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Defining Standards in Colorectal Optimisation (DiSCO): study protocol to achieve international consensus on key standards for colorectal surgery prehabilitation

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3 **Defining Standards in Colorectal Optimisation (DiSCO): study protocol to achieve**
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5 **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 colorectal patients' needs and issues are being overlooked. The DiSCO Study (Defining Standards in Colorectal Optimisation) aims to achieve international consensus from all stakeholders. This protocol (200190120) and the study are registered with the Core Outcome Measures in Effectiveness Trials (COMET) initiative. It aims to achieve consensus 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 that will engage all stakeholders (healthcare professionals and patients). 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 & Life Sciences Ethics Committee has approved the protocol on 7th July 2020 (200190120). Publication of the standards developed by all stakeholders will increase the potential for comparative research that advances understanding of the clinical application of prehabilitation.

Trial registration number. PROSPERO registration ID: CRD42019120381.

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 U.K. [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 colorectal patients' 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, albeit with variable components, implementation and results [4,5]. ERAS protocols focus on intra- and post-operative 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 colorectal patients [6], early trial evidence has reported that prehabilitation reduces the number of patients suffering postoperative complications by 51% [7], as well as improving exercise capacity [8] and decreasing length of hospital stay [9].

Prehabilitation has gained widespread acceptance in recent years with several leading professional bodies supporting: 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. The situation is made complex by prehabilitation research spanning different specialty groups: anaesthetics; surgeons; nurse specialists; exercise oncologists/ physiologists; nutritionists; 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 colorectal patients' care.

To date, there have been limited efforts to involve patients in prehabilitation research. The 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 cancer patients, their caregivers, and health and social care professionals were asked for their key research priorities [12,13]. 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 DiSCO (Defining Standards in Colorectal Optimisation) 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 multi-disciplinary 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 colorectal patient should be offered prehabilitation?
3. Who should deliver prehabilitation?
4. What outcome measures are important?

Methods and Analysis

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3 DiSCO methodology will be guided by the Core Outcome Measures in Effectiveness Trials
4 (COMET) initiative [14], which provides a handbook instructing the development of core outcome
5 sets. However, the scope of this study is broader than a core outcome set, also seeking to define
6 standards for what prehabilitation should consist of, for whom, and how it should be delivered.
7 Accordingly, the COMET recommendations will be modified to facilitate achieving these aims.
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10 11 12 *Patient and Public Involvement* 13

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16 DiSCO will involve adult patients and their carers/supporters, who have undergone elective
17 resection of a part of their colon or rectum for benign or malignant colorectal conditions. These
18 conditions include, but are not limited to colorectal cancer, anal cancer, diverticulitis and its
19 complications, inflammatory bowel disease, and pelvic floor dysfunction. Patients will be invited
20 through social media to allow an international perspective (@DiSCO_study on Twitter and
21 Facebook) and by patient liaison groups of professional bodies and charities, including the
22 Association of Coloproctology of Great Britain and Ireland Patient Liaison Group, and The
23 Ileostomy and Internal Pouch Support Group.
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30 31 32 *Stakeholders* 33

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35 From our systematic review and recent work published by Macmillan Cancer Support [15], the
36 study group will identify key stakeholders that have published on prehabilitation. This is likely to
37 include: colorectal surgeons; colorectal anaesthetists; colorectal nurse specialists; colorectal
38 oncologist (medical or clinical); exercise oncologists; exercise physiologists; sports scientists;
39 sports medicine specialists; physical exercise/ activity specialists; nutritionists/ dieticians;
40 psychologists; geriatricians, pharmacists, General practitioners (GP). To ensure inclusivity,
41 specialist associations related to these stakeholders will be approached: American College of
42 Sports Medicine (ACSM), International Society of Behavioural, Nutrition and Physical Activity
43 (ISBNPA), Scottish Physical Activity Research Collaborative (SPARC), Macmillan, Royal College
44 of Anaesthetists (RCOA); Association of Surgeons of Great Britain and Ireland (ASGBI);
45 Association of Coloproctology of Great Britain and Ireland (ACPGBI); TriPOM (Trainees with an
46 interest in Perioperative Medicine); ERAS (Enhanced Recovery After Surgery) Association.
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3 Members from each stakeholder group will be recruited to form an internationally connected multi-
4 disciplinary study team. The three co-chief investigators are: an expert patient and two consultant
5 colorectal surgeons with research interests in core outcome sets and prehabilitation.
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11 *Study Design*

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15 The DiSCO study will follow a three-stage process [Figure 1].
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18 **Figure 1: Diagram of study design**

19 20 21 22 23 24 **Stage 1: Creating standards longlist**

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

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38 Research aims: to determine the range of interventions used in colorectal prehabilitation studies,
39 who delivers the interventions, how patients are selected for the intervention (eligibility criteria)
40 and how/what prehabilitation outcomes are measured.
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45 Method: a systematic review will be performed of the current prehabilitation literature in patients
46 undergoing colorectal surgery. The full protocol including search strategy and selection criteria is
47 published on the PROSPERO database [CRD42019120381].
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51 *PPI Event*

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54 Research question: what do patients and their family members think is important in a
55 prehabilitation intervention? Specifically: what are the individual components of prehabilitation?
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3 what type of colorectal patient should be offered prehabilitation?; who should deliver
4 prehabilitation?; and what outcome measures are important and how should they be measured?
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8 Method:

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11 Inclusion criteria:

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

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19 Exclusion criteria:

- 20 • Unable to physically attend the PPI event
- 21 • Acute or chronic issues with memory and/or cognition

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24 Sampling:

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27 The patient information sheet (PIS) will be sent to colleagues from one hospital department that
28 includes nurses, colorectal cancer nurse specialists, allied health professionals and surgeons.
29 Proposed participants will then be sent the PIS and asked to confirm their attendance by
30 telephone. All patients will be invited to bring family members and/or caregivers to the event. The
31 second strategy to identify patients will be to approach representatives from local community
32 groups that encourage lifestyle change in patients. Appropriate patients will then be discussed
33 with the research team and the PIS will be sent out accordingly
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40 Event location:

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43 The PPI event will be held over 4-5 hours at the hospital of one of the surgeons, in a designated
44 quiet and easily accessible room with the capacity to hold 20-30 people comfortably. Participants
45 will be reimbursed for travel expenses.
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49 Event format:

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52 The event will be led by the research team that includes expert patient and colorectal surgeons.
53 The event will be facilitated by: colorectal nurse specialist, enhanced recovery nurse specialist,
54 medical students, anaesthetists, and surgical/oncological research fellows.
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5 A PowerPoint presentation will be used to give structure to the event. It will include introductions,
6 definitions and explanation of prehabilitation, and the aims of the DiSCO study. Patients will be
7 invited to share their experiences of colorectal surgery, and any preparation or prehabilitation they
8 underwent beforehand. To explore the four key aims of the DiSCO study, the patients will be
9 divided into small groups each facilitated by members of the research team. The whole group will
10 then reconvene for an open room interactive and patient-led discussion to develop their answers
11 to the four study questions.
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16 17 Analysis:

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20 Comprehensive field notes will be taken by the research team. Thematic analysis will organise
21 the patients' views into themes that will be incorporated into the longlisting. All patients and family
22 members in attendance will be invited to leave their email address to be contacted for inclusion
23 in Stage 2.
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28 **Stage 2: Creating standards shortlist**

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31 A three-round online modified Delphi process will be performed to develop a shortlist [16].
32 Adhering to recommendations by COMET [14], standards will be split into four domains reflecting
33 the key study questions: content of prehabilitation; recipients of prehabilitation; delivery of
34 prehabilitation; and the measurement/assessment of prehabilitation. Participants will be asked to
35 rank the importance of each standard on a validated 9-point Likert scale, which is recommended
36 by the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE_
37 working group) [17]. With this scale, a score of 1 to 3 signifies the standard is of little importance,
38 4 to 6 some importance, and 7 to 9 critical importance. Round one will ask participants to rank
39 every item of the longlist, and differences in rankings between stakeholder groups will be
40 explored. To reduce bias, a predetermined consensus threshold will be used. Only items which
41 are ranked of little importance (1-3) by >70%, and of critical importance (7-9) by <15% of each
42 stakeholder group, will be excluded after round one. Standards may be added or edited between
43 rounds one and two, and between rounds two and three, at the discretion of the study group.
44 Following each of rounds two and three, standards not meeting the predetermined consensus
45 threshold will be excluded, with the remaining standards forming the shortlist.
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3 The online survey will be powered by COMET DelphiManager software. Representatives from
4 each of the key stakeholder groups will be invited to participate to ensure adequate
5 representation. Multiple methods will be used for recruitment to maximise the sample size and
6 participant diversity. Study group members who have membership with professional societies will
7 use there for recruitment, including ACPGIBI, ACPGIBI Patient Liaison Group, ASGIBI, ISBNPA,
8 NCRI. Social media networks (Twitter and Facebook) will also be used to advertise the study,
9 hopefully engaging colorectal patients and members of the public. Patients without access to
10 social media will be targeted through the patient support charities. Participants from the PPI event
11 who left their email addresses will also receive an invitation to partake in the Delphi Study.
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20 **Stage 3: Finalising standards set**

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23 The shortlist from the Delphi process will be reviewed at a meeting of stakeholder representatives
24 to agree on a final set of standards for publishing, as recommended by the COMET initiative [14].
25 The meeting is planned to be held face-to-face, but this will depend on COVID-19 restrictions. If
26 a face-to-face meeting is not possible, then it will be held online using video conferencing
27 software. A random sample of around 50 stakeholders will be invited using contacts from the PPI
28 event and Delphi survey participants who gave permission to be contacted about the stakeholder
29 event. For each standard, the group will anonymously rank its importance on the same 9-point
30 scale used in the Delphi study to establish a group baseline. Following this, there will be a group
31 discussion of the standard with arguments for and against its inclusion in the final standards set.
32 Anonymous voting will follow discussion. A result of at least 70% ranking the standard as critically
33 important, and fewer than 15% ranking it of little importance will be required for inclusion in the
34 final standards set. There are no universally agreed consensus criteria and the criteria used here
35 follow published recommendations [18].
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46 **Ethics and Dissemination**

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49 This work, that includes a wide range of stakeholders, including patients, is performed with robust
50 methodology ensuring that the results accurately reflect the priorities of all stakeholder groups
51 and will be reported using CREDES (Guidance on Conducting and REporting DElphi Studies)
52 [19]. Publication in peer reviewed journals and dissemination through the professional
53 collaborations and associated networks should ensure international adoption of the standards.
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3 Such adoption will help to standardise future prehabilitation study design and reporting to optimise
4 the progression of prehabilitation for researchers, clinicians and patients. The University of
5 Glasgow College of Medical, Veterinary & Life Sciences Ethics Committee approved the protocol
6 on 7th July 2020 (200190120).
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10 11 **Contributors**

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14 SM, SB, and RF planned and designed the study. SD, MW, NM, PK, SRK and NF provided advice
15 and guidance. IP drafted the manuscript with all authors reviewing and subsequently approving
16 the final draft.
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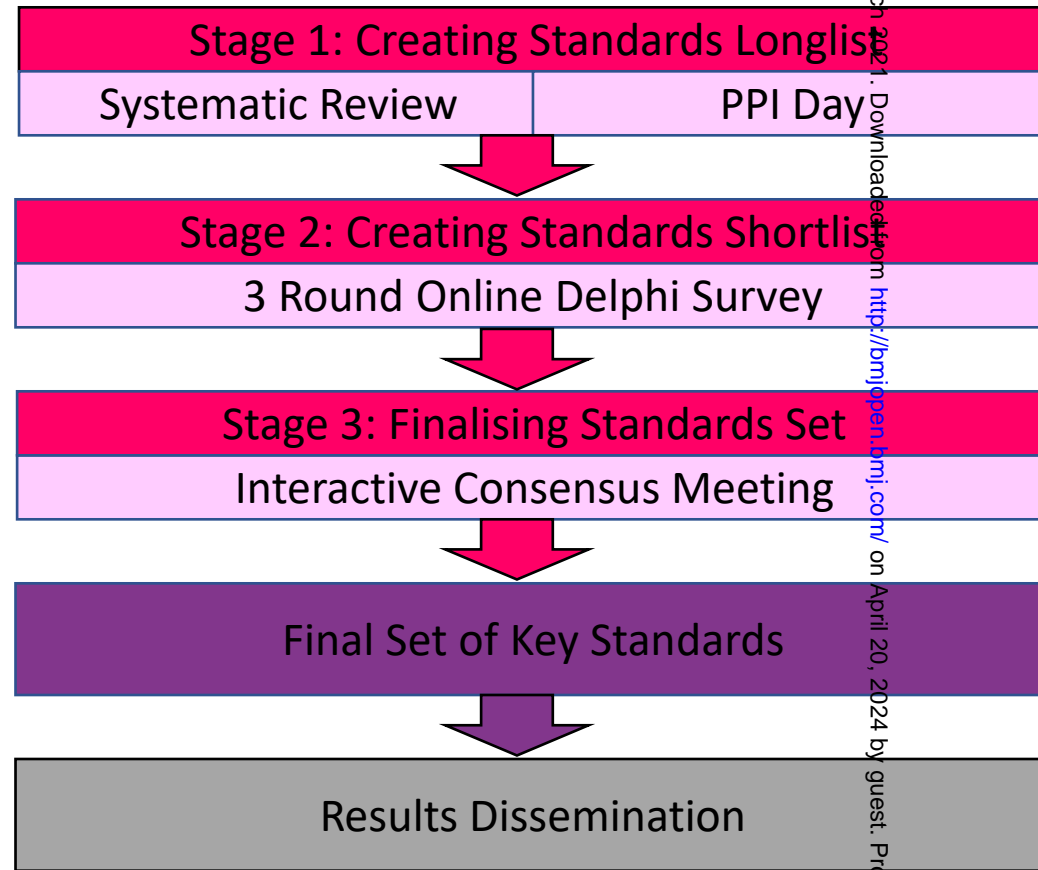
31 32 33 **Competing interests**

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36 There are no competing interests to declare.
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3 **Defining Standards in Colorectal Optimisation (DiSCO): a Delphi study protocol to**
4 **achieve international consensus on key standards for colorectal surgery**
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6 **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 colorectal patients' needs and issues are being overlooked. The DiSCO Study (Defining Standards in Colorectal Optimisation) 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 & Life Sciences Ethics Committee has approved this protocol which is registered as a study (200190120) with the Core Outcome Measures in Effectiveness Trials (COMET) 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.

Trial registration number. PROSPERO registration ID: CRD42019120381.

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.

For peer review only

Introduction

Elective colorectal surgery for benign and malignant conditions is one of the most commonly performed operations in the U.K. [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 colorectal patients' 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, albeit with variable components, implementation and results [4,5]. ERAS protocols focus on intra- and post-operative 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 colorectal patients [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 supporting: 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,

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3 including inflammatory bowel disease (IBD), pelvic floor and diverticular disease. The
4 situation is made complex by prehabilitation research spanning different specialty groups:
5 anaesthetics; surgeons; nurse specialists; exercise oncologists/ physiologists;
6 nutritionists; psychologists. Currently this lack of consensus means prehabilitation is
7 varied across the UK and beyond, preventing effective comparison and compilation of
8 results. Development and implementation of standards would encourage homogeneity of
9 data and consequently improve the quality of the evidence base to enhance colorectal
10 patients' care.
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19 To date, there have been limited efforts to involve patients in prehabilitation research. The
20 NHS advocates for patient-centred-care [10], yet often, research is clinician led and
21 carried out for patients, rather than with them [11]. In one of the recent initiatives by the
22 James Lind Alliance with the National Cancer Research Institute (NCRI), over 3500
23 cancer patients, their caregivers, and health and social care professionals were asked for
24 their key research priorities [12,13, 14]. In the final top 10 was "what specific lifestyle
25 changes help with recovery from cancer treatment, restore health, and improve quality of
26 life?". Prehabilitation research clearly addresses this, and the definition of prehabilitation
27 standards will lay important foundations to facilitate research to definitively answer this
28 question.
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38 The DiSCO (Defining Standards in Colorectal Optimisation) Study intends to achieve
39 consensus on key standards for prehabilitation before elective colorectal surgery. DiSCO
40 will involve patients and their caregivers from the start of the process to ensure that results
41 are relevant to service users as well as clinicians. A three-stage study design using multi-
42 disciplinary stakeholders will be followed: systematic review and patient and public
43 involvement (PPI) event to develop a standards longlist; standards shortlisting using three
44 rounds of online Delphi; and a face-to-face consensus meeting to define the final list of
45 standards for colorectal surgery optimisation.
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55 **Aims and Objectives**

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5 The primary aim of the DiSCO study is to achieve consensus of prehabilitation standards
6 by all stakeholders that are to be applied in future trials on prehabilitation in elective
7 colorectal surgery.
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12 To achieve this objective, four key questions will be asked:

- 13 1. What are the individual components of prehabilitation?
 - 14 2. What type of colorectal patient should be offered prehabilitation?
 - 15 3. Who should deliver prehabilitation?
 - 16 4. What outcome measures are important?
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23 **Methods and Analysis**

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

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42 DiSCO will involve adult patients and their carers/supporters, who have undergone
43 elective resection of a part of their colon or rectum for benign or malignant colorectal
44 conditions. These conditions include, but are not limited to colorectal cancer, anal cancer,
45 diverticulitis and its complications, inflammatory bowel disease, and pelvic floor
46 dysfunction. Patients will be invited through social media to allow an international
47 perspective (@DiSCO_study on Twitter and Facebook) and by patient liaison groups of
48 professional bodies and charities, including the Association of Coloproctology of Great
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3 Britain and Ireland Patient Liaison Group, and The Ileostomy and Internal Pouch Support
4 Group.
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8 *Stakeholders* 9

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11 From our systematic review and recent work published by Macmillan Cancer Support
12 [16], the study group will identify key stakeholders that have published on prehabilitation.
13 This is likely to include: colorectal surgeons; colorectal anaesthetists; colorectal nurse
14 specialists; colorectal oncologist (medical or clinical); exercise oncologists; exercise
15 physiologists; sports scientists; sports medicine specialists; physical exercise/ activity
16 specialists; nutritionists/ dieticians; psychologists; geriatricians, pharmacists, General
17 practitioners (GP). To ensure inclusivity, specialist associations related to these
18 stakeholders will be approached: American College of Sports Medicine (ACSM),
19 International Society of Behavioural, Nutrition and Physical Activity (ISBNPA), Scottish
20 Physical Activity Research Collaborative (SPARC), Macmillan, Royal College of
21 Anaesthetists (RCoA); Association of Surgeons of Great Britain and Ireland (ASGBI);
22 Association of Coloproctology of Great Britain and Ireland (ACPGBI); TriPOM (Trainees
23 with an interest in Perioperative Medicine); ERAS (Enhanced Recovery After Surgery)
24 Association.
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38 Members from each stakeholder group will be recruited to form an internationally
39 connected multi-disciplinary study team. The three co-chief investigators are: an expert
40 patient and two consultant colorectal surgeons with research interests in core outcome
41 sets and prehabilitation.
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48 *Study Design* 49

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51 The DiSCO study will follow a three-stage process [Figure 1].
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55 **Figure 1: Diagram of study design** 56 57 58 59 60

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]. The full protocol including search strategy and selection criteria is also published on the PROSPERO database [CRD42019120381].

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 colorectal patient should be offered prehabilitation?; who should deliver prehabilitation?; and 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, enhanced recovery after surgery 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.

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 (GRADE_ working group) [19]. With this scale, a score of 1 to 3 signifies the standard is of little importance, 4 to 6 some importance, and 7 to 9 critical importance. Round one 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 which are ranked of critical

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3 importance (7-9) by >70% or of little importance (1-3) by <15% of each stakeholder group
4 will be deemed to have reached the threshold for consensus for inclusion in the shortlist
5 of key standards. After round 1 of the Delphi, standards reaching the threshold of
6 consensus for inclusion will be directly added to the shortlist and not included in
7 subsequent rounds. All items not reaching this threshold will be taken forward to round 2.
8 The same criteria will be used after round 2 to select items to take forward into round 3.
9 After round 3 any additional items reaching the threshold for consensus for inclusion will
10 be added to the shortlist. Any items which are ranked of critical importance (7-9) by <50%
11 of each stakeholder group, or of little importance (1-3) by >50% of each stakeholder group
12 after round 3 will be excluded from the final shortlist. Standards that do not meet the
13 criteria for inclusion or exclusion will be considered borderline. The final shortlist and
14 borderline items will be taken forward for discussion at the final consensus meeting.

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

47 48 **Stage 3: Finalising standards set**

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

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34 This work, that includes a wide range of stakeholders, including patients, is performed
35 with robust methodology ensuring that the results accurately reflect the priorities of all
36 stakeholder groups and will be reported using CREDES (Guidance on Conducting and
37 REporting DElphi Studies) [21]. Publication in peer reviewed journals and dissemination
38 through the professional collaborations and associated networks should ensure
39 international adoption of the standards. Such adoption will help to standardise future
40 prehabilitation study design and reporting to optimise the progression of prehabilitation
41 for researchers, clinicians and patients. The University of Glasgow College of Medical,
42 Veterinary & Life Sciences Ethics Committee approved the protocol on 7th July 2020
43 (200190120).
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53 **Contributors**

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3 SM, SB, and RF planned and designed the study. SD, MW, NM, PK, SRK and NF
4 provided advice and guidance. IP drafted the manuscript with all authors reviewing and
5 subsequently approving the final draft.
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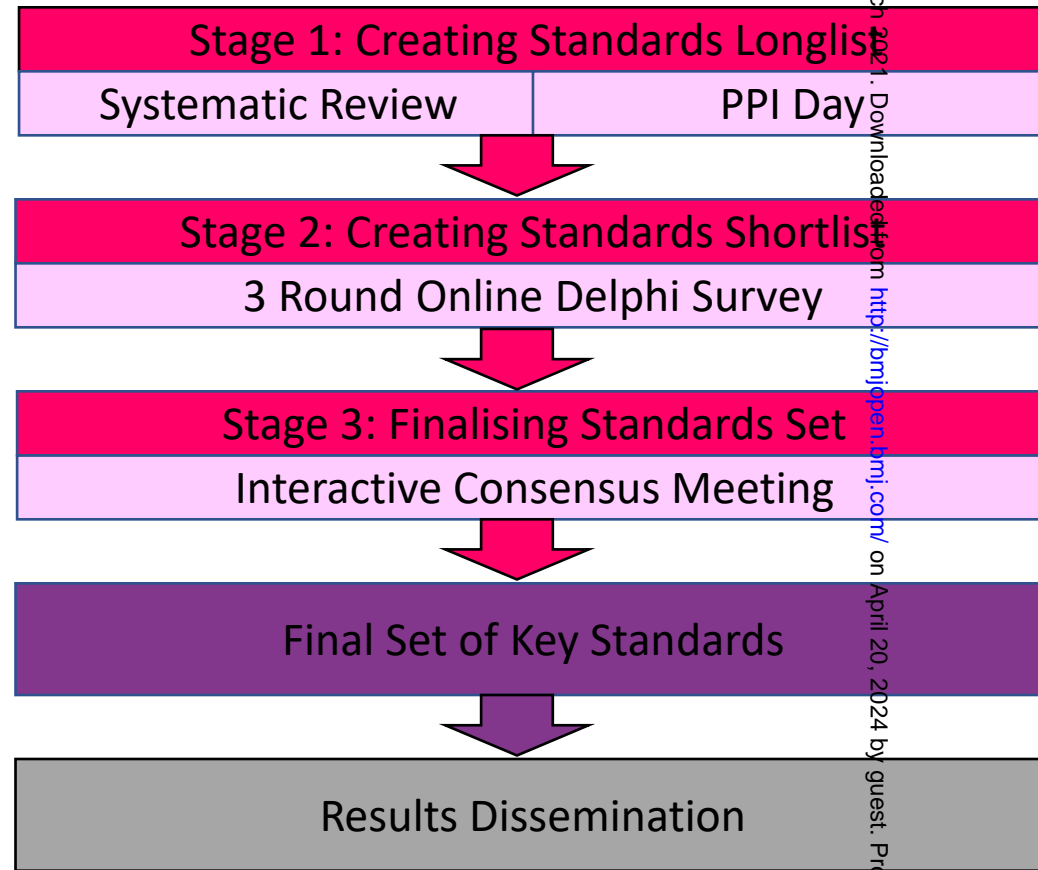
23 **Competing interests**

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25 There are no competing interests to declare.
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