

# BMJ Open 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.

## INTRODUCTION

Worldwide, colorectal cancer (CRC) is the second most commonly occurring cancer in women and the third most commonly

## 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.

occurring cancer in men, with over 1.8 million new cases in 2018.<sup>1</sup> While surgery is the most common treatment,<sup>2</sup> it is also high risk. Unplanned readmission rates within 30 days are high,<sup>3</sup> 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.<sup>4</sup> 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%).<sup>5</sup> In addition to fatigue, pain and reduced activity levels are commonly reported by CRC surgical patients.<sup>6</sup> Among those who experience

complications, there can be persistent long-term quality of life (QoL) deficits.<sup>5</sup> Recovery from CRC surgery is also associated with significant costs to the health system.<sup>7</sup> 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,<sup>8</sup> and the cost per complication (rectal cancer only) was estimated to be US\$5308.<sup>9</sup> This all contributes to CRC having the second highest economic impact of any cancer (US\$99 billion—2010 figure).<sup>10</sup>

Enhanced Recovery After Surgery (ERAS) pathways are multidisciplinary approaches designed to accelerate recovery after surgery and include clinician-led and patient-led steps.<sup>11</sup> 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.<sup>12–13</sup> Systematic reviews have also demonstrated these approaches as cost-effective.<sup>14</sup> 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.<sup>15</sup> 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.<sup>11</sup>

The level of patient adherence to ERAS pathways is positively related to clinical outcomes.<sup>16</sup> 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%).<sup>17</sup> 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,<sup>18</sup> 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.<sup>19</sup> 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.<sup>20–21</sup> 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.<sup>22</sup> 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.<sup>23</sup> However, these results were not replicated in the only RCT to date.<sup>24</sup> Mata *et al* found no between-group differences in patient adherence outcomes or clinical outcomes (including length of stay (LOS), complications and ED visits)<sup>24</sup> despite the significant findings of the pilot.<sup>22</sup>

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).<sup>25</sup> 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<sup>26</sup> and is acceptable to patients across age groups and socioeconomic classes.<sup>27</sup> 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.<sup>28</sup> 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*<sup>29</sup>) 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.<sup>30</sup> 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.<sup>31 32</sup>

### 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).<sup>33 34</sup> This outcome will be defined relative to the date of index surgery (ie,  $DAOH_{30} = 30 - (\text{admitted bed days} + \text{days in a rehabilitation facility} + \text{days not alive})$ ). 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<sup>29</sup>

Strategy (from Wang <i>et al</i> )	Strategy description (from Wang <i>et al</i> )	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.	<p>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.</p> <p>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).</p> <p>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.</p> <p>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 themselves and/or the CRC liaison nurse. Patients are encouraged to print and/or bring their list of questions to medical appointments.</p> <p>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.</p> <p>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.</p>
Social support	Advise on, arrange or provide social support (eg, from friends, relatives, colleagues, 'buddies' or staff)	<p>Support person involvement: The support person can access the website independently of or together with the patient.</p> <p>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).</p>
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	<p>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).</p>

Continued

Table 1 Continued

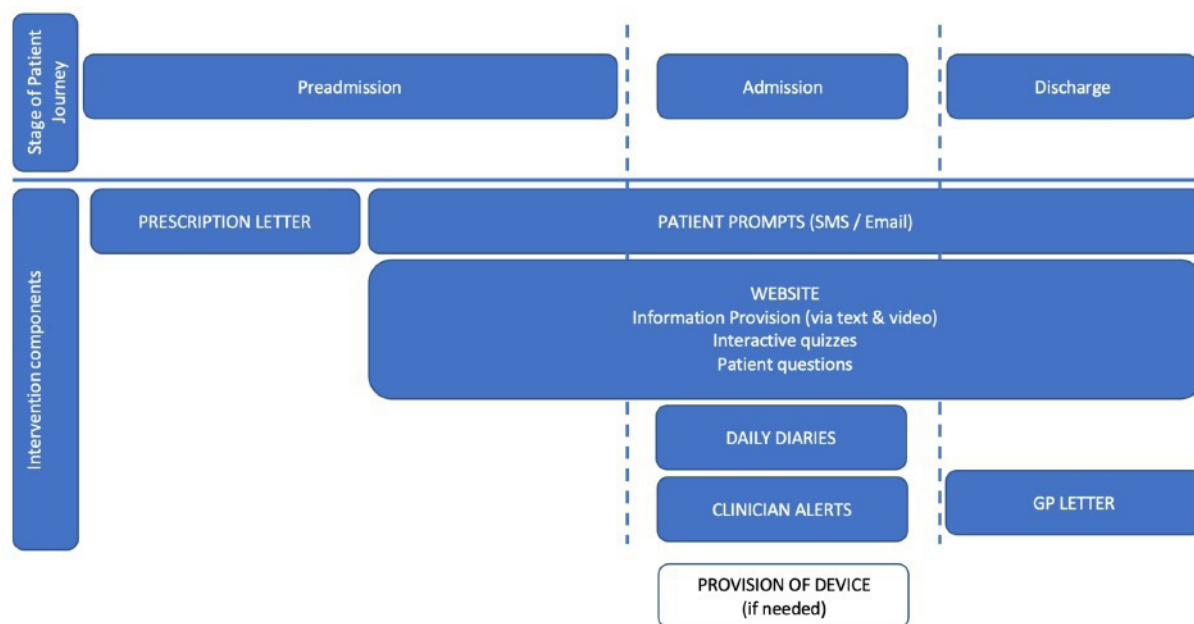
Strategy (from Wang <i>et al</i> )	Strategy description (from Wang <i>et al</i> )	How strategy is operationalised in 'RecoverEsupport'
Feedback on behaviour	Monitor and provide informative or evaluative feedback on the performance of the behaviour	<p>Daily diary:</p> <ul style="list-style-type: none"> <li>▶ The website provides automated and tailored feedback on patient behaviour (eg, mobilisation) based on patient self-monitoring data (see above).</li> <li>▶ 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.</li> </ul> <p>Interactive quizzes:</p> <p>Brief self-assessment tools (with real-time feedback) will be included in each module to ensure patients understand:</p> <ul style="list-style-type: none"> <li>▶ What the key patient-led ERAS recommendations are (eg, opioid minimisation post surgery).</li> <li>▶ Why they are important to their recovery (eg, quickens return to normal bowel function and defecation).</li> <li>▶ What they can do (eg, take all non-opioid analgesia according to the prescribed schedule).</li> </ul>
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)	<p>Patients are provided with text, videos and diagrams explaining step-by-step how to undertake specific behaviours.</p> <p>Specifically, diagrams and videos are included on the website to demonstrate:</p> <ul style="list-style-type: none"> <li>▶ The target behaviours, for example, breathing exercises.</li> <li>▶ 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.</li> </ul>

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

scales is high, and test–retest reliability is acceptable.<sup>35</sup> 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)		
	Post surgery (during admission)				Baseline	30 days	90 days	Baseline	30 days	90 days
	Baseline	30 days	90 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	
▲ Rehabilitation (days, n)		X				X			X	
▲ Dead (days, n)						X			X	
Emergency department admissions						X			X	
Quality of life	X									
Health service utilisation MRN/CSRI		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.<sup>36</sup> This is an inventory of variables required for economic analysis<sup>37</sup> 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 post-discharge 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; post-code; 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<sup>38</sup> 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.<sup>23</sup> 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.<sup>39</sup>

#### 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,<sup>40</sup> there is a significant opportunity to improve recovery outcomes while improving the cost-effectiveness of care.

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