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Evaluation of a physiatrist-directed prehabilitation intervention in frail patients with colorectal cancer: a randomised pilot study protocol

Sherman G Wong,[1] Eugene Maida,[2] David Harvey,[2] Natalie Wagner,[1,3] Ranil Sonnadara,[1,3] Nalin Amin[1]

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[1]Department of Surgery, McMaster University, Hamilton, Ontario, Canada
[2]Department of Medicine, McMaster University, Hamilton, Ontario, Canada
[3]Department of Psychology, Neuroscience & Behaviour, McMaster University, Hamilton, Ontario, Canada

Correspondence to
Dr Nalin Amin;
amin@mcmaster.ca

ABSTRACT

Introduction Prehabilitation interventions have shown efficacy in the orthopaedic and cardiothoracic surgical populations, but there has been limited evidence for general surgical patients. We present the protocol for a pilot trial of a novel prehabilitation intervention, consisting of a physiatrist-directed preoperative assessment and treatment programme.

Methods and analysis This is a single-centre pilot randomised controlled trial investigating physiatrist-directed prehabilitation for a 4 to 6-week preoperative period. We will block randomise 40–50 participants awaiting surgery for colorectal cancer to prehabilitation versus control. Participants in the prehabilitation arm will undergo assessment by a physiatrist and enrol in a supervised exercise programme. The control group will not undergo any prehabilitation interventions in the preoperative period. Our primary outcome is feasibility, measured by examining recruitment, refusal, retention and adherence rates as well as participant satisfaction and feedback. Secondary outcomes include physical fitness, functional ability, health-related quality of life, postoperative complications, mortality, readmissions, length of stay, prehabilitation interventions performed and exercise complications.

Ethics and dissemination This study has been approved by the Hamilton Integrated Research Ethics Board (HIREB reference number 2015–0090-GRA). The results of this pilot study will be used to design a full-scale study and published in peer-reviewed journals.

Trial registration number NCT02531620; Pre-results.

Strengths and limitations of this study

- This is the first study to investigate the feasibility of a physiatrist-directed prehabilitation intervention on the postoperative recovery of colorectal surgery patients.
- A physiatrist-directed prehabilitation intervention is novel to the colorectal surgery literature.
- The small size of this pilot is intended to estimate effect sizes and determine feasibility for a full-scale trial.
- Few studies address patient functional recovery in domains other than fitness; this study intends to contribute to that body of evidence.
- This trial is limited to a colorectal surgical patient population at a single academic centre.

INTRODUCTION

Surgical interventions are significant stressors, particularly to the comorbid patient, which can significantly decrease their functional ability. In order to return to independent or assisted living at home, a minimum functional level is required.[1] Minimal function includes all physical and cognitive aspects of function. Prehabilitation refers to enhancing functional capacity of an individual to enable them to withstand an incoming stressor,[2] and may encompass one or more domains of overall function.

Prehabilitation for elective surgical patients may be an effective intervention to improve baseline functional reserve, which is theorised to allow the postoperative patient to more quickly reach their minimal functional level. Study of prehabilitation interventions in cardiac and thoracic surgery patients has shown decreases in pulmonary complications, measures of physical function and length of stay.[3–5] A meta-analysis of patients who underwent total hip replacement has also shown improvement in postoperative pain and self-reported function with exercise prehabilitation.[6]

There has been increasing interest in prehabilitation in the abdominal surgical population. Selected primary studies in the abdominal surgery population are listed in table 1. The preponderance of current literature in this population describes cardiorespiratory fitness interventions, including exercise, inspiratory muscle training and combinations of the two.

Table 1 Primary studies in prehabilitation for abdominal surgery

Author	Country	Population	Intervention
Exercise only			
Burke *et al*[34]	UK	Colorectal	6 weeks, 30 min daily supervised exercise
Cho *et al*[16]	Japan	Gastric	4 weeks, aerobic three to seven times per week, resistance 1–2 times per week, stretching
Debette-Gratien *et al*[10]	France	Transplant hepatobiliary	12 weeks, two times per week, 20 min aerobic, 20 min strength per session
Dunne *et al*[11]	UK	Hepatobiliary	12 sessions over 4 weeks, 30 min aerobic exercise per session
Kim *et al*[35]	Canada	Colorectal	4 weeks, home-based aerobic exercise prescription
Timmerman *et al*[19]	The Netherlands	Abdominal	Variable duration of intervention, two times per week, 2 hours aerobic and strength exercise per session
West *et al*[36]	UK	Colorectal	6 weeks, 40 min aerobic exercise daily
IMT only			
Barbalho-Moulim *et al*[15]	Brazil	Bariatric	2–4 weeks, six times per week, 15 min IMT session
Dronkers *et al*[37]	The Netherlands	AAA	2+ weeks, six times per week, daily deep breathing exercises and IMT
Kulkarni *et al*[38]	UK	Abdominal	One of the following for 2–3 weeks: Group A: control; group B: deep breathing exercises Group C: incentive spirometer; group D: inspiratory muscle trainer
IMT and exercise			
Carli *et al*[20]	Canada	Colorectal	One of the following for 3–6 weeks: Bike/strength group: daily cycling 30 min, strength 10–15 min Walk/breathing group: daily walking and breathing prescription
Soares *et al*[12]	Brazil	Open abdominal	2–3 weeks, two times per week, 50 min supervised sessions (stretching, IMT, upper/lower extremity exercises, walking, relaxation)
Diet and exercise			
Baillot *et al*[13]	Canada	Bariatric	12 weeks: standard of care (dietician, physical activity consultation) and 30 min aerobic and 20–30 min strength training, two times per week
Kaibori *et al*[14]	Japan	Hepatobiliary	1 month: exercise (60 min walking and stretching, two times per week) and diet (protein and sodium restriction)
Multimodal			
Dronkers *et al*[9]	The Netherlands	Colorectal	2–4 weeks: 60 min supervised session, two times per week (resistance, IMT, aerobic, functional training) and 45 min daily home exercise (walking, cycling, IMT)
Gillis *et al*[7]	Canada	Colorectal	4 weeks: exercise (kinesiologist consult, 50 min aerobic/resistance three times per week), diet (dietician, nutrition prescription) and psychology (psychologist to teach coping strategies)
Li *et al*[8]	Canada	Colorectal	Variable duration: exercise (kinesiologist, 30 min aerobic/resistance three times per week), diet (dietician, whey protein supplement) and psychology (psychologist for anxiety reduction)

AAA, abdominal aortic aneurysm; IMT, inspiratory muscle training.

Several studies from McGill University have investigated multimodal prehabilitation, addressing dietary, exercise and psychological domains.[7 8] Only one study found included focused functional training with the prehabilitation intervention.[9]

Despite the heterogeneity of the interventions studied, prehabilitation has been shown to improve physical fitness,[8 10–14] respiratory function[9 12 14 15] and quality of life.[11 13] Single studies have also found small, statistically significant improvements in postoperative functional measures and complications. A study by Soares *et al*[12] showed an improvement in Functional Independence Measure (FIM) score in the prehabilitation group at 7 days following surgery, but no difference at either the preoperative period or 30 days. One study in the abdominal surgery literature reported a statistically significant difference in postoperative complications: in a gastrectomy population, Cho *et al*[16] reported a decrease in all-cause complications (Clavien-Dindo grades I–V) in the exercise group.

Prehabilitation for abdominal surgery is promising, but continues to be in need of additional primary data. A recent meta-analysis showed that prehabilitation interventions could reduce the incidence of postoperative all-cause and pulmonary complications, and improve physical fitness.[17] This finding is qualified by the poor quality of evidence noted by the authors. Another meta-analysis additionally noted a small, statistically significant decrease in length of stay, but this appears to have been mainly driven by the results of studies in the cardiovascular and orthopaedic populations.[18]

Our pilot study uses a comprehensive physiatrist assessment as the main intervention, which is a novel approach in abdominal surgery. We note that the population of patients undergoing elective cancer resections are significantly different from the orthopaedic and cardiovascular patient populations. For this reason, it is hypothesised that a physiatrist-directed assessment addressing multiple functional domains may do more to improve patient functional status than a fitness intervention alone. There continues to be a need for primary data in this area, and this study hopes to provide more insight into the question.

METHODS AND ANALYSIS

This is a single-centre pilot randomised controlled trial to examine the effect of a physiatrist-directed prehabilitation intervention versus routine care. The primary objective of this study is to determine the feasibility of conducting an adequately powered study with a similar design and intervention. Feasibility will be assessed through recruitment rate, refusal rate, retention rate, adherence rate, participant satisfaction and participant feedback. The secondary objective is to assess the effect of the intervention on measures of patient outcomes, including fitness, quality of life, function, perioperative complications, mortality, length of stay and readmissions. The study design is shown in figure 1.

A randomised study design was selected to identify potential logistical issues prior to scaling to a full-scale study. The current study intervention requires patient visits to a surgeon, physiatrist and the supervised exercise programme, all of which must occur within a short 4 to 6-week period. Randomisation adds additional scheduling challenges, as the timing of recruiting participants into the intervention group is more unpredictable. Understanding these logistical challenges would be valuable to planning a full-scale study, and would allow further optimisation of the intervention and study methodology.

The study will be conducted at St. Joseph's Healthcare Hamilton, a large Canadian urban academic hospital. Appropriate research ethics board approval has been obtained for this study.

Participants

We anticipate recruiting 40–50 study participants (20–25 per group) to the study over the course of 20 months. As many of the outcome measures used in this study have not been used in prehabilitation studies involving patients with colorectal cancer, limited information on effect size and minimal clinically important difference was available for formal sample size calculations. The average sample size of the comparable studies listed in table 1 is 41. Accordingly, this pilot study aims to recruit 40–50 patients. This pilot study will enable us to collect the preliminary data we require to perform an accurate sample size calculation for the full study.

The recruitment period was estimated using recruitment rates of comparable studies. The majority of studies reported a monthly recruitment rate between 2.5[19] and 4.7.[20] Assuming a recruitment rate of three participants per month and a 15% drop-out rate, we estimate that the intended recruitment will be reached within a 20-month period.

Inclusion criteria

Adults with age>18; diagnosis of primary colorectal cancer appropriate for resection; English speaking or with accessible interpreter; and frail, based on a score of 1 or greater on the Cardiovascular Health Study frailty scale[21] or a history of falls in the past month, stroke or chronic pain.

Exclusion criteria

Exclusion criteria for this study will include need for emergent resection or procedure; extensive metastatic or unresectable disease; unwillingness to participate in the CanWell programme; or unwillingness to be assessed by the study physiatrist. All study participants will be enrolled in the CanWell exercise programme, which independently screens and excludes patients with inability to ambulate, acute medical conditions, fever, chest pain or injuries.[22] Participants ineligible for the CanWell programme will be excluded from CanWell only, and will continue with the remainder of the study and physiatrist-directed interventions.

Participants with pre-existing stroke, cardiac disease, impaired respiratory function or other premorbid conditions are intentionally *not* excluded from this study. We theorise that this population has functional deficits in instrumental activities of daily living (IADLs) and activities of daily living (ADLs) that may benefit from focused interventions recommended by the study physiatrist, even in the absence of an exercise programme.

Recruitment and randomisation

Consenting patients referred to a study surgeon for colorectal cancer assessment will be evaluated by the research coordinator for eligibility. Written informed consent will be obtained from all study participants by the study coordinator prior to randomisation.

Study participants will be randomised with an equal (1:1) chance of being allocated to one of the two arms. A computer-generated randomisation log will be created by the study biostatistician. This log will be input into

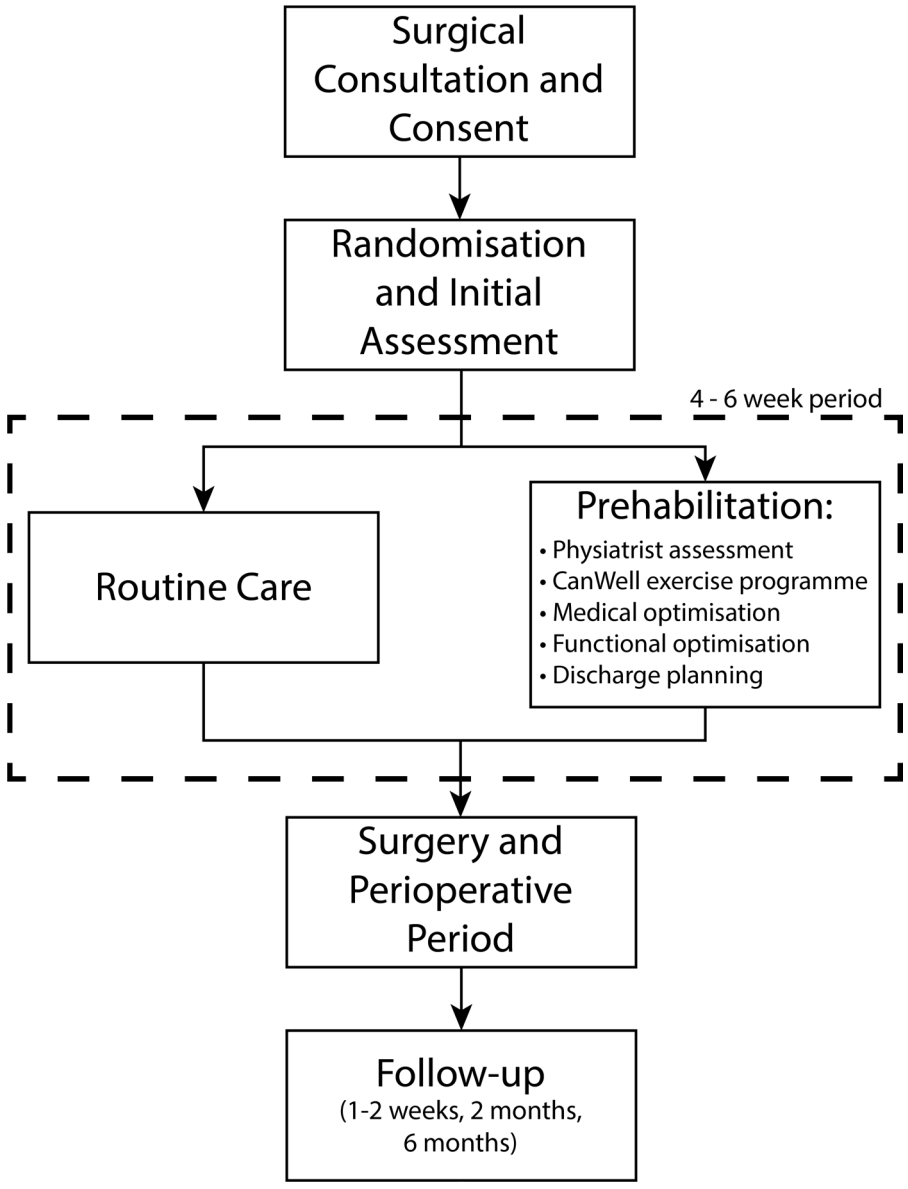

Figure 1 Study participant flow chart.

REDCap,[23] a secure computer-based research system, and used sequentially to perform randomisation. Blocked randomisation will be used to ensure an equal number of participants in each arm. Randomisation allocation will occur by the study coordinator accessing the REDCap randomisation log at the time of enrolment.

Study arms

Participants in the study will be randomised to either an intervention or control arm. The intervention arm will undergo a complete preoperative assessment by a physiatrist, followed by directed prehabilitation interventions to address functional or cognitive barriers to successful postoperative rehabilitation. In addition, all participants in the intervention group will be enrolled in the CanWell supervised exercise programme. The control group will undergo routine preoperative care. Following a 4 to 6-week preoperative period, both groups will proceed to their scheduled operative procedure. This 4 to 6-week period represents the average duration from initial surgical assessment to operative resection seen in our patient population. Both study arms will assess outcomes at baseline, perioperatively and postoperatively at 1–2 weeks, 2 months and 6 months.

Control group

The control group will undergo no specific intervention in the preoperative period. This reflects the current standard of care.

Intervention group

The intervention arm will be seen within 1 week after initial referral for a comprehensive assessment by a physiatrist. Following initial assessment, the participant will be given recommendations for preoperative optimisation. All participants in the intervention arm will also be enrolled in the CanWell supervised exercise programme.[22] There will be a 4 to 6-week period from initial consultation to

operative resection in which the recommendations will be put into place.

CanWell supervised exercise programme

The CanWell programme consists of a 12-week exercise programme, with two supervised exercise sessions and one unsupervised home exercise session per week. Study participants will be enrolled and will participate with the general CanWell participant population. Study participants will undergo the published exercise protocol,[22] except that the programme will be interrupted after the 4 to 6-week preoperative period for surgery. Following surgery, the participant will be assessed for safety at the 1 to 2-week follow-up appointment by their surgeon. If there are no contraindications to exercise at this assessment, the participant will complete the remainder of the 12-week programme.

Enrolled participants are screened prior to participation; those with an inability to ambulate, active medical contraindications, fever, chest pain or injuries are excluded. The exercise prescription is then individualised by a kinesiologist based on baseline testing and contraindications, and includes aerobic exercise, muscular strength training and flexibility exercises. Study participants who are excluded from the CanWell programme at safety screening may continue with their physiatrist assessment and will be assessed with the intervention group on an intention-to-treat basis.

Physiatrist assessment and intervention

Maintenance of participants' functional well-being is a fundamental goal of the physiatrist-directed intervention. Studies have indicated that a thorough assessment of the impact of illness on physical, mental and psychosocial functioning is an essential element of clinical diagnosis, a major determinant of therapeutic choices, a measure of their efficacy and a guide in the planning of rehabilitation services in patients with cancer.[24] Measures of functional competence embracing the domains of ADLs, IADLs, environmental conditions, mental status, and emotional and psychosocial functioning have been increasingly used for this purpose.

The physiatrist's role for this intervention is a comprehensive assessment of the patient to identify impairments (eg, pain, neuropathy, weakness, stiff joints), deficits in IADLs (eg, grocery shopping, driving, entering and exiting a car) and deficits in ADLs (eg, eating, grooming, bathing, dressing, toilet transfers). Participants will be assessed for functional ability, symptoms, physical fitness and quality of life, using outcome measures discussed below. This will be combined with a thorough history and physical examination to identify any impairments in the musculoskeletal or neurological domains.

A prehabilitation plan will be prescribed based on this clinical assessment. This may include starting treatment for unrecognised chronic disease; recommending appropriate referrals for comorbidities; arranging appropriate home modifications based on functional status; reducing polypharmacy as appropriate; arranging early education and motor skills assessments to prepare for stoma care; and recommending follow-up or further consultations in the postoperative period.

Outcome assessments

The primary research question will assess feasibility of a full study by collecting estimates of refusal rate, recruitment rate, retention rate, adherence rates for each intervention, participant satisfaction through the Client Satisfaction Questionnaire 8 (CSQ-8)[25] and participant feedback through anonymous survey responses. Adherence to the CanWell programme will be measured by attendance kept by CanWell staff, while adherence to the physiatrist intervention will be assessed by the study team during follow-up appointments.

The secondary research question will assess the effect of the intervention by collecting participant outcome measures of fitness, symptoms, function and quality of life at initial enrolment, 1–2 weeks postoperatively, 2 months and 6 months. At each follow-up, the research coordinator will assess fitness using the 6 minute walk test,[26] and functional status using the UK FIM and Functional Assessment Measure tool.[27] Symptoms and quality of life will be self-reported by the participant using the following validated measures: the Edmonton Symptom Assessment System,[28] the Short Form 36 Health Survey,[29] pain on a Visual Analogue Scale[30] and the Bowel Function Index.[31]

Perioperative outcomes will be collected by the study team and will include complications classified using the Clavien-Dindo scale,[32] 30-day mortality, length of stay and readmissions within 6 months. Descriptive data will be collected regarding interventions performed and adverse events during the prehabilitation intervention. Any exercise-related adverse events will be described using the National Cancer Institute's Common Terminology Criteria for Adverse Events V. 4.0.[33]

Statistical analysis

To assess our primary research question, we will follow intention-to-treat principles, including all participants who enrolled in the study in our feasibility analysis. The recruitment rate, refusal rate, retention rate and adherence rate will be reported as relative frequencies with 95% CIs. Participant satisfaction scores on the CSQ-8 will be compared through an independent t-test. Lastly, two independent researchers will review all participant survey responses for common themes. Any discrepancies will be resolved through consultation with a third member of our research team.

To assess our secondary research question, descriptive statistics that describe our sample (means and SDs) will be calculated and sorted by group. A split-plot analysis of variance will then be performed for each outcome measure. The condition (intervention or control) will be the between-group factor with two levels. Time (1–2 weeks, 2 months, 6 months) will be the within-group factor with three levels. A Bonferroni correction will be

applied to correct for multiple comparisons. Statistical significance will be considered at p≤0.05. All analyses will be completed in SPSS V. 24.

Blinding

Due to the nature of the prehabilitation intervention, it is not possible to blind the study staff, outcome assessors and participants. Statistical analysis of secondary outcomes will be blinded to study arm.

ETHICS AND DISSEMINATION

The main objective of this study will be to collect pilot data to support the design of a full-scale clinical trial. Study results will also be presented in relevant scientific meetings and published in peer-reviewed journals.

This trial has been approved by the Hamilton Integrated Research Ethics Board (HIREB; reference number 2015–0090-GRA), which has the independent authority to audit trial conduct. Any amendments to the trial protocol will be submitted to HIREB for approval. The trial is registered with clinicaltrials.gov with the study identifier NCT02531620 since 15 August 2015.

Adverse events

The main adverse events anticipated in this study are risks of injury or harm occurring during the exercise intervention. To minimise the risk of harm, participants are evaluated by their surgical team, the study physiatrist and the study coordinator for contraindications to exercise during the initial assessment. The participant will also be screened for safety by CanWell staff prior to exercise, and subsequently monitored for harm during the exercise intervention. Any patient with contraindications to exercise will be excluded from the CanWell programme, but will otherwise continue with the other prehabilitation interventions as directed by the study physiatrist.

Data management and monitoring

Study data will be stored on a secure encrypted server. Any data that must be retained in paper format will be stored in a secure location, accessible only to the study team. A study management team consisting of the principal study surgeon, research assistant, study physiatrist and research resident will meet at least monthly to ensure study implementation. Due to the small sample size, no independent data monitoring committee will be established.

Participant considerations

Participants will not be remunerated for their participation in this study. All fees associated with the study will be reimbursed, including parking fees for study appointments and membership fees for the supervised exercise programme.

Participants may withdraw their consent for participating in this study at any time, and will be given an opportunity to give reasons for withdrawing from the study. Participants who withdraw from the study will continue to receive routine surgical care.

DISCUSSION

The primary goal of this study is to collect feasibility data in support of a full-scale study in the future. Pilot data will be used to refine our methodology and calculate an appropriate sample size. A randomised design was selected to assess the potential logistical challenges of such a programme in a small sample. In the current abdominal surgical literature, prehabilitation interventions have addressed cardiorespiratory fitness, nutrition and psychological coaching. Only one previous study of prehabilitation for abdominal surgery included functional training in their programme.[9] We theorise that functional recovery following surgery can be improved with focused prehabilitation interventions to address specific functional deficits. We believe that a physiatrist has the clinical knowledge and expertise to identify and address such deficits. To our knowledge, this is the first trial to study the feasibility of a physiatrist-directed prehabilitation intervention for patients with colorectal cancer.

Contributors NA conceived the idea of the study. SGW led protocol development, wrote early drafts of the study protocol, prepared the Institutional Research Board submission and is responsible for the day-to-day conduct of the study. EM and DH provided rehabilitation and physical medicine expertise, and performed clinical functional status assessments. NW and RS provided analytical advice and support. All authors commented on this protocol.

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Competing interests None declared.

Ethics approval Hamilton Integrated Research Ethics Board.

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