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Defining standards in colorectal optimisation: a Delphi study protocol to achieve international consensus on key standards for colorectal surgery prehabilitation

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ABSTRACT

Introduction Prehabilitation in colorectal surgery is evolving and may minimise postoperative morbidity and mortality. With many different healthcare professionals contributing to the prehabilitation literature, there is significant variation in reported primary endpoints that restricts comparison. In addition, there has been limited work on patient-related outcome measures suggesting that patients with colorectal cancer needs and issues are being overlooked. The Defining Standards in Colorectal Optimisation Study aims to achieve international consensus from all stakeholders on key standards to provide a framework for reporting future prehabilitation research.

Methods and analysis A systematic review will identify key standards reported in trials of prehabilitation in colorectal surgery. Standards that are important to patients will be identified by a patient and public involvement (PPI) event. The longlist of standards generated from the systematic review and PPI event will be used to develop a three-round online Delphi process. This will engage all stakeholders (healthcare professionals and patients) both nationally and internationally. The results of the Delphi will be followed by a face-to-face interactive consensus meeting that will define the final standards for prehabilitation for elective colorectal surgery.

Ethics and dissemination The University of Glasgow College of Medical, Veterinary and Life Sciences Ethics Committee has approved this protocol, which is registered as a study (200190120) with the Core Outcome Measures in Effectiveness Trials Initiative. Publication of the standards developed by all stakeholders will increase the potential for comparative research that advances understanding of the clinical application of prehabilitation.

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Strengths and limitations of this study

- There is currently no set of standards for prehabilitation research, limiting evidence synthesis.
- This study has international and diverse stakeholders, including patients that have been involved since study inception.
- Limitations of online surveys include selection bias.

INTRODUCTION

Elective colorectal surgery for benign and malignant conditions is one of the most commonly performed operations in the UK.[1] Although mortality is reported as low (3%), postoperative morbidity is common varying from a minor wound infection to a major anastomotic leak that can have significant short-term consequences for the patient. After discharge, a patient's recovery can be delayed with one in ten requiring emergency readmission within 30 days.[2] To improve patients with colorectal cancer outcomes, the development of effective strategies is essential.

Enhanced recovery after surgery (ERAS) programmes seek to optimise perioperative care with the aim of attenuating the stress response to surgery.[3] The first ERAS protocol for colorectal surgery was published in 2005 and has since been delivered across the UK, although with variable components, implementation and results.[4 5] ERAS protocols focus on intraoperative and postoperative strategies, leaving the preoperative period as a potential opportunity for optimisation. Prehabilitation, the process of physical, nutrition and psychological optimisation prior to surgery, takes advantage of this opportunity and has the potential to successfully augment ERAS. Demonstrated as safe and feasible in predominately patients with colorectal cancer,[6] early trial evidence and meta-analyses[7] have reported that prehabilitation reduces the number of patients suffering postoperative complications by 51%,[8] as well as improving exercise capacity[9] and decreasing length of hospital stay.[10]

Prehabilitation has gained widespread acceptance in recent years with several leading professional bodies showing support: Cancer Research UK; the Clinical Oncology Society of Australia; American College of Sports Medicine (ACSM); International Society of Behavioural Nutrition and Physical Activity (ISBNPA); and Macmillan Cancer Support. Although prehabilitation is being introduced into clinical practice, there are shortcomings in the current evidence base making the next important step the definition of standards for the content, delivery and measurement of outcomes in prehabilitation interventions. One major shortcoming is the lack of research performed in non-cancer populations, including inflammatory bowel disease (IBD), pelvic floor and diverticular disease. The situation is made complex by prehabilitation research spanning different specialty groups: anaesthetics, surgeons, nurse specialists, exercise oncologists/physiologists, nutritionists and psychologists. Currently, this lack of consensus means prehabilitation is varied across the UK and beyond, preventing effective comparison and compilation of results. Development and implementation of standards would encourage homogeneity of data and consequently improve the quality of the evidence base to enhance patients with colorectal cancer care.

To date, there have been limited efforts to involve patients in prehabilitation research. The National Health Service (NHS) advocates for patient-centred care,[10] yet often, research is clinician-led and carried out for patients, rather than with them.[11] In one of the recent initiatives by the James Lind Alliance with the National Cancer Research Institute (NCRI), over 3500 patients with cancer, their caregivers and healthcare and social care professionals were asked for their key research priorities.[12–14] In the final top 10 was 'what specific lifestyle changes help with recovery from cancer treatment, restore health, and improve quality of life?'. Prehabilitation research clearly addresses this, and the definition of prehabilitation standards will lay important foundations to facilitate research to definitively answer this question.

The Defining Standards in Colorectal Optimisation (DiSCO) Study intends to achieve consensus on key standards for prehabilitation before elective colorectal surgery. DiSCO will involve patients and their caregivers from the start of the process to ensure that results are relevant to service users as well as clinicians. A three-stage study design using multidisciplinary stakeholders will be followed: systematic review and patient and public involvement (PPI) event to develop a standards longlist, standards shortlisting using three rounds of online Delphi and a face-to-face consensus meeting to define the final list of standards for colorectal surgery optimisation.

Aims and objectives

The primary aim of the DiSCO Study is to achieve consensus of prehabilitation standards by all stakeholders that are to be applied in future trials on prehabilitation in elective colorectal surgery.

To achieve this objective, four key questions will be asked:

1. What are the individual components of prehabilitation?
2. What type of patient with colorectal cancer should be offered prehabilitation?
3. Who should deliver prehabilitation?
4. What outcome measures are important?

METHODS AND ANALYSIS

DiSCO methodology will be guided by the Core Outcome Measures in Effectiveness Trials (COMET) Initiative,[15] which provides a handbook instructing the development of core outcome sets. However, the scope of this study is broader than a core outcome set, also seeking to define standards for what prehabilitation should consist of and for whom and how it should be delivered. Accordingly, the COMET recommendations will be modified to facilitate achieving these aims (registered as a study: 200190120).

Patient and public involvement

DiSCO will involve adult patients and their carers/supporters, who have undergone elective resection of a part of their colon or rectum for benign or malignant colorectal conditions. These conditions include, but are not limited to, colorectal cancer, anal cancer, diverticulitis and its complications, IBD and pelvic floor dysfunction. Patients will be invited through social media to allow an international perspective (@DiSCO_study on Twitter and Facebook) and by patient liaison groups of professional bodies and charities, including the Association of Coloproctology of Great Britain and Ireland (ACPGBI) Patient Liaison Group and The Ileostomy and Internal Pouch Support Group.

Stakeholders

From our systematic review and recent work published by Macmillan Cancer Support,[16] the study group will identify key stakeholders that have published on prehabilitation. This is likely to include colorectal surgeons, colorectal anaesthetists, colorectal nurse specialists, colorectal oncologist (medical or clinical), exercise oncologists, exercise physiologists, sports scientists, sports medicine specialists, physical exercise/activity specialists, nutritionists/dieticians, psychologists, geriatricians, pharmacists and general practitioners. To ensure inclusivity, specialist associations related to these stakeholders will be approached: ACSM, ISBNPA, Scottish Physical Activity Research Collaboration, Macmillan Cancer Support, Royal College of Anaesthetists, Association of Surgeons of Great Britain and Ireland (ASGBI), ACPGBI, Trainees with an Interest in Perioperative Medicine and ERAS Association.

Members from each stakeholder group will be recruited to form an internationally connected multidisciplinary study team. The three cochief investigators are an expert patient and two consultant colorectal surgeons with research interests in core outcome sets and prehabilitation.

Study design

The DiSCO Study will follow a three-stage process (figure 1).

STAGE 1: CREATING STANDARDS LONGLIST

Stage 1 is designed to produce a longlist of standards that will be taken forward into Stage 2. This includes a systemic review and PPI event. At the end of Stage 1, the research team will hold a research meeting to discuss the results and ensure clarity on the longlist of standards that will be used to create the Delphi Survey.

Systematic review

Research aims to determine the range of interventions used in colorectal prehabilitation studies, who delivers the interventions, how patients are selected for the intervention (eligibility criteria) and how/what prehabilitation outcomes are measured.

Method: a systematic review of the current prehabilitation literature in patients undergoing colorectal surgery has been published.[17].

PPI event

Research question: what do patients and their family members think is important in a prehabilitation intervention? Specifically: what are the individual components of prehabilitation? What type of patient with colorectal cancer should be offered prehabilitation? Who should deliver prehabilitation? What outcome measures are important, and how should they be measured?

Method

Inclusion criteria:

- Adults over 18 years of age.
- Patients who have completed or have planned colorectal surgery.
- Underlying indication for surgery could be for benign or malignant pathology.
- Able to understand, interpret and communicate in English.

Exclusion criteria:

- Acute or chronic issues with memory and/or cognition

Sampling

The patient information sheet (PIS) will be sent to colleagues from one hospital department that includes nurses, colorectal nurse specialists (cancer, inflammatory disease, stoma therapists and ERAS specialists), allied health professionals and surgeons. Proposed participants will then be sent the PIS and asked to confirm their attendance by telephone. All patients will be invited to bring family members and/or caregivers to the event. The second strategy to identify patients will be to approach representatives from local community groups that encourage lifestyle change in patients. Appropriate patients will then be discussed with the research team, and the PIS will be sent out accordingly. A target of 20 participants will be sought, with a minimum of 10 of these being patients.

Event location

The PPI event will be held over 4–5 hours at the hospital of one of the surgeons, in a designated quiet and easily accessible room with the capacity to hold 20–30 people comfortably. Participants will be reimbursed for travel expenses. If the event occurs during the COVID-19 pandemic, then the format will be moved to a secure online NHS-approved virtual platform.

Event format

The event will be led by the research team that includes expert patient and colorectal surgeons. The event will be facilitated by colorectal nurse specialist, enhanced recovery nurse specialist, medical students, anaesthetists and surgical/oncological research fellows.

A PowerPoint presentation will be used to give structure to the event. It will include introductions, definitions and explanation of prehabilitation and the aims of the DiSCO Study. Patients will be invited to share their experiences of colorectal surgery and any preparation or prehabilitation they underwent beforehand. To explore the four key aims of the DiSCO Study, the patients will be divided into small groups each facilitated by members of the research team. The whole group will then reconvene for an interactive and patient-led discussion to develop their answers to the four study questions.

Analysis

Comprehensive field notes will be taken by the research team. Thematic analysis will organise the patients' views into themes that will be incorporated into the longlisting. All patients and family members in attendance will be invited to leave their email address to be contacted for inclusion in Stage 2.

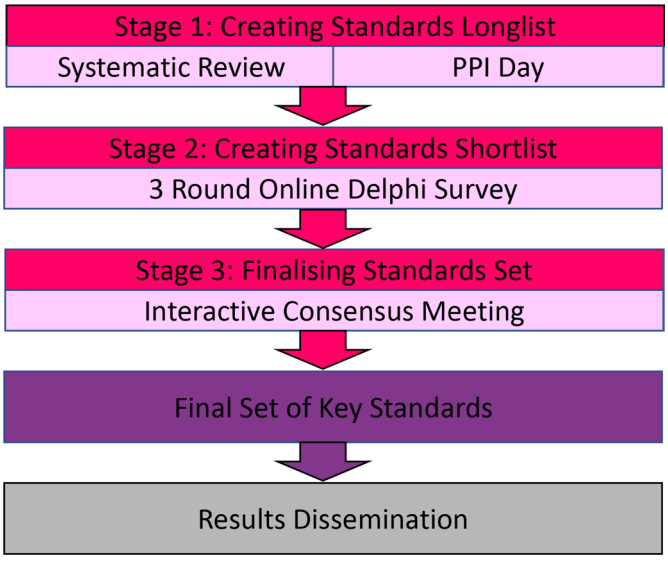

Figure 1 Diagram of study design.

STAGE 2: CREATING STANDARDS SHORTLIST

A three-round online modified Delphi process will be performed to develop a shortlist.[18] Adhering to recommendations by COMET,[15] standards will be split into four domains reflecting the key study questions: content of prehabilitation, recipients of prehabilitation, delivery of prehabilitation and the measurement/assessment of prehabilitation. Participants will be asked to rank the importance of each standard on a validated 9-point Likert scale, which is recommended by the Grading of Recommendations, Assessment, Development and Evaluation working group.[19] With this scale, a score of 1–3 signifies that the standard is of little importance, 4–6 some importance and 7–9 critical importance. Round 1 will ask participants to rank every item of the longlist, and differences in rankings between stakeholder groups will be explored. To reduce bias, a predetermined consensus threshold will be used: Standards that are ranked of critical importance (7–9) by >70% or of little importance (1–3) by <15% of each stakeholder group will be deemed to have reached the threshold for consensus for inclusion in the shortlist of key standards. After round 1 of the Delphi, standards reaching the threshold of consensus for inclusion will be directly added to the shortlist and not included in subsequent rounds. All items not reaching this threshold will be taken forward to round 2. The same criteria will be used after round 2 to select items to take forward into round 3. After round 3, any additional items reaching the threshold for consensus for inclusion will be added to the shortlist. Any items that are ranked of critical importance (7–9) by <50% of each stakeholder group or of little importance (1–3) by >50% of each stakeholder group after round 3 will be excluded from the final shortlist. Standards that do not meet the criteria for inclusion or exclusion will be considered borderline. The final shortlist and borderline items will be taken forward for discussion at the final consensus meeting.

The online survey will be powered by COMET Delphi-Manager software. Representatives from each of the key stakeholder groups will be invited to participate to ensure adequate representation. A target of 100 or more respondents will be sought. Multiple methods will be used for recruitment to maximise the sample size and participant diversity. Study group members who have membership with professional societies will be there for recruitment, including ACPGBI, ACPGBI Patient Liaison Group, ASGBI, ISBNPA and NCRI. Social media networks (Twitter and Facebook) will also be used to advertise the study, hopefully engaging patients with colorectal cancer and members of the public. Patients without access to social media will be targeted through the patient support charities. Participants from the PPI event who left their email addresses will also receive an invitation to partake in the Delphi Study.

STAGE 3: FINALISING STANDARDS SET

The shortlist from the Delphi process will be reviewed at a meeting of stakeholder representatives to agree on a final set of standards for publishing, as recommended by the COMET Initiative.[15] The meeting is planned to be held face-to-face, but this will depend on COVID-19 restrictions. If a face-to-face meeting is not possible, then it will be held online using videoconferencing software. A random sample of around 50 stakeholders will be invited using contacts from the PPI event and Delphi Survey participants who gave permission to be contacted about the stakeholder event. The shortlist of standards that met the threshold for consensus after each round of the Delphi will be presented and ratified by vote. The borderline standards will be discussed and voted on individually. For each standard, the group will anonymously rank its importance on the same 9-point scale used in the Delphi Study to establish a group baseline. Following this, there will be a group discussion of the standard with arguments for and against its inclusion in the final standards set. A further round of anonymous voting will follow. A result of at least 70% ranking the standard as critically important and fewer than 15% ranking it of little importance will be required for inclusion in the final standards set. There are no universally agreed consensus criteria, and the criteria used here follow published recommendations.[20]

Ethics and dissemination

This work that includes a wide range of stakeholders, including patients, is performed with robust methodology ensuring that the results accurately reflect the priorities of all stakeholder groups and will be reported using Guidance on Conducting and REporting DElphi Studies.[21] Publication in peer-reviewed journals and dissemination through the professional collaborations and associated networks should ensure international adoption of the standards. Such adoption will help to standardise future prehabilitation study design and reporting to optimise the progression of prehabilitation for researchers, clinicians and patients. The University of Glasgow College of Medical, Veterinary and Life Sciences Ethics Committee approved the protocol on 7 July 2020 (200190120).

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