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Effectiveness and cost-effectiveness of a digital health intervention to support patients with colorectal cancer prepare for and recover from surgery: study protocol of the RecoverEsupport randomised controlled trial

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ABSTRACT

Introduction Surgery is the most common treatment for colorectal cancer (CRC) and can cause relative long average length of stay (LOS) and high risks of unplanned readmissions and complications. Enhanced Recovery After Surgery (ERAS) pathways can reduce the LOS and postsurgical complications. Digital health interventions provide a flexible and low-cost way of supporting patients to achieve this. This protocol describes a trial aiming to evaluate the effectiveness and cost-effectiveness of the RecoverEsupport digital health intervention in decreasing the hospital LOS in patients undergoing CRC surgery.

Methods and analysis The two-arm randomised controlled trial will assess the effectiveness and cost-effectiveness of the RecoverEsupport digital health intervention compared with usual care (control) in patients with CRC. The intervention consists of a website and a series of automatic prompts and alerts to support patients to adhere to the patient-led ERAS recommendations. The primary trial outcome is the length of hospital stay. Secondary outcomes include days alive and out of hospital; emergency department presentations; quality of life; patient knowledge and behaviours related to the ERAS recommendations; health service utilisation; and intervention acceptability and use.

Ethics and dissemination The trial has been approved by the Hunter New England Research Ethics Committee (2019/ETH00869) and the University of Newcastle Ethics Committee (H-2015-0364). Trial findings will be disseminated via peer-reviewed publications and conference presentations. If the intervention is effective, the research team will facilitate its adoption within the Local Health District for widespread adaptation and implementation.

Trial registration number ACTRN12621001533886.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The RecoverEsupport trial will address the evidence gap in effective interventions to support colorectal cancer (CRC) patients' preparation for and recovery from surgery.
⇒ This trial uses a randomised controlled trial design and an objective, clinical primary outcome (length of stay) to assess intervention effectiveness and a comprehensive set of secondary outcomes to assess the patient experience.
⇒ The intervention is underpinned by evidenced-based behaviour change strategies, delivered digitally, via a website and a series of SMS/email prompts and alerts, for efficient delivery and maximum reach.
⇒ A key limitation is that patients without internet access will not be eligible to participate in the trial.
⇒ Although this trial is conducted with patients with CRC, the findings may be broadly applicable to cancer and non-cancer surgical patients.

INTRODUCTION

Worldwide, colorectal cancer (CRC) is the second most commonly occurring cancer in women and the third most commonly occurring cancer in men, with over 1.8 million new cases in 2018.[1] While surgery is the most common treatment,[2] it is also high risk. Unplanned readmission rates within 30 days are high,[3] with a systematic review finding rates ranging from 7%–19% (11% average), as are postdischarge emergency department (ED) visits, with 9.2 ED encounters per 100 patients.[4] A UK study of 614 CRC surgical patients reported that 35% experienced a complication, for example, a wound complication (10%), chest infection (8%), anastomotic leak (4%) or cardiac event (4%).[5] In addition to fatigue, pain and reduced activity levels are commonly reported by CRC surgical patients.[6] Among those who experience

complications, there can be persistent long-term quality of life (QoL) deficits.[5] Recovery from CRC surgery is also associated with significant costs to the health system.[7] For example, a study of US patients between 2002 and 2008 found that the mean readmission length of stay (LOS) was 8 days, with the median cost per stay was US$8885. Other data suggest the cost of readmission following bowel or colon resection was US$7030,[8] and the cost per complication (rectal cancer only) was estimated to be US$5308.[9] This all contributes to CRC having the second highest economic impact of any cancer (US$99 billion—2010 figure).[10]

Enhanced Recovery After Surgery (ERAS) pathways are multidisciplinary approaches designed to accelerate recovery after surgery and include clinician-led and patient-led steps.[11] Systematic reviews of randomised controlled trials (RCTs) from Asia, Europe, the UK and the USA and have shown that, compared with standard care, ERAS pathways can reduce the LOS and postsurgical complications.[12 13] Systematic reviews have also demonstrated these approaches as cost-effective.[14] Implementing ERAS recommendations requires a coordinated approach from surgeons, anaesthetists, nursing staff and patients. Despite a large proportion of the ERAS recommendations being under the direct control of the clinical team (considered 'passive' for the patient as they do not require patient input, eg, use of pelvic and peritoneal drains only as needed), some recommendations require the 'active' input of the patient.[15] For patients with CRC undergoing surgery, the patient-led ERAS recommendations include:

- Preoperative: patient education concerning recovery milestones; nutrition, exercise and smoking counselling; immune nutrition drinks and carbohydrate loading; and minimal fasting.
- Postoperative: rapid resumption of oral feeding and fluids; early mobilisation; multimodal analgesia (avoidance of opioids); and breathing exercises.[11]

The level of patient adherence to ERAS pathways is positively related to clinical outcomes.[16] However, poor adherence to some ERAS recommendations is well documented. A study of patients with CRC across 12 European hospitals found poor rates of adherence for early mobilisation (19%), early oral solids (27%), early oral fluids (21%) and non-opioid analgesia (21%).[17] There may be variation between clinicians in when they advise their patients to commence solid foods, and in the opioid and antiemetic medications they chart. However, patients have a crucial role to play by only using opioids when needed, by requesting antiemetics early for nausea and by prompting their surgical team that they want to resume eating and drinking. Understanding the importance of early feeding can assist patients to restart nutrition despite the suppression immediately following surgery. As such, strategies to support patient adherence to the patient-led ERAS recommendations are needed.

While patient adherence, knowledge and outcomes can be improved through education sessions with nursing staff,[18] these approaches are resource intensive, making widespread adoption problematic. Digital health interventions are flexible and relatively low-cost solutions that can facilitate dissemination at scale.[19] Digital health interventions, encompassing E-health and M-health innovations, enable information to be tailored to patients' needs, allow patient-provided information to be easily and routinely collected and have been shown to have positive impacts on patient knowledge, and behavioural and clinical outcomes.[20 21] Evidence from a non-controlled pilot trial suggests that a mobile app that included patient education, reminders of daily recovery milestones, and questionnaires and feedback to track patient behaviours following CRC surgery was acceptable to patients and increased their motivation for recovery.[22] Furthermore, a non-controlled trial found that a mobile app containing information and reminders about the surgical procedure and perioperative ERAS components decreased LOS and infection rates.[23] However, these results were not replicated in the only RCT to date.[24] Mata *et al* found no between-group differences in patient adherence outcomes or clinical outcomes (including length of stay (LOS), complications and ED visits)[24] despite the significant findings of the pilot.[22]

Given the high prevalence of surgery and subsequent complications for patients with CRC, high-quality RCTs are needed to test whether interventions to support patient-led ERAS recommendations can optimise patient recovery. This trial will evaluate a digital health intervention to support patients to prepare for and recover from CRC surgery, as assessed via LOS (primary outcome). While a shorter length of hospital stay is associated with fewer patient complications (eg, healthcare-associated infections, falls) as well as decreased health costs, there is potential for a trade-off between such outcomes (eg, decreased LOS vs increased readmission rate).[25] As such, this study assesses a range of secondary outcomes to comprehensively assess the intervention effect on the patient experience including: days alive and out of hospital (DAOH) at 30 days; readmissions, ED presentations; acceptability and healthcare utilisation.

METHODS AND ANALYSIS

Aims

This trial aims to evaluate the effectiveness and cost-effectiveness of the RecoverEsupport digital health intervention for patients undergoing CRC surgery in decreasing hospital LOS (primary outcome). Secondary outcomes will be assessed at 30 and 90 days post surgery and include: DAOH; ED presentations; QoL; patient knowledge and behaviours related to the ERAS recommendations; health service utilisation; and intervention acceptability and use. It is hypothesised that, relative to control patients, intervention patients will have: shorter LOS (primary outcome); fewer ED presentations and lower health service utilisation; and more DAOH, higher

QoL and greater knowledge and incidence of performing behaviours related to the ERAS recommendations.

Design

The intervention will be evaluated through a two-arm parallel-group superiority RCT with participants randomly allocated to either: a control group receiving usual care (standard provision of peri-operative care); or to an intervention group receiving usual care plus the 'RecoverEsupport' intervention to support patients prepare for and recover from CRC surgery. This paper describes the trial protocol based on the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) recommendations, and a completed SPIRIT checklist is available (see online supplemental file 1). The trial was prospectively registered via the Australian New Zealand Clinical Trials Registry ACTRN12621001533886. Any modifications to the trial protocol will be approved by the relevant ethics committees (see below), and the trial registry will be updated.

Setting

The perioperative and colorectal surgery units at a major teaching hospital in NSW, Australia. The trial will run from August 2022 to approximately April 2025.

Sample

Participant eligibility criteria include patients aged 18–80 years with a planned bowel resection for CRC, with an expected length of inpatient stay of at least 3 days, are not considered high risk (ie, are not referred to the high-risk clinic); who have internet access (and access to the email address and/or phone to receive SMS) and are literate in English. The study focuses on the adult population. The upper limit of 80 years was chosen to ensure that general advice provided, particularly around mobilisation, was appropriate for all recruited patients.

Exclusion criteria

Patients who are unable to provide independent informed consent (based on clinician judgement), those with advanced disease who have taken daily opiate analgesia for more than 1 month of the prior 12 months, those referred to the high-risk clinic and those who require emergency surgery or insertion of a stent.

Recruitment

Patient recruitment

All eligible CRC surgical patients at the presurgical or perioperative consultation will be invited to participate. These appointments are typically 2 weeks apart (depending on whether neoadjuvant chemotherapy is required), with the perioperative consultation typically 2 weeks prior to surgery. At these appointments, the CRC liaison nurse will identify eligible patients and provide study information and consent forms. Patients can consent on the spot or at a later time via QR code. Patients who do not consent (or decline) on the spot, will be asked if they agree to receive follow-up contact by SMS or telephone 5 days after the initial invite to confirm participation. The CRC liaison nurse will record the age and gender of consenters and non-consenters to assess consent bias. Only consenters to the trial will have identifiable data (ie, any other data than age and gender) stored within the secured REDCap trial database.

Support person recruitment:

Patient participants are invited to pass on a recruitment pack (containing a study information sheet and consent form) to their support person. For the purposes of this trial, a support person is defined as the main source of support for the patient (as identified by the patient) in coping with cancer and its treatment. Their entry into the study is dependent on the patient inviting them. Support persons who are interested in participating may also consent on the spot if they are present during the patient's presurgical or perioperative consultation and the patient has independently consented to the study.

Baseline data collection

Consenting patients will be invited via SMS and/or email to complete the online baseline survey. Electronic data collection has high accuracy[26] and is acceptable to patients across age groups and socioeconomic classes.[27] A free call telephone number will allow patients to call research staff if they need help accessing or completing the survey. Patients who do not complete the baseline survey will receive up to three reminders up until 5 days prior to their surgery. Alternative options for completing the survey will be available on request (eg, via telephone).

Randomisation and blinding

Following completion of the baseline survey, patients will be randomised in a 1:1 ratio to either a usual care control group or the intervention group, with block sizes varying randomly from 4–6. The randomisation will be programmed by an independent statistician and embedded in the REDCap software programme so that assignment to groups occurs automatically.[28] As blinding of participants and clinicians to group allocation will not be possible, this will run as an open trial.

Arm 1: usual care control

All patients will receive perioperative care as per the local ERAS pathway. All patients will attend the presurgical and/or perioperative clinic, where they will meet with the CRC nurse, perioperative nurse and anaesthetist. All patients for whom a stoma is planned will also receive standard counselling from a stoma nurse. Support persons of patients allocated to the control group will only have access to the usual supports available (eg, freely available information from pamphlets,

websites and information support lines). No additional support will be proactively provided.

Arm 2: the RecoverEsupport digital health intervention

Patients allocated to the intervention group will receive usual care plus access to the RecoverEsupport programme—a purpose-built digital health intervention that supports patients to prepare for and recover from CRC surgery by encouraging them to adhere to patient-led components of the ERAS recommendations pre surgery (eg, smoking cessation) and post surgery (eg, early resumption of oral diet and fluids, early mobilisation, minimisation of opioids, breathing exercises). The programme consists of a website and a series of automatic prompts and reminders, encouraging the use of the platform and uptake of ERAS recommendations. Each patient will receive a unique log-in and password to access the website. The website contains modules that correspond to each stage of the patient journey, from preparing for surgery at home to discharge home and beyond. Each module contains information and evidence-based behaviour change strategies (as described in the framework by Wang *et al*[29]) to support patient adherence to the ERAS recommendations (see table 1). The information on the website is based on a patient booklet produced by John Hunter Hospital (used with permission) and includes links to online content produced by Bowel Cancer Australia, the Cancer Council and ERAS Society. All content was approved by experts in relevant fields of CRC surgery, anaesthesia and nursing. Figure 1 describes when participants are able to access each intervention component. Support persons of patients allocated to receive the intervention will also receive access to the website and automatic prompts and reminders to assist the patient to adhere to the ERAS recommendations.

Development and pilot testing of the 'RecoverEsupport' intervention

The invention was developed by a multidisciplinary group consisting of behavioural scientists, a surgeon, anaesthetist, CRC liaison nurse (all members of the research team), and two stomal therapy nurses.

Patient and public involvement statement

Intervention development was based on findings from a survey (conducted by the research team) of 180 patients with CRC about the care they received and the care they considered optimal during their CRC surgical journey.[30] Beta versions of the website were reviewed in two stages by the research team. The stage 1 review included n=10 previous patients with CRC who underwent surgery within the previous 12 months and 1 carer, and incorporated the clinician videos and quiz questions. Following this, the website was expanded to include additional content, quizzes and patient videos, and additional sections including the 'daily diaries' and 'my questions'. The stage 2 beta testing was conducted with another nine patients with CRC, and a Multidisciplinary Advisory Group consisting of surgeons, anaesthetists, nurses, consumer representatives and health behaviour scientists (all members of the research team).

OUTCOMES

Primary outcome

LOS will be calculated as the date of discharge less the date of surgery, based on information extracted from the patient's medical record.

Secondary outcomes

Secondary outcomes will be collected at baseline, post surgery (day 2 post surgery) and 30 and 90 days post discharge (see table 2), given the 3 months following surgery are the most challenging in terms of recovery.[31 32]

The number of DAOH

The number of DAOH will be assessed at 30 and 90 days post surgery. DAOH is a patient-centred, validated outcome that incorporates: LOS, readmissions due to complications, rehabilitation admissions and early death (ie, morbidity and mortality).[33 34] This outcome will be defined relative to the date of index surgery (ie, $DAOH_{30}$=30–(admitted bed days+days in a rehabilitation facility+days not alive). Admitted bed days include those immediately following the index surgery and during readmissions and will be extracted from the medical records data. Admissions to a rehabilitation facility will be collected via medical record data (where available) and supplemented with data from the Client Service Receipt Inventory (CSRI) (described below). The date of death (where applicable) will be extracted from medical record data.

The number of ED presentations

The number of ED presentations in the 30 and 90 days following surgery will be extracted from participants' medical records. A CRC nurse will review the presentations to identify and extract only those that are related to their colorectal surgery. The CRC nurse will not be blinded to group allocation.

Quality of life (QoL)

QoL will be assessed using the EORTC QLQ-C30 (European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire) and the QLQ-CR29 (Quality of Life Questionnaire-Colorectal Cancer 29). The QLQ-C30 is a 30-item cancer-specific instrument that measures five functioning domains (physical, role, cognitive, emotional and social), nine symptom scales (fatigue, nausea/vomiting, pain, dyspnoea, sleep disturbance, appetite loss, constipation, diarrhoea and financial impact) and global QoL. The CR-29 is a 29-item instrument developed specifically for patients with CRC and assesses their function and symptoms specific to CRC (eg, gastrointestinal issues). The clinical validity of both

Table 1 Behavioural strategies used in the RecoverEsupport intervention[29]

Strategy (from Wang *et al*)	Strategy description (from Wang *et al*)	How strategy is operationalised in 'RecoverEsupport'
Strategies to support intervention engagement		
Prompts/cues	Introduce or define environmental or social stimulus with the purpose of prompting or cueing the behaviour. The prompt or cue would normally occur at the time or place of performance.	Surgeon's 'prescription letter'—intervention participants will receive a letter from their surgeon prescribing the RecoverEsupport Programme to prompt patients to access the website and increase engagement. Patient prompts—patients will receive a series of personalised automated reminders to prompt them to access the website (pre surgery and post surgery) and complete daily diaries (in hospital). Clinician alerts—When patient responses in the 'daily diary' indicate non-adherence to the ERAS recommendations, or when patients flag they are distressed, the website will send an email alert to the CRC liaison nurse to follow-up with the patient within the day. Patient questions—'my questions'—at the end of each website module, patients are asked if they have questions for their clinical team. Patients can record and save their questions centrally within the website and email a copy to themself and/or the CRC liaison nurse. Patients are encouraged to print and/or bring their list of questions to medical appointments. Postdischarge care—at discharge, patients, their support person (if applicable) and their GP will be emailed a list of common side effects/complications following colorectal surgery and how to manage them. The patient will also receive an SMS reminder to make a follow-up appointment with their GP 2 weeks after discharge. Provision of device—to increase website engagement during the inpatient stay, we will provide a tablet to intervention patients without access to a smartphone or tablet or laptop during their hospital stay.
Social support	Advise on, arrange or provide social support (eg, from friends, relatives, colleagues, 'buddies' or staff)	Support person involvement: The support person can access the website independently of or together with the patient. GP involvement: On discharge, a standard information sheet detailing the general care needs for patients with CRC is emailed to the patient's GP. (The patient and support person are also emailed a copy).
Strategies to motivate behaviour change		
Credible source	Present verbal or visual communication from a credible source in favour of or against the behaviour	Information is communicated via videos presented by the clinical team who will be providing care to the patient, including a surgeon, anaesthetist, and stoma nurse. There are also a series of videos of patients with CRC talking first-hand about their experiences.
Framing/reframing	Suggest the deliberate adoption of a new perspective on behaviour (eg, its purpose) in order to change cognitions or emotions about performing the behaviour	The website encourages patients to see themselves as active participants in their own recovery, to empower them to take control of their recovery. Patients are asked to reflect on their motivation for accessing the intervention and optimising their recovery.
Information about health consequences	Provide information (eg, written, verbal, visual) about health consequences of performing the behaviour	Text and videos are included within the website outlining the rationale for undertaking the behaviours specified in the ERAS recommendations, and the benefits of adherence and the consequences of non-adherence are explained, for example, if you remain on opioids, your bowel will take longer to start working again.
Strategies to enact behaviour change		
Self-monitoring of behaviour	Establish a method for the person to monitor and record their behaviour(s) as part of a behaviour change strategy	Daily diary: Each day in the hospital post surgery, the patient is prompted by SMS/email to use the website to monitor and record their behaviours that support recovery (eg, moving, eating, drinking, breathing exercises and minimising opioids).

Continued

Table 1 Continued

Strategy (from Wang *et al*)	Strategy description (from Wang *et al*)	How strategy is operationalised in 'RecoverEsupport'
Feedback on behaviour	Monitor and provide informative or evaluative feedback on the performance of the behaviour	Daily diary: ► The website provides automated and tailored feedback on patient behaviour (eg, mobilisation) based on patient self-monitoring data (see above). ► Non-adherence to ERAS recommendations will trigger an alert to the CRC liaison nurse so that they can follow-up with the patient (ie, if they are not getting up and moving) and attempts to address barriers. Interactive quizzes: Brief self-assessment tools (with real-time feedback) will be included in each module to ensure patients understand: ► What the key patient-led ERAS recommendations are (eg, opioid minimisation post surgery). ► Why they are important to their recovery (eg, quickens return to normal bowel function and defecation). ► What they can do (eg, take all non-opioid analgesia according to the prescribed schedule).
Instruction and demonstration of how to perform the behaviour	Advise how to perform the behaviour (including the provision of an observable sample of the performance of the behaviour)	Patients are provided with text, videos and diagrams explaining step-by-step how to undertake specific behaviours. Specifically, diagrams and videos are included on the website to demonstrate: ► The target behaviours, for example, breathing exercises. ► What to expect at each stage of the patient journey, for example, what patients will see, hear and feel as they are taken into the operating theatre.

CRC, colorectal cancer; ERAS, Enhanced Recovery After Surgery; GP, general practitioner.

scales is high, and test–retest reliability is acceptable.[35] QoL will be assessed at baseline, and 30 and 90 days following surgery.

Patient knowledge and behaviours

Postsurgery (day 2) patients will be asked to complete a

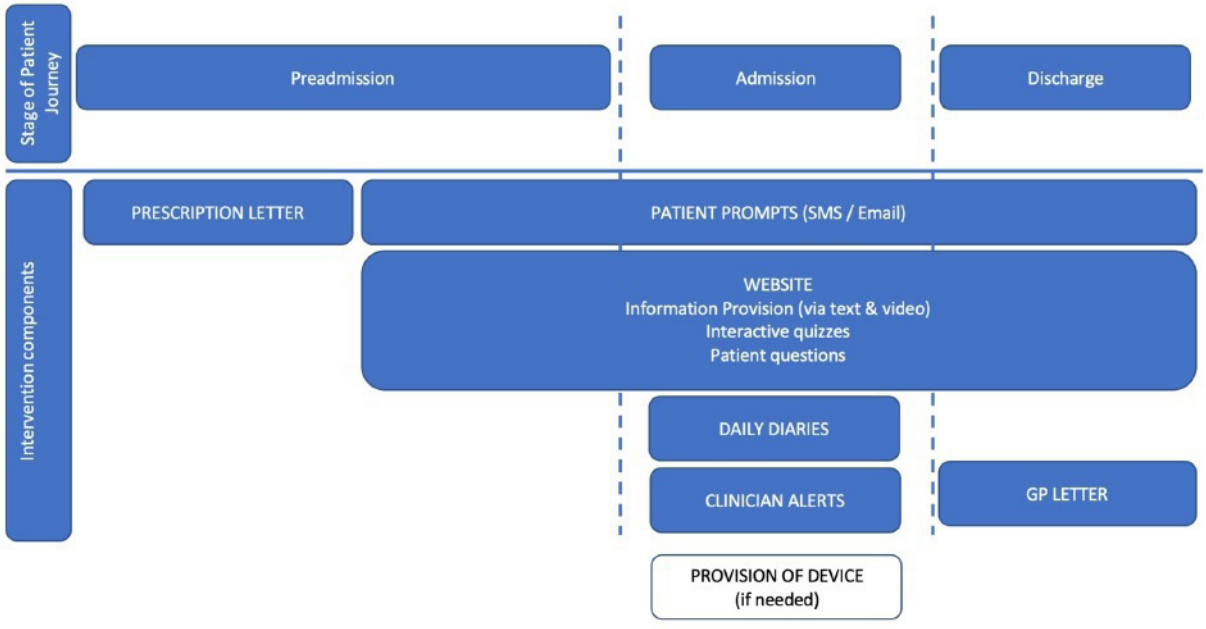

Figure 1 Intervention overview—participant's access to the components of the RecoverEsupport intervention. **(GP General Practitioner).**

Table 2 Data collection schedule

	Participant-completed online survey				Medical record data (reviewed by a colorectal cancer nurse)			Website analytics (automatically collected via the website)	
	Baseline	Post surgery (during admission)	30 days	90 days	Baseline	30 days	90 days	30 days	90 days
Participant characteristics									
Demographics*	X								
Treatment and disease characteristics					X	X	X		
Health risk behaviours	X								
Internet access and use	X								
Surgical history	X								
Primary outcome									
Length of stay						X†			
Secondary outcomes									
DAOH incorporating:									
► Length of stay (days, n)						X			
► Subsequent hospital admissions (days, n)			X	X		X	X		
► Rehabilitation (days, n)			X	X		X	X		
► Dead (days, n)						X	X		
Emergency department admissions						X	X		
Quality of life	X		X	X					
Health service utilisation MRN/CSRI			X	X		X	X		
Patient knowledge and behaviour	X	X							
Intervention use and acceptability*			X					X	X

*Collected from patient and support person.
†Length of stay (discharge date – surgery date)—data extracted ~30 days following surgery.
CSRI, Client Service Receipt Inventory; DAOH, days alive and out of hospital; MRN, medical record number.

survey about their knowledge and behaviours in relation to the ERAS recommendations. Items will include:

1. The number of meals and snacks attempted daily post surgery (resumption of oral diet).
2. The number of cups of fluid consumed daily post surgery (resumption of fluids).
3. The time spent out of bed; and spent walking or moving around post surgery (early mobilisation).
4. Use of patient-controlled analgesia (minimisation of opioids post surgery).
5. The frequency of performing deep breathing, coughing, huffing and puffing exercises daily post surgery (breathing exercises).

Health service utilisation

Health service utilisation will be measured from a health service perspective. This will include access to allied health professionals (such as physiotherapists), access to primary care (GP, general practitioner), rehabilitation admissions and hospital readmissions, including ED visits. Health system utilisation data will be obtained through medical records data and through patient self-report via a modified version of the CSRI at 30 and 90 days following surgery.[36] This is an inventory of variables required for economic analysis[37] and provides a standardised yet adaptable tool for assessing patient use of health services.

Use and acceptability of 'RecoverEsupport'

Use of the digital health intervention will be monitored through website analytics and will be automatically recorded. This will include data at the aggregate level (eg, completion of specific website components, for example, 'my questions', 'daily diaries' etc.) and at the individual participant level (eg, total time spent on the website, the total number of log-ons, dates accessed, participant type (patient and/or support person). Website use will also be assessed by three patient-report items in the 30-day postdischarge survey (as pilot testing identified some limitations with the website analytics, such as device security settings or JavaScript that blocks automated analytics). Acceptability of the intervention will be assessed among intervention participants and support persons as part of the 30-day postdischarge survey. Items specifically developed for the study (ie, with no established psychometrics) will examine the ease of use, relevance and quality of the support and information accessed (eg, using 5-point Likert scales).

Patient characteristics

Sociodemographic data will be collected at baseline via self-reported surveys and will include age at diagnosis; sex; country of birth; language spoken at home; marital status; education; health insurance; employment; postcode; smoking status; alcohol consumption; fruit and vegetable consumption, physical activity, internet access; and previous surgeries. Where possible, these items will be drawn from standard items administered as part of current national or state-based data collections. Disease and treatment characteristics including date of cancer diagnosis; extent of cancer at diagnosis; treatments received; and the presence of a stoma will be collected from medical records.

Data collection and management

Medical record data

Patients' permission will be obtained for access to medical record number (MRN) data recorded and maintained by the Local Health District. MRNs are unique identifiers given to patients who receive services provided by the Local Health District. The MRN stays with the patient for life and records the utilisation, within the Local Health District, of services provided by that health service (including treatments received, hospital provided medications, hospital stays, ED visits, tests etc).

All other data

All data collected from patients and support persons (demographics, intervention use and acceptability) will be directly entered into REDCap. REDCap is a password-protected secure web-based application that will be used to store and manage the data. REDCap dashboard and report functions will be used to check completion rates of online surveys, track and manage participant numbers and other ongoing data quality checks.

Given this is a trial of a behavioural intervention provided in addition to usual care (which all patients will receive), and as few risks are expected from participating, there will be no independent data monitoring committee established. The clinical team members will monitor for adverse events, unintended consequences or harm. All members of the research team will have access to the final datasets, which will have any identifying participant information removed to ensure confidentiality.

Minimising attrition

Recommended strategies from a Cochrane review[38] will be used to reduce attrition. These include: (1) collection of multiple contact details including details of a secondary contact from the participant, (2) providing a free call number and study email address for participants to use to contact the study team and (3) multiple reminders, for example, SMSs and emails to complete study tasks.

Sample size

The sample size calculation is based on a mean LOS of 8.64 days (SD=7.58) (unpublished medical record data) and assuming 75% eligibility and 85% consent rate, and 10% attrition (unpublished pilot data). With 167 participants in each arm, there would be 80% power to detect a decrease in LOS of 2.5 days in the intervention compared with the control arm (ie, a decrease of 29% in the intervention compared with the control). A 2-day decrease in LOS (6.4–4.4 days) was previously observed in a non-controlled pilot trial of a mobile app.[23] The sample size has been inflated by 15% to account for skew in the distribution of the outcome. Approximately 582 patients will

need to be approached to achieve a sample size of 371 participants at baseline and 334 at discharge.

Analysis plan

Participant characteristics (age and gender) will be compared with that of the non-responders to assess the representativeness of the study sample. Data analysis will be on an intent-to-treat basis, with all participants analysed based on the group to which they were originally assigned.

Effectiveness

Primary outcome

Between-group differences in LOS will be compared using regression, adjusted for the presence of a stoma and surgery type (open/laparoscopic) and baseline QLQ-C30 global score. A per-protocol analysis will also be conducted to determine the effect of the intervention strategies accessed as intended. Exploratory subgroup analyses will also be conducted, testing intervention effectiveness by age, gender and cancer stage. The trial data will be reported in adherence with the Consolidated Standards of Reporting Trials guidelines for reporting RCTs.[39]

Cost-effectiveness

The incremental cost-effectiveness ratio will be calculated as the difference in mean total cost divided by the observed difference in the primary outcome (LOS). Sensitivity and scenario analysis will be undertaken to test the impact of changing key design features of the intervention.

ETHICS AND DISSEMINATION

This study was approved by the Human Research Ethics Committees of the Hunter New England Local Health District (2019/ETH00869) and the University of Newcastle (H-2015-0364). All patients and support persons will be required to provide informed consent to participate. It will not be possible to identify any participant through any of the research outputs from the trial.

This study will address the evidence gap in effective strategies to support patients to take an active role in managing their preparation and recovery from surgery. Trial findings will be disseminated via peer-reviewed publications and conference presentations. Authorship of publications and presentations arising from this trial will be informed by authorship guidelines developed by the University of Newcastle.

If the intervention is effective, the multidisciplinary research team will facilitate the adoption of RecoverEsupport as standard practice in all hospitals within the Local Health District. With the support of The Royal Australasian College of Surgeons, the research team will also disseminate the results to colorectal surgeons nationwide and make the intervention available for local adaptation and implementation.

While this trial focuses on CRC surgery, the principles underpinning the RecoverEsupport intervention could be readily adapted to other types of surgery, both cancer and non-cancer. With 2.2 million elective surgical procedures undertaken annually in Australia alone,[40] there is a significant opportunity to improve recovery outcomes while improving the cost-effectiveness of care.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods and analysis section for further details.

Patient consent for publication Consent obtained directly from patient(s).

Provenance and peer review Not commissioned; externally peer reviewed.

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Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	01
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	03, 07
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	Supplement file
Protocol version	#3	Date and version identifier	02
Funding	#4	Sources and types of financial, material, and other support	02

Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	01,02
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	01, 02
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	02
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	01,02
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	05-7
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	05-7
Objectives	#7	Specific objectives or hypotheses	07
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	07
Methods: Participants,			

interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	07
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	07-8
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	09-10
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	14
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	09
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	09
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10-12
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	13

Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	15,16
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	08
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	09
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	09
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	09
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	09
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			

Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	14-16
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14-16
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14-16
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14-16
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	14-16
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14-16
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the	14-16

		protocol. Alternatively, an explanation of why a DMC is not needed	
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	14
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	14
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	14-16
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	03, 15-6
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	16
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	08
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	08
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	03, 08
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	02

Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	16
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	16
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	16
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	16
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	16
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	08
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

Table A: Items from the World Health Organization Trial Registration Data Set

Data category	Information
Primary registry and trial identifying number	ACTRN12621001533886
Date of registration in primary registry	10/11/2021
Secondary identifying numbers	Nil
Source(s) of monetary or material support	NHMRC
Primary sponsor	NHMRC
Secondary sponsor	NHMRC
Contact for public queries	RW (rebecca.wyse@health.nsw.gov.au)
Contact for scientific queries	RW (rebecca.wyse@health.nsw.gov.au)
Public title	The effectiveness and cost-effectiveness of a web-based intervention to support colorectal cancer patients prepare for and recover from surgery: A randomised controlled trial of the RecoverEsupport intervention
Scientific title	A randomised controlled trial of the effectiveness and cost-effectiveness of RecoverEsupport, a web-based intervention to support colorectal cancer patients' preparation for and recovery from surgery
Countries of recruitment	Australia
Health condition(s) or problem(s) studies	Colorectal Cancer
Intervention	Active comparator: RecoverEsupport digital health intervention
	Control comparator: Usual care
Key inclusion and exclusion criteria	Ages eligible for study: adults aged 18 to 80
	Inclusion criteria: planned bowel resection for colorectal cancer; have an expected inpatient stay of at least 3 days; considered to not be high risk (i.e. are not referred to a High Risk clinic); have internet access; and are literate in English
	Exclusion criteria: Patients who are unable to provide independent informed consent; those with advanced disease who have taken daily opiate analgesia for more than 1 month of the prior 12 months; and those who require emergency surgery or insertion of a stent
Study type	Randomised controlled trial
Date of first enrolment	06/07/2022
Target sample size	334
Recruitment status	Recruiting
Primary outcomes	Length of Stay
Key secondary outcomes	Days Alive and Out of Hospital, Quality of life, number of Emergency Department presentations, ERAS behaviours, Health care costs, usability and acceptability of digital intervention