were conducted preoperatively and at one, four and eight weeks, and three- and six-months post-discharge. The primary outcome was recovery in physical functioning, measured using the CAT PROMIS Physical Functioning questionnaire. Secondary outcome was physical activity.

Results: Overall, 163 patients were included (73 intervention, 90 control). An overall intervention effect on physical functioning was found in favour of the intervention group (difference 1.7; p =0.0300). Physical activity levels were also significantly higher in the intervention group (difference = 12.9; p = 0.0146). Additional benefits were observed in protein intake, fatigue, pain, participation, self-efficacy, global perceived effect, and handgrip strength. No significant effects were noted for energy intake, lean body mass, physical performance, and readmission rates.

Conclusion: The OPRAH intervention effectively enhances recovery in physical functioning after curative intent oncological gastrointestinal and pulmonary surgery. Patients were more physically active, met their protein intake requirements more often and experienced less fatigue.

Introduction

Oncological surgery for gastrointestinal and pulmonary cancer often result in substantial physical decline, including loss of muscle mass, reduced strength and impaired functional capacity. [1-5] These impairments can persist for months and significantly affect patients' independence, ability to regain activities and quality of life. [3, 6-12] To mitigate surgical stress and improve outcomes, Enhanced Recovery After Surgery (ERAS) programs have been widely implemented. These programs reduce hospital length of stay and postoperative complications. [13, 14] However, an important consequence of this is discharge at an earlier stage of recovery, requiring patients to manage a substantial part of their functional recovery independently at home. Despite growing recognition of long-term impact of major oncological surgery, effective post-discharge interventions to support physical recovery remain scarce. [2, 11, 15-18]

The prevention of muscle mass loss plays an important role in enhancing postoperative recovery. [19, 20] Anabolic resistance – a reduced capacity for muscle protein synthesis – may occur in the context of inadequate nutritional intake, physical inactivity and illness, ultimately leading to muscle mass loss. [21] To counteract this process and preserve muscle mass, sufficient protein intake (>1.5 g/kg/day) and multimodal interventions combining nutrition with physical activity are essential. [22] However, adherence to nutritional and physical activity recommendations after hospital discharge can be challenging for patients recovering from major oncological surgery, particularly in the absence of structured guidance and support. [18, 23, 24] Blended interventions – combining eHealth tools with remote coaching – offer a promising solution by providing accessible support and continuity of care in patients' own environments. [25-27] These interventions may enhance self-management through behavior change techniques (BCTs), such as self-monitoring.

Self-monitoring empowers patients by providing insight into their own recovery and encouraging an active role in their rehabilitation. However, guidance from a healthcare professional remains important to provide timely support when patients face barriers or need encouragement. [28] Furthermore, combined physical activity and nutritional interventions may improve physical functioning in patients with cancer, although study heterogeneity remains high and evidence specific to the post-discharge period is limited. [29, 30] To address this gap, we developed the Optimal Physical Recovery After Hospitalization (OPRAH) intervention—a blended intervention that combines an activity tracker, smartphone application, and remote coaching by a physiotherapist and dietitian, as previously described in the study protocol. [31] The aim of this multicentre, single-blinded, randomized controlled trial was to investigate the efficacy of the OPRAH intervention

on recovery in physical functioning after curative intent oncological gastrointestinal and pulmonary surgery.

Methods

Study design

The OPRAH trial was a multicentre, single-blinded randomized controlled study between June 2022 and July 2024 in two hospitals in the Netherlands. This study has been approved by the Medical Ethical Committee of Amsterdam UMC, location VUmc (registration number NL78840.029.21) and has been prospectively registered at the International Clinical Trials Registry Platform (registration number NL9793). The study protocol has been published previously. [31] This study is reported according to the Consolidated Standards of Reporting Trials (CONSORT) statement. [32]

Participants

Patients were eligible to participate if they had an oncologic resection of the pulmonary system, upper gastrointestinal tract (including esophageal and stomach cancer), hepato-pancreato-biliary (HPB) system, or colorectal region scheduled at Amsterdam UMC (location VUmc) or St. Antonius Nieuwegein, were 18 years of age or older, the surgery had a curative intent, there was an indication for postoperative hospital stay ≥ 2 nights, they were able to complete online questionnaires in Dutch and provide informed consent. Exclusion criteria were: pulmonary wedge resection, surgery with open/close procedure, no access to a mobile device compatible for applications, less than 5 days between inclusion and surgery, patients who were wheelchair dependent, Mini-Mental State Examination (MMSE) ≤ 24 and already participating in a conflicting study.

Patients were recruited by the treating dietitian, physiotherapist or specialized oncology nurse during a preoperative consultation and, if eligible and interested, contacted by a researcher to further explain the study procedures. If patients were willing to participate, they had to sign written informed consent.

Randomization and blinding

After completion of the baseline measurements, patients were randomized with a 1:1 allocation ratio to the control group (usual care) or intervention group. Randomization was performed using the Castor Electronic Data Capture randomization tool with variable block sizes (4, 6, 8) and was stratified per hospital by type of surgery (pulmonary, upper GI, HPB, colorectal) and American Society of Anaesthesiologists physical status classification (ASA) score (1-2 or ≥ 3). Patients were informed about the group allocation face-to-face

or by e-mail. Follow-up assessments were conducted by a blinded researcher. Blinding of patients and healthcare professionals was not possible, as participants used a mobile app with an activity tracker whose data guided personalized treatment.

Procedures

The OPRAH intervention is described according to the template for intervention description and replication (TIDIER) checklist (Supplementary File 1). OPRAH is a blended intervention consisting of an activity tracker and corresponding smartphone app (Atris app, Peercode B.V. Geldermalsen, the Netherlands) in combination with remote coaching by a physiotherapist and dietitian. The purpose of OPRAH was to facilitate faster and better recovery in physical functioning by stimulating patients' self-management regarding protein intake and level of physical activity after hospital discharge. OPRAH was developed by a multidisciplinary team with the use of the Behavioral Change Wheel. More details about the development of the intervention are described in the trial protocol. [31]

Approximately one week before surgery, patients in the intervention group received the Physical Activity Monitor (PAM) and access to the Atris app. The app allowed patients to monitor their physical activity and register their daily protein intake through a simple in-app registration tool combined with personalized goals (See Figure 1). During hospitalization, the physiotherapist and dietitian guided patients in using the app. As hospital discharge approached, the physiotherapist and dietitian set goals on active minutes and protein intake in consultation with the patient. After hospital discharge, patients were encouraged to actively engage in their recovery by wearing the PAM device 24 hours a day and recording their daily protein intake for three months. They received remote coaching from a physiotherapist and a dietitian via phone or the applications' chat function when indicated. Physiotherapists and dietitians had access to patients' physical activity levels and protein intake through a corresponding web application, enabling them to monitor progress, discuss goals, and provide timely support when needed. Patients could ask questions through the app's chat function. The goal for physical activity was to gradually improve activity to pre-operative levels and the goal for protein intake was to meet personal daily requirements. Goals and the level of coaching were tailored to individual needs and preferences using a Shared Decision Making process. Physiotherapists and dieticians involved in this study received a three-day training on Motivational Interviewing techniques, which were applied during coaching sessions to support patient self-management. [33]

Both patients in the control and intervention group received usual care. Post-discharge physiotherapy care was not standard, but physiotherapists could advise patients to continue treatment in primary care based on their clinical assessment. Post-discharge

dietetic care varied between centers; at Amsterdam UMC, patients after esophagus-, stomach-, pancreas-, biliair cancer surgery received standard follow-up consultations at multiple time points, while at St. Antonius, only patients after pancreas surgery had a scheduled consultation at two weeks post-discharge. Patients after hepatic, colorectal or pulmonary cancer surgery received postoperative consultations by the dietician only on indication or the dietician may advised the patient to continue dietetic treatment in primary care. All patients who underwent esophageal cancer surgery received tube feeding, whereas other patients received it only if indicated by the dietitian. All participants were allowed to use allied healthcare services during the study period.

Figure 1. *Screenshots of the English language version of the Atris app*



Outcomes

Baseline measurements (T_0) were conducted prior to surgery and follow-up measurements took place at hospital discharge (T_1), and one (T_2), four (T_3) and eight (T_4) weeks and three (T_5) and six (T_6) months after hospital discharge. The primary outcome was recovery in physical functioning during six months after hospital discharge. Physical functioning was measured at all follow-up time points with the Computer Adaptive Testing (CAT) version of the Dutch-Flemish Patient Reported Outcome Measurement Information System (PROMIS) Physical Function (PF) questionnaire. [34] The CAT PROMIS PF is a reliable, sensitive computer-adaptive questionnaire using a 5-point Likert scale to assess physical function over the past week, with T-scores standardized to the US population.

[35-38] The secondary outcome was physical activity, which was measured using the thigh-worn tri-axial ActivPAL accelerometer (PAL Technologies Ltd., Glasgow, UK), a widely used and validated tool for assessing posture and stepping. [39-41] Patients in both the intervention and control group wore the ActivPAL for 5 days at T_0, T_1, T_3, T_5 and T_6. For the analysis, the mean number of active minutes of the valid measured days were calculated. Data was considered missing if the number of valid days was less than 3 days.

Additional outcomes were protein and energy intake (48h dietary recall), fatigue (CAT PROMIS Fatigue), pain (Numeric Pain Rating Scale [NPRS]), quality of life (EQ-5D-5L), participation (CAT PROMIS ability to and satisfaction with participation in social roles and activities), self-efficacy (General Self-Efficacy Scale [GSES]), global perceived effect (GPE), lean body mass (Bioelectrical Impedance Analysis [BIA]), Handgrip strength (Hand-held dynamometer), physical performance (30 second chair stand test [30SCST], two minute step test [TMST]), hospital readmissions within 30 days after hospital discharge and adverse events. A detailed description of the outcome measures is provided in the study protocol. [31]

Statistical analysis

The calculation of the sample size was based on an estimated between-group effect of 0.40 on the outcome physical functioning. Based on a alpha of 0.05, power of 0.80, a two-sided test for repeated measures with an expected within-subject correlation coefficient of 0.6 and 5 follow-up measurements the minimum number of 67 subjects per group was required, with a total sample size of 134. Allowing for a drop-out rate of 20% during the study, a sample of 161 patients was required.

The statistical analyses were done according to the statistical analysis plan, which was approved by the chief investigators (MvdL and MvdS) before data analyses. Analysis was conducted by the first author (MdL) blinded to group allocation using dummy codes for group allocation. The data analysis was reviewed by an experienced statistician (JWRT). All analyses were performed in Rstudio (version 4.4.3).

Descriptive statistics were calculated for all parameters, include mean, median, standard deviation, standard error of the mean and the interquartile range. The primary analysis was an intention to treat analysis conducted on the full analysis set. The primary outcome was the difference in recovery over time between groups, and was analysed using linear mixed model analysis, with group as independent variable and the PROMIS PF at all post-operative measurement points (T_1 – T_6) as dependent variable, adjusting for baseline PROMIS PF (T_0). [42] In addition, the effects per measurement point were analysed by

including an interaction between group and time (treated as categorical variable). To ensure the equality between groups, additional analyses were conducted adjusted for age, sex, tumour location and ASA score. Effect sizes were measured using Cohen's d. Dichotomous outcomes were analyzed using logistic mixed model analysis, with group as independent variable and the outcomes as dependent variable. To explore potential effect modification by tumour location, an interaction term between group and tumour location was included in the models. Also, the course of recovery in physical functioning, physical activity and protein intake per tumour location group was plotted to explore differences in the effect of the intervention between groups. To explore a potential learning effect, "days since first inclusion" was added as an interaction term with randomization group. In addition, per-protocol analyses were conducted among participants who adhered sufficiently to the intervention protocol, defined as having physical activity data for more than 80% of the study days and at least 14 days of recorded protein intake.

The study was monitored according to a predefined monitoring plan to ensure compliance with the Human Research Act (WMO), Good Clinical Practice (ICH-GCP), and ISO14155 guidelines. The Clinical Monitoring Center (CMC) conducted six on-site and one remote monitoring visits to verify protocol adherence, data integrity, and patient safety. Monitoring activities included source data verification, risk assessment, and safety reporting, following the study-specific monitoring plan.

Results

Between June 24, 2022 and December 1, 2023, 387 patients were assessed for eligibility (Figure 2). Of these patients, 92 were excluded based on the in- and exclusion criteria and 102 patients declined to participate in the study. A total of 193 patients consented for the study and were randomized to the intervention arm (N=90) or the control arm (N=103). In the intervention and control groups, 17 and 13 patients, respectively, dropped out or were excluded before hospital discharge and were therefore considered screen failures (Figure 2). Eventually, there were 73 patients participating in the intervention group and 90 patients in the control group. In the control group, 3 patients were excluded from analysis as there was no follow-up measurement available. In the intervention group, 57 patients (78%) used the intervention as intended and were included in the per-protocol analysis. Follow-up was completed on July 23, 2024. In the intervention and control group, respectively 9 (12%) and 14 (16%) patients were lost to follow up (Figure 2). An overview of complete data of the primary outcome is presented in Supplementary File 2.

Baseline characteristics of the intervention and control group are presented in Table 1. The percentage of males was 56% in the intervention group and 68% in the control group. Mean age was 64 in both groups. Upper GI was the most common tumour location (intervention 40%, control 38%), followed by pulmonary (intervention 31%, control 35%), HPB (intervention 18%, control 14%) and colorectal (intervention 11%, control 13%). The percentage of complications within 30 days after surgery was 37% in the intervention group and 43% in the control group. Early postoperative mobilization was different between the groups. On postoperative day 1, 59% of patients in the intervention group reached the goal of walking at least 75 meters, compared to 40% in the control group. On day 2, these numbers increased to 73% in the intervention group and 53% in the control group.

The observed recovery in physical functioning for both study arms is visually presented in figure 3. A significant overall intervention effect was found on physical functioning (difference = 1.72 [95%CI 0.18 – 3.26], p = 0.0300) with an effect size of 0.21. At six months post-discharge, 55% of intervention patients and 35% of control patients returned to baseline physical functioning (OR = 2.45 [95%CI 1.18; 5.52], p = 0.0166).

Figure 2. *Consort 2010 Flow Diagram*

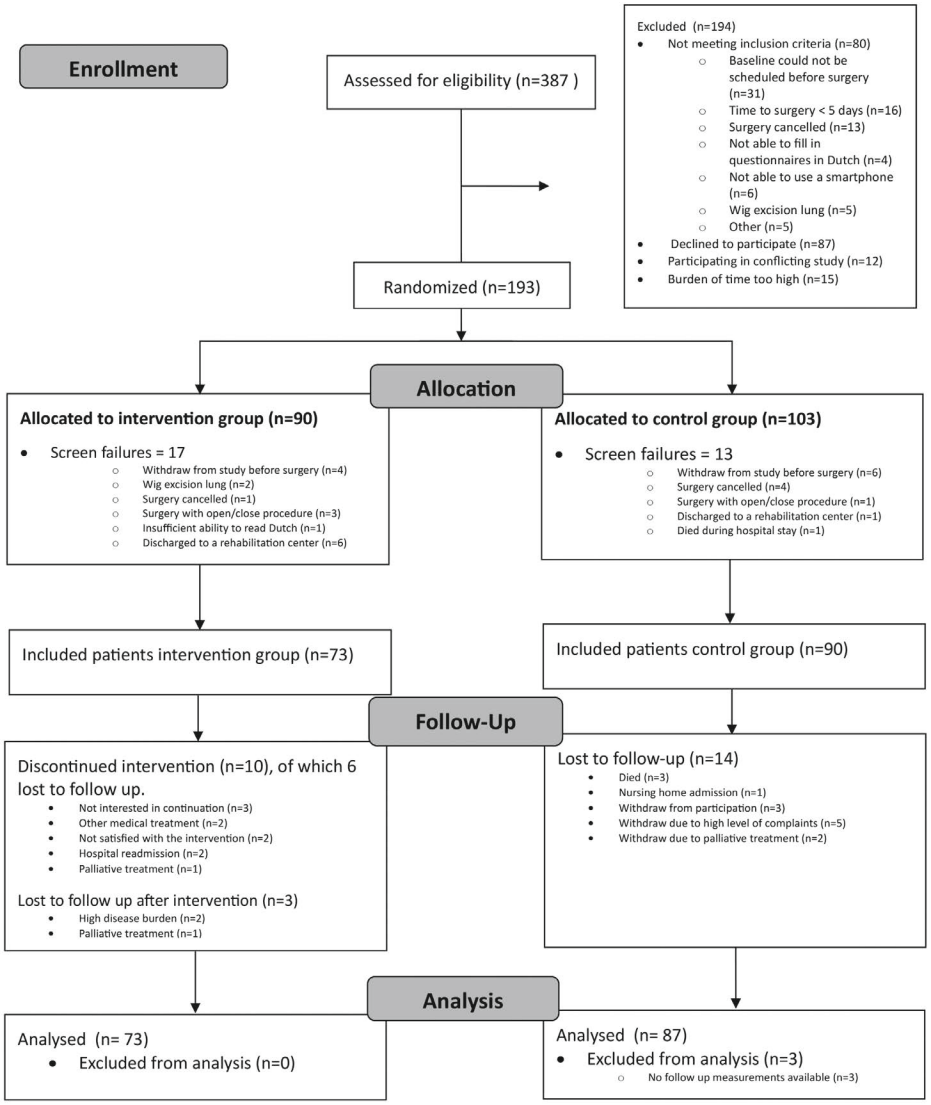


Table 1. *Patient and perioperative characteristics.*

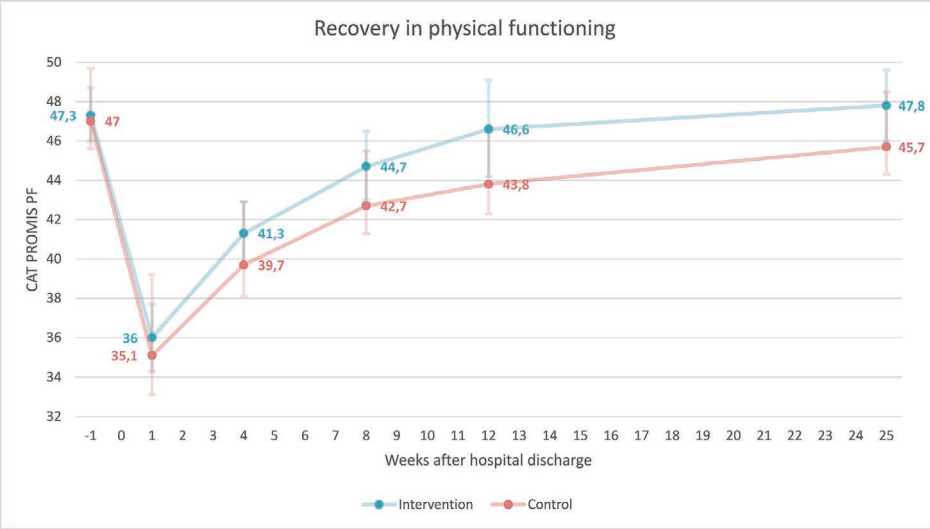
	Variable	Intervention (N=73)	Control (N=90)
Patient characteristics	**Sex (male), n (%)**	41 (56)	61 (68)
	Age (years), mean ± SD	64 ± 10.6	64 ± 10.2
	BMI, mean ± SD	25.9 ± 4.7	26.5 ± 4.8
	BMI categorial, n (%)		
	Underweight (< 18.5)	1 (1)	1 (1)
	Normal (18.5 – 25)	37 (51)	39 (43)
	Overweight (25-30)	22 (30)	34 (38)
	Obese (> 30)	13 (18)	16 (18)
	Educational Level, n (%)		
	Low	12 (16)	15 (17)
	Middle	37 (51)	33 (37)
	High	24 (33)	40 (44)
	Household, n (%)		
	Living alone	15 (21)	17 (19)
	Living together	58 (79)	72 (80)
	Unknown		1 (1)
	Tumour location, n (%)		
	Pulmonary	23 (31)	31 (35)
	Upper GI	29 (40)	34 (38)
	Esophageal	*20 (27)*	*29 (32)*
	Gastric	*9 (12)*	*5 (6)*
	HPB	13 (18)	13 (14)
	Hepatic	*11 (15)*	*11 (12)*
	Pancreatic	*0 (0)*	*1 (1)*
	Biliary	*2 (3)*	*1 (1)*
	Colorectal	8 (11)	12 (13)
	Tumour size, n (%)		
	1	10 (14)	16 (18)
	2	22 (30)	25 (28)
	3	24 (33)	32 (35)
	4	9 (12)	7 (8)
	Unknown	8 (11)	10 (11)
	ASA grade ≥3 , n (%)	19 (26)	31 (34)
	Charlson Comorbidity Index, mean ± SD	5.1 ± 2.0	4.9 ± 1.9

Table 1. *Continued*

	Variable	Intervention (N=73)	Control (N=90)
Perioperative characteristics	**Type of surgery, n (%)**		
	Thoracoscopic/Laparoscopic	54 (74)	66 (73)
	Open	19 (26)	24 (27)
	Operation duration (min), mean ± SD	218 ± 96	250 ± 125
	Unknown, n(%)	*26 (36)*	*29 (32)*
	Complications, n (%)		
	Yes	27 (37)	39 (43)
	No	46 (63)	51 (57)
	Comprehensive Complication Index, mean ± SD (if complications = yes)	27.3 ± 10.8	31.1 ± 14.5
	Severe complications (Clavien Dindo ≥ 3), n(%)	10 (14)	19 (21)
	AMEXO ≥ 8 at postoperative day 1, n (%)	43 (59)*	36 (40)
	AMEXO ≥ 8 at postoperative day 2, n (%)	53 (73)*	48 (53)
	AMEXO ≥ 9 at postoperative day 2, n (%)	10 (14)	4 (4)
	Length of hospital stay, median (IQR)	6 (3 - 8)	6.5 (3 - 10)
	Tube feeding pre-operative, n (%)	2 (3)	1 (1)
	Tube feeding post-discharge, n (%)	27 (37)	39 (43)
	Preoperative treatment, n (%)		
	No treatment	36 (49)	41 (46)
	Chemotherapy	14 (19)	16 (18)
	Chemoradiotherapy	20 (28)	31 (34)
	Radiotherapy	3 (4)	2 (2)
	Number of days between last treatment and surgery, mean ± SD	69 ± 21	70 ± 24
	Postoperative treatment, n (%)		
	No treatment	50 (69)	62 (69)
	Chemo- or immunotherapy	19 (26)	21 (23)
	Chemoradiotherapy	0 (0)	0 (0)
	Radiotherapy	1 (1)	3 (3)
	Unknown	3 (4)	4 (5)
	Number of days between hospital discharge and first treatment, mean ± SD	70 ± 18	78 ± 21

ASA = The American Society of Anesthesiologists Classification of physical health; BMI = body mass index; Complications; occurred within 30 days after surgery or during hospital stay; AMEXO = Amsterdam UMC Extension of the John Hopkins Highest Level of mobility. AMEXO ≥ 8 = walking approximately 250ft/75m or more. AMEXO ≥ 9 = Walking approximately 750ft/225m or more. *significantly different compared to control group ($p<0.05$)

Figure 3. *Observed mean values of physical functioning over time per group, with error bars representing 95% confidence interval.*



CAT PROMIS PF = Computer Adaptive Testing (CAT) Patient Reported Outcome Measurement Information System (PROMIS) Physical Function (PF).

Observed values for the other outcomes are presented in Supplementary File 3. A significant overall intervention effect was found for the most important secondary outcome, physical activity (B = 12.85 [95%CI 2.66 – 23.04], p = 0.0146) with an effect size of 0.32. Additional significant effects were noted on protein intake, fatigue, pain, participation in social roles and activities, self-efficacy, global perceived effect, and handgrip strength. No significant differences were found on energy intake, quality of life, satisfaction with participation in social roles and activities, lean body mass or physical performance tests. Estimated mean differences and effect sizes for the overall intervention effects are presented in Table 2. The outcomes at each measurement point are presented in Supplementary File 4. No significant effect was found on readmission rates (odds ratio [95%CI] = 0.56 [0.61; 5.06], p = 0.6000). No (serious) adverse events related to the intervention occurred; one minor adverse event possibly linked to measurement procedures was reported, without lasting harm. Per-protocol analysis confirmed the significant intervention effects and revealed additional effect on VAS Quality of Life score (Supplementary File 5). No significant interaction was found between tumour location and the intervention effect on physical functioning or physical activity. Recovery trajectories of physical functioning, physical activity, and the percentage of protein intake requirements, stratified by tumour location, are presented in Supplementary File 6. No significant learning effect was observed, as

the interaction between days since first inclusion and the intervention effect on physical functioning was not significant.

The frequency of contact by telephone and chat with the physiotherapist and dietitian for intervention patients, stratified by tumour location, is shown in Supplementary File 7.

Table 2. *Overall intervention effect per outcome measure.*

	Crude			**Adjusted***		
Outcome	Estimated mean difference (95%CI)	P value	Effect size (Cohens' d)	Estimated mean difference (95%CI)	P value	Effect size (Cohens' d)
Physical functioning	1.41 (-0.16; 2.99)	0.0792	0.17	**1.72 (0.18; 3.26)**	**0.0300**	**0.21**
Physical activity	**11.60 (0.92; 22.28)**	**0.0338**	**0.29**	**12.85 (2.66; 23.04)**	**0.0146**	**0.32**
Protein intake	**10.06 (4.37; 15.74)**	**0.0007**	**0.34**	**7.82 (2.64; 13.01)**	**0.0036**	**0.26**
Energy intake	**5.82 (0.26; 11.38)**	**0.0410**	**0.20**	4.67 (-0.81; 10.16)	0.0970	0.16
Fatigue	**-2.96 (-5.20; -0.72)**	**0.0101**	**-0.30**	**-2.95 (-5.18; -0.73)**	**0.0101**	**-0.29**
Pain	**-0.54 (-0.97; -0.11)**	**0.0142**	**-0.30**	**-0.57 (-0.99; -0.15)**	**0.0081**	**-0.32**
Quality of life	0.02 (-0.02; 0.06)	0.2997	0.12	0.02 (-0.02; 0.06)	0.2973	0.12
VAS Quality of life	3.49 (-0.41; 7.38)	0.0795	0.19	3.72 (-0.13; 7.58)	0.0600	0.21
Participation (ability)	2.27 (-0.29; 4.83)	0.0830	0.19	**3.00 (0.54; 5.46)**	**0.0178**	**0.25**
Participation (satisfaction)	0.78 (-1.77; 3.32)	0.5477	0.07	1.15 (-1.34; 3.64)	0.3363	0.10
Self-efficacy	**1.17 (0.16; 2.18)**	**0.0241**	**0.23**	**1.22 (0.19; 2.25)**	**0.0210**	**0.25**
Global perceived effect	**0.39 (0.12; 0.65)**	**0.0045**	**0.38**	**0.42 (0.18; 0.67)**	**0.0010**	**0.34**
Lean body mass	0.05 (-0.92; 1.01)	0.9252	0.004	0.40 (-0.51; 1.31)	0.3887	0.16
Handgrip strength	1.04 (-0.19; 2.28)	0.0984	0.09	**1.26 (0.06; 2.45)**	**0.0425**	**0.11**
30 second chair stand test	0.12 (-0.63; 0.87)	0.7561	0.03	0.24 (-0.46; 0.93)	0.5127	0.06
Two minute step test	2.80 (-1.52; 7.11)	0.2054	0.12	3.62 (-0.60; 7.84)	0.0982	0.15

*Adjusted for sex, age, ASA and tumour location

Discussion

This multicentre, single-blinded randomized controlled trial demonstrated that the OPRAH intervention – combining self-monitoring with remote coaching by a physiotherapist and dietitian to promote post-discharge physical activity and protein intake – significantly enhances recovery of physical functioning up to six months following oncological gastrointestinal and pulmonary surgery. Additionally, the intervention positively impacted

physical activity levels, protein intake, fatigue, pain, participation, self-efficacy and handgrip strength. With sufficient adherence, this intervention also shows potential to improve patients' quality of life.

Most research on combined nutrition and physical interventions in cancer focus on breast or prostate cancer and rarely addresses the post-discharge period. [29, 43] Chang et al. tested a 12-week multimodal programme (walking with smart bracelet, dietary guidance, symptom management, nurse-led coaching) in patients after esophagectomy and reported higher functional scores at one and three months post-discharge, consistent with our findings. [27] Similarly, Den Bakker et al. evaluated a perioperative blended eHealth programme (activity tracker, app, website, e-consultations) after major abdominal surgery; intervention patients returned to normal activities sooner, in line with our results, although no PROMIS PF differences were observed up to 12 months. [44] Granger et al. examined a home-based exercise and self-management programme after pulmonary resection (exercise booklet, education, activity monitor, weekly physiotherapy calls) and found no differences in patient-reported physical functioning but clinically relevant improvements in objectively measured functioning. This contrasts with our significant patient-reported but not objectively measured effects, possibly due to differences in intervention focus: their exercise-based approach versus our behaviour change strategy targeting daily activity and protein intake. Combining structured exercise training with behaviour change interventions may therefore offer added benefit.

Although it was initially hypothesized that preserving muscle mass through increased protein intake and physical activity would enhance recovery in physical functioning after surgery, no significant differences in lean body mass were observed. Nevertheless, improvements in physical functioning and handgrip strength were evident. This suggests that muscle function and strength may be more critical determinants of functional recovery than muscle mass itself - except for patients with low muscle mass, e.g. sarcopenia, where low muscle mass contributes significantly to impaired function and performance, alongside other factors. [46] In our study, however, only three patients met the European Working Group on Sarcopenia in Older People (EWGSOP) criteria for sarcopenia, which may explain the absence of group differences in muscle mass. [47]

To date, no clinically meaningful difference has been established for the CAT PROMIS PF in oncological surgery patients. In broader cancer populations, proposed thresholds for clinical significance range from 2 to 6 points. [48-50] In our study, the estimated mean difference in physical functioning across the five follow-up assessments was 1.72 points. Although this falls just below the lower threshold for clinical relevance, the

smaller differences observed early in the recovery phase—when the intervention was still in its initial stages—may account for this. By the end of the intervention period (12 weeks post-discharge), the mean difference increased to 2.36 points (95% CI 0.08–4.64), suggesting a potentially clinically meaningful effect. While effect sizes were small to moderate, it remains uncertain whether larger between-group differences should be expected, considering that all patients were recovering from major surgery and likely followed a natural recovery trajectory. Importantly, intervention patients reported greater global perceived recovery at 3 and 6 months (effect sizes 0.45 and 0.40) and had higher odds of returning to baseline functioning at 6 months, supporting the subjective and clinical relevance of the intervention.

Our results indicate that the behavioural change techniques in OPRAH were effective, with significant improvements in targeted behaviour compared to controls. This aligns with a realist review identifying self-monitoring, goal-setting, action planning, social support and knowledge shaping as key components for physical activity interventions. [51] However, effects varied between patient groups: pulmonary cancer patients showed the greatest improvements in physical activity and protein intake despite the least coaching. This may reflect differences in surgical impact and barriers to behaviour change, or suggest that coaching frequency does not directly determine effectiveness. Qualitative findings confirmed that patients valued coaching as providing a sense of support regardless of frequency [52], in line with a review in breast cancer patients showing no consistent benefit of increased supervision. [53] Thus, coaching may work through its perceived presence rather than intensity, highlighting the need to tailor frequency to individual needs while ensuring timely support.

This study has some limitations. First, this trial was conducted in a heterogeneous population, including patients with various tumour locations. This broad inclusion was intentional, as physical activity and nutrition are relevant across these cancer groups. Although subgroup analyses were performed to explore potential differences in outcomes, they were underpowered and therefore not suitable to make reliable statements. Second, patients with high postoperative symptom burden were more likely to withdraw, causing possible selective dropout. Third, despite the use of block randomization to promote balance, an unequal group distribution occurred. These imbalances underline the importance of adjusting for baseline variables in the analysis to reduce potential confounding. Fourth, patients with low health literacy, migration backgrounds, or low socio-economic status were somewhat underrepresented. This underrepresentation is common in clinical research and hampers the ability to understand the specific needs of these populations and to develop appropriately tailored interventions. [43] Barriers

such as language difficulties, low (health) literacy, cultural incongruence, limited digital access, and practical constraints often hinder their participation, making it a key priority to better reach and engage these populations in future studies. [54]

A strength of this study is the robust multicentre randomized controlled trial design, including blinding of assessors and data analysis, and the use of reliable and valid outcome measures. Moreover, the intervention was tailored and individualized, allowing physiotherapists and dietitians to adjust the level of coaching based on patients' needs rather than adhering to a fixed protocol. Importantly, implementation appeared stable over time, as no measurable learning effect was observed. Finally, the conduct of a pilot study prior to the RCT facilitated refinement of both the intervention and study procedures, enhancing the overall feasibility and methodological rigor of the trial. [55]

In conclusion, our findings indicate that the OPRAH intervention – a blended intervention that combines an activity tracker, smartphone application, and remote coaching by a physiotherapist and dietitian – enhances recovery in physical functioning after oncological gastrointestinal and pulmonary surgery. While this blended intervention shows promising results, the optimal patient selection and intensity of coaching to maximize patient benefit while minimizing costs need to be determined. Additionally, further adaptations and personalization are essential to reach a broader and more diverse patient population, particularly patients with low (health) literacy.

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Contributors

MvdS and MvdL supervised the study. MEdL was the coordinating researcher. EG, HK, CD, MIvBH, MGB, JEE, VdG, MvdS and MvdL contributed to the study design. MEdL, CvW and WMC contributed to the recruitment and data-collection. MEdL did the literature review and the data management. MEdL, JWT, MvdS and MvdL contributed to the data analysis and data interpretation. MEdL drafted and revised the manuscript. All authors critically revised the manuscript. All authors had full access to the data in the study and had final responsibility for the decision to submit for publication.

Data sharing

The statistical analysis plan, anonymized datasets and statistical code used in this study can be made available upon reasonable request to the corresponding author.

Declaration of interests

The authors declare that they have no competing interests.

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Supplementary File 1. Intervention description and replication (TiDieR).

Name	OPRAH: A blended intervention, focused on self-monitoring, personal feedback and coaching regarding physical activity (PA) and protein intake, in patients with cancer planned for GI or lung surgery.
Why	Higher levels of PA in the perioperative period has a potential positive effect on recovery of physical functioning. However, stimulating PA in patients during hospitalization is challenging. The challenge to be physically active and resume daily activities can be even greater in the patient's own environment, where patients often experience barriers, such as physical symptoms, insecurity and lack of motivation or social support. Besides stimulating PA, it is also important to optimize the nutritional intake in the perioperative period, especially protein intake. Protein is the essential building block of muscle tissue and is needed in order to preserve muscle mass. Higher muscle mass has been shown to be an important factor in improving clinical outcomes in patients with cancer. Furthermore, protein is most effectively used for protein synthesis in combination with the stimulating effect of PA. However, previous studies found that many surgical patients were unable to meet their protein requirements after surgery and therefore additional support in protein intake is needed. Improved protein intake supports improvement in recovery of physical functioning. Self-monitoring is an effective and important behavior change technique, especially in combination with other coaching techniques e.g. goal setting, feedback on performance and social support.
What (materials)	The patients in the intervention group receive an ankle-worn PA monitor (PAM) and access to the corresponding application, Atris app, one week prior to surgery. The Atris app provides feedback on the number of active minutes per day. In addition, patients are able to self-monitor their protein intake by a simple self-registration tool. Patients have insight in their personal activity and protein goals, which are set in collaboration with their physiotherapist and dietitian. The app provides non-specific rewards if their goals have been met. In addition, the physiotherapist and dietitian will get notifications if the patients is not reaching their goal within a certain amount of time. These reminders can be tailored per patient. Via the app, patients are also able to chat with and receive personalized advice from the physiotherapist and dietitian. Patients in the intervention group will also be given a leaflet containing information about physical activity and protein intake after surgery and additional information about the Atris app. Patients receive additional behavioural change support by a physiotherapist and dietitian via telephone calls and chat messages. The coaching strategies of the physiotherapist and dietitian will be based on the principles of Motivation Interviewing (MI).

What (procedures)	One week prior to surgery, patients receive the PAM and will receive access to and instructions about the Atris app to get familiarized with the application. Patients will be instructed by a flyer and a telephonic consultation with a researcher. Patients are asked to wear the PAM in a strap around the ankle, from at least one week prior to surgery until 3 months after surgery. During hospitalization, the treating physiotherapist and dietitian guide the patients in the use of the app during their standard consultations. As discharge approaches, the patient will be supported by the physiotherapist and dietitian using the shared decision making (SDM) process to set goals on active minutes and protein intake for after discharge. In case the dietitian or physiotherapist is not able to meet the patient during hospitalization, the goals will be discussed by telephone in the first week after discharge. After discharge to home, patients are coached remotely (by telephone) by a physiotherapist and dietitian about physical activity and protein intake. The goals and the degree of coaching will be tailored using a SDM process to the personal needs and preferences of the patient during the intervention period. To support patients in improving their self-management, MI techniques will be applied during the coaching sessions with the physiotherapist and dietitian.
Who provides	The intervention will be provided by the physiotherapist and dietitian
How	After randomization, the patients in the intervention group will receive the PAM, instructions to download the Atris app and informational leaflet by post. Patients will have access to the Atris app via their smartphone. During hospitalization or in the first week after discharge, goals will be set in collaboration with the physiotherapist and dietitian. Patients will receive chat messages or telephone calls after discharge based on their personal needs and preferences.
Where	The intervention will be delivered remotely and participants will be able to access al the intervention elements at a location of their choice.
When and how much	Frequency of using the PAM, Atris app and informational leaflet will be at the discretion of the patients. Patients will receive chat messages and/or telephone calls by the physiotherapist and dietitian based on their personal needs and preferences.
Tailoring	All patients will receive the same intervention materials. Personal goals on physical activity and protein intake will be tailored based on a SDM process with the physiotherapist and dietitian. These goals can be adapted at any time and will be discussed via the chat or telephone calls. The number of phone calls and chat messages will be tailored based on the personal needs and preferences and if the physiotherapist or dietitian assesses that there is added value for a contact moment, for example, if a patients has not achieved his goal for one week. The physiotherapist and dietitian can tailor the notifications per patient (e.g. if a goal for 7 number of days is below 70%).

How well	In order to determine whether the intervention techniques used in the intervention (MI and SDM) have been implemented properly, some consultations with the physiotherapist and dietitian will be recorded. The audio records will be made with professional recording equipment and in no case with a telephone. The consultations will only be recorded if the patients has given his or her specific consent to record their consultations. Researchers trained in the use of MI and SDM will listen to these consultation to determine if the techniques have been used appropriately. The recordings will be made at multiple times during the study as a learning effect of the health professionals is expected. In addition, other aspects of the treatment fidelity will be recorded: • The number of consultations with the physiotherapist and dietitian • The delivery method of the intervention (telephone or chat).

Supplementary File 2. Overview of complete data of primary outcome

	Intervention (N=73)	Control (N=90)
Baseline (T_0), N (%)	73 (100%)	87 (97%)
1 week after hospital discharge (T_2)	62 (85%)	66 (76%)
4 weeks after hospital discharge (T_3)	62 (85%)	73 (85%)
8 weeks after hospital discharge (T_4)	60 (82%)	71 (82%)
3 months after hospital discharge (T_5)	61 (84%)	70 (80%)
6 months after hospital discharge (T_6)	55 (76%)	67 (77%)

Supplementary File 3. Observed outcomes of primary and secondary outcome measures.

Outcome	Intervention		Control	
Physical functioning	**Mean (SD)**	**N**	**Mean (SD)**	**N**
Baseline	47.3 (6.0)	73	47.0 (6.5)	87
1 week	36.0 (6.7)	62	35.1 (8.3)	66
4 weeks	41.3 (6.6)	62	39.7 (7.0)	73
8 weeks	44.7 (6.9)	60	42.7 (6.0)	71
12 weeks	46.6 (9.7)	61	43.8 (6.4)	70
6 months	47.8 (6.8)	55	45.7 (5.7)	67
Physical activity				
Baseline	106 (50)	71	96 (36)	86
1 week	59 (32)	58	49 (25)	66
4 weeks	83 (45)	65	66 (30)	67
12 weeks	87 (46)	61	77 (34)	64
6 months	89 (50)	52	82 (35)	52

Supplementary File 3. Continued

Outcome	Intervention		Control	
Protein intake (% of requirement)				
Baseline	98 (41)	71	96 (30)	88
1 week	104 (27)	63	91 (29)	75
4 weeks	107 (29)	65	92 (30)	77
12 weeks	96 (29)	65	83 (31)	71
6 months	86 (26)	58	83 (26)	62
Energy intake (% of requirement)				
Baseline	104 (30)	71	106 (28)	88
1 week	101 (26)	63	95 (28)	75
4 weeks	108 (29)	65	99 (30)	77
12 weeks	102 (30)	65	95 (30)	71
6 months	97 (27)	58	98 (26)	62
Fatigue	**Mean (SD)**	**N**	**Mean (SD)**	**N**
Baseline	48.8 (9.9)	72	49.6 (11.6)	87
1 week	53.6 (8.8)	67	56.8 (6.3)	73
4 weeks	53.1 (7.9)	60	55.8 (7.4)	71
8 weeks	50.3 (10.8)	60	55.1 (9.4)	70
12 weeks	49.8 (10.6)	62	54.3 (11.3)	70
6 months	48.7 (12.7)	57	51.3 (11.4)	65
Pain				
Baseline	0.8 (1.5)	72	1.0 (1.5)	87
1 week	1.9 (1.8)	67	2.3 (1.7)	73
4 weeks	1.1 (1.4)	60	1.7 (1.7)	71
8 weeks	1.1 (1.5)	59	1.7 (2.3)	70
12 weeks	0.8 (1.4)	62	1.4 (1.9)	70
6 months	0.8 (1.5)	57	1.2 (1.7)	65
Quality of life				
Baseline	0.84 (0.15)	73	0.85 (0.15)	87
1 week	0.68 (0.18)	67	0.68 (0.20)	73
4 weeks	0.75 (0.16)	61	0.72 (0.19)	71
8 weeks	0.80 (0.16)	59	0.77 (0.15)	70
12 weeks	0.82 (0.16)	62	0.77 (0.18)	70
6 months	0.82 (0.18)	57	0.78 (0.16)	65

Supplementary File 3. Continued

Outcome	Intervention		Control	
VAS quality of life				
Baseline	70.8 (20.9)	73	74.0 (18.0)	87
1 week	61.5 (16.9)	67	61.1 (18.4)	73
4 weeks	68.8 (16.1)	61	64.3 (15.8)	71
8 weeks	71.2 (18.2)	60	68.5 (17.7)	70
12 weeks	74.3 (17.4)	62	66.6 (20.5)	70
6 months	75.4 (18.1)	57	73.3 (14.5)	65
Participation (ability)				
Baseline	52.8 (13.2)	73	54.3 (15.1)	87
1 week	44.1 (10.1)	67	43.6 (9.4)	73
4 weeks	46.1 (9.7)	60	44.5 (9.4)	71
8 weeks	49.2 (12.2)	60	47.1 (9.2)	70
12 weeks	52.3 (14.2)	62	47.7 (10.1)	70
6 months	53.2 (16.2)	57	51.7 (15.7)	65
Participation (satisfaction)	**Mean (SD)**	**N**	**Mean (SD)**	**N**
Baseline	49.5 (9.0)	73	50.3 (11.2)	87
1 week	40.8 (7.9)	67	40.9 (7.3)	73
4 weeks	44.5 (9.9)	60	43.3 (9.2)	71
8 weeks	47.9 (10.3)	60	46.1 (9.9)	70
12 weeks	50.0 (11.7)	62	48.2 (12.7)	70
6 months	51.0 (13.2)	57	51.9 (17.6)	65
Self-efficacy				
Baseline	33.2 (4.0)	71	33.1 (4.4)	87
1 week	32.9 (4.3)	66	31.7 (5.5)	73
4 weeks	33.8 (3.9)	60	32.4 (5.3)	71
8 weeks	33.9 (4.1)	59	32.2 (6.0)	69
12 weeks	34.7 (4.2)	61	32.7 (5.7)	70
6 months	35.1 (4.3)	57	34.3 (4.6)	64
Lean body mass				
Baseline	54.5 (12.0)	71	56.4 (10.6)	89
4 weeks **Δ baseline**	51.5 (10.2) 2.8 (4.0)	68	52.8 (9.9) 3.3 (3.3)	73
12 weeks **Δ baseline**	53.1 (11.4) 2.2 (3.3)	62	53.9 (9.8) 2.1 (4.3)	68

Supplementary File 3. Continued

Outcome	Intervention		Control	
Handgrip strength				
Baseline	37.5 (11.7)	73	39.2 (11.3)	90
4 weeks **Δ baseline**	36.3 (11.9) 1.2 (3.2)	67	36.4 (10.5) 2.4 (4.8)	75
12 weeks **Δ baseline**	37.5 (11.9) 0.5 (4.2)	64	38.0 (11.1) 1.9 (5.1)	70
Physical performance – 30 second chair stand test				
Baseline	12.6 (3.3)	72	12.0 (3.3)	89
4 weeks	12.3 (3.8)	64	11.9 (4.0)	75
12 weeks	13.1 (3.7)	59	13.0 (3.7)	66
Physical performance – Two minute step test				
Baseline	77.8 (22.2)	73	76.4 (22.3)	89
4 weeks	72.0 (21.3)	61	69.2 (23.2)	72
12 weeks	79.3 (22.3)	58	75.3 (26.0)	66
Global Perceived Effect				
1 week, n(%)				
- **Much better**	3 (4)		3 (3)	
- **Better**	22 (30)		19 (21)	
- **Little better**	35 (48)		33 (37)	
- **Same**	3 (4)		8 (9)	
- **Little worse**	3 (4)		3 (3)	
- **Worse**	1 (2)		6 (7)	
- **Much worse**	0 (0)		1 (1)	
missing	*6 (8)*		*17 (19)*	
4 weeks, n(%)				
- **Much better**	7 (10)		5 (6)	
- **Better**	32 (44)		29 (32)	
- **Little better**	15(21)		23 (26)	
- **Same**	1 (1)		5 (6)	
- **Little worse**	4 (6)		6 (7)	
- **Worse**	2 (3)		3 (3)	
- **Much worse**	0 (0)		0 (0)	
missing	*12 (16)*		*19 (21)*	
8 weeks, n(%)				
- **Much better**	18 (25)		10 (11)	
- **Better**	22 (30)		34 (38)	
- **Little better**	13 (18)		15 (17)	
- **Same**	2 (3)		2 (2)	
- **Little worse**	4 (6)		5 (6)	
- **Worse**	1(1)		3 (3)	
- **Much worse**	0(0)		1 (1)	
missing	*13 (18)*		*20 (22)*	
Hospital readmission				
Hospital readmission within 30 days after hospital discharge, n (%)	6 (8)		11 (15)	

Supplementary File 4. Longitudinal data analysis of primary and secondary outcome measures.

	Crude			Adjusted*		
Outcome	**Estimated mean difference (95%CI)**	**P value**	**Effect size (Cohens' d)**	**Estimated mean difference (95%CI)**	**P value**	**Effect size (Cohens' d)**
Physical functioning						
Overall intervention effect	*1.41 (-0.16; 2.99)*	*0.0792*	*0.17*	***1.72 (0.18; 3.26)***	***0.0300***	***0.21***
1 week	0.86 (-1.46; 3.17)	0.4691	0.11	1.10 (-1.21; 3.40)	0.3552	0.15
4 weeks	1.43 (-0.84; 3.71)	0.2196	0.21	1.68 (-0.58; 3.94)	0.1500	0.25
8 weeks	1.91 (-0.40; 4.22)	0.1078	0.30	2.14 (-0.16; 4.43)	0.0714	0.33
12 weeks	2.17 (-0.13; 4.48)	0.0663	0.27	**2.36 (0.08; 4.64)**	**0.0454**	**0.29**
6 months	1.69 (-0.69; 4.07)	0.1666	0.27	1.96 (-0.40; 4.32)	0.1078	0.31
Physical activity						
Overall intervention effect	***11.60 (0.92; 22.28)***	***0.0338***	***0.29***	***12.85 (2.66; 23.04)***	***0.0146***	***0.32***
1 week	8.86 (-3.52; 21.24)	0.1630	0.31	10.07 (-1.87; 22.01)	0.1027	0.35
4 weeks	**16.69 (4.48; 28.91)**	**0.0082**	**0.43**	**18.01 (6.24; 29.79)**	**0.0034**	**0.46**
12 weeks	10.28 (-2.08; 22.65)	0.1052	0.25	11.39 (-0.51; 23.30)	0.0643	0.28
6 months	5.20 (-7.69; 18.09)	0.4307	0.12	6.21 (-6.25; 18.67)	0.3330	0.15
Protein intake						
Overall intervention effect	***10.06 (4.37; 15.74)***	***0.0007***	***0.34***	***7.82 (2.64; 13.01)***	***0.0036***	***0.26***
1 week	**10.23 (1.91; 18.54)**	**0.0172**	**0.35**	**8.27 (0.29; 16.25)**	**0.0453**	**0.29**
4 weeks	**13.23 (4.98; 21.48)**	**0.0020**	**0.43**	**10.83 (2.90; 18.76)**	**0.0087**	**0.35**
12 weeks	**12.20 (3.84; 20.56)**	**0.0049**	**0.40**	**10.06 (2.03; 18.08)**	**0.0158**	**0.33**
6 months	5.04 (-3.75; 13.84)	0.2631	0.20	2.78 (-5.68; 11.24)	0.5225	0.11

Supplementary File 4. Continued

	Crude			Adjusted*		
Outcome	**Estimated mean difference (95%CI)**	**P value**	**Effect size (Cohens' d)**	**Estimated mean difference (95%CI)**	**P value**	**Effect size (Cohens' d)**
Kcal intake						
Overall intervention effect	***5.82 (0.26; 11.38)***	***0.0410***	***0.20***	*4.67 (-0.81; 10.16)*	*0.0970*	*0.16*
1 week	4.88 (-3.37; 13.13)	0.2486	0.18	3.87 (-4.33; 12.07)	0.3589	0.14
4 weeks	**9.07 (0.88; 17.25)**	**0.0316**	**0.31**	7.79 (-0.36; 15.94)	0.0647	0.26
12 weeks	7.50 (-0.80; 15.80)	0.0789	0.25	6.42 (-1.83; 14.67)	0.1315	0.21
6 months	1.55 (-7.19; 10.30)	0.7280	0.06	0.44 (-8.24; 9.13)	0.9211	0.02
Fatigue						
Overall intervention effect	***-2.96 (-5.20; -0.72)***	***0.0101***	***-0.30***	***-2.95 (-5.18; -0.73)***	***0.0101***	***-0.29***
1 week	-2.56 (-5.54; 0.42)	0.0940	-0.33	-2.51 (-5.48; 0.47)	0.1023	-0.33
4 weeks	-2.25 (-5.31; 0.81)	0.1511	-0.29	-2.20 (-5.25; 0.85)	0.1610	-0.29
8 weeks	**-4.39 (-7.46; -1.31)**	**0.0058**	**-0.43**	**-4.37 (-7.43; -1.31)**	**0.0061**	**-0.42**
12 weeks	**-3.77 (-6.82; -0.71)**	**0.0171**	**-0.34**	**-3.75 (-6.79; -0.70)**	**0.0177**	**-0.34**
6 months	-2.10 (-5.25; 1.05)	0.1926	-0.18	-2.10 (-5.23; 1.04)	0.1950	-0.17
Pain						
Overall intervention effect	***-0.54 (-0.97; -0.11)***	***0.0142***	***-0.30***	***-0.57 (-0.99; -0.15)***	***0.0081***	***-0.32***
1 week	-0.51 (-1.06; 0.06)	0.0819	-0.29	-0.54 (-1.10; 0.02)	0.0613	-0.31
4 weeks	**-0.73 (-1.31; -0.15)**	**0.0151**	**-0.46**	**-0.76 (-1.34; -0.19)**	**0.0104**	**-0.48**
8 weeks	**-0.63 (-1.21; -0.04)**	**0.0373**	**-0.32**	**-0.66 (-1.23; -0.08)**	**0.0281**	**-0.34**
12 weeks	-0.55 (-1.13; 0.03)	0.0670	-0.31	-0.57 (-1.14; 0.00)	0.0536	-0.33
6 months	-0.44 (-1.04; 0.15)	0.1484	-0.27	-0.48 (-1.06; 0.11)	0.1164	-0.29

Supplementary File 4. Continued

	Crude			Adjusted*		
Outcome	**Estimated mean difference (95%CI)**	**P value**	**Effect size (Cohens' d)**	**Estimated mean difference (95%CI)**	**P value**	**Effect size (Cohens' d)**
Quality of life						
Overall intervention effect	*0.02 (-0.02; 0.06)*	*0.2997*	*0.12*	*0.02 (-0.02; 0.06)*	*0.2973*	*0.12*
1 week	-0.01 (-0.06; 0.05)	0.7648	-0.04	-0.01 (-0.06; 0.05)	0.7694	-0.04
4 weeks	0.03 (-0.03; 0.08)	0.2972	0.17	0.03 (-0.03; 0.08)	0.3019	0.17
8 weeks	0.03 (-0.03; 0.08)	0.2903	0.20	0.03 (-0.03; 0.09)	0.2991	0.20
12 weeks	0.04 (-0.02; 0.09)	0.1876	0.22	0.04 (-0.02; 0.09)	0.1942	0.22
6 months	0.04 (-0.02; 0.09)	0.2063	0.22	0.04 (-0.02; 0.09)	0.2105	0.22
Quality of life VAS						
Overall intervention effect	*3.49 (-0.41; 7.38)*	*0.0795*	*0.19*	*3.72 (-0.13; 7.58)*	*0.0600*	*0.21*
1 week	0.44 (-4.92; 5.81)	0.8717	0.03	0.68 (-4.67; 6.03)	0.8040	0.04
4 weeks	4.79 (-0.72; 10.29)	0.0905	0.30	4.92 (-0.56; 10.40)	0.0818	0.31
8 weeks	3.31 (-2.24; 8.86)	0.2439	0.19	3.40 (-2.12; 8.92)	0.2311	0.19
12 weeks	**6.87 (1.37; 12.37)**	**0.0156**	**0.35**	**7.04 (1.57; 12.50)**	**0.0132**	**0.36**
6 months	3.05 (-2.63; 8.73)	0.2948	0.19	3.27 (-2.37; 8.92)	0.2601	0.20
Participation (ability)						
Overall intervention effect	*2.27 (-0.29; 4.83)*	*0.0830*	*0.19*	***3.00 (0.54; 5.46)***	***0.0178***	***0.25***
1 week	0.63 (-2.89; 4.15)	0.7266	0.07	1.31 (-2.15; 4.77)	0.4621	0.13
4 weeks	1.98 (-1.65; 5.60)	0.2872	0.21	2.67 (-0.89; 6.24)	0.1457	0.28
8 weeks	2.58 (-1.07; 6.22)	0.1679	0.24	3.24 (-0.33; 6.82)	0.0791	0.30
12 weeks	**4.76 (1.15; 8.37)**	**0.0108**	**0.39**	**5.41 (1.87; 8.95)**	**0.0034**	**0.44**
6 months	1.78 (-1.94; 5.51)	0.3495	0.11	2.43 (-1.23; 6.09)	0.1972	0.15

Supplementary File 4. Continued

	Crude			Adjusted*		
Outcome	**Estimated mean difference (95%CI)**	**P value**	**Effect size (Cohens' d)**	**Estimated mean difference (95%CI)**	**P value**	**Effect size (Cohens' d)**
Participation (satisfaction)						
Overall intervention effect	*0.78 (-1.77; 3.32)*	*0.5477*	*0.07*	*1.15 (-1.34; 3.64)*	*0.3363*	*0.10*
1 week	-0.13 (-3.75; 3.50)	0.9460	-0.02	0.25 (-3.35; 3.84)	0.8937	0.03
4 weeks	1.60 (-2.14; 5.34)	0.4036	0.17	1.86 (-1.84; 5.57)	0.3280	0.20
8 weeks	2.01 (-1.75; 5.77)	0.2960	0.20	2.31 (-1.41; 6.03)	0.2281	0.23
12 weeks	1.71 (-2.02; 5.43)	0.3704	0.14	2.01 (-1.67; 5.69)	0.2891	0.16
6 months	-0.99 (-4.84; 2.86)	0.6146	-0.06	-0.61 (-4.42; 3.20)	0.7547	-0.04
Self-efficacy						
Overall intervention effect	***1.17 (0.16; 2.18)***	***0.0241***	***0.23***	***1.22 (0.19; 2.25)***	***0.0210***	***0.25***
1 week	0.96 (-0.44; 2.35)	0.1801	0.19	1.01 (-0.40; 2.42)	0.1627	0.20
4 weeks	1.34 (-0.09; 2.77)	0.0678	0.28	1.39 (-0.05; 2.83)	0.0625	0.29
8 weeks	1.44 (-0.002; 2.89)	0.0524	0.27	**1.49 (0.03; 2.94)**	**0.0486**	**0.28**
12 weeks	1.42 (-0.02; 2.85)	0.0548	0.28	1.46 (0.02; 2.91)	0.0503	0.28
6 months	0.80 (-0.68; 2.27)	0.2928	0.18	0.85 (-0.64; 2.34)	0.2682	0.19
Global perceived effect						
Overall intervention effect	***0.39 (0.12; 0.65)***	***0.0045***	***0.38***	***0.42 (0.18; 0.67)***	***0.0010***	***0.34***
1 week	0.38 (-0.03; 0.78)	0.0685	0.33	**0.42 (0.03; 0.81)**	**0.0390**	**0.37**
4 weeks	0.30 (-0.11; 0.72)	0.1567	0.25	0.33 (-0.07; 0.74)	0.1112	0.28
8 weeks	0.29 (-0.12; 0.71)	0.1682	0.23	0.33 (-0.08; 0.74)	0.1178	0.25
12 weeks	**0.52 (0.11; 0.93)**	**0.0150**	**0.43**	**0.55 (0.14; 0.95)**	**0.0091**	**0.45**
6 months	**0.49 (0.06; 0.92)**	**0.0263**	**0.38**	**0.53 (0.11; 0.95)**	**0.0149**	**0.40**

Supplementary File 4. Continued

	Crude			Adjusted*		
Outcome	**Estimated mean difference (95%CI)**	**P value**	**Effect size (Cohens' d)**	**Estimated mean difference (95%CI)**	**P value**	**Effect size (Cohens' d)**
Lean body mass						
Overall intervention effect	*0.05 (-0.92; 1.01)*	*0.9252*	*0.004*	*0.40 (-0.51; 1.31)*	*0.3887*	*0.16*
4 weeks	0.35 (-0.77; 1.47)	0.5412	0.04	0.70 (-0.38; 1.77)	0.2100	0.07
12 weeks	-0.28 (-1.44; 0.87)	0.6309	-0.03	0.08 (-1.03; 1.19)	0.8934	0.01
Handgrip strength						
Overall intervention effect	*1.04 (-0.19; 2.28)*	*0.0984*	*0.09*	***1.26 (0.06; 2.45)***	***0.0425***	***0.11***
4 weeks	1.06 (-0.32; 2.44)	0.1344	0.10	1.28 (-0.07; 2.63)	0.0682	0.12
12 weeks	1.00 (-0.41; 2.41)	0.1679	0.09	1.20 (-0.17; 2.57)	0.0910	0.11
30 Second chair stand test						
Overall intervention effect	*0.12 (-0.63; 0.87)*	*0.7561*	*0.03*	*0.24 (-0.46; 0.93)*	*0.5127*	*0.06*
4 weeks	0.02 (-0.83; 0.88)	0.9570	0.01	0.15 (-0.66; 0.96)	0.7231	0.04
12 weeks	0.21 (-0.68; 1.10)	0.6478	0.06	0.31 (-0.53; 1.16)	0.4744	0.09
Two minute step test						
Overall intervention effect	*2.80 (-1.52; 7.11)*	*0.2054*	*0.12*	*3.62 (-0.60; 7.84)*	*0.0982*	*0.15*
4 weeks	2.54 (-2.26; 7.33)	0.3019	0.11	3.37 (-1.33; 8.08)	0.1676	0.15
12 weeks	2.96 (-1.93; 7.86)	0.2377	0.12	3.82 (-0.99; 8.62)	0.1267	0.15

*Adjusted for sex, age, ASA and tumour location

Supplementary File 5. Results of per protocol analysis: Longitudinal data analysis of primary and secondary outcome measures.

	Crude			Adjusted*		
	Estimated mean difference (95%CI)	P value	Effect size (Cohens' d)	Estimated mean difference (95%CI)	P value	Effect size (Cohens' d)
Physical functioning						
Overall intervention effect	***2.06 (0.43; 3.69)***	***0.0137***	***0.26***	***2.31 (0.74; 3.88)***	***0.0044***	***0.29***
1 week	1.21 (-1.21; 3.62)	0.3295	0.16	1.39 (-1.00; 3.78)	0.2591	0.19
4 weeks	1.12 (-1.23; 3.48)	0.3530	0.16	1.31 (-1.09; 3.58)	0.2747	0.19
8 weeks	**2.52 (0.15; 4.89)**	**0.0388**	**0.41**	**2.74 (0.40; 5.07)**	**0.0240**	**0.44**
12 weeks	**2.97 (0.63; 5.32)**	**0.0142**	**0.37**	**3.17 (0.86; 5.48)**	**0.0085**	**0.39**
6 months	2.24 (-0.18; 4.67)	0.0729	0.35	**2.50 (0.10; 4.89)**	**0.0445**	**0.39**
Physical activity						
Overall intervention effect	***15.73 (4.62; 26.84)***	***0.0060***	***0.40***	***16.46 (5.78; 27.14)***	***0.0030***	***0.42***
1 week	**13.27 (0.52; 26.02)**	**0.0434**	**0.46**	**14.05 (1.71; 26.40)**	**0.0284**	**0.49**
4 weeks	**19.89 (7.22; 32.55)**	**0.0025**	**0.52**	**20.72 (8.46; 32.98)**	**0.0013**	**0.55**
12 weeks	**15.80 (3.11; 28.49)**	**0.0160**	**0.39**	**16.47 (4.19; 28.75)**	**0.0101**	**0.41**
6 months	8.54 (-4.66; 21.75)	0.2069	0.20	9.09 (-3.73; 21.91)	0.1696	0.22
Protein intake						
Overall intervention effect	***9.76 (3.77; 15.76)***	***0.0017***	***0.33***	***7.96 (2.52; 13.41)***	***0.0048***	***0.27***
1 week	**10.55 (1.77; 19.32)**	**0.0199**	**0.37**	**8.99 (0.59; 17.39)**	**0.0390**	**0.31**
4 weeks	**13.80 (5.06; 22.55)**	**0.0024**	**0.45**	**11.87 (3.49; 20.25)**	**0.0067**	**0.39**
12 weeks	**11.85 (3.15; 20.54)**	**0.0085**	**0.39**	**10.08 (1.76; 18.40)**	**0.0197**	**0.33**
6 months	4.71 (-4.41; 13.83)	0.3134	0.18	2.79 (-5.96; 11.55)	0.5356	0.11

Supplementary File 5. Continued

	Crude			Adjusted*		
	Estimated mean difference (95%CI)	P value	Effect size (Cohens' d)	Estimated mean difference (95%CI)	P value	Effect size (Cohens' d)
Kcal intake						
Overall intervention effect	*5.58 (-0.33; 11.49)*	*0.0649*	*0.19*	*4.77 (-1.02; 10.57)*	*0.1089*	*0.17*
1 week	4.04 (-4.69; 12.78)	0.3656	0.15	3.35 (-5.30; 11.99)	0.4520	0.12
4 weeks	8.72 (0.03; 17.42)	0.0514	0.29	7.79 (-0.84; 16.41)	0.0810	0.26
12 weeks	7.17 (-1.48; 15.82)	0.1068	0.24	6.42 (-2.15; 14.99)	0.1470	0.21
6 months	2.76 (-6.32; 11.84)	0.5526	0.10	1.93 (-7.08; 10.93)	0.6776	0.07
Fatigue						
Overall intervention effect	***-3.85 (-6.24; -1.46)***	***0.0018***	***-0.38***	***-3.78 (-6.11; -1.45)***	***0.0018***	***-0.37***
1 week	**-3.30 (-6.47; -0.12)**	**0.0439**	**-0.42**	-3.15 (-6.28; -0.01)	0.0526	-0.40
4 weeks	-2.40 (-5.63; 0.82)	0.1466	-0.31	-2.29 (-5.48; 0.89)	0.1627	-0.30
8 weeks	**-5.27 (-8.48; -2.06)**	**0.0016**	**-0.51**	**-5.18 (-8.36; -2.02)**	**0.0018**	**-0.50**
12 weeks	**-4.69 (-7.89; -1.49)**	**0.0047**	**-0.42**	**-4.63 (-7.79; -1.48)**	**0.0049**	**-0.41**
6 months	-3.24 (-6.54; 0.06)	0.0563	-0.27	-3.21 (-6.46; 0.05)	0.0566	-0.27
Pain						
Overall intervention effect	***-0.65 (-1.10; -0.20)***	***0.0052***	***-0.37***	***-0.66 (-1.09; -0.23)***	***0.0033***	***-0.37***
1 week	-0.53 (-1.12; 0.06)	0.0817	-0.30	-0.54 (-1.12; 0.04)	0.0709	-0.31
4 weeks	**-0.78 (-1.38; -0.18)**	**0.0124**	**-0.48**	**-0.78 (-1.37; -0.20)**	**0.0104**	**-0.49**
8 weeks	**-0.74 (-1.34; -0.14)**	**0.0172**	**-0.38**	**-0.75 (-1.34; -0.16)**	**0.0142**	**-0.38**
12 weeks	-0.60 (-1.19; 0.00)	0.0511	-0.35	**-0.61 (-1.19; -0.02)**	**0.0446**	**-0.35**
6 months	-0.57 (-1.19; 0.04)	0.0697	-0.36	-0.58 (-1.18; 0.02)	0.0608	-0.37

Supplementary File 5. Continued

	Crude			Adjusted*		
	Estimated mean difference (95%CI)	P value	Effect size (Cohens' d)	Estimated mean difference (95%CI)	P value	Effect size (Cohens' d)
Quality of life						
Overall intervention effect	*0.03 (-0.02; 0.07)*	*0.1868*	*0.17*	*0.03 (-0.01; 0.07)*	*0.1909*	*0.17*
1 week	-0.01 (-0.07; 0.04)	0.6126	-0.08	-0.02 (-0.07; 0.04)	0.6004	-0.08
4 weeks	0.02 (-0.04; 0.08)	0.4673	0.12	0.02 (-0.04; 0.08)	0.4841	0.11
8 weeks	0.04 (-0.02; 0.09)	0.2193	0.24	0.04 (-0.02; 0.09)	0.2297	0.24
12 weeks	0.05 (-0.01; 0.10)	0.1096	0.28	0.05 (-0.01; 0.10)	0.1148	0.27
6 months	0.05 (-0.01; 0.11)	0.0886	0.32	0.05 (-0.01; 0.11)	0.0934	0.31
Quality of life VAS						
Overall intervention effect	***4.91 (0.82; 8.99)***	***0.0192***	***0.28***	***5.19 (1.17; 9.20)***	***0.0124***	***0.29***
1 week	0.58 (-4.97; 6.14)	0.8369	0.03	0.85 (-4.67; 6.37)	0.7637	0.05
4 weeks	4.62 (-1.01; 10.24)	0.1101	0.28	4.84 (-0.74; 10.42)	0.0932	0.30
8 weeks	5.38 (-0.24; 11.00)	0.0630	0.32	5.57 (-0.01; 11.15)	0.0537	0.33
12 weeks	**9.19 (3.61; 14.76)**	**0.0016**	**0.50**	**9.46 (3.93; 14.98)**	**0.0011**	**0.51**
6 months	3.90 (-1.85; 9.65)	0.1863	0.25	4.18 (-1.52; 9.89)	0.1548	0.26
Participation ability						
Overall intervention effect	***3.24 (0.55; 5.93)***	***0.0191***	***0.26***	***3.82 (1.27; 6.36)***	***0.0038***	***0.31***
1 week	1.24 (-2.51; 5.00)	0.5173	0.13	1.72 (-1.94; 5.38)	0.3618	0.17
4 weeks	2.01 (-1.81; 5.82)	0.3046	0.21	2.58 (-1.14; 6.31)	0.1795	0.26
8 weeks	3.46 (-0.34; 7.26)	0.0768	0.32	**4.00 (0.29; 7.71)**	**0.0376**	**0.37**
12 weeks	**5.99 (2.22; 9.75)**	**0.0022**	**0.48**	**6.53 (2.86; 10.20)**	**0.0007**	**0.52**
6 months	2.85 (-1.04; 6.75)	0.1538	0.18	3.40 (-0.40; 7.21)	0.0829	0.21

Supplementary File 5. Continued

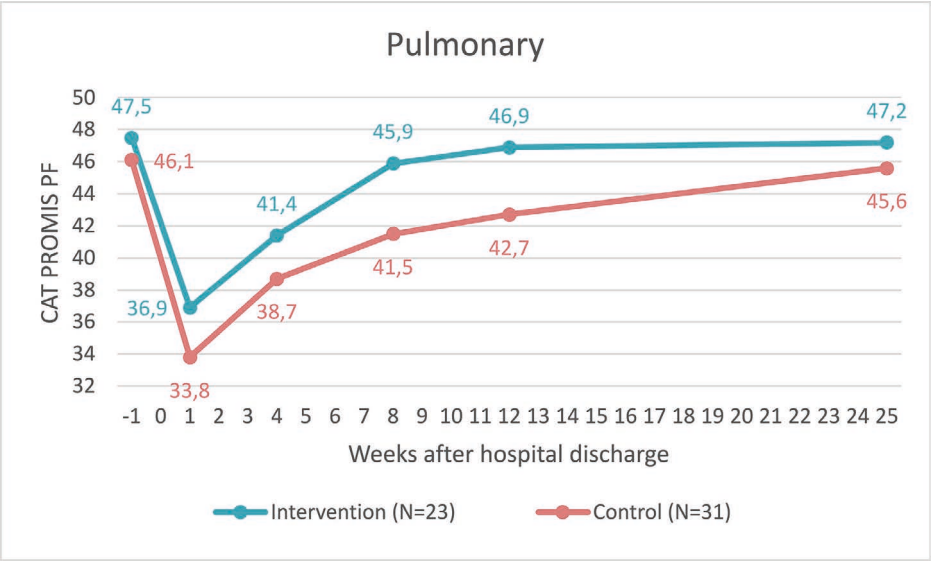
	Crude			Adjusted*		
	Estimated mean difference (95%CI)	P value	Effect size (Cohens' d)	Estimated mean difference (95%CI)	P value	Effect size (Cohens' d)
Participation satisfaction						
Overall intervention effect	*1.74 (-0.92; 4.41)*	*0.2000*	*0.15*	*2.04 (-0.53; 4.60)*	*0.1211*	*0.17*
1 week	0.42 (-3.44; 4.29)	0.8298	0.06	0.68 (-3.11; 4.48)	0.7261	0.09
4 weeks	1.80 (-2.13; 5.73)	0.3718	0.19	2.02 (-1.85; 5.89)	0.3104	0.21
8 weeks	2.74 (-1.18; 6.66)	0.1731	0.27	2.98 (-0.87; 6.83)	0.1334	0.29
12 weeks	2.83 (-1.05; 6.71)	0.1548	0.23	3.11 (-0.69; 6.92)	0.1130	0.25
6 months	0.12 (-3.90; 4.14)	0.9540	0.01	0.46 (-3.49; 4.41)	0.8190	0.03
Self-efficacy						
Overall intervention effect	***1.48 (0.42; 2.53)***	***0.0066***	***0.29***	***1.55 (0.49; 2.62)***	***0.0049***	***0.31***
1 week	1.21 (-0.25; 2.68)	0.1066	0.24	1.29 (-0.18; 2.77)	0.0896	0.26
4 weeks	1.34 (-0.15; 2.83)	0.0802	0.28	1.41 (-0.09; 2.91)	0.0682	0.29
Global perceived effect						
Overall intervention effect	***0.52 (0.24; 0.79)***	***0.0003***	***0.42***	***0.55 (0.30; 0.80)***	***0.0000***	***0.45***
1 week	**0.48 (0.06; 0.90)**	**0.0256**	**0.42**	**0.52 (0.11; 0.92)**	**0.0143**	**0.45**
4 weeks	0.40 (-0.02; 0.83)	0.0666	0.34	**0.43 (0.02; 0.84)**	**0.0439**	**0.36**
8 weeks	0.36 (-0.06; 0.79)	0.0935	0.28	0.40 (-0.01; 0.81)	0.0596	0.30
12 weeks	**0.65 (0.23; 1.07)**	**0.0028**	**0.54**	**0.68 (0.28; 1.09)**	**0.0013**	**0.57**
6 months	**0.66 (0.22; 1.09)**	**0.0036**	**0.53**	**0.70 (0.27; 1.12)**	**0.0017**	**0.56**

Supplementary File 5. Continued

	Crude			Adjusted*		
	Estimated mean difference (95%CI)	P value	Effect size (Cohens' d)	Estimated mean difference (95%CI)	P value	Effect size (Cohens' d)
Lean body mass						
Overall intervention effect	*0.10 (-0.91; 1.11)*	*0.8433*	*0.01*	*0.42 (-0.54; 1.38)*	*0.3949*	*0.16*
4 weeks	0.32 (-0.87; 1.51)	0.6049	0.03	0.63 (-0.51; 1.78)	0.2845	0.07
12 weeks	-0.17 (-1.38; 1.04)	0.7871	-0.02	0.14 (-1.02; 1.30)	0.8130	0.01
Handgrip strength						
Overall intervention effect	*1.20 (-0.13; 2.53)*	*0.0795*	*0.11*	***1.34 (0.06; 2.62)***	***0.0445***	***0.12***
4 weeks	1.04 (-0.45; 2.54)	0.1747	0.10	1.19 (-0.26; 2.65)	0.1151	0.11
12 weeks	1.26 (-0.24; 2.76)	0.1029	0.11	1.40 (-0.06; 2.85)	0.0659	0.12
30 Second chair stand test						
Overall intervention effect	*0.31 (-0.47; 1.09)*	*0.4405*	*0.08*	*0.40 (-0.32; 1.12)*	*0.2786*	*0.11*
4 weeks	0.25 (-0.66; 1.15)	0.5943	0.06	0.35 (-0.50; 1.20)	0.4312	0.09
12 weeks	0.34 (-0.59; 1.27)	0.4783	0.09	0.43 (-0.45; 1.31)	0.3440	0.12
Two minute step test						
Overall intervention effect	*3.75 (-0.96; 8.47)*	*0.1201*	*0.16*	*4.43 (-0.16; 9.02)*	*0.0634*	*0.19*
4 weeks	3.29 (-1.96; 8.54)	0.2220	0.15	3.99 (-1.15; 9.12)	0.1362	0.18
12 weeks	3.94 (-1.37; 9.25)	0.1484	0.16	4.66 (-0.53; 9.86)	0.0854	0.19

Supplementary File 6. Course of recovery in physical functioning, physical activity and protein intake per tumour location.

Fig 1. *Course of recovery in physical functioning in patients after pulmonary cancer surgery*



CAT PROMIS PF = Computer Adaptive Testing (CAT) Patient Reported Outcome Measurement Information System (PROMIS) Physical Function (PF)

Fig 2. *Course of recovery in physical functioning in patients after upper gastrointestinal cancer surgery*

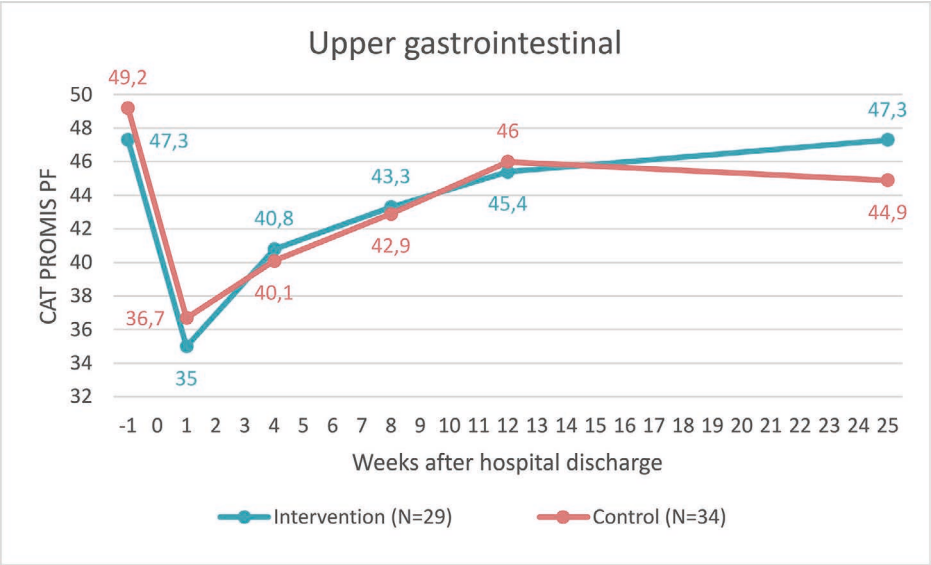


Fig 3. *Course of recovery in physical functioning in patients after HPB cancer surgery*

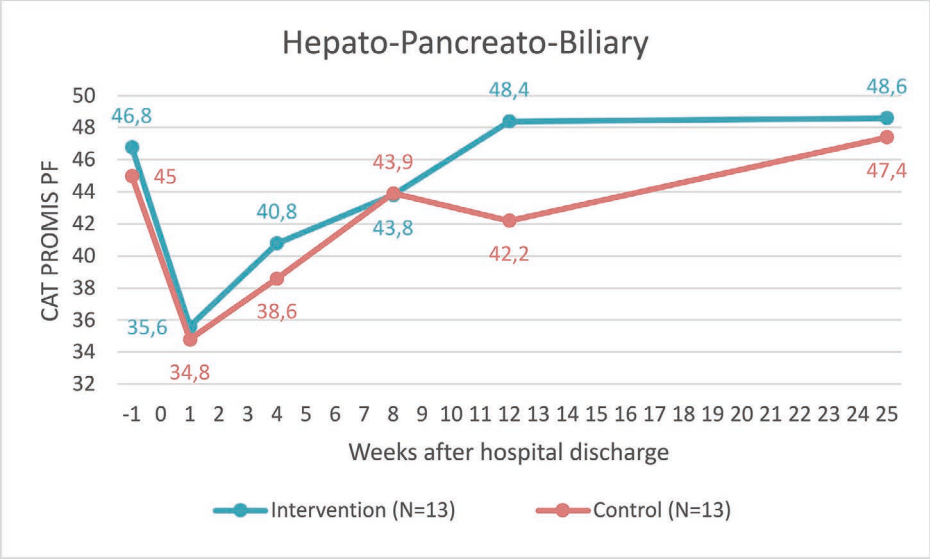


Fig 4. *Course of recovery in physical functioning in patients after colorectal cancer surgery*

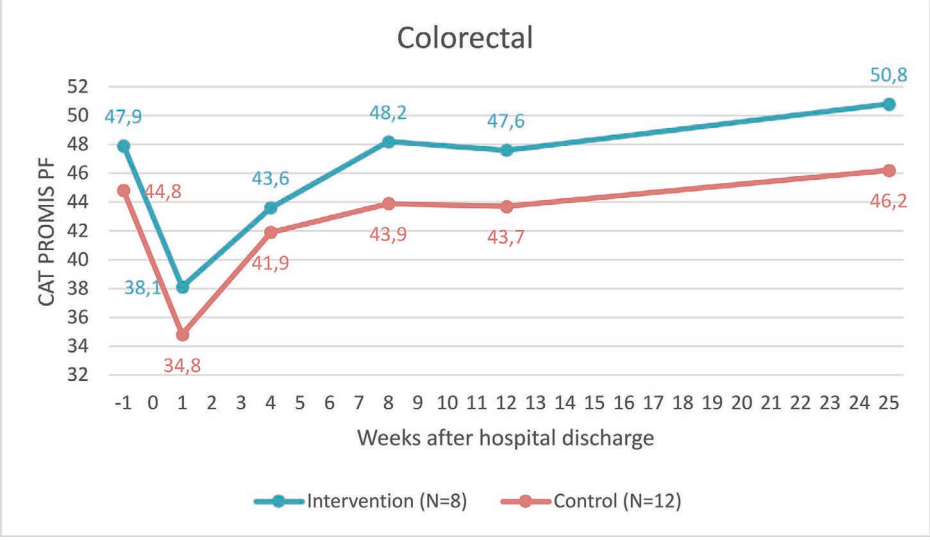


Fig 5. *Course of recovery in physical activity in patients after pulmonary cancer surgery*

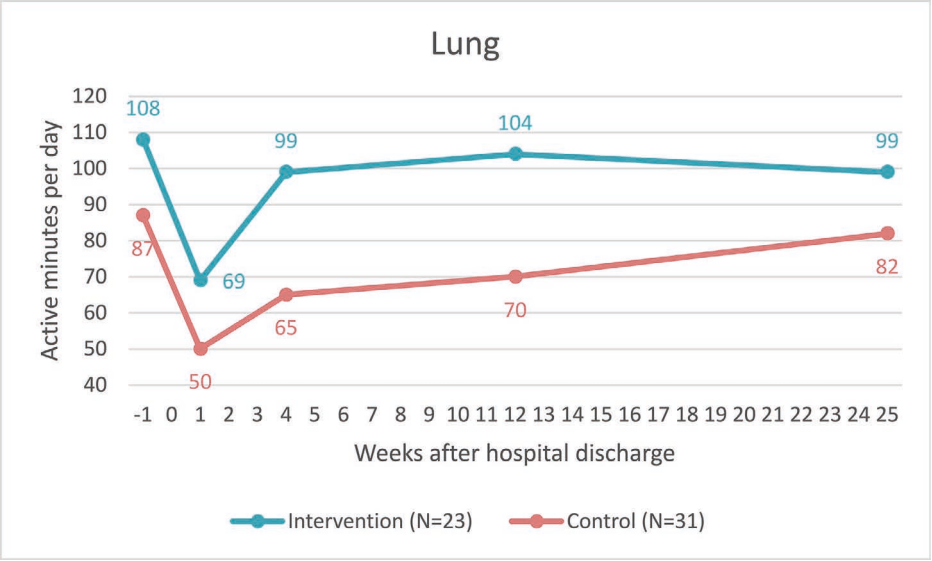


Fig 6. *Course of recovery in physical activity in patients after upper gastrointestinal cancer surgery*

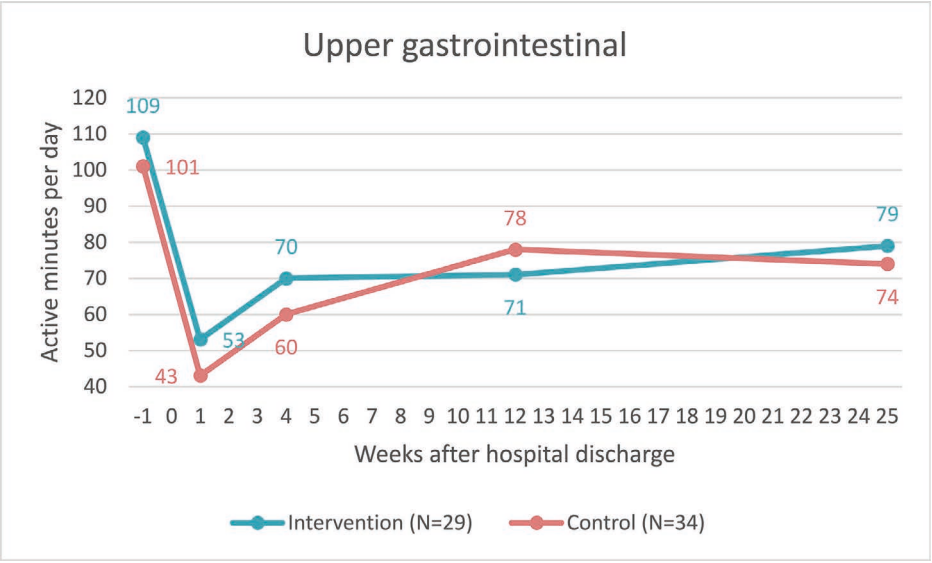


Fig 7. *Course of recovery in physical activity in patients after HPB cancer surgery*

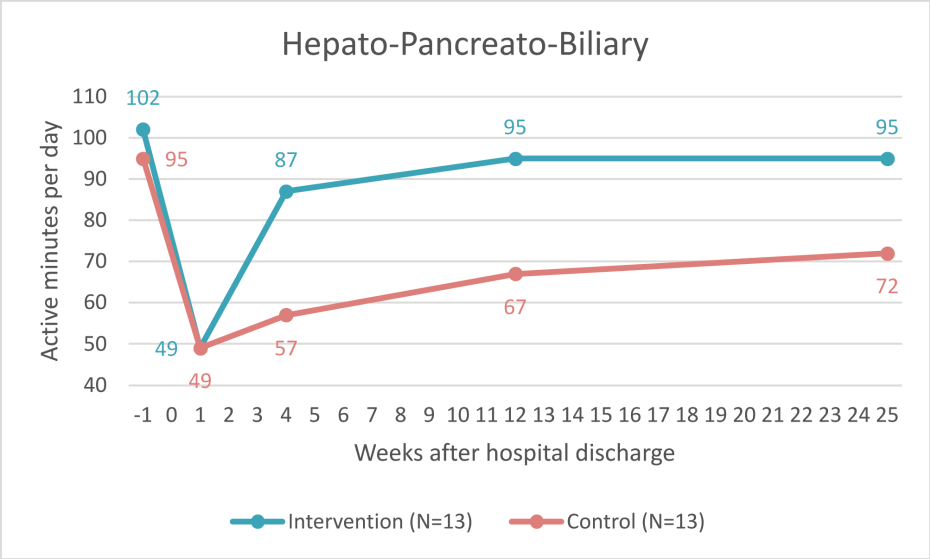


Fig 8. *Course of recovery in physical activity in patients after colorectal cancer surgery*

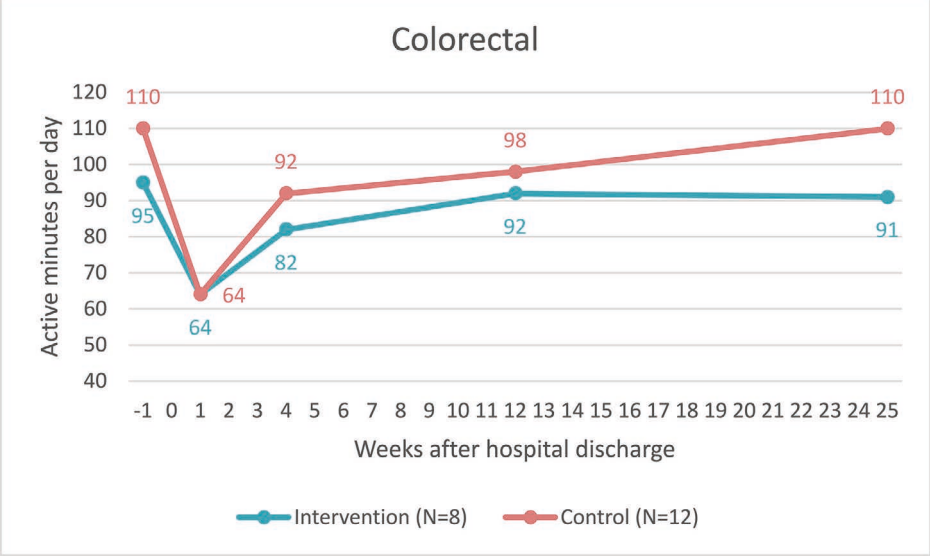
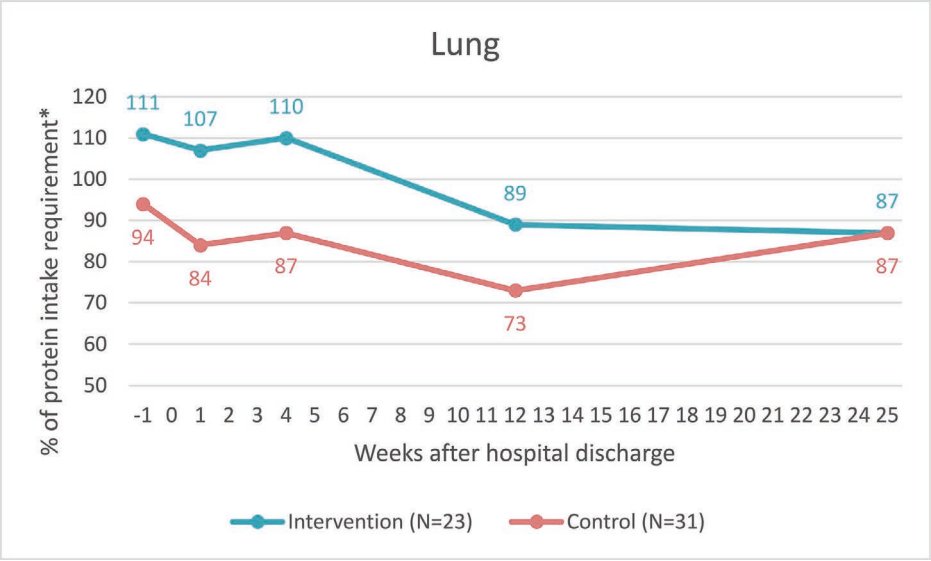
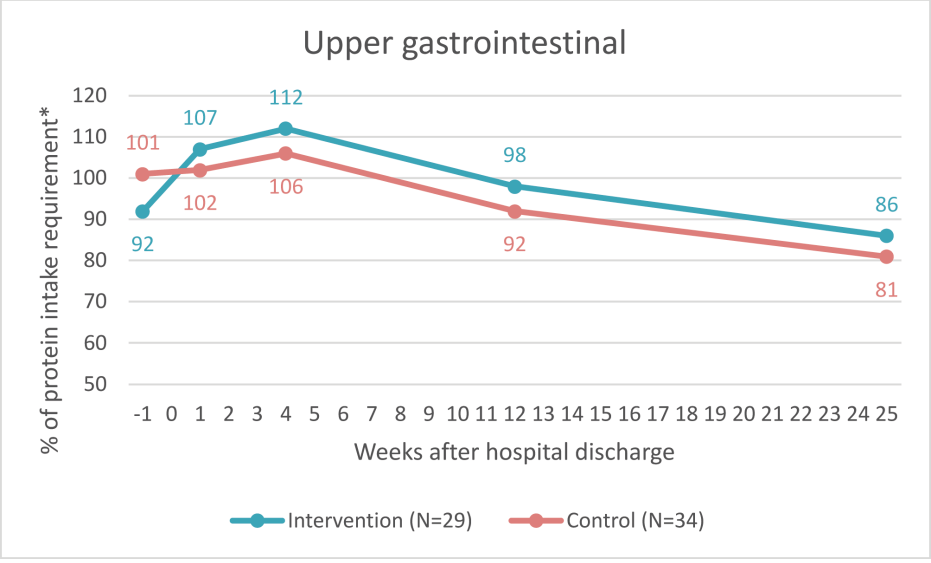


Fig 9. *Percentage of protein intake requirements in patients after pulmonary cancer surgery*



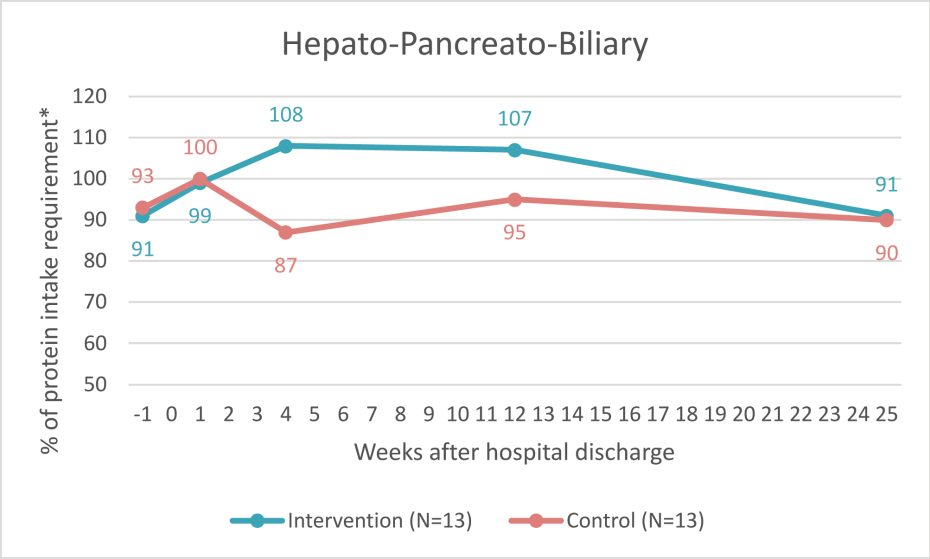
*Requirement is based on 1.9g protein per kg fat free mass or 1.5g protein per kg body weight.

Fig 10. *Percentage of protein intake requirements in patients after upper gastrointestinal cancer surgery*



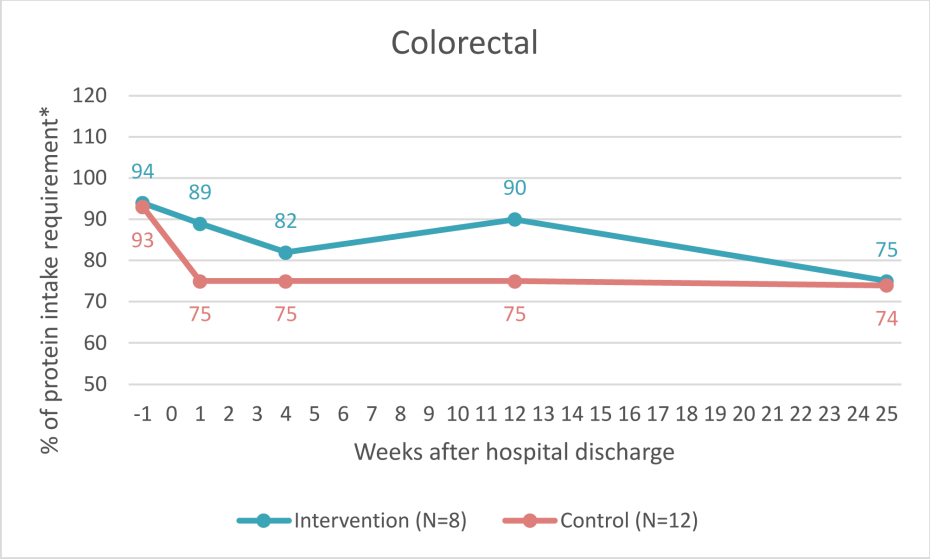
*Requirement is based on 1.9g protein per kg fat free mass or 1.5g protein per kg body weight.

Fig 11. *Percentage of protein intake requirements in patients after HPB cancer surgery*



*Requirement is based on 1.9g protein per kg fat free mass or 1.5g protein per kg body weight.

Fig 12. *Percentage of protein intake requirements in patients patients after colorectal cancer surgery*



*Requirement is based on 1.9g protein per kg fat free mass or 1.5g protein per kg body weight

Supplementary File 7. Frequency of contact by phone and chat with the physiotherapist and dietitian.

	Physiotherapist		Dietitian		Patient
	Phone (median [IQR])	**Chat** (median [IQR])	**Phone** (median [IQR])	**Chat** (median [IQR])	**Chat** (median [IQR])
Overall	2 [3]	8 [5]	2 [3]	4 [8.5]	11 [12.5]
Per tumour location:					
- **Pulmonary**	0 [0.5]	8 [2.5]	0 [0.5]	0 [0]	9 [5]
- **Upper GI**	3.5 [4]	8 [4]	4 [2]	7 [8.5]	14 [13]
- **HPB**	4 [1]	8 [9]	2 [2]	7 [7.5]	15 [18]
- **Colorectal**	2 [1]	6 [4]	1 [1]	3 [4.5]	11 [15.5]



Chapter 7

Promising patient experiences with a smartphone app and remote coaching for improving physical activity and protein intake to enhance recovery after oncological surgery: a multi methods study

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Abstract

Purpose: The Optimal Physical Recovery After Hospitalization (OPRAH) Intervention is a blended intervention, combining a smartphone app for self-monitoring of physical activity and protein intake with coaching from a physiotherapist and dietician, to enhance the functional recovery after gastro-intestinal or lung cancer surgery. The aim was to evaluate patients' experiences with the OPRAH intervention.

Methods: This study used a multi-method approach, incorporating semi-structured interviews and an online questionnaire. The questionnaire included the System Usability Scale (SUS) to evaluate the smartphone app. Sixty-eight patients were invited to complete the online survey, 58 providing responses. Purposeful sampling guided the selection of participants for interviews (n=24), which focused on experiences with the application, activity tracker, and remote coaching. The interview data were analyzed qualitatively using an inductive thematic approach.

Results: The app was rated with an excellent usability (mean ± SD SUS of 86.2 ± 12.0) and 97% of the patients would recommend the intervention to others. Patients reported that the intervention enhanced their understanding of their recovery process, motivated them to achieve protein and physical activity goals, and contributed to their overall recovery. The combination of app usage and monitoring by a physiotherapist and dietician fostered a sense of being supported. However, patients suggested that the intervention could be improved by further tailoring it to individual needs, detailing the nutritional component of the app, and redesigning the activity tracker bracelet.

Conclusions: The OPRAH intervention demonstrated excellent system usability and predominantly positive experiences. Incorporating patient recommendations could further support its integration into regular healthcare.

Background

With increasing oncology diagnoses and improved curative treatments, the number of cancer survivors is rising, particularly for patients with lung and gastrointestinal (GI) malignancies [1]. Surgery often provides the best medical outcome for these patients, but frequently results in impaired physical recovery [2,3]. The body's stress response to surgery accelerates catabolism, causing muscle mass loss and reduced physical functioning. This contributes to complications, increased morbidity and mortality, and diminished quality of life [2–8]. Muscle mass loss is mainly attributed to reduced muscle sensitivity to the anabolic effects of protein intake after surgery and reduced physical activity [3,7–9]. Therefore, adequate physical activity and nutrition are essential for preventing further muscle mass loss and improving one-year postoperative survival rates [10–14]. Together, these factors synergistically help maintain and rebuild muscle mass, supporting better recovery in physical functioning after surgery [15–17].

While the importance of adequate physical activity and protein intake levels to reduce loss in muscle mass and physical functioning after lung and gastrointestinal cancer surgery is well recognized, many patients struggle to achieve these goals [16–18]. Consequently, support from a physical therapist and dietitian is important during the recovery process. However, healthcare providers face challenges in delivering consistent support due to constraints in time, work structure, finances, and staffing [19]. As a result, patients are often expected to take more responsibility for their own recovery, making self-management essential [20]. While apps and activity trackers can help improving physical activity and nutritional behaviors, their effectiveness increases when combined with professional coaching [21]. Blended care, combining technology and remote coaching, has shown promise in delivering personalized and efficient care. Studies indicate that eHealth can enhance postoperative recovery in oncology patients by promoting self-management, increasing motivation and providing more personalized care and data-driven feedback, which may ultimately improve patient outcomes [22–24]. However, no intervention has been developed to support post-discharge recovery in patients following gastro-intestinal or lung cancer surgery that focuses on both physical activity and protein intake.

Therefore, to support patients in achieving adequate physical activity and protein intake after oncological surgery, we developed the Optimal Physical Recovery After Hospitalization (OPRAH) intervention. The Behavioral Change Wheel was used to develop the intervention, identifying which behavioral change techniques could increase patients' ability, opportunity and motivation to improve their protein intake and physical activity [25]. This resulted in an intervention with the aim of promoting self-management during recovery through a

smartphone application paired with an activity tracker, supported by remote coaching from a physiotherapist and dietitian. This approach also enables healthcare professionals to monitor patients, provide timely interventions, and better coordinate care to optimize recovery.

Patients' subjective experiences can provide valuable contextual insights, facilitating the evaluation of whether and how the intervention enhances the desired behavior within this patient group. These insights can generate valuable knowledge for advancing the implementation of scientific evidence into practice and contribute to future research projects. Therefore, the aim of this study is to evaluate patients' experiences with the OPRAH intervention, focusing on its practical application and implementation into rehabilitation programs.

Methods

Design

We conducted a multi-method study, combining quantitative surveys with in-depth semi-structured interviews using inductive thematic analysis as described by Braun and Clarke [26]. This study was part of the Dutch multicenter single-blinded OPRAH randomized controlled trial (RCT) at Amsterdam UMC and St. Antonius Nieuwegein, the study protocol of which has been previously[27]. The study protocol was approved by the Medical Ethical Research Committee (METC) of Amsterdam UMC, location VUmc (METC 2021.0627).

Eligibility Criteria and Recruitment

Patients scheduled for curative intent surgery for gastrointestinal cancer, including esophageal and stomach cancer (upper GI), colorectal and hepato-pancreato-biliary (HPB) cancer, or lung cancer with a planned hospital stay of ≥ 2 nights, aged 18 years or older, and able to fill in online questionnaires in Dutch, were eligible for the OPRAH study. Exclusion criteria were pulmonary wedge resection, surgery with open/close procedure, having no access to a mobile device compatible for applications, less than 5 days between inclusion and surgery, wheelchair dependence, a Mini-Mental State Examination (MMSE) ≤ 24 and already participating in a conflicting study. Patients were recruited from two hospitals in the Netherlands: Amsterdam UMC, location VUmc and St. Antonius, location Nieuwegein [27]. At one week after the end of the intervention period, patients in the intervention group received a questionnaire focused on their recovery and experiences of the intervention. The patients received an email to complete the online survey on a secured web-based system (Online PROMS). Additionally, patients were approached for an in-depth interview. A purposive sampling approach was applied to assemble a heterogeneous participant

sample regarding diversity in age, gender, and kind of surgery to enhance transferability of the findings. No exclusion criteria were used. Participation was voluntary.

OPRAH intervention

The OPRAH intervention was developed with the use of the Behavioral Change Wheel, resulting in 15 Behavioral Change Techniques to improve the patient' capability, opportunity and motivation to improve their physical activity and reach their protein intake goals after hospital discharge [27]. Using a smartphone app and activity tracker, patients' self-management is encouraged with the ultimate goal of the intervention a faster and better recovery in physical functioning. Patients in the intervention group received access to the Atris application on their mobile phone and a corresponding activity tracker (PAM) about one week before surgery, both supported by the Atris software (Peercode B.V. Geldermalsen, the Netherlands) and the eiFIT method [28]. The app allowed patients to monitor their physical activity and register their daily protein intake through a simple in-app registration tool combined with personalized goals (See Figure 1). Patients wore the PAM continuously around their ankle and recorded their protein intake starting five days before surgery. During hospitalization, the physiotherapist and dietician guided patients in using the app. As hospital discharge approached, patients worked with the physiotherapist and dietician using a Shared Decision Making (SDM) process to set goals for physical activity and protein intake after discharge. After leaving the hospital, patients wore the PAM 24 hours a day and recorded their protein intake daily for three months. They received remote coaching via phone and the application chat function from their physiotherapist and dietician. Patients could ask questions through the app's chat function, and healthcare providers could send additional information. The primary goal for physical activity was to return to pre-surgery levels, and the goal for protein intake was to meet personal daily requirements. If recovery stagnated and goals were not met, the physiotherapist or dietician could contact the patient to identify potential barriers. Sub-goals and the level of coaching were tailored to individual needs and preferences using the SDM process. Motivational Interviewing (MI) techniques were applied during coaching sessions to support patients' self-management [27].

Figure 1. *Screenshots of the English language version on the Atris app*



Data collection

Online questionnaire

The questionnaire consisted of the Dutch translation of the System Usability Scale (SUS) and 16 additional questions about the acceptability, satisfaction and added value of the application. The SUS contains ten statements about efficiency, learnability, and satisfaction and has been validated to assess the usability of electronic systems [29]. Patients indicated the degree of agreement with each statement on a 5-point Likert scale. The total SUS score ranges from 0 to 100, with a score of ≥70 considered good [29]. See Appendix 1 for the questionnaire.

Interviews

Semi-structured interviews were conducted by phone or at the hospital between April 2023 and April 2024 after obtaining written consent. Interviews were scheduled after the three months intervention period. They were informed that their data will remain confidential. Interviews were conducted by trained researchers MEdL and CvW. All interviews were audio recorded and transcribed verbatim by CvW and EvdW. The interview guide was based on the OPRAH pilot study (METC 2021.0112) focusing on evaluating patients' experiences and recommendations across three topics of the OPRAH study: the 'Atris app', 'coaching', and the 'duration of the intervention (Appendix 2). Researchers aimed the interview to be between 20-40 minutes. After fifteen interviews, a reflection meeting

was held with the research team, MedL, CvW, MvdL, and MvdS, to review the interview guide and interviewer techniques.

Descriptive data

Demographic and clinical data were collected retrospectively from electronic medical records. Preoperative physical functioning was measured using the Computer Adaptive Testing Dutch-Flemish Patient Reported Outcome Measure Information System for Physical Functioning (CAT PROMIS PF) questionnaire[30].

Data analysis

Participants characteristics were described as mean (SD), median (IQR) or percentage. The mean (SD) SUS was calculated using the method described in the study by Brooke [29]. Subgroup analysis based on age, sex, and tumor location were performed to explore potential differences in SUS. Additional questions about user experiences were presented as percentages. SPSS (version 28; IBM Corp) was used for quantitative data analysis of the questionnaire.

The interviews were analyzed using a thematic analysis to investigate patients' experiences about the OPRAH intervention to identify advantages, disadvantages and recommendations. Three evaluators (MEdL, CvW and EvdW) followed the six-phase process outlined by Braun and Clark (See Appendix 3 for details) [26]. During each phase of the thematic analysis, specific activities were performed to establish trustworthiness. The evaluators started phase one till four with the first six transcripts. In the first phase, the evaluators read and familiarized themselves with qualitative data, while making initial notes about potential themes. After an in-depth reading of the transcripts, during phase two, the three evaluators independently generated initial codes and recognized themes. Periodic meetings with the three analyzing evaluators were held throughout the coding procedure for peer debriefing. During phase three, the evaluators grouped the generated codes, supported by texts, such as words, phrases, statements or entire paragraphs, from which to extract meaningful core themes. This process of inferential analysis was performed independently by the three evaluators. Afterwards, during phase four, potential themes were reviewed during reflexive meetings, to identify patterns of shared meaning underpinned by central ideas (domains). These meetings helped ensure that the scope and focus of each theme were agreed upon, and to minimize personal bias. After finishing phases four for the first six transcripts, the first four phases were repeated for the other transcripts, before continuing to phase five and six. During phase five, themes were revised and defined with the three evaluators together, with the description of a set of codes representing single words or short phrases that best described the experiences of the patients. The results were

produced during phase six, categorized by themes and supported by illustrative quotes All decisions and changes were documented in an audit trail, along with field notes and memos. MAXQDA 2022 was used for the coding process.

Reflexivity

Credibility of data was achieved by data triangulation, using both questionnaire data and interview paraphrasing. The team's diverse expertise enriched the exploration of patients' experiences. MEdL, a hospital physiotherapist and PhD candidate, had experiences with quantitative analyses and offered insights from previous pilot studies with similar patients. CvW, with a background in primary care physiotherapy and nutrition, and PhD candidate, had experiences conducting interviews and was trained in qualitative research. In addition to MEdL and CvW, the research team involved in the analysis consisted of individuals with diverse backgrounds, including dietetics and nutrition (HK), physiotherapy (MvdL, MvdS, EG), rehabilitation medicine (VdG) and lifestyle coaching (EvdW). Efforts were made to mitigate potential biases by promoting open discussions and critical reflections within the research team. The COnsolidated criteria for REporting Qualitative research (COREQ) guidelines were followed to ensure rigorous reporting [31].

Results

A total of 387 patients were assessed for trial eligibility, of which 193 consented to participate in the study. Of the 90 patients assigned to the intervention group, 13 were excluded before the first follow-up measurement for various reasons, such as withdrawal from participation, cancelled surgery, surgery that deviated from original plan and thus no longer met inclusion criteria, or discharge to a rehabilitations center. Of the 73 patients that started with the intervention, 63 completed the intervention period. Reasons for discontinuation were not interested in continuation (N=3), other medical treatment (N=2), not satisfied with the intervention (N=2), hospital readmission (N=2), and palliative treatment (N=1).

SUS and Additional Questions

Of the 68 patients who completed the intervention, 58 (85%) filled out the online questionnaire. Patient and perioperative characteristics of the respondents are presented in Table 1. No significant differences were found between the characteristics of the respondents and non-responders (data not shown).

The mean SUS was 86.2 (SD 12.0). No significant differences were found in the subgroup analysis. Of all respondents, 97% would recommend the use of the PAM and Atris app to

other patients after surgery. Patients rated the general experiences of the Atris app with a mean of 7.7 out of 10 (SD 1.2). Other results of the questionnaire are presented in Table 2.

Interviews

A total of 27 patients were invited to participate in an interview, of which 24 (89%) were willing to participate. Patient characteristics of the interviewed patients are presented in Table 1. Three main themes emerged from the interviews, focusing on patients' experiences with the app, activity tracker and remote coaching: 1) the advantages of the OPRAH intervention, 2) the disadvantages of the OPRAH intervention and 3) recommendations to optimize the OPRAH intervention. The three main themes were described with subthemes and supported by quotes. A complete overview of the results is shown in Table 3.

Advantages of the OPRAH intervention

Overall, patients had a positive experience with the OPRAH intervention. One of the most frequently mentioned benefits was that patients felt empowered to take an active part in their cancer treatment. Cancer treatment typically felt like a passive period, with patients relying on healthcare professionals for their care (e.g., surgery, radiation, or chemotherapy). The OPRAH intervention gave them the opportunity to take action themselves, through guidance that was personalized to their daily activities, without making it too complex. Not only did it provide a sense of empowerment, but patients also noted that it improved their self-efficacy.

> *"I think I might have encountered more difficulties if I hadn't been guided in this way. Of course, I'm very stubborn with certain things, so I definitely pushed myself beyond my limits. But this process allowed me to set my boundaries earlier, and that's something I really needed. So, I found that very helpful.."* ***[Female, 55 years, HPB-cancer]***

> *"The surgery was successful. But you never know what it will be like afterwards. But then along the way you see in the app, 'hey, I'm hitting my goals', which in turn gives you more confidence that you can get back to your original level.* ***"[Male, 78 years, Upper GI cancer]***

Table 1. *Patient and perioperative characteristics of the respondents*

	Variable	Respondents' questionnaire (N=58)	Respondents Interview (N=24)
Patient characteristics	**Sex (male), n (%)**	33 (57%)	13 (54%)
	Age (years), mean ± SD	64 ± 10.2	64 ± 10.7
	BMI, mean ± SD	26.1 ± 4.9	25.5 ± 4.8
	Educational Level, n (%)		
	Low	10 (17%)	4 (17%)
	Middle	28 (48%)	11 (46%)
	High	20 (35%)	9 (37%)
	Household, n (%)		
	Living alone	13 (22%)	6 (25%)
	Living together	45 (78%)	18 (75%)
	Tumor location, n (%)		
	Lung	18 (31%)	10 (42%)
	Upper GI	26 (45%)	10 (42%)
	HPB	10 (17%)	3 (13%)
	Colorectal	4 (7%)	1 (4%)
	ASA grade ≥3, n (%)	16 (28%)	6 (25%)
	Charlson Comorbidity Index, mean ± SD	5.2 ± 2.0	5.3 ± 2.1
	Preoperative physical functioning*, mean ± SD	47.7 ± 5.8	47.5 ± 4.9
Perioperative characteristics	**Hospital, n (%)**		
	Amsterdam UMC	53 (91%)	22 (92%)
	St. Antonius Nieuwegein	5 (9%)	2 (8%)
	Type of surgery, n (%)		
	Laparoscopic	44 (76%)	18 (75%)
	Open	14 (24%)	6 (25%)
	Comprehensive Complication Index, mean ± SD (if complications = yes)	28.6 ± 9.7	27.1 ± 7.9
	Length of hospital stay, median (IQR)	6 (4)	7 (4)
	Hospital readmission within 30 days after hospital discharge, n (%)	6 (10%)	2 (8%)
	Postoperative treatment, n (%)		
	No treatment	40 (69%)	20 (83%)
	Chemo- or immunotherapy	16 (27%)	3 (13%)
	Radiation therapy	1 (2%)	1 (4%)
	Unknown	1 (2%)	0 (0%)
	Number of days between hospital discharge and first treatment, mean ± SD	74 ± 17	74 ± 16

*Measured with the CAT PROMIS Physical Functioning, ASA = The American Society of Anesthesiologists Classification of physical health; BMI = body mass index; upper GI = upper gastro-intestinal (esophagus and stomach); HPB = hepato-pancreato-biliary; Comprehensive Complication Index: complications occurred within 30 days after surgery or during hospital stay;

Table 2. *Summary of results of SUS and additional questions (N=58)*

Criteria	Results
System usability	
Efficiency	Mean 88.2 (SD 2.8)
Learnability	Mean 90.2 (SD 1.7)
Satisfaction	Mean 81.6 (SD 4.8)
Average degree for general experiences with the application (0-10)	7.7 (SD 1.2)
Average degree for the coaching experiences by the physiotherapist (0-10)	7.9 (SD 1.9)
Number of contacts with physiotherapist	
>1x / week	N = 7 (12%)
1-2x / two weeks	N = 12 (21%)
1-2x / month	N = 27 (47%)
<1-2x / month	N = 9 (16%)
Never	N = 3 (5%)
Average degree for the coaching experiences by the dietician (0-10)	7.8 (SD 1.4)
Number of contacts with dietician	
>1x / week	N = 22 (38%)
1-2x / two weeks	N = 25 (43%)
1-2x / month	N = 6 (10%)
<1-2x / month	N = 3 (5%)
Never	N = 2 (3%)
Number of app openings	
>3x / day	N = 20 (34%)
1-3x / day	N = 30 (52%)
Every other day	N = 7 (12%)
1x / week	N = 1 (2%)
<1x / week	N = 0 (0%)
Never	N = 0 (0%)

In addition to enhancing self-efficacy, patients mentioned that they learned a lot about the importance of sufficient protein intake and regular physical activity. Visualizing their nutrition and physical activity through the app, specific nutritional information, combined with personalized goals, motivated patients to improve their behavior.

> *"I was indeed motivated by the app and the sensor. I was fully aware that it was important to start moving as soon as possible. And to pay attention to my diet, and that for recovery, I needed to eat more proteins."* ***[Female, 58 years, lung cancer]***

Almost all patients were convinced that without the OPRAH intervention, and more specific attention to the importance of combining physical activity and protein intake, their recovery would have taken longer. They believed the intervention motivated them

to be more physically active at an earlier stage of their recovery. Additionally, some patients mentioned that the intervention also contributed to lifestyle change after the intervention period.

> *"Usually, I do move…. but now I'm extra motivated by the monitor and the sensor. And protein, yes, that's definitely been a learning moment for me, realizing how important it is for muscle development. So, I'll definitely take that with me in the future."**[Male, 68 years, lung cancer]***

The feeling of being seen and supported by the dietician and physiotherapist through the app, was mentioned as a beneficial aspect. This especially helped them in the first weeks after discharge, a period when patients would normally feel quite lonely and insecure. Knowing that healthcare professionals had insight in their recovery in physical activity and protein intake gave patients a sense of safety, and the in-app chat feature made it easy to get in touch if needed.

> *"The contact and the stimulation you get from it. Yes, you have to do it all for yourself, of course. Because that's what it's all about, how you do it and not how someone else does it. But it is nice that there is someone watching along and encouraging you. Yes, I don't think this is applicable to everyone, but I think it is for a lot of people."* ***[Female, 69 years, upper GI cancer]***

Disadvantages of the OPRAH intervention

While patients were generally positive about the OPRAH intervention, they also noted some critical points. One concern involved the digital-only format of the intervention. Some patients would have preferred a combination of face-to face and video consultations with healthcare professionals, while others felt that video consultations would have met their need for more personal contact.

> *"Yes, sometimes I found it frustrating that I felt I couldn't express myself. For example, when I started missing my goals. If you get something like a lung hernia, for instance, you're less able to meet those goals. And no one can see that through the app."* ***[Male, 69 years, lung cancer]***

Currently, the intervention focuses solely on tracking daily steps and active minutes to assess physical activity levels. For some patients, this was enough to encourage physical activity and support their recovery. However, patients who recovered more smoothly

indicated that they would also benefit from additional advice on how to improve their endurance and strength later in their recovery.

> *"But after just walking, which you naturally do at first, do you also have guidance on what you can do next? Like what kind of exercises? […] That's obviously something that can be incorporated into the app as well, because right now it only showed the minutes of activity."* ***[Female, 58 years, lung cancer]***

Another disadvantage mentioned by patients was the design of the activity tracker, which many compared to a prison bracelet. Several patients felt uncomfortable wearing it, as they often received comments from others that reminded them of this association. Some patients found such comments to be annoying, which could potentially have had a demotivating effect on their motivation and behavior.

> *"…And especially since it was during the summer months. For example, at one point I was walking through the garden, and then the neighbor called me, asking when I would be released, you know, that kind of thing. Well, yeah, you know, I found that a bit annoying, but it's just a matter of getting used to it."* ***[female, 67 years, lung cancer]***

Specific to the nutrition component of the app, patients felt that the app provided a limited and somewhat inaccurate view of their protein intake. They noted that the app lacked details, making it difficult to accurately record what they had eaten. Additionally, they mentioned that the portion sizes were not always well-suited to this specific patient population, making the nutritional tracking feel less relevant for some. Those components could have influenced the motivating behavior effect of the application on patients.

> *" However, what I did find unfortunate in the app is that you can't specifically check or indicate what proteins you've consumed. So, you have to search for what corresponds to it. And that's quite…yeah, I find that quite a hassle."* ***[female, 64 years, lung cancer]***

> *" Because I had esophageal cancer and now have a stomach tube, I can no longer take in more than about 300-350 grams or milliliters at a time. Is that half a plate, a quarter of a plate, or a whole plate? I don't know."* ***[male, 64 years, upper GI cancer]***

Recommendations to optimize the OPRAH intervention

Based on these advantages and disadvantages, patients provided several recommendations to improve the intervention. A more personalized program was suggested, which could take various aspects into account to better suit individual needs. For instance, patients

have advised that the duration of the intervention should be tailored, given that recovery is a highly individual process and therefore the length of support required will vary from one patient to another. Also, the frequency of contact between patients and healthcare professionals should be adapted to patients' needs. In addition, the intervention could be tailored by offering a choice between digital-only, face-to-face, or blended care, designing recovery programs that include endurance and strength training, and allowing the involvement of different healthcare providers, such as dieticians, physiotherapists, doctors, and specialized nurses. Additionally, patients suggested offering the program during both pre- and post-hospitalization phases to maximize benefits.

> *"I don't have a great need for it, but maybe sometimes they should seek more contact. Call more often to check in on how things are going. It went very well for me, but there might be people for whom it's not going as smoothly. Yeah, maybe they should reach out to those people more frequently, I think."* ***[Male, 60 years, upper GI cancer]***

Finally, patients strongly recommended redesigning the ankle tracker or selecting a different type of wearable, especially women who wanted to wear dresses or skirts in warmer weather. A more discreet option would make them feel more comfortable, which could positively impact their recovery experience.

> ***"****Yeah, I've said before, you shouldn't send a black ankle monitor. Send a, what do you call it, a skin-colored ankle monitor. Because when us women walk around with bare legs in the summer, well, it really stands out, I have to say."* ***[Female, 84 years, colorectal cancer]***

Discussion

This study demonstrates the positive patient experiences with the OPRAH intervention and the excellent usability of the app, reflected by a SUS score of 86.2. Patients reported that the intervention enhanced their understanding of their recovery process, motivated them to achieve their protein and physical activity goals, and contributed to their overall recovery and, in some cases, even lifestyle changes. The combination of using an app and being monitored by a physiotherapist and dietician fostered a sense of being supported. However, patients suggested that the intervention could be improved by tailoring it further to individual needs, making the nutritional component of the app more detailed, and redesigning the activity tracker.

The usability of the app has been notably improved compared to our previous studies. The earlier versions of the Atris app reported a mean SUS score of 77.3 (SD 20.7) [32,33]. The current version scored better in efficiency, learnability, and satisfaction, likely due to pilot study evaluations and app optimization. Enhancements such as alarm or messages for unreached goals, tailored personal goals, optimization of the nutritional part of the app and an extended information folder for application installation and protein-rich products, likely contributed to the improved usability, particularly the learnability, which increased from 74.0 and 76.6 to 90.2. Our systematic review revealed that interventions combining activity trackers with coaching yielded superior outcomes [21]. Consequently, coaching by a physiotherapist and dietician was integrated into the intervention after the first pilot study. The incorporation of coaching may also have enhanced the usability, facilitating low-key contact in case of any uncertainties.

The SUS score of the app is excellent compared to other studies using activity trackers and apps. Jonker et al. reported a mean SUS of 71.3 for a home monitoring system and wrist-worn tracker in older adults' post-oncological surgery [34]. Low et al. reported a mean SUS of 83.8 for a Fitbit and app in abdominal cancer surgery patients [35]. Van der Linden et al. found similar results with a mean SUS of 85 for colorectal patients using a tracker, app, and food diary perioperatively [36]. The positive feedback observed in these studies aligns with our findings, as patients similarly highlighted the value of gaining insight into their physical activity. Additionally, the studies underscored the importance of providing more personalized care as a key requirement [35].

The qualitative results suggest that the OPRAH intervention addressed the three components of the Behavior Change Wheel: capability, opportunity and motivation [25]. Regarding the capability component of the Behavior Change Wheel, patients mentioned that self-monitoring and goal setting helped them understand how to improve their physical activity and protein intake, which made them capable to improvement and self-management. When facing barriers, they had the possibility to low-key contact with the healthcare professionals to increase their capability. Some patients reported that they found it difficult to discuss these barriers through chat or phone. For these patients, in-person contact might further improve their capability. Regarding opportunity, patients mentioned that the intervention empowered them to act, increasing their sense of control. This was supported by physical opportunities such as in-app prompts to track their progress, as well as social support through access to healthcare professionals via chat. This empowerment may contribute to improved quality of life in patients with cancer [37]. Regarding motivation, patients indicated that the intervention raised awareness about the importance of physical activity and protein intake, which increased their motivation

to engage in the desired behavior. Reaching their goals also motivated them to have confidence in being able to recover to pre-operative levels (reflective motivation). Some patients even continued these behaviors after the intervention, suggesting that the intervention also addressed automatic motivation.

An important finding in this study is that despite the personalization already applied in the intervention, patients indicated a need for more personalized care, particularly in the level and amount of coaching. Coaching was added as a component of the intervention, because it facilitated the goal setting and information provision. It was expected that the need for coaching would vary between patients, as the recovery process is likely to differ between patients due to different types of surgery, complications or personal factors. Therefore, the OPRAH intervention did not employ a specific coaching protocol regarding the amount and timing of coaching. It was therefore considered appropriate to provide healthcare professionals the flexibility to match personal needs. This may have led to differences in patients' experiences with the coaching. Some patients had more or less intensive contact with the physiotherapist or dietician, which was acceptable to them. Some patients reported a need for more frequent contact. Therefore, it is suggested that healthcare professionals should conduct assessment of their patients' needs before and during the intervention to ensure that these needs are being met. Advising healthcare professionals to identify the patient's needs could help to optimize the OPRAH intervention, especially in case of remote coaching.

Strengths and limitations

A strength of this study is the multi-methods approach of interviews and online questionnaires. The utilization of semi-structured interviews enabled a comprehensive exploration of patient experiences and perspectives. The online questionnaire quantitatively measured the usability and experiences of the patients with the intervention. This methodology yielded rich, detailed data, facilitating the identification of nuanced insights into the experiences of the intervention and areas for enhancement.

A limitation of this study is the potential selection bias, as only 17% of the included patients had a low education level, and patients who were unable to complete questionnaires in Dutch were excluded from participation. This limited our ability to explore whether the intervention is usable for this group and meets their needs and preferences, highlighting the importance of addressing this in future research. It should also be noted that patients who consented to participate in studies using apps may be more inclined to perceive the self-monitoring tool as acceptable and beneficial. In our study, this may also have had an impact, as patients open to using apps were more likely to participate. In addition,

not all patients were invited for an interview; in some cases, such as recent readmission, patients were not approached in order to avoid overburdening them with study-related tasks. This selective inclusion may have introduced a biased perspective of the overall patient experience, as patients experiencing setbacks or a high level of complaints did not participate in the interviews. Lastly, researchers participated in interventions' evaluation were involved in the OPRAH study and therefore may have biases about the importance of evaluating patient experiences, and thereby the interpretation of the experiences.

Practical relevance

The findings of this study highlight the potential for blended interventions, like the OPRAH intervention, in post-operative care. The high usability of the app demonstrates that digital tools can support patient during their recovery by promoting self-management. Combined with personalized coaching from physiotherapists and dieticians, this approach allows for flexible, tailored support that adapts to individual recovery needs. Despite that this intervention was only tested in hospitals, it may also be interesting for the primary care, given the increase in care being moved from hospital towards primary care. However, the need for further personalization, especially in coaching intensity and app features, is key to optimize the intervention.

Conclusion

The results of our study showed an excellent system usability of the app and predominantly positive user experiences in patients who received the OPRAH intervention after oncological surgery. The results of the interviews indicate that the intervention had a positive impact on the patients' capacity, opportunity and motivation to engage in physical activity and increase their protein intake following hospital discharge. Patients highly valued this type of support, as the combination with remote coaching provided a low-key communication possibility with involved healthcare professionals. However, patients with lower digital literacy or more complex disease trajectories may have different needs, such as face-to-face support or more individualized goal setting. While the OPRAH intervention appears suitable for integration into routine care, its implementation should be tailored to patient-specific characteristics and needs to ensure broader applicability.

List of abbreviations

CAT PROMIS PF - Computer Adaptive Testing Dutch-Flemish Patient Reported Outcome Measure Information System for Physical Functioning
COREQ - COnsolidated criteria for REporting Qualitative research
GI – Gastrointestinal
HPB – Hepato-Pancreato-Biliary

METC – Medical Ethical Research Committee
MI – Motivational Interviewing
MMSE – Mini-Mental State Examination
OPRAH – Optimal Physical Recovery After Hospitalization
PAM – Physical Activity Monitor
RCT – Randomized Controlled Trial
RCTs – Randomizes Controlled Trials
SMD – Shared Decision Making
SUS – System Usability Scale

Declarations

Ethics approval and consent to participate

This study was part of the OPRAH trial, which has been approved by the Medical Ethical Research Committee (METC) of Amsterdam UMC, location VUmc (METC 2021.0627). This trial was conducted according to the principles of the Declaration of Helsinki (version 9, October 2013), in accordance with the Dutch Medical Research Involving Human Subjects Act (WMO) and the Dutch Personal Data Protection Act (General Data Protection Regulation (GDPR)). The trial has been registered at the International Clinical Trials Registry Platform (NL9793) and the study description is available at the following web link: https://trialsearch.who.int/Trial2.aspx?TrialID=NL9793. All patients signed informed consent prior to participation in the trial and additionally before interviews. All participants were informed that they are under no obligation to enter the trial and that they can withdraw at any time during the trial without having to give a reason and that this will not affect the medical care they receive.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and/or analyzed are available from the corresponding author upon reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

A research grant of the Amsterdam Movement Sciences Institute was received for financing 50% of a PhD project aiming to develop and evaluate an activity tracker-based feedback and coaching intervention for patients at risk for functional decline admitted to the hospital. This current RCT was conducted in support of this project. The funder had no role in the study design, the data collection, analysis, writing of the article, or in the decision to submit the paper for publication. In addition, a research grant from Regieorgaan SIA supported this project financially (Grant SBV/ RAAK.PUB09.039) was conducted.

Authors' contributions

MvdS and MvdL are principal investigators and share last authorship. CvW and MdL performed the interviews. Interviews were transcribed verbatim by CvW and EvdW. Analyses were performed by CvW, MdL and EvdW. CvW and MdL drafted the manuscript. Both made equal contribution to this manuscript, therefor they share first authorship. MvdS, MvdL, HK, VdG and EW substantially revised the manuscript. All authors read and approved the final manuscript.

Ethical approval

The trial protocol has been approved by the Medical Ethical Research Committee (METC) of Amsterdam UMC, location VUmc (METC 2021.0627). This study will be conducted according to the principles of the Declaration of Helsinki (version October 2013), in accordance with the Dutch Medical Research Involving Human Subjects Act (WMO) and the Dutch Personal Data Protection Act (General Data Protection Regulation (GDPR)). The trial has been registered at the International Clinical Trials Registry Platform (NL9793) and the study description is available at the following web link: https://trialsearch.who.int/Trial2.aspx?TrialID=NL9793. All amendments of the protocol will be notified to the METC and the competent authority. Non-substantial amendments will not be notified to the accredited METC and the competent authority but will be recorded and filed by the sponsor. Participating sites in the study will be notified of any changes to the study protocols. This will enable them to make the necessary arrangements to incorporate the changes, if necessary, and to confirm their continued support for the study after the implementation of the changes. All patients will sign informed consent prior to participation in the trial. All participants will be informed that they are under no obligation to enter the trial and that they can withdraw at any time during the trial without having to give a reason and that this will not affect the medical care they receive.

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Table 3. *Summary of advantages, disadvantages, and recommendations of the OPRAH intervention*

Subtheme	Advantages and disadvantages	Recommendations
General intervention	• Provides feedback on recovery • Creates a feeling of being seen • Creates incentive to change physical activity and nutrition behaviour • Contributes to the perceived recovery • Can contribute to lifestyle changes • Provides easy and convenient contact	• Tailoring the intervention to individual needs and preferences • More collaboration between healthcare professionals
	• Degree and type of coaching is not sufficiently adapted to personal needs • Not all health care professionals are involved	
The application		
Usability	• Easy to use	• More information about post-surgery regimen and protein products • Add more variables such as pain scores, mental health status, body weight
	• Some patients needed help with on-boarding • More in-app information would be of added value	
Physical activity	• Graphs were clearly understandable • Provides insight into progress in goals • Provides insight into daily physical activity behaviour • Motivating to reach goals	• More clarity on when an activity is light and when it is more heavy • Post a comment on a specific day to give an explanation • Incorporation of particular exercises or trainings schedules
	• Distinction between light, moderate and heavy activities was unclear • Can be confrontable when not able to reach the goal	
Nutrition	• Provides insight into nutritional behaviour • Motivating to reach goals • Easy to find the right category	• Food categories could be more specific • Focus also on calories or healthy food • Diversity in nutrition products that can be chosen in the app • A finer distinction between dinner options • Six instead of three nutrition moments a day
	• Food categories are not specific enough • Doubts about the accuracy • Complicated to calculate the number of stars • Focus only on protein intake and not on calories or healthy eating • May give the feeling to be constantly occupied with food	

Table 3. *Continued*

Subtheme	Advantages and disadvantages	Recommendations
Activity tracker	• Good adherence in wearing • Wearing the activity tracker becomes daily routine • Advantages of wearing the activity tracker outweighs the disadvantages	• Different material and design of the bracelet • Solve technical problems • Improve reliability of the activity tracker
	• The appearance of the activity tracker is suboptimal • The ankle bracelet can sometimes irritate • Technical problems • Uncertainty about reliability • Does not recorded all activities, such as rowing or arm exercises	
Coaching		
General	• Enables personalized advice • Provides a listening ear • Stimulates to be more physical active and to achieve daily protein goals	• Tailoring the intervention to personalized needs • Adding pictures of the healthcare professionals to the application to enhance the personalized experience
	• Needs to be more personalized • Absence of face-to-face contact	
Type and degree	• Provides low-key contact via the chat when required	
	• Needs to be more personalized • Ability to use the chat function is perceived differently	
Physiotherapist	• Provides effective guidance and appropriate advice • Creates a personal connection • Compliments and coaching are stimulating • Coaching establishes boundaries • Frequency of contact is overall appropriate	
	• Lack of in-persons sessions	
Dietician	• Coaching is friendly and compassionate • Provides effective guidance • Provides guidance on how to use the app • Provides specific advice upon request	
	• Differences in degree of contact • Not always adequately monitoring • Nutritional guidance not personalized enough • Lack of consistency in the dieticians that contacts the patients	
Duration of the intervention		
	• Generally appropriate • Intervention creates the ability to continue recovery independently	• Tailoring the duration of the intervention to personal needs and preferences
	• No personalization in duration of the intervention • Intervention only took place after surgery, not during pre-operative treatment	

Supplementary Files

Appendix 1: Questionnaire evaluation OPRAH study and Atris app



Scan QR code

Appendix 2 – Semi-structured interview guide



Scan QR code

Appendix 3 – Phases of thematic analysis described by Braun and Clark et al. (2023)



Scan QR code



Chapter 8

Implementation fidelity of the blended Optimal Physical Recovery After Hospitalization (OPRAH) intervention for patients after oncological surgery

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Abstract

Purpose: To evaluate the implementation fidelity of a blended intervention aimed at optimizing physical recovery following gastrointestinal or lung cancer surgery, involving patients, dietitians, and physiotherapist.

Methods: Implementation fidelity was evaluated alongside a Randomized Controlled Trial (RCT) investigating the effect of the Optimal Physical Recovery After Hospitalization (OPRAH) intervention. For three months post-discharge, dietitians and physiotherapists remotely coached patients using data on physical activity and protein intake collected via a smartphone application and activity tracker. Carroll's framework guided the evaluation of the intervention using both quantitative and qualitative data.

Results: Patient adherence to wearing the activity tracker and monitoring protein intake was high. All patients received coaching from at least one of the two allied healthcare professionals. The frequency of coaching varied between patient populations, with the highest frequency for patients after gastrointestinal surgery. A negative moderating factor was that the OPRAH intervention was difficult to implement in daily work routine. Positive moderating factors included positive responsiveness of physiotherapists, dietitians, and patients, well-functioning technology, and facilitation strategies that effectively engaged physiotherapists and dietitians.

Conclusions: As adherence to the intervention was high, the observed effects of the RCT can be more confidently attributed to the OPRAH intervention. The main challenge for long-term implementation is integrating the intervention into routine clinical practice.

Implications for Cancer Survivors: OPRAH can support cancer survivors during a vulnerable phase of recovery, with the potential to improve physical outcomes. Sustainable implementation requires embedding the intervention into standard care and maintaining close collaboration among healthcare providers.

Introduction

The recovery process following oncological surgery poses significant challenges for patients, both physically and psychologically [1-5]. As cancer treatments and surgical interventions continue to improve, the importance of optimizing post-surgical recovery has become increasingly evident [6-12]. A recent systematic review showed promising results when combining physical activity and nutritional interventions to enhance recovery outcomes [13].

In response to the need for effective post-hospital support for patients after oncological lung- or abdominal surgery, we developed the Optimal Physical Recovery After Hospitalization (OPRAH) intervention [14]. The aim of the OPRAH intervention was to promote self-management during recovery through a smartphone application and activity tracker, supported by remote coaching from a physiotherapist and dietitian. Results of the multicenter randomized controlled trial have shown that the OPRAH intervention is effective in enhancing physical activity and protein intake and contributes to faster and better recovery in physical functioning [15].

Blended interventions, integrating e-health with remote coaching by physiotherapists and dietitians, offer a scalable solution amid growing healthcare demands [16, 17]. By combining digital tools with personalized support, these interventions enhance accessibility, adherence, and patient engagement from home. Therefore, blended interventions may provide sustainable and effective solutions for optimizing physical recovery after oncological surgery.

To increase scientific confidence that the reported findings are due to the intervention, it is important to assess the implementation fidelity of the intervention, as implementation fidelity is a moderator between the content of the intervention and the intended outcome [18]. Implementation fidelity is defined as the degree to which interventions are implemented as planned by the developers. Previous studies have demonstrated that implementation fidelity influences its level of success [19-21]. In addition, evaluation of implementation fidelity could support improvement of the intervention and dissemination of the research findings into practice.

Therefore, the aim of this study was to investigate the implementation fidelity of the OPRAH intervention during the execution of a randomized controlled trial to assess how well the intervention is implemented as intended and to identify factors influencing its effectiveness. To evaluate implementation fidelity, the framework of Caroll et al.

was used to evaluate adherence to content, coverage, frequency, and duration of the intervention, as well as the impact of potential moderating factors [18]. Understanding the implementation fidelity will support further optimization of the OPRAH intervention and facilitate its effective and sustainable integration into usual care.

Methods

Design

This study is part of the OPRAH Multicentre Randomized Controlled Trial (RCT) of which the study design has been described in more detail elsewhere [14]. The study was conducted at Amsterdam UMC and St. Antonius Nieuwegein, the Netherlands. The study protocol has been approved by the Medical Ethical Research Committee (METC) of Amsterdam UMC, location VUmc (METC 2021.0627). During and after trial completion, both qualitative and quantitative data were used to evaluate the implementation fidelity of the intervention. Quantitative data were collected by the electronic health record, the dashboard of the used application (Atris), and questionnaires. For qualitative data collections, we conducted follow-up sessions with the physiotherapists and dietitians during the implementation period and conducted semi-structured interviews and focus group meetings afterwards.

The OPRAH intervention

The OPRAH intervention was designed to support patients after gastro-intestinal or lung cancer surgery after their return home after hospital discharge. The purpose of the OPRAH intervention was to facilitate faster and better recovery in physical functioning by stimulating patients' self-management regarding their level of physical activity and protein intake. The two key components of the intervention were self-monitoring and remote coaching by a physiotherapist and dietitian.

Self-monitoring

The Atris software (Peercode B.V., Geldermalsen, the Netherlands) was used in combination with the ankle-worn PAM AM400 accelerometer (PAM B.V., Doorwerth, the Netherlands) to monitor physical activity and protein intake. The Atris software includes a patient app and a backend website for the physiotherapist and dietitian. The Atris app allows patients to self-monitor their daily physical activity and protein intake through wearing the PAM and tracking daily protein intake by using a simple in-app self-registration system. See Figure 1 for screenshots of the app. The Atris app provided feedback on progress related to their goals. In addition, patients could ask questions via the app's chat, with responses provided by the physiotherapist or dietitian. Through the backend website, the

physiotherapist and dietitian monitored activity and protein data, sent messages, and were able to send automatic triggers.

Figure 1. *Screenshots of the English version of the Dutch Atris app.*



Remote coaching

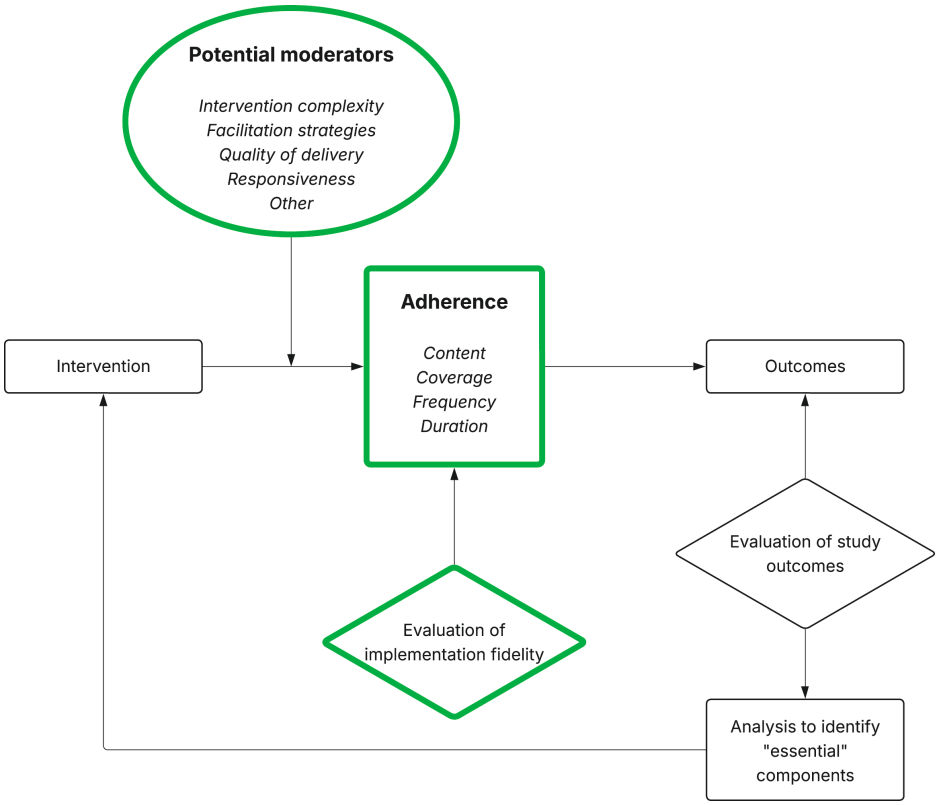
Remote coaching was performed by a physiotherapist and dietitian by telephone or chat. Coaching was added as a component of the intervention to ensure that the intervention could be tailored to the patients' needs. Goal setting—focused on physical activity and protein intake—was a key component, established in consultation with patients. The protocol did not prescribe the frequency or mode of contact, allowing the physiotherapist and dietitian to tailor contact accordingly. To support behavior change, Motivational Interviewing (MI) was included in the coaching. MI aims to enhance patient autonomy, intrinsic motivation, and self-efficacy to improve self-management [22]. All involved professionals received MI training (three-day course or e-learning) prior to the study.

Conceptual framework for implementation fidelity

The Framework of Carroll et al. was used to evaluate the implementation fidelity of the OPRAH intervention [18]. This framework allows to evaluate both adherence to the intervention and moderating factors to degree of adherence. Adherence is the extent to which the intervention was conducted as designed and includes the dimensions of coverage, content, frequency, and duration. Following the framework of Carroll et al., moderating

factors for adherence to the intervention includes the dimensions of intervention complexity, facilitation strategies, quality of delivery, and participant and provider responsiveness (Figure 2). To evaluate the implementation fidelity of the intervention, we used the two key components of the intervention, self-monitoring and remote coaching, as described above. Specific research questions and outcomes per key component for each dimension of the framework are presented in Table 1 and Table 2.

Figure 2. *Caroll's conceptual framework for implementation fidelity. Green boxes show the components evaluated in this study.*



Data collection

To evaluate the implementation fidelity and answer the corresponding research questions, different data sources were used to evaluate the themes of adherence and potential moderator from the framework of Caroll et al. (Table 1 and Table 2).

Adherence measurements

Coverage was measured by the percentage of days the PAM was worn and the protein intake was registered by patients, which was extracted from the Atris software. In addition, the percentage of patients that received coaching (by telephone and/or chat) during the intervention period was measured, which was extracted from the Atris software and the electronic health record. For *content*, the percentage of patients for whom a goal has been established regarding physical activity and protein intake were measured and how often these goals were adjusted. During the interviews, we also explored to what extent the collected data was used for remote coaching. To determine the *frequency,* the median number of contact moments with the physiotherapist and dietitian via telephone and chat were measured. From the interviews with physiotherapists and dietitians, we extracted how they determined the frequency of contact. To determine the *duration*, the percentage of patients who completed the three months intervention period was extracted from the trial administration.

Moderating factors measurements

To gain insight into the factors that may have influenced the adherence, we evaluated the possible moderating factors as presented in Figure 1. To assess the moderating factor *intervention complexity*, we assessed the usability of the Atris application (patients) and Atris dashboard (physiotherapists and dietitians) with the System Usability Scale. In addition, to investigate the overall experience of physiotherapists and dietitians with the intervention, we asked them to rate the intervention on a scale from 1 to 10. During the interviews, we also explored the extent to which the intervention fits into the daily work of physiotherapists and dietitians. To assess the *facilitation strategies*, we determined how many educational, evaluation, and peer-review sessions were organized. The experiences with these sessions were evaluated during interviews with physiotherapists and dietitians. To assess the *quality of delivery*, physiotherapists and dietitians were asked if the Atris dashboard was a good support for coaching patients remotely. Also, physiotherapists and dietitians were asked which capabilities they need to perform the intervention. In addition, the use of motivational interviewing techniques in recorded conversations between patients and physiotherapists and dietitians were evaluated using the Motivational Interviewing Treatment Integrity (MITI) score [23]. To assess *participant and provider responsiveness*, general experiences with the intervention were investigated during the interviews with physiotherapists, dietitians and patients. In addition, physiotherapists and dietitians were asked if they would like to use the OPRAH intervention in usual care. Patients were asked if they would recommend the intervention to others. In addition to the predefined moderating factors, the interviews were also evaluated to identify whether any *other potential moderators* emerged.

Qualitative data collection

To gain a more comprehensive understanding of adherence and to identify potential moderators, we collected qualitative data. Semi-structured interviews were conducted with both physiotherapists and dietitians (n=10) and patients (n=24) to evaluate their experiences with the OPRAH intervention. The results of the patients' experiences are already published and will only briefly be discussed in this manuscript [24]. For patients, we included the following topics: general experiences, preparing phase before intervention, Atris application, remote coaching, value to rehabilitation recommendation, and future perspective. For physiotherapists and dietitians, we included the following topics: general experiences, the use of collected data for remote coaching, frequency and delivery of the coaching, combining usual daily tasks and the intervention, goal setting, educational-, evaluation-, and peer-review sessions, required competencies, barriers and facilitators to carrying out the intervention as intended. Two focus group meetings were conducted with all participated physiotherapists and dietitians, one with professionals of Amsterdam UMC (3 physiotherapists and 4 dietitians) and one with professionals of St. Antonius hospital (2 physiotherapists and 2 dietitians) after the trial. Identification of strengths, weaknesses, opportunities and treats (SWOT) of the interventions long-term implementation was conducted. Narrative summaries were conducted to establish the SWOT analysis.

Data analysis

RStudio (version 4.4.3) was used for quantitative data analysis. Descriptive data was present as mean (SD), median (IQR) or percentage. The mean (SD) SUS was calculated using the method described in the study by Brooke (2). Additional questions about user experience were presented as mean, range, or percentages.

In order to ascertain to what extent the MI techniques have been implemented, the behavioural count component of the Motivational Interviewing Treatment Integrity (MITI) manual version 4.2.1 was used [23]. Behaviour counts included the specific MI techniques used: giving information, persuade, persuade with permission, question, simple reflection, complex reflection, affirm, seeking collaboration, emphasizing autonomy and confront. Behaviour counts were typically established through categorization and predefined decision rules based on the MITI manual. After transcription, there was a practice phase for coding using the MITI manual. Two students (LB and AM) of the Master Clinical Psychology who were involved in analysing these conversations received guidance during the practice phase from a qualified researcher experienced in coding many MI conversations using this MITI manual. Subsequently, the conversations were officially coded, and the results were discussed by multiple researchers (LB, AM, MdL, CvW, MvdS, MvdL).

Interviews were transcribed verbatim. MdL and CvW performed qualitative analysis and interpretation of the interviews using a thematic methodology, as described by Braun and Clark, supported by MAXQDA 2022 [25]. MdL and CvW performed open, axial, and selective coding, using an inductive approach. After selective coding, experiences were categorized into the different components of Carrolls' framework (Table 1 and Table 2).

Table 1. *Overview per intervention component of research question, data course, and outcomes for the evaluation of adherence.*

Intervention component	Research questions	Data source	Outcome
Adherence			
Coverage Main question: What proportion of participants were exposed to the intervention as intended?			
Self-monitoring	What percentage of days was the activity tracker worn by the patients?	Atris software	The median (IQR) percentage of days the activity tracker was worn by patients was 100% (94% - 100%). 5 of the 63 patients who completed the intervention (8%) wore the activity tracker less than 80% of the days.
	What percentage of days did patients record their protein intake?		The median (IQR) percentage of days the protein intake was recorded by patients was 98% (76% - 100%). 3 of the 63 patients who completed the intervention period (5%) recorded their protein intake less than 14 days.
Remote coaching	What percentage of patients received coaching during the intervention period (by telephone or chat)?	EHR and Atris software	All patients received remote physiotherapy coaching. 76% of patients received coaching from a dietitian.
Content Main question: Are the active ingredients of the intervention conducted as described in the protocol?			
Self-monitoring	For what percentage of patients were goals established regarding physical activity and protein intake?	Atris software	A goal related to physical activity was set for all patients. In two patients (3%), no protein intake goal was established.

Table 1. *Continued*

Intervention component	Research questions	Data source	Outcome
Adherence			
Remote coaching	How many times were goals adapted?	Atris software	The mean (range) number of times the physical activity goals were adapted during the intervention period was 3 (1-7). The mean (range) number of protein goals per patient was 2 (0-4).
	To what extent was the collected data used for the remote coaching?	Interviews	Physiotherapists and dietitians mentioned that the data was used to get an overall impression of the well-being of patients. The data also supported coaching sessions as a discussion tool and control mechanism to verify patient-reported information. Most physiotherapists and dietitians used the data to determine the frequency of contact.
Frequency and duration Main question: Was the duration of the intervention as planned and how often was there contact between patients and physiotherapists and dietitians?			
Self-monitoring	How many patients completed the three months intervention?	Trial administration	In total, 63 of the 73 patients (86%) completed the three months intervention period. Reasons for discontinuation were not interested in continuation (N=3), other medical treatment (N=2), not satisfied with the intervention (N=2), hospital readmission (N=2) and palliative treatment (N=1).
Remote coaching	How many telephone and chat contact moments (median [IQR]) on average were there during the intervention with the dietitian and physiotherapist?	EHR and Atris software	Physiotherapists had a median (IQR) of 2 [4] contact moments by telephone and 8 [5] contact moments by chat. Dietitians had median (IQR) of 2 [3] contact moments by telephone and 4 [8.5] contact moments by chat.
	How was the frequency and delivery of the coaching determined by physiotherapists and dietitians?	Interviews	It was noted by both physiotherapists and dietitians that they were searching for an adequate frequency of coaching. Some provided structured coaching (e.g., biweekly), while others adapted contact dynamically based on patient data, goal progress, and chat questions.

EHR: Electronic Health Record; **SUS:** System Usability score.

Table 2. *Overview per intervention component of research question, data course, and outcomes for evaluation of moderating factors.*

Intervention component	Research questions	Data source	Outcome
Moderators			
Intervention complexity Main question: How complex was the intervention?			
Self-monitoring	What is the usability of the Atris app?	Questionnaire	Patients rated the application as acceptable with a mean SUS of 86.2 (SD 12.0)
Remote coaching	How would you rate the intervention?	Questionnaire and interviews	The overall intervention was rated by the physiotherapist and dietitians with 8.1 points out of 10.0 (range 7.0-10.0). The complexity of the intervention was influenced by the usability of the Atris software, the extent to which the intervention fits into daily work, goal setting and patient characteristics.
	What is the usability of the Atris dashboard?	Questionnaire	Physiotherapists and dietitians rated the dashboard as acceptable with a mean SUS of 71.5 (SD 12.2).
	To what extent did the intervention fit into daily tasks?	Interviews	It was a challenge to incorporate OPRAH into daily tasks. Activities related to OPRAH were often carried out in between other duties, and at times rushed when their schedules were too full.
	What components of the intervention are experiences as complex by the physiotherapists and dietitians?		Physiotherapist reported difficulties with goal setting, due to the lack of a protocol to guide initial goals. Dietitians found goal setting easier, as existing protocols for protein intake provided more guidance. Both noted that allowing patients to take the lead in formulating goals was challenging. Patients' motivations, digital skills, and complexity of recovery trajectories influenced the intervention complexity.

Table 2. *Continued*

Intervention component	Research questions	Data source	Outcome
Moderators			
Facilitation strategies Main question: What facilitation strategies were used for implementation of the intervention?			
Educational sessions	What were the strategies to support the implementation of the intervention in the daily routine of the physiotherapists and dietitians?	Trial administration	1 Pilot study 1 Motivational Interviewing course, with an e-learning alternative 3 evaluation meetings with consortium 1 kick-off meeting 5 peer-review meetings
	What were the dietitians' and physiotherapists' experiences with the educational and training session?	Interviews	The training session and e-learning were relevant to their work; however, they noted that MI techniques should be part of basic knowledge. The meetings were valuable for creating awareness of their discipline involvement, understanding of each discipline's role, sharing experiences not only within, but also between hospitals.
Quality of delivery Main question: Is the intervention delivered in a way that is appropriate to achieve its intended goal (improving recovery after hospital discharge)			
Remote coaching	Offers the Atris dashboard good support for remote coaching?	Questionnaire	93% of the physiotherapists and dietitians (totally) agreed that the dashboard was a good support for coaching patients remotely.
	To what extent was motivation interviewing used?	Recordings of telephone consultations	MI was not consistently applied to the MITI manual standards. More questions were asked compared to given reflections. Very fewer complex reflections were made. A lot of information was given during conversations.
	Which specific skills are required for remote coaching?	Interviews	No extra capabilities were required, only good working software and reliable data.

Table 2. *Continued*

Intervention component	Research questions	Data source	Outcome
Moderators			
Participant and provider responsiveness Main question: How satisfied were participants and physiotherapists and dietitians with the intervention?			
Experiences of physiotherapists and dietitian	Would you like to use the OPRAH intervention in usual care for this population?	Questionnaire	86% supported integrating OPRAH into usual care, noting its potential to enable more personalized and efficient care when embedded in daily routines.
	What are the general experiences of physiotherapists and dietitians with the intervention?	Interviews	Physiotherapists and dietitians agreed that the intervention improved patients' self-management. It also improved their understanding of the recovery process. They felt that OPRAH filled a gap in post-discharge support and increased their sense of making a meaningful contribution to patient recovery. However, there is a need for triage too, as not all patients require the same intensity and duration of support.
Experiences of patients	How many patients would recommend the intervention to others?	Questionnaire	97% of the patients would recommend the intervention to other patients.
	What are the general experiences of patients with the intervention?	Interviews	Patients were predominantly positive about the intervention. For more detailed insights into patient experiences, we refer to our recently published article [24].
Other moderators			
General	What other factors modified adherence?	Interviews	A key facilitator was the strong consensus among physiotherapists and dietitians on the importance of optimal nutritional and physical activity guidance, as well as promoting patient self-management. A second key facilitator was the collaboration between physiotherapists and dietitians. Supporting the same patient created a sense of unity, strengthened the feeling of working as a team, and increased awareness of each other's roles in patient guidance. Technical issues and difficulties with app onboarding were also identified as moderating factor as well as the availability of funding to cover time investment, software licensing costs, and the purchase of activity trackers.

EHR: Electronic Health Record; **SUS:** System Usability score.

Results

An overview of the outcomes per intervention component for each aspect of Carolls' framework are presented in Tables 1 and 2.

Adherence

Coverage

From the 73 patients allocated to the intervention group, 63 patients (86%) completed the intervention period. Reasons for discontinuation were not interested in continuation (N=3), other medical treatment (N=2), not satisfied with the intervention (N=2), hospital readmission (N=2) and palliative treatment (N=1). Among the remaining 63 patients the median (IQR) percentage of days the activity tracker was worn by patients was 100% (94% - 100%). Five patients (8%) wore the activity tracker less than 80% of the days, due to hospital readmission (N=1), empty battery (N=1), oedema (N=1), high disease burden (N=1), and one unknown reason. Protein intake was recorded on a median (IQR) of 98% (76% - 100%) of days. Three patients (5%) recorded protein intake on fewer than 14 days, due to a vegan diet (N=1) and unknown reasons (N=2). All patients received remote physiotherapy coaching. Remote coaching by a dietitian was provided to 48 patients (76%) overall. Among patients who underwent lung surgery, 5 (26%) received dietitian support after hospital discharge, representing the lowest proportion across all surgical groups.

Content

A physical activity goal was established for all patients, and a protein intake goal was set for 97% of them. Physical activity goals were adjusted a mean of 3 times per patient (range 1–7), and protein goals were adjusted a mean of 2 times (range 0–4). All physiotherapists mentioned that they used the physical activity data to set and adjust goals. Most dietitians based protein goals on patients' nutritional needs (1.9 g protein/kg lean body mass), while some used preoperative intake data to define more achievable targets. Both physiotherapist and dietitians mentioned that they used the physical activity data to get an overall impression of the well-being of patients and to ascertain whether the patients' recovery trajectory aligned with a normal recovery pattern. The data also supported coaching sessions as a discussion tool and control mechanism to verify patient-reported information. Most physiotherapists and dietitians also utilized the data to ascertain the frequency of contact.

Frequency and duration

Table 2 provides an overview of the frequency of contact by phone and chat. It was noted by both physiotherapists and dietitians that they were searching for an adequate frequency

of coaching. The findings of the interviews revealed two distinct strategies: some provided structured coaching (e.g., biweekly), while others adapted contact dynamically based on patient data, goal progress, and chat questions. One physiotherapist noted that phone calls were time-consuming and only necessary for more complex patients.

Table 3. *Frequency of contact by phone and chat with the physiotherapist and dietitian (N=63).*

	Physiotherapist		**Dietitian**		**Patient**
	Phone (median [IQR])	**Chat** (median [IQR])	**Phone** (median [IQR])	**Chat** (median [IQR])	**Chat** (median [IQR])
All patients	**2 [3]**	**8 [5]**	**2 [3]**	**4 [8.5]**	**11 [12.5]**
Per tumor location:					
- Lung	0 [0.5]	8 [2.5]	0 [0.5]	0 [0]	9 [5]
- Upper GI	3.5 [4]	8 [4]	4 [2]	7 [8.5]	14 [13]
- HPB	4 [1]	8 [9]	2 [2]	7 [7.5]	15 [18]
- Colorectal	2 [1]	6 [4]	1 [1]	3 [4.5]	11 [15.5]

GI: Gastrointestinal; **HPB:** Hepato Pancreato Biliary; **IQR:** Interquartile range

Moderating factors

Intervention complexity

In total, 58 patients (85%) completed the online questionnaire, rating the app as acceptable with a mean SUS of 86.2 (SD 12.0) [24]. All fourteen physiotherapists and dietitians involved completed the online evaluation, though one did not complete the SUS. Physiotherapists and dietitians rated the usability of the dashboard as acceptable with a mean SUS of 71.5 (SD 12.2). The overall intervention was rated with 8.1 points out of 10.0 (range 7.0-10.0).

Most physiotherapists and dietitians experienced OPRAH as an additional workload, often carried out in between other duties, and at times rushed when schedules were full. They emphasized the need for dedicated time to better integrate it into daily work. Physiotherapists found goal setting challenging due to the lack of a clear protocol and, at times, missing preoperative data, while dietitians benefited from existing nutritional guidelines. Both groups noted challenges in getting patients to formulate their own goals, as patients often lacked understanding of what constituted appropriate goals. Patient characteristics also influenced the complexity: motivated and digitally literate patients were easier and more satisfying to coach remotely, while those with limited app use or complex recovery required more time. In addition, not seeing patients face-to-face during their hospital stay hindered the development of a therapeutic relationship and the accurate interpretation of remote data.

Facilitation strategies

Several strategies were used to support physiotherapists and dietitians in adhering to the intervention. A pilot study at Amsterdam UMC prior to the RCT led to refinement of the intervention. To support implementation, a motivational interviewing (MI) course was offered, with an e-learning option for those unable to attend. Participants found the training relevant and appreciated. During the RCT, three evaluation meetings were held with the OPRAH consortium. Additionally, a kick-off and three peer-review meetings were organized for Amsterdam UMC, and two for St. Antonius Hospital. These meetings were seen as helpful for fostering interdisciplinary collaboration, clarifying roles, and sharing experiences within and between hospitals.

Quality of delivery

93% of the physiotherapists and dietitians (totally) agreed that the dashboard effectively supported remote coaching. As part of the evaluation, conversations between physiotherapists and dietitians and patients were analyzed for the use of Motivational Interviewing (MI) techniques. Results indicated that MI was not consistently applied according to the MITI manual standards [23] (Supplementary File 1). Although dietitians showed a higher use of complex reflections, the overall communication was dominated by questions rather than reflections, even though reflections are essential in the practice of MI. In the interviews, both physiotherapists and dietitians questioned MI's relevance for this patient group, as many were already motivated due to their cancer diagnosis. Time constraints—particularly the short 10-minute phone calls—were cited as a barrier to fully applying MI techniques. This also affected goal setting, where MI is intended to support patient-led formulation. Physiotherapists and dietitians indicated that delivering the intervention required no additional resources, aside from well-functioning software and reliable data.

Participant and patient responsiveness

All physiotherapists and dietitians agreed that OPRAH improved patients' self-management during recovery by providing insight into their exercise and dietary behaviors. It also improved professionals' insight into the recovery process, particularly after discharge, where follow-up is often lacking in usual care, allowing for more personalized advice and better discharge preparation. Both physiotherapists and dietitians mentioned that OPRAH filled a gap in post-discharge support and increased their sense of making a meaningful contribution to patient recovery. Most physiotherapists and dietitians (86%) supported integrating OPRAH into usual care, noting its potential to enable more personalized and efficient care when embedded in daily routines. The shared dashboard facilitated coordination and communication among professionals and with patients. Physiotherapist

and dietician mentioned that their was increased collaboration with the other professional as a result of OPRAH. However, interviews revealed that this collaboration had not yet developed into true interprofessional collaboration, as communication was mostly limited to exchanging updates rather than joint planning or the establishment of shared goals. Physiotherapist and dietitians also noted that, for broader implementation, a triage system is recommended to tailor the intensity of support to individual patient needs.

Patients were predominantly positive, reporting that the intervention enhanced their understanding of their recovery process, motivated them to achieve protein and physical activity goals, and contributed to their overall recovery [24]. The combination of app usage and monitoring by a physiotherapist and dietitian fostered a sense of being supported. However, patients suggested that the intervention could be improved by further tailoring it to individual needs, for example by combining remote coaching with face-to-face contact.

Other moderating factors

Qualitative findings identified additional moderating factors that influenced adherence to the intervention. A key facilitator was the physiotherapists' and dietitians' shared belief in the importance of providing optimal nutrition and physical activity support and promoting patient self-management. This shared motivation helped to maintain their commitment and integrate the intervention into daily routines. Interdisciplinary collaboration was another facilitator: working together to support the same patients fostered a sense of teamwork, increased mutual role awareness and enabled more consistent, personalized care. A negative moderating factor identified was the presence of technical issues or difficulties with app onboarding. For instance, malfunctions of the activity tracker were reported to demotivate patients and, at times, hinder their adherence to the intervention. Another moderating factor was the availability of funding to cover time investment, software licensing costs, and the purchase of activity trackers.

Recommendations for long-term implementation

Although physiotherapists and dietitians were generally positive about the intervention, they identified several requirements for successful long-term implementation. Structural time and reimbursement were regarded essential, as is the development of a triage tool to identify suitable patients by assessing digital skills and health literacy, and then selecting the appropriate form of contact (face-to-face, remote-, or blended care). To improve usability, they recommended integrating the dashboard into the electronic health record. In addition, a tool to support goal setting and determine appropriate treatment dose, frequency, and duration of the intervention is needed to enable personalized care and ensure consistency across professionals. All physiotherapists and dietitians may be

eligible to deliver the intervention, as no additional competencies were deemed necessary to perform the OPRAH intervention. A SWOT analysis in Supplementary File 2 outlines the strengths, weaknesses, opportunities and threats associated with the long-term implementation of OPRAH.

Discussion

This multi-methods study was part of the OPRAH RCT and was used to assess the implementation fidelity of the intervention, a blended intervention to improve physical activity and protein intake after oncological surgery. Adherence to the key components of the intervention – self-monitoring and remote coaching – by both patients and physiotherapists and dietitians was considered high. For long-term implementation, the main challenges include embedding the intervention into routine care and further tailoring it to patient's needs, digital skills and health literacy.

OPRAH can be considered as a new care pathway integrating a combination of physiotherapy and dietetic support. Our findings showed that the implementation of this new pathway faced some challenges. For dietitians, who already provided post-discharge support as part of usual care, the main challenge was integrating the Atris dashboard and the use of remotely collected data into their routines and advice. In addition, for physiotherapists and dietitians for whom post-discharge guidance was not part of usual care, the main barrier was the reported lack of time to take on these new responsibilities. This lack of time is a commonly reported barrier in implementing new clinical care pathways [26, 27]. Possible solutions to address this issue should be explored, as it may also be caused by difficulties in prioritizing new tasks or an imbalanced distribution of workload within teams. Potential approaches include task shifting – for example, encouraging patients to take more responsibility during hospitalization by promotion self-management. The time saved could then be allocated to postoperative support. Another approach is to optimize triage by prioritizing patients who are most in need of support.

Despite the limited time availability, adherence to the new care pathway was generally good. This was likely facilitated by the high responsiveness of the dietitians and physiotherapists. Unlike findings from previous studies, where a common barrier is stakeholders' lack of belief in the added value or effectiveness of a new intervention or pathway, this was not the case in our study [26]. A key contributing factor appears to be the flexibility in timing of OPRAH-related tasks, as checking the dashboard and sending chat massages could be scheduled flexibly, allowing physiotherapists and dietitians to integrate them

into their daily routines. Such flexibility is a well-documented facilitator of successful implementation [26].

Determining the appropriate frequency of remote coaching tailored to patients' needs was perceived as challenging by some physiotherapists and dietitians. Those who had regular contact found it difficult to rely solely on patients' self-management skills when determining the frequency of contact, often resulting in more time spent on coaching as the overall number of interactions was higher compared to those who only reached out when indicated. However, previous research on physical activity and behavior change interventions stated that higher frequency of contact may not be better [28]. To provide efficient, personalized care, it may be important to support healthcare professionals with a more needs-based approach—for example, by using a tool to assess a patient's self-management skills [29]. Such a tool can help identify potential barriers to self-management that need to be addressed, thereby facilitating tailored coaching and support to enhance patient self-management.

As outlined in the OPRAH trial protocol, several behavior change techniques (BCTs) were incorporated to promote physical activity, protein intake, and self-management, including motivational interviewing (MI) and shared decision-making (SDM) [22, 30]. Nevertheless, many patients struggled to set realistic goals and relied on the expertise of physiotherapists and dietitians. In turn, physiotherapists and dietitians expressed a need for more structured guidelines in formulating specific and appropriate goals. Interviews revealed that goal setting often focused on quantifiable outcomes, such as active minutes or protein intake, rather than on meaningful daily activities that patients wished to resume. While numerical goals support self-monitoring, the goal-setting process should ideally begin with activity and participation goals. Professionals can then help translate these goals into measurable targets that better align with the principles of MI and SDM.

A strength of our study is the high response rate of physiotherapist and dietitians, as all of them who actively participated in the intervention responded to the questionnaires and participated in the interviews. Moreover, the use of a conceptual framework made it possible to systematically evaluate the implementation fidelity. Lastly, by using different data sources we obtained a wide variety of quantitative and qualitative information.

This study has also limitations. First, the generalizability is limited, as the intervention was implemented in only two hospitals. As such, the results may not be directly transferable to other settings with different organizational structures and care pathways. Second, although it is recommended to assess the complexity of an intervention using an

independent external team [31], this was not feasible within the current study design due to time and resource constraints . This may have introduced bias in the interpretation of the intervention's complexity.

Conclusion

Overall, the adherence to the intervention protocol was high, meaning that the key components of the intervention were delivered as intended. The positive observed effects of the randomized controlled trial can therefore be more confidently attributed to the OPRAH intervention itself rather than to coincidence or to deviations in its execution. Integrating OPRAH into daily work routines was experienced as complex. However, due to high participant and patient responsiveness and appropriate facilitation strategies, the adherence to implementation of OPRAH was high. To ensure OPRAH's long-term implementation, intervention complexity should be reduced by optimizing its integrating into daily work routines. Solutions for financial barriers should also be devised. In addition, continuing facilitation strategies that support communication between physiotherapist and dietitians remains important.

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Statements and Declarations

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Competing interests

The authors have no relevant financial or non-financial interests to disclose.

Data Availability

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics approval

The study has been approved by the Medical Ethical Research Committee (METC) of Amsterdam UMC, location VUmc (METC 2021.0627).

Consent to participate

Informed consent was obtained from all individual participants included in the study.

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Supplementary Files

Supplementary File 1: Motivational Interviewing Treatment Integrity (MITI) score



Scan QR code

Supplementary File 2: SWOT analysis for long-term implementation of OPRAH



Scan QR code



Chapter 9

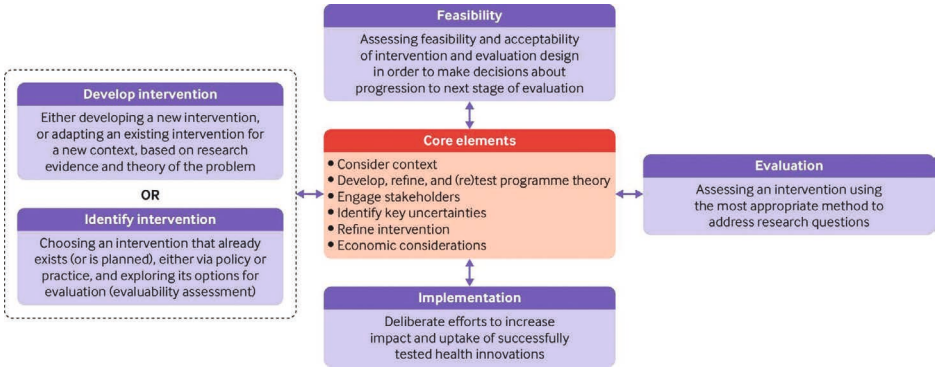
General discussion

The primary aim of this thesis was to develop and evaluate a blended intervention designed to enhance recovery in physical functioning following hospital discharge in patients who have undergone gastrointestinal or lung cancer surgery. Additionally, this thesis explored how the impact and uptake of this intervention could be optimized for integration in existing care pathways. In this final chapter, I discuss the main findings, methodological considerations, and recommendations for clinical practice and future research.

Main findings

This thesis addresses all phases of the Medical Research Council (MRC) framework for developing and evaluating complex interventions (Figure 1) [1]. Therefore, the main findings are outlined based on these phases.

Figure 1. *Medical Research Council (MRC) framework for developing and evaluating complex interventions.*



Phase 1 - Development of the intervention

In recent years, there has been growing attention on promoting physical activity during hospitalization as a key component of Enhanced Recovery After Surgery (ERAS) programs. Higher levels of physical activity have been shown to enhance recovery in physical functioning, reduce the risk of readmission and shorten hospital stay [2-6]. However, encouraging physical activity should not be limited to hospital stay alone, as improving physical activity after hospital discharge is also important to optimize functional recovery [7]. Self-monitoring of physical activity, by using activity trackers, seems promising in increasing physical activity levels and addressing common barriers such as insecurity, lack of motivation and social support [8, 9]. To determine whether this type of support is appropriate for patients following gastrointestinal or lung cancer surgery, we investigated the feasibility of self-monitoring of physical activity after hospital discharge in these patients

(**chapter 2**). A mixed methods study was conducted in 41 patients with gastrointestinal or lung cancer scheduled for surgery. Patients wore an ankle worn physical activity monitor (PAM) and used the corresponding smartphone app (Atris app) from one week preoperatively until six weeks after hospital discharge.

Results suggested that self-monitoring of physical activity using the PAM is feasible in these patients, based on good system usability and predominantly positive user experiences. The usability was assessed using the System Usability Scale (SUS), a widely used and validated tool in the evaluation of health-related technologies, offering a standardized metric to ensure that interfaces meet user needs and supports user adherence [10]. The mean SUS in our study was 77.3, which exceeds the benchmark for digital health apps (SUS > 68), indicating good system usability [11]. These findings align with other studies evaluating the feasibility of mobile health apps in patients with cancer [12-15].

However, the number of dropouts and amount of missing data was relatively high, underlining the importance of improving user adherence for future implementations. Based on the findings of **chapter 2,** technical problems were addressed and the ankle-worn device was replaced with a more comfortable alternative to enhance user adherence. Moreover, strategies to improve self-efficacy, self-motivation and social support were considered, in line with evidence from a systematic review identifying these factors as key predictors of adherence in home-based physical activity interventions [16]. Notably, as no structured coaching was provided, several participants in our study expressed a desire for more support in addition to self-monitoring. This underscored a potential value of combining self-monitoring with coaching.

These considerations were confirmed by the results of our systematic review and meta-analysis investigating the effectiveness of interventions using activity trackers in divers patient populations during and after an inpatient period on the outcomes physical activity and physical functioning **(chapter 3).** These findings revealed that interventions using activity trackers effectively increase physical activity levels (Standardized Mean Difference (SMD) = 0.34) and that the effectiveness on physical activity seems to improve by incorporating coaching by a healthcare professional (SMD = 0.44). Likewise, reviews in cancer survivors reported positive effects on physical activity (SMD = 0.54 [17] and SMD = 0.70 [18]). Results of subgroup analysis of these studies also suggested that including coaching by a healthcare professional enhanced the effectiveness of the interventions. The smaller effect size in our review may be due to the inclusion of patients during or immediately after an inpatient period, who may experience more barriers to physical activity, such as pain or fatigue.

Our systematic review and meta-analysis also showed that interventions based on a theoretical model and incorporating multiple Behaviour Change Techniques (BCTs) were more effective. This aligns with findings from a review on digital technologies supporting behaviour change in surgical patients, published in the same period, which found that interventions are more effective when underpinned by BCTs [19].

Despite the positive effects on physical activity, our systematic review found no effect on performance based physical functioning. This is in contrast with a systematic review in cancer survivors, where positive effects on aerobic fitness and physical function were reported [17]. A likely explanation is the heterogeneity in outcome measures and small sample sizes in our review, leading to low certainty of evidence. Another explanation relates to the natural course of recovery. In our review population—patients recovering during or after an inpatient period—physical functioning generally improves over time, regardless of the intervention. Patients in the intervention group may have a physical functioning level similar to that of the control group after a certain time, but it may take them less time to reach that level. Therefore, we considered it important to include multiple follow-up measurements over time in our future study on functional recovery, to adequately capture changes in physical functioning.

Based on the results of **chapter 2 and 3**, we developed the Optimal Physical Recovery After Hospitalization (OPRAH) intervention, which combines self-monitoring of physical activity and protein intake with remote coaching by a physiotherapist and dietician during three months after hospital discharge. The OPRAH intervention incorporated multiple BCTs, delivered through in-app features (e.g., self-monitoring and goal setting) and coaching (e.g. feedback on behavior and social rewards). A self-monitoring tool for protein intake was added as component of the smartphone app, recognizing the crucial interplay between nutrition and physical activity in promoting functional recovery after oncological surgery (**chapter 1**). This self-monitoring tool was based on the "Rate-a-Plate" method, which is an easy method to obtain general estimation of protein intake [20]. The aim of the OPRAH intervention was to improve patients' self-management by providing insight into their recovery in physical activity and into whether they were meeting their protein requirements, while the coaching component enabled the physiotherapist and dietitian to offer timely support when patients experienced barriers or symptoms that could hinder recovery.

Phase 2 – Feasibility of the OPRAH intervention

A pilot study was performed to assess the feasibility of the OPRAH intervention and evaluate associated study procedures, which is outlined in **chapter 4.** Results of this single-arm

feasibility study revealed that the OPRAH intervention is feasible for implementation in a larger study involving adult patients scheduled for gastrointestinal or lung cancer surgery. While adherence to self-monitoring of physical activity was high (91%), adherence to using the protein registration tool was suboptimal (59%). In a comparable feasibility study in patients after colorectal cancer surgery, adherence to self-monitoring of physical activity was substantially lower (50%), while user adherence to nutritional intake was similar (54%)[21]. Interestingly, in that study, patients reported that recording nutritional intake was time-consuming and complex. In contrast, participants in our study indicated that the limited number of options in the app made it difficult to accurately register individual food items, leading to a sense of inadequacy in reporting their intake. As a result, further modifications were made to the in-app protein registration tool. Nevertheless, the challenge remains to find the optimal balance between the level of detail, the complexity of use, and the time required to register protein intake – especially considering that patients are asked to register their protein intake on a daily basis.

As the majority of patients did not recover to preoperative levels at six weeks after hospital discharge and most patients mentioned that the intervention should have lasted longer, the duration of the intervention was extended from six weeks to three months after hospital discharge. The drop-out rate was relatively high (25%), but comparable to other trials in patients with cancer [22].

Phase 3 – Evaluation of the OPRAH intervention

Given the limited evidence on the effectiveness of blended interventions focusing on physical activity and protein intake after discharge on physical functioning in patients following gastrointestinal or lung cancer surgery, we conducted a multicenter randomized controlled trial. The protocol and results are presented in **chapter 5** and **chapter 6**, respectively. In this trial, the OPRAH intervention was conducted in addition to usual care and was compared to usual care only. The primary outcome was recovery in physical functioning up to six months after hospital discharge measured with the Computer Adaptive Testing (CAT) Patient Reported Outcome Measure Information System (PROMIS) for physical functioning [23]. The OPRAH intervention significantly improved recovery of physical functioning up to six months after hospital discharge following oncological gastrointestinal and lung surgery, although effect sizes were small (estimated mean difference (EMD) = 1.72 [95%CI 0.18; 3.26], effect size = 0.21). Notably, patients in the intervention group reported significantly better perceived recovery at 3 and 6 months (effect sizes 0.45 and 0.40). Moreover, recovery appeared faster in the intervention group, with 55% of patients returning to baseline physical functioning at six months compared with 35% in the control group (OR = 2.45 [95%CI 1.18; 5.52], p = 0.0166). In

addition, patients were more physically active (EMD = 12.85 [95%CI 2.66; 23.04], effect size = 0.32), met their protein intake requirements more often (EMD = 7.82 [95%CI 2.64; 13.01], effect size = 0.26) and experienced less fatigue (EMD = -2.95 [95%CI -5.18; -0.73], effect size = -0.29). With sufficient adherence, this intervention also shows potential to improve patients' quality of life.

Recent studies in oncology patients support our findings, as they also reported positive effects on physical functioning. In a recently published RCT by Granger et al., a home-based exercise and self-management program was evaluated in patients after pulmonary resection, which included an activity tracker and weekly telephone support by a physiotherapist for 12 weeks [24]. In contrast with our study, they found clinically meaningful improvements in performance based physical functioning, whereas no significant differences were found in patient-reported physical functioning. This discrepancy may reflect differences in intervention focus: Granger et al.'s primarily exercise-based approach versus our behaviour change strategy emphasizing daily physical activity and protein intake. The importance of combining physical activity with a nutritional component is further supported by a recently published systematic review among cancer survivors, which found no effect on physical functioning in studies using exercise alone, whereas studies combining exercise with nutrition showed overall benefits on physical functioning [25]. These findings highlight the potential of physical activity and nutrition interventions to enhance functional recovery in patients with cancer.

Phase 4 – Towards implementation in clinical practice

To generate valuable insights for enhancing the implementation of the OPRAH intervention in practice, patient experiences with the intervention were evaluated using both quantitative and qualitative data (**chapter 7**). Results indicated excellent app usability (SUS 86.2), which is considerably higher than the scores reported for the earlier app versions in **chapter 2** and **chapter 4.** This improvement is most likely due to the app optimization and enhanced information material informed by those earlier evaluations. In addition, interviews revealed predominantly positive user experiences. Patients reported that the intervention enhanced their understanding of their recovery process, motivated them to achieve protein and physical activity goals, and contributed to their overall recovery. The combination with coaching fostered a sense of being supported. However, some complaints remained regarding the nutritional component of the app and the design of the bracelet of the activity tracker. Nevertheless, most patients emphasized that the benefits of the intervention outweighed these disadvantages. This is also reflected in the fact that 97% of the patients would recommend the intervention to other patients scheduled for oncological surgery. Recommendations for optimizing the intervention included more

personalization based on patients' needs, particularly regarding the duration of the intervention and the frequency of contact. The findings are consistent with the evaluation of a mobile intervention aimed at reducing sedentary behaviour before and after cancer surgery [14]. In that study, patients similarly described the app as motivating and insightful for understanding their recovery, while also expressing a need for more personalization.

In **chapter 8**, Carroll's framework for implementation fidelity was used to evaluate adherence to the intervention, as well as the moderating factors influencing the degree of adherence [26]. Evaluating the implementation fidelity of the OPRAH intervention could support improvements to the intervention and facilitate implementation, as previous studies have demonstrated that implementation fidelity influences an interventions' success [27-29]. Furthermore, it can increase scientific confidence that the reported effects of the OPRAH intervention are attributable to the intervention itself rather than to coincidence or to deviations in its execution. Patient adherence to wearing the activity tracker and monitoring protein intake was good and all patients received coaching from at least one of the two allied healthcare professionals. Therefore, the overall adherence to the intervention protocol was considered high, meaning that the key components of the intervention were delivered as intended. Integrating OPRAH into healthcare professionals' daily work routines was experienced as complex, as the intervention tasks were additional workload and often carried out between other duties. Despite these challenges, the high responsiveness of both patients and healthcare professionals, along with appropriate facilitation strategies, led to strong adherence to the implementation of OPRAH.

Determining the appropriate frequency of remote coaching tailored to patient needs was challenging for some physiotherapists and dietitians. Those who maintained regular contact often struggled to rely on patients' self-management skills, leading to more frequent interactions. However, previous research [30] and subgroup findings in **chapter 6** suggest that more contact is not necessarily better: patients undergoing lung cancer surgery, who received the least coaching, showed the greatest improvements in physical activity and protein intake. This may reflect differences in recovery challenges, variations in self-management skills, or indicate that coaching frequency does not directly determine effectiveness. **Chapter 7** further showed that, regardless of frequency, patients valued the sense of support that coaching provided. These findings highlight the importance of a needs-based approach, using tools to assess self-management capacity and guide personalized, efficient support [31]. Such a tool can help identify potential barriers to self-management, enabling more personalized coaching that effectively supports patient self-management.

In conclusion, the OPRAH intervention can be considered successful, as it positively influences patients' capacity, opportunity and motivation for behavior change – specifically improving physical activity and protein intake – following gastro-intestinal or lung cancer surgery, leading to improved recovery in physical functioning compared to usual care.

Intervention mechanisms

The findings of this study indicate that the OPRAH intervention primarily target psychological mechanisms, including enhanced self-efficacy and behavior change, rather than direct physiological adaptations like changes in muscle mass or physical performance.

With regard to physiological outcomes, no between-group differences in muscle mass were observed, despite significant improvements in physical activity and protein intake in the intervention group. This suggests that the positive effects of increased physical activity and protein intake on physical functioning are not mediated by changes in muscle mass only. Nevertheless, significant improvements in physical functioning and handgrip strength were observed. A possible explanation is the influence of muscle quality. Muscle quality includes factors such as fat infiltration, fiber type composition, and neuromuscular efficiency, all of which strongly influence muscle function regardless of muscle mass [32]. It is known that low muscle quality (e.g. myosteatosis), serves as a crucial prognostic factor for impaired outcomes in cancer patients [33, 34]. In our study population we also found that patients with myosteatosis showed consistently lower scores across all physical performance measures (*unpublished data)*. This suggests that in addition to muscle mass, other factors such as muscle quality and muscle function, also play an important role in improving functional recovery. This aligns with current sarcopenia criteria, which emphasize not only muscle mass but also muscle strength and function in diagnosis [35].

The psychological effect of the intervention likely played an important role in the positive effects found. It was hypothesized that providing patients with insight into physical activity and nutritional behaviours, along with feedback through self-monitoring and social support, would increase their sense of control and empowerment. This was expected to enhance self-efficacy, thereby improving their level of physical activity and protein intake. Our results support this hypothesis: the intervention group demonstrated higher self-efficacy compared to the control group, and both physical activity and protein intake were significantly higher. This psychological pathway is well established in the context of physical activity [36]: an increased sense of control enhances self-efficacy, which positively influences physical self-worth and overall self-confidence. These improvements

can, in turn, promote greater engagement in physical activity and thereby reinforcing a positive feedback circle.

Taken together, the effect of the OPRAH intervention on physical functioning might be more mediated by psychological mechanisms than by direct physiological adaptations. Future mediation analysis within our data could further explore this.

Finally, since the intervention group received more attention than te control group, it remains unclear whether the observed effects are due to the intervention itself or merely the additional attention. For future research, this can be addressed by using a attention control group, in which patients receive the same amount of social interaction as the intervention group but without the specific active components of the intervention [37].

One size does not fit all

Although it was expected that all patients undergoing oncological surgery for cancers of the digestive system and pulmonary region would benefit from increased physical activity and protein intake after hospital discharge, the findings suggest that one size may not fit all. Although the subgroup analyses were underpowered and their findings should be interpret with caution, the analysis indicated that the intervention has differential effects across patient groups. Patients who underwent pulmonary resection and Hepato-Pancreato-Biliary (HPB) resection seem to benefit more from the intervention in terms of recovery in physical functioning compared to patients who underwent surgery for upper gastrointestinal cancers, including esophageal and stomach cancer (**chapter 6**). This difference is also reflected in the effectiveness on the targeted behaviours – physical activity and protein intake – which appear to be less in this group. A possible explanation is the impact of these types of surgery, as esophagectomy is a highly invasive surgery and is more likely to cause postoperative low activity behaviour compared to other digestive system surgeries [7]. In addition, nearly all patients in this group receive postoperative tube feeding for approximately six weeks, which limits variability in protein intake compared to the control group. Previous studies also reported that physical functioning in these patients is still impaired at six months after hospital discharge [38]. Therefore, it may be worth considering whether these patients could benefit more from this type of intervention at a later stage in their recovery, when their physical capacity to increase activity and protein intake may be greater. Alternatively, the intervention could potentially focus more on other aspects, such as symptom management or strength exercises.

Methodological considerations

In the following paragraphs, strengths and limitations will be discussed about the theoretical frameworks, study design, study population, intervention and outcome measures used in this thesis.

Theoretical frameworks

A strength of this thesis is its strong theoretical underpinning, supported by the use of multiple frameworks. The MRC Framework for complex interventions was applied for the development and evaluation of the OPRAH intervention. This framework offered a structured approach, ensuring that the intervention was well-defined, evidence-based, and tailored to the specific context [1]. For the theoretical foundation of the intervention itself, the behavioral change wheel (BCW) was used [39]. This framework enabled us to clarify how the intervention brings about change, identify its active ingredients, and explain how these components exert their effect. Based on these results, relevant behavioral change techniques were identified and linked to a mode of delivery in order to improve the capability, opportunity and motivation of patients to target the desired behavior.

Motivational interviewing is a practice-based approach to utilize principles from theoretical models like the BCW. Therefore, we incorporated motivational Interviewing (MI) in the intervention. It was expected that MI in combination with self-monitoring would improve autonomous motivation [40]. However, results indicated that MI was not consistently applied by the physiotherapists and dieticians, as overall communication was dominated by questions rather than reflections (**chapter 8**). Reflections – statements that mirror the patients thoughts and feelings – are considered more essential in practice of MI, as they foster a collaborative environment which is crucial for facilitating behavior change. Physiotherapist and dieticians questioned the relevance of MI in these patients, as many were already motivated due to their cancer diagnosis. Time constraints—particularly the short 10-minute phone calls—were cited as a barrier to fully applying MI techniques. In a study on motivational strategies to improve adherence to physical activity in breast cancer survivors, the effectiveness of different intervention components was compared: activity trackers combined with coaching, activity trackers combined with MI and activity trackers with printed material and no coaching [18]. The results showed no difference in effect between coaching and MI, while both were more effective than providing printed material alone. These findings also suggest that the presence of coaching plays a key role in enhancing motivation, whereas the specific use of MI may only necessary for patients experiencing motivation challenges, indication that its application should be personalized.

Study design

A strength of the study design in this thesis is the inclusion of feasibility studies (**chapter 2 and 4)** and the use of a robust RCT design (**chapter 6**). The feasibility studies enabled us to assess patient experiences with the intervention and to implement improvements based on their feedback. However, patients with low educational level were underrepresented in our study (17%). Not only was their initial enrollment low, but a smaller proportion of these patients continued throughout the study. Specifically, 42% of participants with a low educational background dropped out of the study, compared to just 16% of those with a higher educational level (*unpublished data)*. These patients face barriers such as limited health literacy, lack of trust in healthcare systems, and difficulties navigating complex care pathways, all of which contribute to their unwillingness to participate and higher dropout rates. The underrepresentation of patients with low (health) literacy is common in comparable research [41]. These patients may have different needs, and the current intervention may not be optimally suited to them. This issue was further exacerbated by the use of Dutch questionnaires and information letters, which also has an extensive format required for WMO research. The inclusiveness and applicability of the OPRAH intervention and study design might have been higher if we had conducting a needs assessment specific to this population and if we had incorporate more patient engagement strategies [42].

The multi method approach, by evaluating both the effectiveness of the intervention and the experiences of patients and healthcare professionals, is a strength of the study design. This approach provided valuable insights that can support further improvements of the intervention and facilitate implementation in clinical practice.

Study population

When this project was initiated, the importance of physical activity and nutrition as part of cancer rehabilitation was already well established. However, research was rarely focused on the immediate post-discharge period. Most studies focused either on prehabilitation, i.e. the process to enhance the patient's functional capacity prior to major surgery, or on long-term recovery in cancer survivors [41, 43-45]. Recognizing the need to support patients during the critical transition following hospital discharge, effective post-discharge interventions were needed [7, 38, 46-49]. Therefore, by focusing on this specific patient population we filled an important gap in support for patients with cancer.

A limitation of **chapter 3** is the heterogeneous patient population included in the meta-analysis. However, only a small number of studies were available focusing on patients with cancer during or immediately after hospital stay, which is a critical timeframe in

which patients are vulnerable due to the significant life event of diagnosis or treatment. Therefore, we chose to broaden the patient population rather than the time period (during/after hospital stay), as our primary interest was to evaluate whether interventions using activity trackers provide added value specifically within this vulnerable phase.

The study population chosen in **chapter 2, 4 and 6** was a heterogeneous population with various tumor locations, as physical activity and nutrition are relevant across these patients. While subgroup analyses were conducted to explore potential differences in outcomes, these analyses were underpowered and therefore not suitable for drawing definitive conclusions for specific patient groups. Nevertheless, including different patient groups was a valuable choice. If we had focused solely on one specific patient group where no significant effect was observed, we might have prematurely dismissed an intervention that appears to hold promise for other populations.

Intervention

Use of real-time data

A major strength of the OPRAH intervention is its ability to provide objective, real-time insight into patients' recovery through continuous monitoring of physical activity in daily life. It captures patients' baseline activity levels and tracks whether they return to these levels after surgery, moving beyond often-overestimated subjective self-reports[50]. Therefore, this real-time, data-driven approach offers a unique and more accurate understanding of recovery for both patients and healthcare professionals.

For patients, this can enhance their level of self-management, which is increasingly emphasized as an important part of cancer care to optimize health outcomes and accelerate recovery [51]. For healthcare professionals, it enables the use of real-time data to monitor progress and identify patients who may require additional support. However, this also presents a challenge of the intervention: hospital based physiotherapist who performed the intervention had no experience or prior knowledge in both recovery patterns of oncological surgery patients after discharge and coaching patients remotely, making this phase of the care pathway new for them. Because coaching was remotely, they had to rely on objective data combined with patients' subjective input. We noticed that they often struggled to interpret the objective data and to integrate it into their clinical reasoning when exploring which symptoms might hinder improvements in physical activity. Although this issue was addressed during peer review sessions (**chapter 8**), more focus on symptom management might have strengthened their new role to identify patients in need for more help. However, as symptom management is not primarily a role for physiotherapist but

rather for specialized nurses or case managers, more attention should have been given to multidisciplinary collaboration to enhance their signaling role.

By making the intervention blended, combining eHealth with remote coaching, we were able to provide ongoing support in patients' own environment. However, these types of interventions require a certain level of digital literacy, which may limit their suitability for some patients and healthcare professionals. At the same time, this highlights the responsibility for researchers and software developers to design digital tools that are accessible and inclusive, thereby reducing the risk of excluding those with limited digital skills.

Smartphone app

Several strengths and limitations can be identified regarding the Atris app used in the intervention. One key strength is the integration of self-monitoring for both physical activity and protein intake, eliminating the need for separate apps. This not only enhances usability but also emphasizes the synergy between physical activity and protein intake in supporting recovery. The Atris software also included a shared dashboard for the physiotherapist and dietician, which provided insight into patient data and featured a chat function to communicate with the patient. This facilitated timely interaction with the patient and interdisciplinary collaboration between the physiotherapist and dietician. In addition, the app was connected with the PAM accelerometer, which has been validated for accurately measuring active minutes [52]. Although some participants reported dissatisfaction with the appearance of the PAM device, adherence to wearing it remained high throughout the intervention. Moreover, the Atris app demonstrated excellent usability, as reflected in positive user experiences and system usability scores. (**chapter 2,4,7**)

The simplified protein intake registration system may have affected the accuracy of reported intake. This was a deliberate choice, as patients were required to log their intake daily and a simpler system was expected to reduce user burden. Also, the food categories used in the registration tool were based on typical Dutch dietary patterns, which limited its reliability and ease of use for individuals with different eating habits. This also applied to non-Dutch speakers, who were unable to use the app and were therefore excluded from the study. Expanding the app to include multiple languages and cultural dietary variations would improve its applicability and generalizability to more diverse patient populations.

Contextual factors

By applying the BCW, multiple behaviour change techniques were carefully selected and integrated into the intervention, such as self-monitoring, goal setting and social support.

These techniques were embedded in both in-app features and coaching sessions, ensuring that the intervention's core components are not dependent on the specific software used in this study. This theoretically grounded approach increases the potential for adaptation and generalization to other settings. However, the effectiveness of the intervention was assessed without considering important contextual factors, such as the patient-professional relationship, which is known to significantly influence healthcare outcomes [53, 54]. These factors are often not reported in RCTs due to the challenges involved in quantifying such interpersonal dynamics [55]. Incorporating these contextual elements in future research could improve the implementation and adaptability of the intervention across diverse patient groups and clinical settings.

Outcome measures

A strength of this thesis is the combined use of both quantitative and qualitative outcome measures in evaluating the OPRAH intervention. Within the quantitative outcomes, both questionnaires and performance measures were used as outcomes, offering a broader perspective on the effectiveness of the intervention and supporting its potential for future implementation in clinical practice.

To assess the effectiveness of the OPRAH intervention, a patient-reported outcome was used as primary outcome measure **(chapter 5 and 6).** Patient-reported outcome measures are an important component of cancer research, as they offer insights into the patients' experience of treatment beyond traditional clinical parameters such as disease response and survival outcomes [56, 57]. Moreover, returning to habits and routines and regaining independence are important elements of recovery indicated by patients after abdominal surgery [58].

A computer adaptive testing (CAT) system was used for the primary outcome physical functioning. This system uses a computer algorithm to select successive items based on previous responses, resulting in a tailored and efficient assessment [23]. The resulting scores range from 0 (unable to function) to 100 (able to run a marathon without any effort), thereby minimizing floor and ceiling effects. In contrast, another often used questionnaire to measure physical functioning, the European Organization for Research and Treatment of Cancer (EORTC) subscale for physical functioning, minor floor effects and notable ceiling effects were found, which creates uncertainty about the ability to detect changes in physical functioning among low- and high- functioning patients [59].

In **chapter 4 and 6**, a Bioelectric Impedance Analysis (BIA) was used to measure muscle mass. Although Computed Tomography (CT) is the gold standard for assessing muscle

mass, and Dual-energy X-ray absorptiometry (DXA) shows a higher correlation with CT than BIA, both methods are less practical in routine follow-up due to cost, radiation exposure (CT), and limited portability [60]. Moreover, follow-up measurements in our study were conducted in patients' home environments to reduce participant burden, making the use of CT and DXA impractical. Given these considerations, BIA was deemed the most feasible and appropriate method for this study. The European society for Parental and Enteral Nutrition (ESPEN) recommends that BIA measurements in research settings should be conducted in a fasting state of at least 8 hours [61]. However, considering that our study population consisted of patients recovering from major surgery, maintaining adequate nutritional intake was a priority. We therefore chose not to require fasting prior to the assessments. Additionally, existing research suggests that non-fasting BIA measurements do not lead to clinically relevant differences [62]. Nonetheless, given the use of BIA and the deviation from standard measurement conditions, the results should be interpreted with some caution.

Due to the long inclusion period and overall duration of the RCT (**chapter 6**), different researchers and research assistants conducted the baseline and follow-up measurements. This may have introduced some variability in the execution of measurements, particularly the 30 second chair stand test and two minute step test. However, the inter-rater reliability for both tests are high [63, 64]. By using standardized protocols for performing these tests and providing training for research assistants, we tried to minimize differences.

Recommendation for clinical practice and future research

In the following paragraphs, recommendations for clinical practice and future research will be discussed, drawing on the findings of this thesis as well as recent developments in the field. The discussion will focus on three main themes: optimizing OPRAH for hard-to-reach patients, personalizing support and addressing implementation barriers.

Optimizing OPRAH for hard-to-reach patients

Cancer incidence is higher among individuals with a lower socioeconomic position (SEP), who are often considered hard-to-reach due to limited education, low health and language literacy, and financial barriers [65]. This population is also more likely to engage in unhealthy lifestyle behaviors, including smoking, physical inactivity, and obesity. Furthermore, patients with low SEP often have limited access to physiotherapy interventions due to financial constraints and low health literacy, exacerbating health disparities and reducing the effectiveness of rehabilitation efforts. A recent report by the Netherlands Comprehensive Cancer Organization (IKNL) highlighted that patients with

low SEP face more significant challenges in maintaining physical functioning and quality of life post-treatment [66]. This pattern is also reflected in our study, in which patients with a lower educational level showed poorer recovery outcomes compared to those with medium or high education (*unpublished data,* **Chapter 6**). These findings highlight the need to prioritize strategies aimed at mitigating functional decline and improving recovery in this vulnerable population.

eHealth has the potential to improve accessibility, efficiency and quality of care. However, there is also a considerable risk of increasing the already existing health inequalities [67]. Among hard-to-reach patients, uptake of eHealth is often limited, as current interventions may not align with their skills, needs, or access to technology [68]. The need for a wider accessibility of e-Health is also emphasized by the Dutch eHealth monitor rapport [69]. Digital tools must be user-friendly, culturally appropriate, and designed to overcome barriers such as low health literacy and limited digital skills. This underscores the importance of adapting the OPRAH intervention to better serve the needs of these hard-to-reach patients, and of identifying strategies to optimize its implementation in order to increase reach, engagement, and effectiveness.

Personalizing support

Type and timing of support

Future research should focus on personalizing both type and timing of support for functional recovery by considering clinical and personal factors, including patient preferences, environmental context, educational level, culture, and digital (health) literacy. Regarding the type of support, some patients may only require information and advice about physical activity and nutrition. Others might benefit from self-monitoring without coaching but with the option to ask questions when needed. Some patients may require more intensive support, such as self-monitoring combined with coaching by a physiotherapist and dietician. For others, blended care may not be suitable, and support provided through primary care may be more applicable. In addition to tailoring the type of support, its timing should also be adapted to the individual. While this thesis primarily focused on support after oncological surgery, support can be valuable through the whole care pathway following diagnosis of gastrointestinal or lung cancer (**Chapter 1**). For example, preoperative support (prehabilitation) also has the potential to improve postoperative outcomes and should be considered for patients in whom it is likely to be beneficial, as it is also not a one-size-fits-all approach [70, 71].

Improving triage

To provide appropriate support for patients most in need for support, it is essential to optimize triage for those at risk of functional decline following oncological surgery. Preoperative functioning is generally associated with postoperative outcomes after abdominal surgery and should therefore be considered when identifying at-risk patients [72, 73]. Nonetheless, a high level of preoperative functioning does not guarantee favorable recovery: patients with high levels of preoperative functioning may still experience a steep decline and slow recovery. Conversely, patients with low preoperative functioning may recover to levels above their baseline [74]. This variability highlights the heterogeneity in functional recovery patterns, which are not always predictable based on preoperative risk assessments alone. Therefore, improved triage at the time of hospital discharge could enhance decision making regarding post-discharge support. Future research should aim to identify predictive factors not only preoperatively but also during hospitalization, as factors such as complications and early mobilization also predict recovery [3, 75, 76]. This knowledge could support healthcare professionals in providing appropriate and timely care after discharge. Continuous monitoring of parameters, such as physical activity, may offer valuable insights into whether recovery is progressing as expected and whether the type of support provided remains appropriate.

Use of big data and Artificial Intelligence (AI)

In the future, as continuous monitoring becomes part of routine care, big data and AI could further improve personalization of care. For example, it could support more dynamic risk prediction. Rather than relying on a one-time risk assessment, these technologies could use real-time data physical activity to update the risk of functional decline over time [77]. This would allow for earlier identification of patients whose recovery is not progressing as expected, and more timely adjustment of support.

AI could also facilitate personalized automated advice for patients, or even support through chatbots, which can reduce the burden on healthcare providers and potentially lowering costs. However it is important to recognize that such automated support may not be suitable for all patients and that the use should be personalized, taking into account patient needs, preferences and capabilities. Moreover, the reliability and effectiveness of AI-driven advice and chatbots must first be thoroughly evaluated before implementation.

Supporting healthcare professionals

An important focus for future research is not only how to personalize support for patients, but also how to effectively support healthcare professionals in this process. They need to develop new skills related to remote coaching, the use of technology and playing an role in

patient triage. It is essential to recognize that determining the right type of support requires shared decision-making between the patient and the professional, taking into account clinical, personal, and contextual factors. Healthcare professionals need tools, training, and possibly decision-support systems to make informed, tailored recommendations. Therefore, future research should also explore how professionals can best be supported in performing triage and in guiding patients with respect to physical activity, nutrition, and recovery needs after oncological surgery.

Addressing implementation barriers

Digital health technologies, such as wearables and smartphone applications, are rapidly expanding worldwide. However, many innovations in this field remain stuck in the pilot phase, often referred to as "pilotitis", due to a lack of robust clinical evidence and limited reimbursement or funding options [78]. Successful implementation of digital technologies in medical centers also faces several challenges, including data security, privacy concerns, legal and ethical approvals and necessary adjustments to the existing IT infrastructure [79]. In case of the Atris software used in this thesis, many of these hurdles have already been taken, allowing its integration into usual care. Nevertheless, the absence of structural reimbursement remains a key barrier to broader adoption. Future research should therefore prioritize the cost-effectiveness. Demonstrating the economic value may help secure sustainable reimbursement and facilitate long-term implementation, moving beyond the pilot stage. Until then, my advice is to keep the momentum going within the available financial constraints.

General conclusion

The findings of this thesis indicate that a blended nutrition and physical activity intervention can effectively enhance functional recovery following gastrointestinal and lung cancer surgery. While the OPRAH intervention shows promising results, further research is needed to determine the optimal patient selection criteria and coaching intensity to maximize patient benefit while ensuring cost-effectiveness. Moreover, targeted adaptations and greater personalization are crucial to address health inequities and improve accessibility for hard-to-reach populations. For structural and broader implementation, sustainable funding must be secured.

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Appendices

English summary

Major oncological surgery is frequently associated with substantial functional decline. To limit muscle mass loss and associated decline in physical functioning, it is crucial for patients to increase their physical activity levels and meet protein intake requirements following oncological surgery. However, post-discharge supportive care interventions focusing on functional recovery are limited. Patients emphasize the need for more support to improve physical activity levels and protein intake, thereby facilitating a return to normal activities after cancer surgery. Digital health tools— such as smartphone apps and activity trackers— in combination with coaching by allied healthcare professionals may offer a promising solutions by providing accessible support and continuity of care in patients' own environments. The aim of this thesis was to develop and evaluate a blended intervention designed to provide optimal physical recovery after hospitalization in patients who have undergone gastrointestinal or lung cancer surgery. The background and rationale underlying this aim are described in **chapter 1.**

In **chapter 2** the feasibility of self-monitoring of physical activity after hospital discharge using an activity tracker and smartphone app was evaluated in 41 patients who underwent gastrointestinal or lung cancer surgery. Patients received the Physical Activity Monitor (PAM), an ankle-worn activity tracker, and access to the corresponding smartphone app approximately one week before surgery. They were instructed to wear the PAM 24hours a day until six weeks postoperatively. Feasibility was assessed through study procedures, the System Usability Scale (SUS) and user experiences. The willingness to participate (76%) and the final participation rate (63%) were considered good. The retention rate was acceptable at 72%, although the rate of missing PAM data was relatively high (31%). The primary reason for missing data were technical problems and discomfort caused by the ankle-worn activity tracker. Patients rated the app's usability as good, with a mean SUS of 77.3. Interviews revealed that participants found the PAM and app easy to use, motivating, and supportive during their recovery period after discharge. These findings indicate that self-monitoring is feasible, though future improvements should focus on enhancing device comfort and resolving technical problems.

Chapter 3 presents the results of a systematic review and meta-analysis of randomized controlled trials (RCT) evaluating the effectiveness of interventions using activity trackers during or after inpatient care. A total of 21 RCTs were included, covering a broad range of clinical populations. Physical activity and physical functioning were reported as outcome measures in 13 RCT's, with data from 1435 and 1415 participants, respectively. A small but significant positive effect on physical activity was observed in favour of the intervention

group (standardized mean difference [SMD] = 0.34; 95CI 0.12-0.56). In contrast, no significant effect was found for objectively measured physical functioning (SMD = 0.09; 95CI -0.02; 0.19). Subgroup analyses indicated that the effectiveness on physical activity was enhanced when the intervention was provided both during and after the inpatient period, and when it was supported by a theoretical model, multiple behavioural change techniques, and coaching by a healthcare professional. These findings suggest that interventions using activity trackers can positively influence physical activity levels in patients during or after inpatient care, particularly when combined with behavioural and professional support strategies. Further research is needed to explore the effects on patient reported physical functioning.

Based on the results of chapter 2 and 3, we developed the Optimal Physical Recovery After Hospitalization (OPRAH) intervention, which combines self-monitoring of physical activity and protein intake with remote coaching by a physiotherapist and dietician after hospital discharge. To address the technical issues and user discomfort identified in chapter 2, optimized versions of the PAM were purchased and a different bracelet was used. Furthermore, informed by chapter 3, the OPRAH intervention includes multiple behavioural change techniques and self-monitoring is supported by coaching. Self-monitoring of protein intake was added as a new component of the intervention, recognizing the crucial interplay between nutrition and physical activity in promoting functional recovery after oncological surgery.

As a prelude to conducting a RCT, a pilot study was conducted to investigate the feasibility of the OPRAH intervention, as described in **chapter 4.** A single-arm intervention study was performed in 32 adults scheduled for curative-intent gastrointestinal or lung cancer surgery. Patients received the PAM and a modified version of the app approximately one week before surgery and continued using it until six weeks after hospital discharge. In addition, patients received remote coaching by a physiotherapist and dietician. Feasibility was assessed by evaluating participant and completion rates, SUS scores, user adherence, as well as patient experiences, and safety. The participation rate was 69% and 75% completed the intervention. The mean SUS was acceptable (73.5). Adherence to wearing the PAM was deemed satisfactory (91%), whereas adherence to self-registration of protein intake was suboptimal (59%). Patients mentioned a lack of options in the protein registration tool, making them feel unable to provide sufficient information about their intake. Despite this, patient experiences with the OPRAH intervention were predominantly positive and no safety concerns were identified. These findings suggest that the OPRAH intervention is feasible for conducting a RCT. Based on these results, improvements were made to

the protein self-registration tool to enhance usability and adherence. Furthermore, the sample size for the multi-center RCT accounted for a higher dropout rate.

In **chapter 5**, a study protocol is described of a multicenter, single-blinded two-arm randomized controlled study comparing the OPRAH intervention delivered alongside usual care with a control arm (usual care) in patients after hospital discharge who have undergone gastrointestinal or lung cancer surgery. The study was conducted at Amsterdam UMC, location VUmc and St. Antonius, location Nieuwegein. Eligible patients were screened and recruited preoperatively, after which baseline measurements were taken. Randomization (1:1), stratified by tumor location and ASA score, assigned patients to either the intervention or control group. The targeted sample size, accounting for 20% dropout, was 161 patients. Patients in the intervention group received a smartphone app, an ankle-worn activity tracker (PAM), and three months of remote coaching by a physiotherapist and dietitian, in addition to usual care. Assessments were conducted preoperatively and at 1, 4, and 8 weeks, and at 3 and 6 months post-discharge. The primary outcome was recovery in physical functioning, measured using the the Computer Adaptive Testing (CAT) version of the Dutch-Flemish Patient Reported Outcome Measurement Information System (PROMIS) Physical Functioning questionnaire. The secondary outcome was physical activity. Other outcomes included protein and energy intake, fatigue, pain, quality of life, participation, self-efficacy, global perceived effect, lean body mass, handgrip strength, physical performance, hospital readmissions and adverse events. Differences in recovery trajectories were analyzed using linear mixed model analysis.

Chapter 6 presents the results of the above described multicentre randomized controlled trial. A total of 193 patients consented for the study and were randomized to the intervention arm (N=90) or the control arm (N=103). In the intervention and control group, respectively 17 and 13 patients dropped out or were excluded before the first follow-up measurement. Eventually, there were 73 patients participating in the intervention group and 90 patients in the control group. In the intervention and control group, respectively 9 (12%) and 14 (16%) patients were lost to follow up. Results revealed a significant overall intervention effect on the primary outcome physical functioning (difference = 1.72 [95%CI 0.18 – 3.26), p = 0.03) with an effect size of 0.21. At six months post-discharge, 55% of intervention patients and 35% of control patients returned to baseline physical functioning (OR = 2.45 [95%CI 1.18; 5.52]). For the secondary outcome, physical activity, an overall intervention effect was also found (difference = 12.85 [95%CI 2.66 – 23.04], p = 0.01) with an effect size of 0.32. Additional significant effects were noted on protein intake, fatigue, pain, participation in social roles and activities, self-efficacy, global perceived effect, and handgrip strength. No significant differences were found on energy intake, quality of life, satisfaction with

participation in social roles and activities, lean body mass, physical performance tests or readmission rates. These findings indicate that the OPRAH intervention enhances recovery in physical functioning and has other positive effects, such as reducing fatigue and pain and increasing self-efficacy. However, further adaptations and personalization are essential to reach a broader and more diverse patient population, particularly patients with low (health) literacy.

In addition to results about the efficacy of the OPRAH intervention, the experiences of patients with the OPRAH intervention were also investigated and described in **chapter 7** of this thesis. A multi-method study was conducted, combining quantitative surveys with in-depth semi-structured interviews. All patients in the intervention group received the online survey at the end of the intervention period. The survey consisted of the SUS and sixteen additional questions about the acceptability, satisfaction and added value of the OPRAH intervention. Interviews were analysed using thematic analysis to investigate patients' experiences about the OPRAH intervention. A total of 58 patients filled out the online questionnaire. The mean SUS was 86.2 (SD 12.0). Of all respondents, 97% would recommend the use of the PAM and Atris app to other patients after oncological surgery. A total of 27 patients were purposively sampled to participate in an interview, of which 24 (89%) were willing to participate. The results of the interviews indicated that the intervention enhanced the patients' understanding of their recovery process, motivated them to achieve their protein and physical activity goals, and contributed to their overall recovery and, in some cases, even lifestyle changes. Patients highly valued this type of support, as the combination with remote coaching provided a low-key communication possibility with involved healthcare professionals. Based on patients' experiences, the OPRAH intervention seems suitable for implementation in usual care. Improving the nutritional part of the app and design of the activity tracker and more personalization of the intervention may further enhance user experiences.

To increase scientific confidence that the reported findings are due to the intervention, it was deemed important to assess the implementation fidelity of the OPRAH intervention. In addition, evaluation of implementation fidelity could support improvement of the intervention and dissemination of the research findings into practice. Therefore, in **chapter 8,** the implementation fidelity of the OPRAH intervention during the execution of the RCT was evaluated, in order to assess how well the intervention was implemented as intended and to identify factors influencing its effectiveness. Carroll's framework guided the evaluation of the two key components of the intervention: (1) self-monitoring using an activity tracker and a smartphone application, and (2) remote coaching. This framework allows to evaluate both adherence to the intervention and moderating factors

to the implementation. Adherence and moderating factors were evaluated using both quantitative and qualitative data. Overall, the adherence to the intervention protocol was high, meaning that the key components of the intervention were delivered as intended. The positive observed effects of the randomized controlled trial can therefore be more confidently attributed to the OPRAH intervention itself rather than to coincidence or to deviations in its execution. Integrating OPRAH into daily work routines was experienced as complex. However, due to high participant and patient responsiveness and appropriate facilitation strategies, the adherence to implementation of OPRAH was high. To ensure OPRAH's long-term implementation, intervention complexity should be reduced by optimizing its integrating into daily work routines. Solutions for financial barriers should also be devised.

Chapter 9 summarizes the key findings of this thesis, discusses methodological considerations and provides recommendations for future research and clinical practice. By conducting this thesis we now know that a blended, remotely delivered intervention can be effective in bridging the gap in post-discharge care for patients following oncological surgery. The developed OPRAH intervention provides a promising strategy to enhance functional recovery after hospital discharge by offering accessible, home-based support and continuity of care. Ensuring accessibility for diverse patient groups, including those with low health literacy, will be essential for broader implementation and equity of care.

Nederlandse Samenvatting

Patiënten die een grote oncologische operatie ondergaan, ervaren vaak een aanzienlijke achteruitgang in hun fysiek functioneren. Om verlies van spiermassa en de daarmee samenhangende afname in fysiek functioneren te beperken, is het van belang dat zij na de operatie voldoende blijven bewegen en eiwitrijk eten. Er zijn echter weinig interventies die zich specifiek richten op deze aspecten in de periode na ontslag uit het ziekenhuis, wanneer patiënten weer thuis zijn. Patiënten geven aan behoefte te hebben aan meer ondersteuning om hun beweeggedrag en eiwitinname te verbeteren, zodat zij sneller kunnen terugkeren naar hun dagelijkse activiteiten. Digitale gezondheidstools, ook wel eHealth genoemd, kunnen in combinatie met coaching door paramedische zorgverleners, een goede oplossing bieden. Deze tools zijn meestal laagdrempelig en kunnen de continuïteit van de zorg in de thuissituatie bevorderen. Het doel van dit proefschrift was het ontwikkelen en evalueren van een voeding- en bewegingsinterventie na ontslag uit het ziekenhuis voor patiënten die zijn geopereerd vanwege kanker aan de spijsverteringsorganen of longen. De achtergrond en rationale achter dit doel staat beschreven in **hoofdstuk 1.**

Hoofdstuk 2 gaat over het onderzoek naar de haalbaarheid van activiteitenmonitors en een smartphone-app voor zelfmonitoring van lichamelijke activiteit (beweging) na ontslag uit het ziekenhuis. Dit hebben we onderzocht bij 41 patiënten die een operatie ondergingen voor kanker aan de spijsverteringsorganen of longen. Patiënten ontvingen de activiteitenmonitor (PAM) en toegang tot de bijbehorende smartphone app ongeveer een week vóór de operatie en gebruikte deze tot zes weken na de operatie. De haalbaarheid werd beoordeeld door het evalueren van de onderzoeksprocedures, een vragenlijst over de gebruiksvriendelijkheid van de app (System Usability Scale [SUS]) en een vragenlijst en interview over de gebruikservaringen. De bereidheid tot deelname aan de studie (76%) en het uiteindelijke deelnamepercentage (63%) werden als goed beoordeeld. Het percentage patiënten dat de app bleef gebruiken gedurende de studieperiode was acceptabel (72%), hoewel er toch relatief veel missende data was van de PAM (31%). De belangrijkste redenen hiervoor waren technische problemen en ongemak van de PAM, die in een bandje om de enkel moest worden gedragen. Patiënten beoordeelden de gebruiksvriendelijkheid van de app als goed, met een gemiddelde SUS-score van 77,3. Uit interviews bleek dat deelnemers de PAM en app gebruiksvriendelijk, motiverend en ondersteunend vonden tijdens hun herstel. Deze bevindingen tonen aan dat zelfmonitoring van lichamelijke activiteit haalbaar is, hoewel toekomstige verbeteringen zich moeten richten op meer comfort van de PAM en het voorkomen van technische problemen.

In **hoofdstuk 3** vergelijken we 21 wetenschappelijke onderzoeken met elkaar (systematische review) met betrekking tot het effect van interventies waarbij activiteitenmonitors werden ingezet tijdens of na een opname in een ziekenhuis of revalidatiecentrum. We hebben hierbij gekeken naar het effect van deze interventies op lichamelijke activiteit en fysiek functioneren. Lichamelijke activiteit en fysiek functioneren werden beide in 13 studies als uitkomstmaat meegenomen, met gegevens van 1435 respectievelijk 1415 deelnemers. Er werd een klein maar significant positief effect op de lichamelijke activiteit gevonden in het voordeel van de interventiegroep, maar er werd geen significant effect gevonden voor de uitkomst met betrekking tot het fysiek functioneren. Subgroep analyses toonden aan dat het effect op lichamelijke activiteit groter is wanneer de interventie zowel tijdens als na de ziekenhuisopname werd aangeboden. Ook is het effect groter op lichamelijke activiteit bij interventies waar meerdere gedragsveranderingstechnieken zijn ingezet en interventies waarbij het gebruik van een activiteitenmonitor werd gecombineerd met coaching door een zorgprofessional. Deze resultaten laten zien dat het gebruik van activiteitenmonitors kan helpen om patiënten tijdens of na een ziekenhuisperiode meer te laten bewegen, vooral als dit wordt gecombineerd met andere gedragsveranderingstechnieken en ondersteuning door zorgverleners. Verder onderzoek is nodig naar het effect op het fysiek functioneren.

Op basis van de resultaten uit **hoofdstuk 2 en 3** hebben we de Optimal Physical Recovery After Hospitalization (OPRAH) interventie ontwikkeld. In deze interventie worden activiteitenmonitors ingezet voor zelfmonitoring van lichamelijke activiteit. Om de technische problemen en het ongemak van de PAM (beschreven in hoofdstuk 2) aan te pakken, zijn verbeterde versies van de PAM aangeschaft en werd een ander type enkelband gebruikt. Geïnspireerd door de inzichten uit hoofdstuk 3 bevat de OPRAH interventie meerdere gedragsveranderingstechnieken. Gezien de belangrijke relatie tussen eiwitinname en lichamelijke beweging voor het herstel na oncologische chirurgie, is zelfmonitoring van eiwitinname toegevoegd aan de app als nieuw onderdeel. Naast zelfmonitoring van lichamelijke activiteit en eiwitinname werden patiënten op afstand, via telefoon of chat, gecoacht door een fysiotherapeut en diëtist.

Als voorloper op een studie naar het effect van de OPRAH interventie, hebben we eerst een pilotstudie uitgevoerd om de haalbaarheid van de interventie te onderzoeken en om eventueel aanpassingen te maken aan de interventie. Deze uitkomsten staan in **hoofdstuk 4**. Aan deze pilotstudie hebben 32 volwassen patiënten deelgenomen die een operatie hebben ondergaan vanwege kanker aan de spijsverteringsorganen of longen. Patiënten ontvingen ongeveer een week voor de operatie de PAM en een aangepaste versie van de app en gebruikten deze tot zes weken na ontslag uit het ziekenhuis. Daarnaast werden zij telefonisch en via de app gecoacht door een fysiotherapeut

en diëtist. De haalbaarheid werd beoordeeld aan de hand van het evalueren van de onderzoeksprocedures, de SUS vragenlijst, de mate van therapietrouw, veiligheid en patiëntervaringen. Het deelnamepercentage was 69% en 75% voltooide de gehele interventieperiode. De gemiddelde SUS-score was acceptabel (73,5). De therapietrouw rond het dragen van de PAM was goed (91%), maar de registratie van eiwitinname was suboptimaal (59%). Patiënten gaven aan dat er te weinig producten in de app stonden om hun eiwitinname goed te kunnen registreren. Desondanks waren de ervaringen overwegend positief en er werden geen veiligheidsproblemen gemeld. Deze bevindingen lieten zien dat de OPRAH interventie voldoende basis biedt voor het uitvoeren van een grotere studie. Op basis van de resultaten is de voedingsmodule van de app verbeterd om de gebruiksvriendelijkheid en therapietrouw te verhogen. Ook werd in de steekproefgrootte voor de vervolgstudie rekening gehouden met een hoger uitvalpercentage.

Het effect van de OPRAH interventie werd onderzocht door het uitvoeren van een multicenter, enkelblind, gerandomiseerde studie (RCT). Dit betekent dat het onderzoek plaatsvond in meerdere ziekenhuizen, in dit geval in het Amsterdam UMC en in het St. Antonius Ziekenhuis in Nieuwegein. Enkelblind refereert aan het feit dat de onderzoekers die de metingen deden bij de patiënten niet wisten in welke groep de patiënten zaten, waardoor hun verwachtingen geen invloed konden hebben op de resultaten. Gerandomiseerd betekent dat de deelnemers willekeurig werden verdeeld over twee groepen: de ene groep kreeg de OPRAH interventie in aanvulling op de gebruikelijke zorg (interventiegroep) en de andere groep kreeg alleen de gebruikelijke zorg (controlegroep). Randomiseren zorgt ervoor dat de groepen goed vergelijkbaar met elkaar zijn. In **hoofdstuk 5** staat het onderzoeksprotocol van deze studie uitgebreid beschreven. Geschikte patiënten werden voorafgaand aan de operatie gescreend en geïncludeerd, waarna ze werden gerandomiseerd in de interventie of controlegroep. De beoogde steekproefgrootte, met inachtneming van 20% uitval, was 161 patiënten. De interventiegroep kreeg naast de gebruikelijke zorg een smartphone app, een PAM en drie maanden coaching op afstand. Metingen werden uitgevoerd vóór de operatie, en op 1, 4 en 8 weken, en 3 en 6 maanden na ontslag. De belangrijkste uitkomst betrof het herstel in fysiek functioneren, gemeten met een digitale vragenlijst. De secundaire uitkomst was de lichamelijke activiteit. Andere uitkomsten betroffen eiwit- en energie-inname, vermoeidheid, pijn, kwaliteit van leven, participatie, zelf-effectiviteit, globaal ervaren effect, vetvrije massa, handknijpkracht, fysieke fitheid, heropnames en bijwerkingen. Hersteltrajecten werden geanalyseerd met een statistische methode die verandering over tijd kan vergelijken tussen de interventie en controle groep (lineaire mixed model-analyse).

De resultaten van de OPRAH RCT staan beschreven in **hoofdstuk 6** van dit proefschrift. In totaal gaven 193 patiënten toestemming om deel te nemen, waarvan 90 werden gerandomiseerd naar de interventiegroep en 103 naar de controlegroep. Respectievelijk 17 en 13 patiënten vielen uit vóór of tijdens ziekenhuisopname. Uiteindelijk namen 73 patiënten deel in de interventiegroep en 90 patiënten in de controlegroep. In de interventie- en controlegroep vielen respectievelijk 9 (12%) en 14 (16%) patiënten uit gedurende de doorlooptijd van de studie. Resultaten toonden aan dat de OPRAH Interventie een significant positief effect heeft op de belangrijkste uitkomstmaat fysiek functioneren. Zes maanden na ontslag uit het ziekenhuis was 55% van de patiënten uit de interventiegroep terug op hun niveau van voor de operatie, terwijl dit percentage slechts 35% was in de controlegroep. Voor de uitkomst lichamelijke activiteit werd eveneens een significant interventie-effect gevonden. Ook werden significante effecten gevonden voor eiwitinname, vermoeidheid, pijn, zelf-effectiviteit, globaal ervaren effect en handknijpkracht. Geen significante verschillen werden gevonden op energie-inname, kwaliteit van leven, vetvrije massa, fysieke fitheid of heropnames. Deze resultaten suggereren dat de OPRAH-interventie het functioneel herstel bevordert bij patiënten die een operatie hebben ondergaan vanwege kanker aan de spijsverteringsorganen of longen. Verdere aanpassing en personalisatie van de interventie zijn nodig om patiënten met lage gezondheidsvaardigheden beter te bereiken, omdat die groep onvoldoende vertegenwoordigd was in onze studie.

Naast het onderzoeken of de interventie effect heeft, vonden we het ook belangrijk om de ervaringen van patiënten met de OPRAH interventie te evalueren. Deze resultaten staan beschreven in **hoofdstuk 7.** De ervaringen van patiënten zijn geëvalueerd door middel van een vragenlijst en interviews. Alle patiënten in de interventiegroep ontvingen na afloop van de interventie een online vragenlijst, met daarin vragen over de gebruiksvriendelijkheid (SUS) en zestien aanvullende vragen over acceptatie, tevredenheid en ervaren meerwaarde. In totaal vulden 58 patiënten de vragenlijst in. De gemiddelde SUS-score was 86,2. Van alle patiënten zou 97% de OPRAH interventie aanbevelen aan andere patiënten die een vergelijkbare operatie moeten ondergaan. Er werden 27 patiënten benaderd voor interviews; 24 (89%) deden mee. De interviews toonden aan dat patiënten dankzij de OPRAH interventie meer inzicht kregen in hun herstelproces, gemotiveerd werden om hun doelen te behalen, en dat de interventie soms ook leidde tot leefstijlveranderingen. De combinatie met coaching werd zeer gewaardeerd, omdat het hen het gevoel gaf dat zij er niet alleen voor stonden. Op basis van deze ervaringen lijkt de OPRAH interventie geschikt voor implementatie in de reguliere zorg. Verbetering van het voedingsgedeelte van de app en verdere personalisatie kunnen de gebruikerservaring verder versterken.

In hoofdstuk 8 wordt verslag gedaan van het onderzoek naar de vraag of de OPRAH interventie daadwerkelijk werd uitgevoerd zoals beschreven in het protocol (implementatiegetrouwheid). Door middel van een wetenschappelijk onderbouwd raamwerk werd beoordeeld hoe de naleving was van de twee belangrijkste onderdelen van de interventie, namelijk zelfmonitoring met activiteitenmonitor en app en de coaching op afstand door de fysiotherapeut en diëtist, en welke factoren deze naleving positief of negatief hebben beïnvloed. Resultaten hiervan laten zien dat de naleving van het protocol over het algemeen hoog was, wat betekent dat de interventie zoals bedoeld is uitgevoerd. De positieve effecten gevonden in **hoofdstuk 6** kunnen dus met vertrouwen aan de interventie worden toegeschreven. Het integreren van OPRAH interventie in het dagelijks werk werd als complex ervaren, maar dankzij hoge betrokkenheid van patiënten, betrokken fysiotherapeuten en diëtisten en goede ondersteuning, was de implementatiegetrouwheid hoog. Om de interventie blijvend te kunnen inzetten in de dagelijkse zorg, is het belangrijk dat er aanpassingen worden gemaakt opdat de interventie beter in het dagelijkse werk past van fysiotherapeuten en diëtisten en dat er structurele financiering wordt gewaarborgd.

Hoofdstuk 9 vat de belangrijkste bevindingen van dit proefschrift samen, bespreekt methodologische overwegingen en geeft aanbevelingen voor toekomstig onderzoek en de klinische praktijk. Uit dit proefschrift blijkt dat een voeding- en bewegingsinterventie met gebruik van eHealth en coaching door zorgprofessionals effectief kan zijn bij het overbruggen van de zorgkloof na ontslag bij patiënten die een operatie hebben ondergaan vanwege kanker aan de spijsverteringsorganen of longen. De ontwikkelde OPRAH interventie biedt een veelbelovende strategie om herstel thuis te verbeteren met toegankelijke ondersteuning en continuïteit van zorg. Voor bredere implementatie en gelijke toegang tot zorg is het essentieel dat de interventie ook toegankelijk wordt gemaakt voor patiëntgroepen met lage gezondheidsvaardigheden.

About the author



Marijke de Leeuwerk was born on August 12th 1993, in Elst, the Netherlands. After graduation from high school at Overbetuwe College Bemmel, she started with the Bachelor of Business Administration (in Dutch: Bedrijfskunde) in Groningen. After a few months she realized that the field did not match her interests. In the months that followed, she explored other options and eventually enrolled in the Bachelor of Physiotherapy at HAN University of Applied Sciences. During her bachelor, she completed the honours program and co-founded a student company named 'Range of Monitor' with three fellow students. In 2016, their company won the national award for Best Student Company of the Year. That same year, she was also awarded the Jaco den Dekker Thesis Prize.

After completing her bachelor's degree, she gained work experience as a physiotherapist in several settings: first in primary care physiotherapy and later in long-stay and geriatric rehabilitation. After finishing her bachelor's, she also began the part-time pre-master's and Master's program in Clinical Health Sciences at Utrecht University, which she successfully completed in 2019, including an internship at the University Medical Center Utrecht (UMCU). During this internship, she was first introduced to the use of technology in patients following oncological surgery, which ultimately led her to begin her current PhD trajectory at Amsterdam UMC.

In January 2020, she began her PhD trajectory at Amsterdam UMC, location VUmc. Her project initially focused on the development and evaluation of an accelerometer-based feedback and coaching intervention for patients at risk of functional decline after oncological surgery. Over time, the integration of nutritional guidance also became an important component of the project. During the early years of her PhD, when the COVID-19 pandemic began, Marijke also worked part-time as a physiotherapist at VUmc. This experience provided her with valuable insight into the impact of oncological surgery on patients, which ultimately proved highly beneficial throughout her PhD.

Currently, Marijke works as postdoctoral researcher in the department of Rehabilitation Medicine at Amsterdam UMC, location VUmc. In the coming years, she hopes to focus on further improving and implementing the OPRAH intervention, with the aim of optimizing physical recovery for all patients after oncological surgery. In addition to her current

research activities, Marijke is also considering the direction of her future career, exploring how she can continue contributing to patient care in a way that suits her skills and interests.

Marijke lives together with Sjors Wagemakers in Zeist and they are parents of Jurre (2022) and Maud (2024).

Portfolio

Courses and Workshops	
BROK course (1.5 ECTS)	2020
Data Science: R Basics (0.5 ECTS)	2020
Writing a data management plan (1 ECTS)	2020
Video Games for skills training (VERSA project) (3 ECTS)	2021
Talents in PhD course (1 ECST)	2021
Regression techniques (4 ECTS)	2021
Multilevel models and longitudinal data-analysis (4 ECTS)	2023
Clinical prediction models and machine learning (2 ECTS)	2023
Research Integrity (2 ECTS)	2023
Research meetings	
Participation in research meetings of the department of Rehabilitation Medicine	2019 – present
Organization and participation of OPRAH+ research meetings	2023 – present
(Inter)national conference	
AMS Annual meeting, *virtual*	2021
International Conference on Physiotherapy in oncology (ICPTO), *virtual*	2021
AMS Annual meeting, *Amsterdam, NL*	2022
Dag van de Fysiotherapeut, KNGF, *'s-Hertogenbosch, NL*	2022
International Conference on Physiotherapy in oncology (ICPTO), *Amsterdam, NL*	2023
AMS Annual meeting, *Amsterdam, NL*	2023
Symposium *'Samen sterk tegen sarcopenie en obesitas', Amsterdam, NL*	2024
De kracht van voeding en beweging bij patiënten na oncologische chirurgie (organizer and speaker), *Amsterdam, NL*	2025
AMS Annual meeting, *Amsterdam, NL*	2025
World Physiotherapy Congress, *Tokyo, Japan*	2025
Cancer Center Amsterdam Conference, *Noordwijk, NL*	2025

Conference and symposium presentations	
Self-monitoring of physical activity after hospital discharge in patients who have undergone oncological surgery, *AMS Annual meeting (virtual poster)*	2021
The effectiveness of interventions using activity trackers during or after inpatient care, *AMS Annual meeting (virtual poster)*	2021
Feasibility of self-monitoring of physical activity after hospital discharge in patients who have undergone oncological surgery, *International Conference on Physiotherapy in oncology (virtual poster)*	2021
Study protocol for a randomized controlled trial on the effect of a blended intervention to improve physical activity after oncological surgery, *AMS Annual meeting (poster)*	2022
De ontwikkeling van een blended voeding- en beweeginterventie bij patiënten na een electieve gastro-intestinale of longkankeroperatie, *Dag van de fysiotherapeut (poster and oral)*	2022
Self-monitoring of physical activity and protein intake after hospital discharge in surgical oncological patients: a feasibility study, *AMS Annual meeting (poster and pitch)*	2023
The efficacy of a blended intervention to improve physical activity and protein intake after oncological surgery: a multicenter RCT, *AMS Annual meeting (poster and pitch)*	2025
Optimal Physical Recovery After Hospitalization after oncological surgery, a feasibility study *World Physiotherapy Congress (poster)*	2025
The efficacy of a blended intervention to improve physical activity and protein intake after oncological surgery: a multicenter RCT, *CCA annual conference (oral)*	2025

Mentoring Students	
Martine Botjes. The recovery of physical activity after lung and gastrointestinal cancer surgery an observational study. *Master Clinical Health sciences, Utrecht University*	2020
Sanne van Aarssen. Prediction of the course of postoperative physical activity by nutrition-related factors in lung and gastrointestinal cancer patients: a longitudinal prospective study. *Master Health Sciences, VU Amsterdam*	2021
Maarten van Veen en Robin van der Laan. Herstel in fysiek functioneren en participatie na oncologische chirurgie. *Bachelor Fysiotherapie, Hogeschool van Amsterdam*	2022
Astrid Sanders. Specifying the competencies of physiotherapist for using remote monitoring with coaching for patients. *Master Clinical Health Sciences, Utrecht University*	2022
Karin Oegema. Protein intake before undergoing surgery and muscle mass los in patients with gastrointestinal and lung cancer. *Master Health Sciences, VU Amsterdam*	2023
Marieke van der Heide. The longitudinal association between accelerometer-based physical activity and patient reported physical functioning up to six weeks after hospital discharge in patients following gastrointestinal or lung cancer surgery. *Master Clinical Health Sciences, Utrecht University*	2023
Jasmijn van Dijk. Preoperative predictors of physical functioning in patients after gastrointestinal or lung cancer surgery. *Master Clinical Health Sciences, Utrecht University*	2023
Michelle Kraaijenoord en Evelien van Brugge. Het ontwikkelen van content over adviezen, tips en informatie betreft voeding voor oncologisch chirurgische patiënten. *Bachelor Voeding en Dietetiek, Hogeschool van Amsterdam*	2024
Anne Mijnten. Exploring the association between self-efficacy, fatigue and the role of usability in patients following a blended physical activity and nutrition intervention after oncological surgery. *Master Clinical Psychology, VU Amsterdam*	2024
Britt Oudenes. Comparative assessment o flow muscle mass using bioelectrical impedance analysis and computed tomography and the association between low muscle mass and muscle quality in lung and gastrointestinal cancer patients. *Master Health Sciences, VU Amsterdam*	2024

Chrisje Thone. Exploring the association between preoperative CT-determined muscle characteristics and postoperative recovery in physical functioning in patients undergoing gastrointestinal or lung cancer surgery. *Master Health Sciences, VU Amsterdam*	2024
Iris Korbee. The association between protein intake and physical functioning after oncologic surgery and validation of the eiFIT app to screen low protein intake. *Master Health Sciences, VU Amsterdam*	2024
Emily van der Werf. Experiences of patients with an intervention to improve physical activity and protein intake after oncological surgery: a qualitative study. *Master of Medicine, VU Amsterdam*	2024

Board and committee positions

PhD committee Amsterdam Movement Sciences (AMS)	2021-2024
PhD Representative in the board of AMS	2023-2024

Award

Best poster Award – AMS Annual meeting 2025 *Poster title: Optimal Physical Recovery After Hospitalization (OPRAH) after oncological surgery*	2025

List of publications

Publications as part of this thesis

- **de Leeuwerk ME**, Bor P, van der Ploeg HP, de Groot V, van der Schaaf M, van der Leeden M; OPRAH consortium. The effectiveness of physical activity interventions using activity trackers during or after inpatient care: a systematic review and meta-analysis of randomized controlled trials. *Int J Behav Nutr Phys Act*. 2022 May 23;19(1):59.
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Dankwoord

Mijn promotietraject begon met één centrale vraag: hoe kunnen we het herstel van patiënten na ontslag uit het ziekenhuis beter begrijpen en ondersteunen? Vanuit die vraag ben ik de afgelopen jaren een traject ingegaan dat vol zat met leermomenten en mijlpalen. Ik heb van dichtbij ervaren hoe belangrijk het is om mensen in hun kracht te zetten, en hoe waardevol inzicht en begeleiding daarbij zijn. Het geeft veel voldoening om te zien dat patiënten hierdoor meer richting en vertrouwen krijgen tijdens hun herstel.

Het beeld van Mount Fuji op de cover van dit proefschrift symboliseert het herstel na een operatie: een berg die beklommen moet worden. Net als bij een echte beklimming vraagt herstel om voorbereiding, kracht en doorzettingsvermogen. Maar hoe goed je ook voorbereid bent, zonder begeleiding is het een moeilijke tocht. Mount Fuji is vaak verborgen achter wolken, net zoals herstel na ziekenhuisontslag ook weinig zichtbaar was. Met de OPRAH interventie hebben we dit inzichtelijk kunnen maken, voor zowel de patiënt als zorgverleners. Het pad dat langs de berg omhoog slingert staat voor de interventie zelf: een route die richting probeert te geven in een periode van onzekerheid.

Dat ik dit werk heb mogen presenteren tijdens een congres in Japan, maakt deze symboliek voor mij persoonlijk extra bijzonder. Vooral het moment waarop Mount Fuji bij zonsopkomst tevoorschijn kwam, nadat hij twee dagen verborgen bleef achter de wolken, was buitengewoon magisch en een absoluut hoogtepunt. Naast deze persoonlijke ervaring weerspiegelt de cover ook mijn eigen promotietraject. De bloesem verwijst naar mijn persoonlijke bloei en ontwikkeling als persoon en onderzoeker. Enkele jaren geleden besloot ik het pad richting deze promotie omhoog te bewandelen, een keuze die ik zonder twijfel opnieuw zou maken. Maar net als bij elke beklimming heb ik dit niet alleen gedaan. De groei die ik heb doorgemaakt, én het vertrouwen dat ik de juiste keuze heb gemaakt, dank ik aan de mensen die vanaf het begin met mij meeliepen, én aan de mensen die ik in de afgelopen jaren heb leren kennen. Daarom neem ik in dit dankwoord graag de ruimte om jullie te bedanken.

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