

BMJ Open Accelerated enhanced *Recovery* following Minimally Invasive colorectal cancer surgery (*RecoverMI*): a study protocol for a novel randomised controlled trial

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ABSTRACT

Introduction Definitive treatment of localised colorectal cancer involves surgical resection of the primary tumour. Short-stay colectomies (eg, 23-hours) would have important implications for optimising the efficiency of inpatient care with reduced resource utilisation while improving the overall recovery experience with earlier return to normalcy. It could permit surgical treatment of colorectal cancer in a wider variety of settings, including hospital-based ambulatory surgery environments. While a few studies have shown that discharge within the first 24 hours after minimally invasive colectomy is possible, the safety, feasibility and patient acceptability of a protocol for short-stay colectomy for colorectal cancer have not previously been evaluated in a prospective randomised study. Moreover, given the potential for some patients to experience a delay in recovery of bowel function after colectomy, close outpatient monitoring may be necessary to ensure safe implementation.

Methods and analysis In order to address this gap, we propose a prospective randomised trial of accelerated enhanced *Recovery* following Minimally Invasive colorectal cancer surgery (*RecoverMI*) that leverages the combination of minimally invasive surgery with enhanced recovery protocols and early coordinated outpatient remote televideo conferencing technology (*TeleRecovery*) to improve postoperative patient-provider communication, enhance postoperative treatment navigation and optimise postdischarge care. We hypothesise that *RecoverMI* can be safely incorporated into multidisciplinary practice to improve patient outcomes and reduce the overall 30-day duration of hospitalisation while preserving the quality of the patient experience.

Ethics and dissemination *RecoverMI* has received institutional review board approval and funding from the American Society of Colorectal Surgeons (ASCRS; LPG103). Results from *RecoverMI* will be published in a peer-reviewed publication and be used to inform a multisite trial.

Trial registration number NCT02613728; Pre-results.

Strengths and limitations of this study

- This study is the first randomised trial testing the feasibility of short hospital stay after minimally invasive colorectal cancer surgery.
- Early discharge promotes an earlier return to normalcy for patients.
- The risk of bias is reduced by computer generation of allocation and prospective trial registration.
- The study aims to examine if the combination of minimally invasive surgery, enhanced recovery after surgery and *TeleRecovery* can safely accelerate recovery after colectomy and reduce total length of hospitalisation within 30 days.
- The risks of performance and detection bias are increased since neither patients nor providers are blinded.

BACKGROUND

Colorectal cancer is the third leading cause of cancer-related death in the USA and currently affects approximately 132 700 new individuals each year.¹ Although treatment of colorectal cancer is multidisciplinary, the majority of patients will present with localised disease for whom definitive treatment will include radical surgical resection of the primary tumour.²⁻³ The perioperative management of colorectal cancer can influence patient outcome and healthcare resources.⁴ Traditionally, surgical resection has been associated with a 6–7 day or longer hospitalisation, in part due to the need for effective analgesia (usually narcotic based), suboptimal perioperative management (mainly with fluid therapy) and conventional open surgical techniques⁴⁻¹¹ (figure 1). Two major advances in perioperative care have resulted in improved surgical outcomes



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Surgical Procedure Impacts LOS

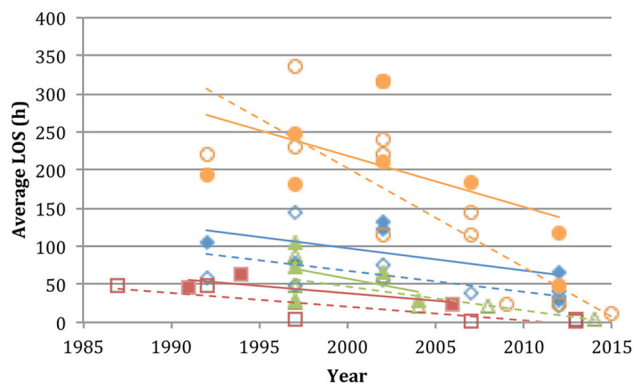


Figure 1 Overall length of stay (LOS) has decreased with the introduction of minimally invasive surgeries (MIS), and many elective procedures (eg, cholecystectomies and appendectomies) are performed on an outpatient basis. Open symbols are MIS (laparoscopy and robotic). Closed symbols are conventional surgeries. Diamonds, hysterectomy; triangles, appendectomy; squares, cholecystectomy; circles, colectomy. Solid lines are trend lines for conventional surgeries. Dashed lines are trend lines for minimally invasive procedures. Orange, colectomy; blue, hysterectomy; green, appendectomy; red, cholecystectomy.

and a reduction in this length of stay (LOS): minimally invasive surgery (MIS) and enhanced recovery after surgery (ERAS) protocols. Furthermore, the addition of enhanced recovery principles, such as fluid optimisation, minimisation of narcotics and early feeding, to minimally invasive colectomy has been associated with additional recovery benefits and further reductions in LOS.^{12–15}

These advances now permit the consideration of minimally invasive colectomy with a 23-hour hospital stay. The feasibility of this approach has been demonstrated in small retrospective single-centred case reports, but it has only been applicable to a small highly selected subset of patients undergoing colorectal surgery.^{12–14} Transition to short-stay colorectal cancer surgery with a 23-hour discharge programme may improve the efficiency of colorectal cancer care delivery while preserving or improving patient outcomes by permitting earlier discharge if it does not increase the rate of complications or readmission.

The growing availability of telemedicine technology now provides a means for remote monitoring and engagement of patients to improve their treatment experience, enhance patient–provider communication and permit earlier intervention to improve the efficiency of care delivery.^{15–19} We have designed the accelerated enhanced *Recovery* following *Minimally Invasive* colorectal cancer surgery (*RecoverMI*) randomised study that leverages the combination of MIS with enhanced recovery protocols and remote televideo conferencing technology with non-urgent text messaging communication on a dedicated platform (*TeleRecovery*) to facilitate perioperative care through the postoperative recovery continuum and permit transition of eligible patients from prolonged

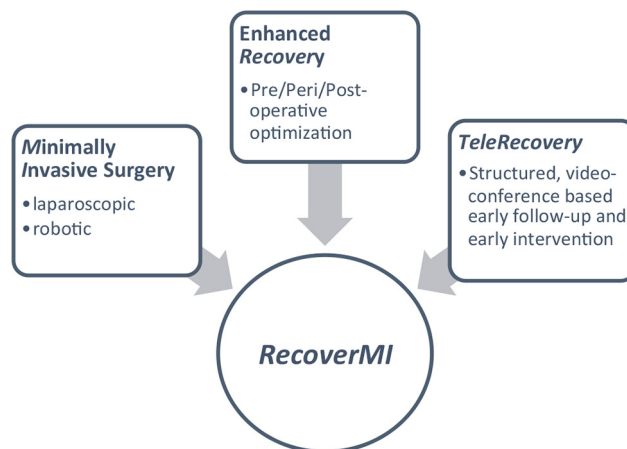


Figure 2 Conceptual model of the *RecoverMI* trimodality integrated approach to accelerate recovery and improve patient care.

inpatient to short-stay colorectal surgery (figure 2). The goal of this research is to determine if the trimodality combination of MIS, ERAS and *TeleRecovery* can safely accelerate recovery after colectomy and reduce the total length of hospitalisation within 30 days.

METHODS AND DESIGN

Study design

RecoverMI is an investigator-initiated, single-centre, open, randomised phase II pilot study to examine the feasibility of short-stay minimally invasive colorectal cancer surgery (figure 3). All participants must provide written informed consent. The trial is registered with clinicaltrials.gov (NCT02613728). This is the first version of the protocol to be activated.

Trial organisation

The study is being conducted at the University of Texas MD Anderson Cancer Center (MDACC) and is supported in part by a limited project grant from the American Society of Colon and Rectal Surgeons Foundation and philanthropic support from the Aman Family Trust for Colorectal Cancer Research and Education. The funders will not participate in the study design; data collection, analyses and interpretation, and manuscript preparation. An independent data and safety monitoring board will monitor the conduct and safety of the trial to ensure patient safety. Stopping guidelines and monitoring practices have been established.

Patient selection

Patients will be identified by appointments scheduled in the Colorectal Surgery Clinic at MDACC or physician referral to the study. Eligible patients (table 1) will be approached in clinic by a member of the research staff, who will thoroughly explain the study and consent patients who choose to participate. Patients will be enrolled during their preoperative clinic visit. Informed

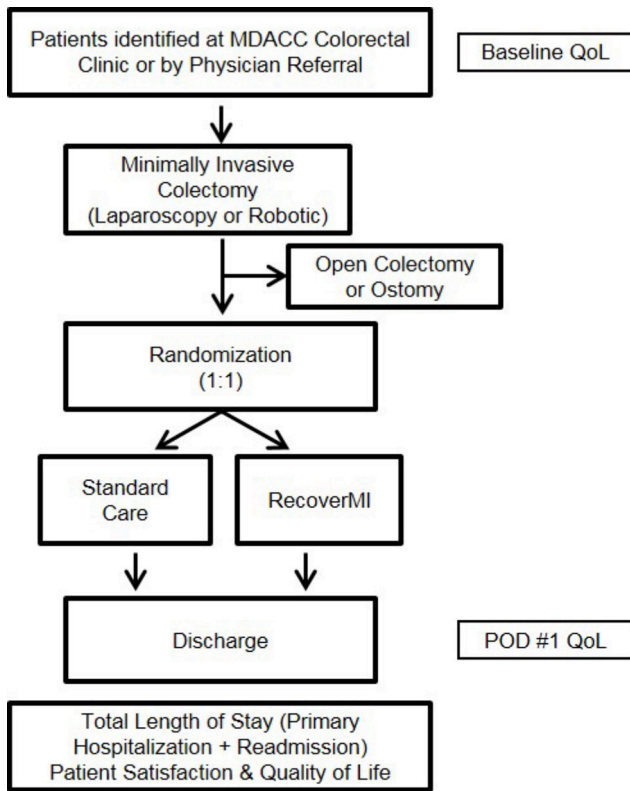


Figure 3 *RecoverMI* schema. Patients will be enrolled and registered at the preoperative surgical planning visit. Randomisation will occur in the operating room once it is confirmed that the patient will receive minimally invasive surgery without an ostomy. Patients randomised to the intervention arm will be discharged on postoperative day (POD) 1 if their pain is controlled by oral medication and they can tolerate liquids by mouth without nausea. Intervention patients will be monitored by *TeleRecovery* to reduce postoperative complications, including dehydration and readmission. Quality-of-life (QoL) measurements will be recorded throughout the study.

consent will be obtained during the preoperative visit by study personnel who will not be involved in the patient’s care. Independent of *RecoverMI*, our local policy strongly recommends that patients travelling more than 100 miles for surgery stay within the immediate surrounding area for 7–10 days postoperatively. Patients converted to open colectomy or requiring ostomy during the surgical procedure will be removed from the study. Each subject will

be asked to identify two locators, defined as persons who would be able to find him or her in the event of change of telephone number, address, job or school.²⁰ Following discharge, the primary mode of communication will be by telephone. To enhance communication, patients in the study arm will receive a *TeleRecovery* device (iPad) for use during the study. *RecoverMI* received institutional review board (IRB) approval on 24 September 24 2015 and was activated on 13 May 13 2016.

Randomisation

Eligible patients will undergo minimally invasive colon cancer surgery with standardised enhanced recovery intraoperative anaesthetic care and then be randomised with a 1:1 ratio to either *RecoverMI* or routine care. Permuted-block randomisation with variable block size will be performed on the completion of surgery and conducted through the MDACC Clinical Trial Conduct (CTC) website (<https://biostatistics.mdanderson.org/ClinicalTrialConduct>), which is hosted on a secure server at MDACC and maintained by the MDACC’s Department of Biostatistics. Access to the website will be gained through usernames and passwords provided by the MDACC’s Department of Biostatistics to personnel responsible for enrolling patients and reviewing and analysing the patient data. Training on the use of the CTC website will be provided by the study statistician for study personnel prior to the study initiation.

Statistics

The primary outcome is the cumulative length of hospital stay within 30 days postoperatively (including all readmissions). The hypothesis is that following the *RecoverMI* pathway will lead to a 50% reduction in the mean LOS. Based on the historical data, the median LOS in the control arm is anticipated to be 96 hours. With a total of 28 evaluable patients (14 per treatment arm), the study will have 80% power to detect an effect size of approximately 27 hours with regard to the mean difference in LOS between the two groups using a two-sample t-test and with a two-sided type I error rate of 0.05 (nQuery software version 7.0). The effect size corresponds to a reduction from 96 hours (control arm) to 48 hours (*RecoverMI* arm) when assuming the common SD is 42.

Table 1 Eligibility criteria

Inclusion criteria	Exclusion criteria
1. Histologically proven colorectal cancer or polyp(s) that planned treatment involves surgical resection with curative intent. 2. Patient is at least 18 years old and younger than 80. 3. Elective minimally invasive operation. 4. No planned ostomy creation at time of enrolment. 5. Serum creatinine level less than 1.5 ng/ml measured within 30 days of surgery. 6. Able to speak, read and understand English.	1. Strong, self-reported history of postoperative nausea and vomiting. 2. History of congestive heart failure. Systolic heart failure defined as ejection fraction (EF) less than or equal to 40% or diastolic heart failure defined as EF greater than 40% in addition to systemic manifestation of heart failure. ³³

Intervention/comparison

All patients enrolled in the study will undergo standardised preoperative and intraoperative care, which consists of mechanical bowel preparation with oral antibiotics and premedication with oral celecoxib, gabapentin and tramadol hydrochloride extended-release (ER). Intraoperative strategies consist of intravenous dexamethasone, narcotic-sparing anaesthetic technique, intraoperative fluid optimisation and MIS (laparoscopic or robotic). Postoperatively, all patients will receive liquids ad lib on postoperative day (POD) 0. All patients are discharged to their home or alternative lodging in the immediate surrounding area.

Patients randomised to RecoverMI will be discharged on POD 1 if they are afebrile, have satisfactory pain control with oral analgesics and maintain oral hydration. Prior to discharge, a TeleRecovery appointment with the surgical team will be scheduled for POD 2. Patients will be instructed on recording their daily urine output, if deemed necessary by the clinical team, and given instructions on how to perform video conferencing and instant messaging. Patients who are deemed to have inadequate oral intake (defined as less than 1 L of oral fluid intake/day and less than 0.3 cc/kg/hour²¹ urine output for 8 hours) and those at high risk of dehydration (nausea, vomiting, light-headedness and dietary intolerance) may receive outpatient intravenous fluid hydration on POD 2 and/or 3.

Patients randomised to the control arm will undergo routine postoperative management and be eligible for discharge when criteria have been met (able to tolerate oral hydration, have satisfactory pain control with oral analgesics and have either passed flatus or had a bowel movement as evidence of antegrade bowel function).

All patients will undergo ambulatory office-based follow-up within 14 days postoperatively and by a study personnel-initiated telephone call on POD 30. The incidence of adverse events and complications including readmissions and need for emergency room evaluation within 30 days after surgery will be closely monitored and graded in severity using Clavien-Dindo classification for surgical complications.²² Postoperative quality of life and patient satisfaction will also be assessed.

ETHICS AND DISSEMINATION POLICY

Ethics and informed consent

The MDACC IRB approved the final protocol. The study will be conducted in agreement with the requirements of the Code of Federal Regulations and the IRB. All patients will be required to sign an IRB-approved consent form, indicating their agreement to participation (online supplementary appendix 1). The consent form includes the nature, objectives and potential benefits and consequences of the study. Additionally, the consent details the required length of follow-up, supportive care, the name of the principal investigator (GJC) responsible for the protocol and the patient's right to accept or refuse

treatment and to terminate participation and withdraw from the protocol. During the preoperative clinic visit, patients and their caregivers will receive detailed explanation of both minimally invasive colorectal cancer postoperative pathways—routine hospitalisation or shorter stay with TeleRecovery follow-up. All data collection will be performed in accordance with the human subjects research policies of MDACC.

Dissemination

Final trial results will be disseminated via publication and clinicaltrials.gov. Authorship will be determined by ICMJE guidelines.

DISCUSSION

Advances in MIS and increasingly widespread adoption of enhanced recovery programmes for perioperative management have resulted in significant incremental improvements in outcomes for patients undergoing colorectal cancer surgery.^{23–26} For many patients, hospital discharge on the second or third POD can now be anticipated, improving the overall recovery experience with earlier return to normalcy. Therefore, it is now appropriate to consider transition to a short-stay recovery approach with discharge within 24 hours after minimally invasive colectomy as a new model for colorectal surgical care delivery. However the safety, feasibility and patient acceptability of such an approach must be evaluated. Moreover, a mechanism for close outpatient monitoring and coordination, particularly during the early postoperative period, is necessary to ensure safe implementation of such an approach.

The feasibility of a 23-hour discharge programme has been described in retrospective observational studies of highly selected patients, representing fewer than 10% of the total number of patients who underwent colon resection within highly experienced centres.^{14 27} Key factors for the success of these efforts have included emphasis on preoperative and postoperative management of patient expectations, adherence to intraoperative anaesthetic management protocols, which may have included regional anaesthetic techniques, and early mobilisation and feeding of patients. However, there has not been a significant uptake of short-stay protocols perhaps because the median LOS even after minimally invasive colectomy in the USA is still 5–6 days and potential concerns may exist among patients and their providers regarding the ability for adequate monitoring following earlier discharge. Moreover, there exists no randomised evaluation to demonstrate the potential generalisability of such an approach in eligible patients and patient satisfaction and acceptability have not been well evaluated.

The increasing availability of personal electronic devices with high-speed wireless connectivity that can be used for secured point-to-point contact between patients and providers is another major enabling technology for short-stay colorectal cancer surgery. Telemedicine

technology has the potential to improve access, quality and efficiency of patient care while enhancing patient satisfaction. There has been growing interest in the use of telemedicine technology to assess patient well-being following surgery.^{15 16 28–31} In addition, video-based technology enables visual inspection of incisions and healing and can verify prescriptions, which, if used in the immediate postdischarge time period, can quickly rectify potential complications prior to escalation and potentially reduce the need for hospital readmissions.³² Moreover, recent data suggest that telehealth technology is well-accepted by patients and can decrease patient anxiety and improve quality of life.^{15 16 18 19} Thus, when incorporated into structured postoperative care strategies, telemedicine technology may aid to accelerate recovery and improve the patient experience.

The RecoverMI trial is designed with the aim of testing the feasibility of a trimodality approach with MIS, perioperative care optimisation and structured video conference-based follow-up and early intervention to permit the transition to short-stay colorectal cancer surgery. Eligibility criteria are intentionally broad to provide insights into the potential generalisability of this approach. There is broad availability of MIS, and the approaches to optimal intraoperative management have been simplified. The RecoverMI trial will assess functional recovery, quality of life and patient satisfaction. It will also provide an opportunity for post hoc economic analysis. If successful, it will demonstrate the potential for broad implementation to accelerate recovery and improve the delivery of colorectal cancer surgical care with short-stay colorectal cancer surgery.

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Contributors GJC, ZMA, BBS and BAP conceived of the study and participated in its design. GJC and BAP coordinated the protocol through IRB approval and grant submission. MM is the study coordinator. GJC, BKB, CAM and YNY contributed patients. GJC, EMD, MW, BKB, CAM, YNY, RLM, BBS and VG participated in patient care in addition to reviewing the literature and helping to draft the manuscript. ZMA and WQ provided statistical support. GJC and BAP helped to prepare the figures and

draft the manuscript in accordance with the SPIRIT guidelines 34. All the authors read and approved the final manuscript.

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Competing interests TeleRecovery is facilitated by the exceptional service of our midlevel providers, Kelly R. Maldonado, Brianna L. Whitener, Shanae L. Ivey and Erika L. Schlette. This study protocol and any subsequent manuscripts will be presented in accordance with the SPIRIT guidelines.

Ethics approval IRB.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement There is no data available for sharing at this point.

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