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Preoperative Risk Evaluation for Cancer Treatment (PREdiCT): protocol for an international cohort study evaluating a trimodal screening tool to predict outcomes following gastrointestinal cancer surgery

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ABSTRACT

Introduction Gastrointestinal cancer surgery commonly leads to postoperative complications and other adverse outcomes. While prehabilitation shows promise in reducing adverse postoperative outcomes, most hospitals have resource limitations that preclude its use as standard of care. Additionally, the need to expedite surgery from diagnosis often creates a narrow window for prehabilitation initiatives. Online, self-reported screening tools may address these challenges by facilitating early identification of high-risk patients and enabling targeted preoperative interventions, thereby allowing equitable allocation of limited resources. Therefore, the primary aim of this study is to evaluate the predictive utility of a trimodal (physical, nutritional, psychological) screening tool for patients undergoing gastrointestinal cancer surgery.

Methods This prospective international cohort study will recruit 1214 adults undergoing elective gastrointestinal cancer surgery across 35 sites from 19 countries. Participants will complete an online screening tool developed through a comprehensive, multistep, predefined process. The screening tool comprises the Duke Activity Status Index, Patient-Generated Subjective Global Assessment Short Form and the Patient Health Questionnaire-4, in English, Spanish, French or Portuguese. These tools were selected based on a scoping review, followed by an international Delphi consensus process. The primary outcomes include rate of postoperative complications, major complications (Clavien-Dindo Classification grade III–V) and overall complication severity assessed by the Comprehensive Complications Index; all assessed 30 days postoperatively. Secondary outcomes include hospital length of stay, readmission rate within 30 days, discharge destination (home vs other), days at home and alive in 30 days postsurgery, 30-day all-cause

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A large, prospective, international study recruiting 1214 participants from 35 sites across 19 countries.
⇒ Use of validated, self-reported screening instruments selected through a rigorous scoping review and international Delphi consensus.
⇒ Online administration of the screening tool enables timely preoperative assessment without requiring in-person testing, supporting equitable access in resource-limited settings.
⇒ Restriction to four languages (English, Spanish, French, Portuguese) may limit inclusivity and applicability in settings where patients are unable to complete self-reported measures in these languages.

mortality and 12-month survival. Primary analyses will establish optimal screening tool cut-points to stratify patients into clinically actionable risk categories for postoperative complications and examine the independent predictive value of these screening scores after adjusting for established clinical risk factors.

Ethics and dissemination This study has received ethical approval from the Sydney Local Health District Human Research and Ethics Committee (X25-0333 and 2025/ETH02465) and has been registered on the Open Science Framework (10.17605/OSF.IO/HVCGD). The results of Preoperative Risk Evaluation for Cancer Treatment will be submitted to reputable journals and presented at national and international conferences.

INTRODUCTION

Gastrointestinal cancers account for one-third of all cancer-related deaths worldwide[1] and are primarily managed through surgical intervention, with or without neoadjuvant treatment.[2] While surgery offers curative intent and survival benefits, postoperative complications remain common and carry substantial consequences, including prolonged hospital stay, increased healthcare costs, higher readmission rates, delayed access to adjuvant therapy and mortality.[3–5] Prehabilitation (ie, preoperative interventions aimed to optimise health status and enhance resilience to surgical stressors)[6] has emerged as a promising strategy to mitigate these risks. Trials evaluating prehabilitation in patients undergoing gastrointestinal cancer surgery have demonstrated benefits in reducing complications, improving functional capacity and enhancing quality of life outcomes.[7–9]

A recent global survey involving experts in prehabilitation from 663 hospitals across six continents found that only 21% employed prehabilitation as standard of care, mostly owing to limited institutional funding and resources.[10] Despite growing evidence from prehabilitation trials demonstrating improved postoperative outcomes in patients undergoing surgery,[11] widespread resource limitations continue to preclude patients from receiving evidence-based and timely prehabilitation services, particularly important as multimodal programmes have demonstrated effectiveness over unimodal programmes in esophagogastric surgery.[12] As such, thorough preoperative screening with high clinical utility and excellent discriminative ability may allow the reallocation of resources towards populations most at risk of negative postoperative outcomes and provide an opportunity for individualised perioperative care.

Many preoperative screening tools require clinician involvement to be completed, whether through conducting an in-person physical assessment or through reviewing a patient's biochemical markers obtained through pathology assays. These require a patient to physically attend a healthcare facility. Metastatic, life-threatening cancer necessitates patients undergo surgery soon after diagnosis, as time from diagnosis to surgery is independently associated with overall survival.[13] This leaves limited time to address health status deficiencies of surgical candidates through prehabilitation initiatives, especially if in-person clinical assessment delays screening and patient selection for prehabilitation. Online, self-reported screening tools offer a pragmatic approach to timely preoperative assessment; however, their predictive utility remains to be established through methodologically rigorous studies.

The primary aim of the Preoperative Risk Evaluation for Cancer Treatment (PREdiCT) study is to establish optimal cut-points for the online, self-reported, tri-modal (physical, nutritional, psychological) PREdiCT screening tool to stratify patients into clinically actionable risk categories for postoperative complications and to determine its independent predictive value beyond established clinical risk factors. Secondary aims include (1) examining the associations between screening tool scores and a range of postoperative outcomes including hospital length of stay, readmission rate, discharge destination (home vs other), days alive and at home within 30 days post-surgery (DAH-30), 30-day all-cause mortality and 12-month overall survival and (2) an implementation analysis exploring the perspectives of research staff involved in delivering the screening tool survey.

METHODS

Study design

The PREdiCT study will be an international prospective cohort study recruiting 1214 participants from 35 sites across 19 countries including Argentina, Australia, Belgium, Brazil, Canada, Egypt, England, Germany, Greece, Italy, Jordan, Netherlands, New Zealand, Russia, Spain, Sudan, Sweden, Türkiye and Yemen. Sites have been selected based on indicators of feasibility including surgical volume, research expertise of staff and percentage of patients able to respond in a language in which the screening tool will be offered. A list of included research sites can be seen in box 1. The reporting of this study will follow the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist[14] and the Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis (TRIPOD) statement.[15] Flow through the study is shown in figure 1.

Participants

Participants will be adults scheduled to undergo elective gastrointestinal cancer surgery. To be eligible, patients must be ≥18 years undergoing gastrointestinal surgery with curative intent on their colon, rectum, pancreas, stomach, liver, spleen or oesophagus and must have capacity to provide informed consent. The screening tool will be available in four languages, and therefore, those who are not able to complete the screening tool (or are unable to be physically assisted in completing the screening tool) in either English, Spanish, French or Portuguese will be excluded. Participants may not use an interpreter to undertake the screening tool as literal translation may not preserve the meaning and measurement properties across languages and cultures which could compromise the validity of the study.[16] All participants

Box 1 International research sites for the Preoperative Risk Evaluation for Cancer Treatment study

Research site

- ⇒ Dunedin Hospital, Otago, New Zealand
- ⇒ Martini General Hospital, Groningen, Netherlands
- ⇒ Maastricht University Medical Centre+, Maastricht, Netherlands
- ⇒ McGill University Health Centre, Montreal, Canada
- ⇒ Southlake Regional Hospital, Ontario, Canada
- ⇒ The Christie Hospital, Manchester, England
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- ⇒ Laikon General Hospital, Athens, Greece
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- ⇒ Hippocrateio Hospital of Athens, Greece
- ⇒ St Bartholomew's Hospital, London, England
- ⇒ Nasser Institute Hospital for Research and Treatment, Cairo, Egypt
- ⇒ Madonna del Soccorso Hospital, San Benedetto del Tronto, Italy
- ⇒ Fondazione Policlinico Universitario, Rome, Italy
- ⇒ San Raffaele Hospital, Milano, Italy
- ⇒ Al-Waleedeen Specialised Hospital, Gezira State, Sudan
- ⇒ University of Health Sciences Gülhane Training and Research Hospital, Ankara, Türkiye
- ⇒ Ghent University Hospital, Ghent, Belgium
- ⇒ Karolinska University Hospital, Sweden
- ⇒ Hospital Clinic de Barcelona, Spain
- ⇒ Al Jumhuri Hospital, Sana'a, Yemen
- ⇒ Althawra Hospital, Sana'a, Yemen
- ⇒ Justus-Liebig University, Giessen, Germany
- ⇒ Lomonosov Moscow State University, Moscow, Russia
- ⇒ Alfred Hospital, Victoria, Australia
- ⇒ St Vincent's Hospital, Victoria, Australia
- ⇒ Royal Prince Alfred Hospital, New South Wales, Australia
- ⇒ Chris O'Brien Lifehouse, New South Wales, Australia
- ⇒ Launceston General Hospital, Tasmania, Australia
- ⇒ The Prince Charles Hospital, Queensland, Australia
- ⇒ Hospital Universitario Austral, Buenos Aires, Argentina
- ⇒ Nepean Hospital, New South Wales, Australia
- ⇒ King Hussein Cancer Centre, Amman, Jordan
- ⇒ Hospital Británico, Buenos Aires, Argentina
- ⇒ General Hospital of Chania, Saint George, Greece.

will provide written or electronic informed consent prior to study recruitment. Recruitment is anticipated to begin in June 2026 and continue for 18 months.

Procedures

Participants will be approached by a member of their treating medical team during the initial surgical consultation at a preoperative clinic after eligibility screening. Eligible patients will be informed of the study and provided with a participant information sheet. Following informed consent, participants will receive a unique Research Electronic Database Capture link to complete the survey which contains the PREdiCT screening tool, with hardcopy completion available for those who prefer this option. To ensure accurate prediction of postoperative outcomes, participants must complete the PREdiCT screening tool within 6 weeks prior to surgery. Importantly, as some centres offer prehabilitation interventions that may modify screening scores over time, participants must complete the screening tool following the completion of any prehabilitation intervention (ie, preoperative evaluation rather than baseline). This timing ensures that screening scores reflect health status immediately prior to surgery, enabling valid assessment of the tool's predictive utility for postoperative outcomes. For the purpose of this study, we define prehabilitation as any newly introduced health professional-led intervention conducted preoperatively to address a health status deficiency.

PREdiCT screening tool development

The PREdiCT screening tool was developed through a comprehensive, multi-step, pre-defined process.[17 18] First, we undertook a scoping review exploring the use of preoperative screening tools in patients undergoing gastrointestinal cancer surgery, which identified 77 unique screening tools across physical (n=21), nutritional (n=16) and psychological (n=40) domains.[19] Following this, we conducted an international Delphi consensus study involving 308 prehabilitation experts from 49 countries to iteratively rate self-reported screening tools identified through the scoping review based on the appropriateness of their use specific to patients undergoing gastrointestinal cancer surgery.[20] This resulted in a refined list of 10 screening tools across physical (n=3), nutritional (n=3) and psychological (n=4) domains. Selection of the final three tools was guided by explicit criteria prioritising clinical utility and implementation feasibility. Investigators systematically evaluated these ten screening tools based on key implementation criteria, including availability, licensing costs, validated language versions and completion time. Through this comprehensive evaluation process, three tools were selected for inclusion in the PREdiCT screening tool based on their optimal balance of psychometric properties and pragmatic feasibility. These include the Duke Activity Status Index (DASI)[21] for physical health, the Patient-generated Subjective Global Assessment short-form (PG-SGA-SF)[22] for nutritional health and the Patient Health Questionnaire-4 (PHQ-4)[23] for psychological health. The screening tool survey takes approximately 15 min to complete and is included as online supplemental document 2.

The DASI was designed to assess the functional capacity of adults. It evaluates an individual's ability to perform daily activities, ranging from basic self-care to strenuous physical tasks, and provides an estimate of peak oxygen uptake (VO_2 peak) and metabolic equivalents (METs). The DASI involves responding to 12 differently weighted yes/no questions based on current functional ability to provide a VO_2 peak estimate and MET estimates at different thresholds. The PHQ-4 is a four-item screening tool that uses two items from the 9-item PHQ (PHQ-9)[24] which assesses depression and two items from the 7-item Generalised Anxiety Disorder[25] questionnaire which assesses anxiety to provide a measure of both depression and anxiety in a single, ultra brief screening tool. Each item is scored from 0 to 3, comprising an overall

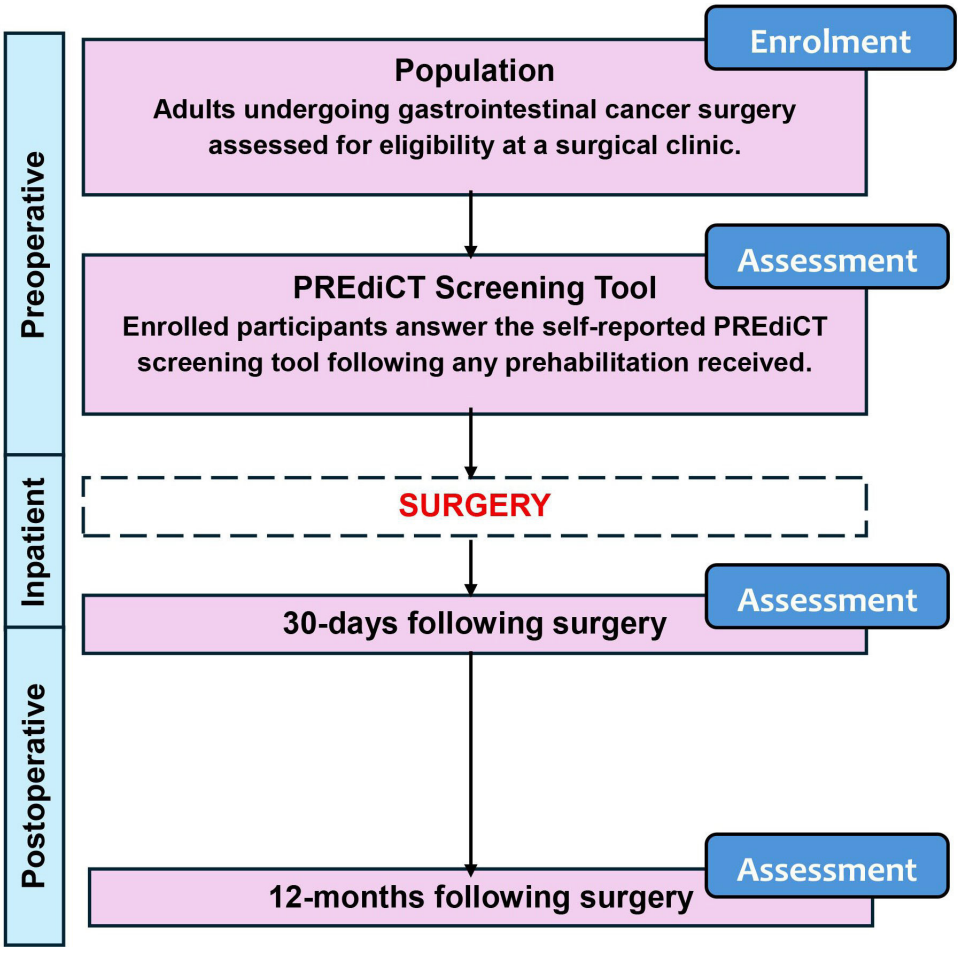

Figure 1 Participant flow through the study. PREdiCT, Preoperative Risk Evaluation for Cancer Treatment.

score of 12 where higher scores denote greater anxiety and/or depression. The four-item tool has shown to have convergent validity and good internal consistency (Cronbach's α >0.88) in those with gastrointestinal cancer.[26] The PG-SGA-SF is the short, patient-reported version of the comprehensive PG-SGA[27] and measures malnutrition risk. It includes four items related to unintentional weight loss, nutrition-impact symptoms, recent changes in food intake and function, with a maximal score of 36 points where higher scores represent poorer nutrition.

Outcomes

The primary aim of this study is to evaluate whether the PREdiCT screening tool provides incremental prognostic value for postoperative complications. The primary outcome is 30-day postoperative complications and will be assessed in three ways: (1) yes/no whether any complication occurred; (2) complications that occurred based on the Clavien-Dindo Classification[28] (see table 1); (3) major complications and minor complications that occurred

Table 1 The Clavien-Dindo classification of postoperative complication severity

Clavien-Dindo grade	Criteria
I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions Allowed drug treatments are antiemetics, antipyretics, analgesics, diuretics, electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside.
II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.
III	Requiring surgical, endoscopic or radiological intervention.
IV	Life-threatening complication (including cerebral haemorrhage, ischaemic stroke and subarachnoid bleeding, but not transient ischaemic attacks) requiring monitored bed (eg, step down unit) or critical care unit monitoring.
V	Death of a patient.

based on the Clavien-Dindo Classification (see table 1) where 0 represents no complication, I–II represents a minor complication and III–V represents a major complication and (4) overall complication severity using the Comprehensive Complications Index[29] which uses the Clavien-Dindo scores of each experienced complication to provide a single overall score from 0 (representing no complications) to 100 (representing death). We define a postoperative complication as any deviation from the normal postoperative recovery course that is not inherent to the surgery itself (according to the Clavien-Dindo Classification).[30]

A range of secondary outcomes will be collected to evaluate associations between PREdiCT screening tool scores and postoperative outcomes. We will also evaluate both hospital and intensive care unit length of stay, readmission rate and discharge destination following index admission (ie, home vs other). DAH 30 days postsurgery is a patient-centred measure which incorporates hospital length of stay, readmission, discharge destination and mortality in a single score out of 30.[31] Additionally we will collect all-cause mortality at 30 days and at 12 months. We will collect patient-level outcomes (eg, age, sex, body mass index, comorbidities and smoking status), disease-related outcomes (eg, cancer type, cancer stage and exposure to neoadjuvant therapy) and surgical outcomes (eg, surgery type, surgical approach (categorised as open, minimally invasive or robotic) and procedure complexity). All outcomes will be assessed by review of the medical record after the 30-day time point to ensure the patients trajectory is not altered by the study. Survival at 12 months will be collected according to the standard process of the individual site.

Qualitative substudy

We will undertake a nested qualitative study exploring the perspectives of staff involved in implementing the screening tool survey. Our approach will use hermeneutic inquiry,[32] enabling the capture of clinician perspectives through a one-on-one, open-ended, semistructured interview (online supplemental document 1). Interviews will be conducted online, audio-recorded, and be approximately 30 min in duration.

Sample size calculation

The sample size required has been calculated based on change in the primary outcome of 30-day postoperative complications (yes/no for major complications ie, Clavien-Dindo III-V). To achieve an 85% sensitivity with a 5% margin of error and 95% confidence level, the required positive cases for at least one postoperative complication is 196. Considering a 95% response rate (as there is no follow-up) and typical 30% prevalence of postoperative complications[33] including 17% prevalence of major complications[34] in the cohort, the required sample size is 1214 participants. For the nested qualitative study, purposive sampling will be employed to ensure diversity across key characteristics including geographic region, hospital surgical volume, cancer types treated, local resources and prehabilitation practices. Recruitment will continue until thematic saturation is achieved regarding perspectives on implementation of the PREdiCT screening tool, anticipated to occur with approximately 15 to 25 participants.[35]

Distress management plan

All participants will be provided with local contact numbers for support services linked to the recruiting site. The site principal investigator will acknowledge that the participant may experience emotional concerns or distress as they prepare for surgery, and that questions from the PREdiCT screening tool may elicit uncomfortable emotions given the participant will be required to reflect on their current health status. The participant will be reminded of their freedom to withdraw from the study should they wish and that their withdrawal will not be disclosed to the wider clinical team nor will it affect the care they receive.

Statistical analysis

To understand the characteristics of participants who develop complications, we will first compare baseline features between those who do and do not experience postoperative complications using the appropriate statistical test based on the type and distribution of data. A two-sided alpha of 0.05 will be used for all analyses. Variables for data collection can be seen in online supplemental document 3.

The primary objective of this analysis is to determine whether the PREdiCT screening tool, which includes screening scores for exercise capacity (DASI), nutritional status (PG-SGA-SF) and psychological well-being (PHQ-4), can effectively identify patients at high risk of developing postoperative complications. Our analytical approach will progress through three main stages: (1) we will examine the independent predictive value of screening scores after adjusting for established clinical risk factors; (2) we will determine optimal cut-points to stratify patients into clinically actionable risk categories and (3) we will assess whether these screening tools provide added value beyond standard preoperative assessment and whether their performance varies across important patient subgroups.

1. Primary predictive analysis

   Multivariate logistic regression models will be used to assess whether preoperative screening scores predict postoperative outcomes. These models will adjust for key clinical confounders that are known to influence postoperative complication risk including patient-level factors, disease-related factors and surgical factors. Given the multicentre nature of this study, we will also account for potential centre-level variation using random effects or fixed effects as appropriate. We will evaluate both individual domain scores and a composite screening score involving all three screening tools. Prior to finalising the model, we will run thorough

diagnostics for linearity assumptions, multicollinearity and model calibration.

2. Cut-points and risk stratification
   Area under the curve (AUC) through receiver operating characteristics (ROC) analysis will be used to evaluate how well scores distinguish those who develop complications. An AUC of ≥0.7will be considered acceptable discrimination and values ≥0.8 considered to indicate good discrimination. We will use ROC analysis to identify cut-points that optimally balance sensitivity and specificity; however, recognise that clinical priorities may differ from statistical optimality (eg, we may prefer higher sensitivity to ensure we capture most at-risk patients even if this means more false positives). Once candidate cut-points are identified for each screening domain, we will use these to categorise patients into low, medium and high risk groups. We will then examine complication rates across these risk categories using χ^2 tests for a trend that confirms complication risk increases progressively across categories. Classification and regression tree analysis will also be performed to create homogenous subgroups through recursive partitioning with respect to complication risk.
3. Added value of screening and subgroup analyses
   Critically, we want to understand whether adding these screening scores to standard preoperative assessment improves the ability to predict complications. To quantify this added value, we will compare models with and without screening scores using net reclassification improvement and integrated discrimination improvement. These metrics will tell us whether the screening tool meaningfully reclassifies patients into more appropriate risk categories and improves overall discrimination beyond what we can achieve with traditional clinical variables alone. We will perform subgroup analyses to assess whether predictive performance differs by cancer type, as different malignancies may present distinct physiological challenges and baseline risk profiles. Given that we are conducting multiple subgroup comparisons, as multiple cancer types are included in our study (ie, any gastrointestinal cancer), we recognise the increased risk of false-positive findings and will interpret these results cautiously, considering adjustment for multiplicity where appropriate and regarding subgroup findings as hypothesis-generating unless very robust. We will also perform a subgroup analysis based on the time between answering the screening tool and surgery to help inform the feasibility of implementation, and an evaluation of early recovery after surgery (ERAS) versus non-ERAS sites.

In addition to our primary analyses, we will perform a range of exploratory analyses to generate hypotheses for future research. This will include: (1) a comparison of each domain-specific screening component as screening could potentially be simplified to a single domain if there is sufficient predictive utility; (2) any synergistic or additive effects between domain scores (eg, poor nutrition might amplify the impact of low exercise capacity on complication risk); (3) dose–response relationships using Clavien-Dindo grades which may reveal threshold effects where complication risk dramatically increases beyond certain thresholds; (4) whether the screening tool, and its included domains, predicts complications differently based on their type (ie, respiratory complication vs anastomotic leak) and (5) centre-level variations in screening tool performance to assess generalisability and implementation considerations such as the effect of institutional factors on screening tool effectiveness. We will also perform sensitivity analyses to evaluate the effect of neoadjuvant therapy use and the effect of alternate outcome definitions (ie, Clavien-Dindo grade III or higher compared with using any complication).

Qualitative study

We will use reflexive thematic analysis to identify, analyse and report patterns of meaning within the qualitative data. Analysis will be conducted iteratively and concurrently with data collection, allowing themes to inform subsequent interviews. Two researchers will meet regularly to code, discuss codes, and refine the coding structure through consensus. Codes will then be grouped into broader themes that capture key patterns relevant to implementation experiences. The analysis will move beyond descriptive summaries to interpretive accounts that examine the underlying assumptions, contexts and implications of clinician perspectives. We will use NVivo (QSR International, Melbourne, Victoria, Australia) software to support data management and coding.

Patient and public involvement

Patients and members of the public were not directly involved in the design of this research. However, the PREdiCT screening tool is composed exclusively of established patient-reported outcome measures, selected to prioritise patient acceptability, brevity and feasibility of self-completion in routine clinical settings. Future implementation work following the PREdiCT study will involve consumers.

DISCUSSION

The PREdiCT study will be the first large, international, prospective cohort study to evaluate the predictive utility of a tri-modal (physical, nutritional, psychological), online, self-reported screening tool for patients undergoing gastrointestinal cancer surgery. The three tools which comprise the PREdiCT screening tool are the DASI,[21] PHQ-4,[23] and the PG-SGA-SF.[22]

A previous large international cohort study, the METS Study, investigated patients undergoing non-cardiac surgery, with an elevated cardiac risk profile. The study demonstrated that a cut-point of <34 points, as measured by the DASI, was associated with increased odds of 30-day mortality or myocardial infarction (OR 1.05 per 1 point decrease below 34; 95% CI 1.00 to 1.09) and

moderate-to-severe postoperative complications (OR: 1.03 per 1 point decrease below 34; 95% CI 1.01 to 1.05).[36] The PREdiCT study will verify whether such a cut-point is also observable in a gastrointestinal cancer population and additionally will provide cut-points for nutritional and psychological aspects of preoperative health status.

This study uses questionnaires to assess physical function as opposed to a physical test such as a Six-Minute Walk Test (6MWT). A limitation of using a 6MWT to stratify risk is the requirement for a 30 m corridor and a trained health professional to conduct the test. Additionally, participants must attend a centre, which could mean travelling large distances in geographically dispersed countries. An advantage of the PREdiCT study is that screening is self-reported and conducted online, allowing for timely assessment of an individual's risk profile which may facilitate early prehabilitation interventions for those at greatest risk of poor postoperative outcomes.

Preoperative screening and subsequent prehabilitation interventions can be resource intensive. A strength of this study is the incorporation of a hermeneutic inquiry (an interpretive methodology concerned with understanding the meaning of human experience within its broader context) through qualitative interviews to investigate barriers to routine implementation. These qualitative findings will be integrated with quantitative results to provide a comprehensive understanding of both whether the screening tool works (predictive validity) and how it works in practice (implementation feasibility). Specifically, qualitative insights about implementation barriers may help explain variations in screening completion rates or centre-level differences in tool performance observed in quantitative analyses. Conversely, quantitative findings about which patient subgroups benefit most from screening may inform qualitative recommendations about targeting implementation efforts. This approach will ultimately provide more actionable evidence for future implementation and scale-up of preoperative screening for prehabilitation referral. A limitation of this study is that diversity of the patient population and treatment approach at treating centres may confound interpretation of results; however, we plan to account for these differences in our analysis.

ETHICS AND DISSEMINATION

This study has received ethical approval from the Sydney Local Health District Human Research and Ethics Committee (X25-0333 & 2025/ETH02465) and has been registered on the Open Science Framework (10.17605/OSF.IO/HVCGD). All sites will obtain local governance approvals prior to initiating the study. Any protocol amendments will require approval from the trial Steering Committee and the ethics committee prior to implementation. No identifiable participant information will be included in any dissemination outputs. Deidentified individual-level data will be stored on secure University of Sydney servers in accordance with the study's data management plan and may be made available on reasonable request, subject to ethics approval. A plain language summary of the study findings will be provided to all consenting participants.

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