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Improving patient information about recovery after bowel surgery

Submission date 02/10/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 10/10/2023	**Overall study status** Ongoing	
Last Edited 10/04/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Bowel cancer is the fourth most common cancer in the UK. Many patients with bowel cancer have an operation, followed by several months of recovery. There is guidance about eating and moving around after an operation but most hospitals give patients poor-quality information about their recovery, which is not accessible, engaging, or supportive. If people understand the recovery process and are more actively engaged in their own recovery, they may have a better and faster return to their everyday lives.
Recover Together is an information package (comprising a booklet, video and goal board) to support patients recovering from bowel surgery. The booklet and video give information about preparing for the operation, and recovering in hospital and at home. The goal board sits at the end of the patient's hospital bed and is used to set daily goals for their inpatient recovery. These were developed by patients, clinicians and information design experts and are based on existing guidelines for recovery after bowel surgery. They are not currently used in the NHS.
This is a small study (called a feasibility study) which aims to find out whether it is worthwhile running a large trial to see how helpful the new Recover Together booklet, video and goal board are.

Who can participate?
Any patient aged 18 years or over who is due to have an operation for bowel cancer

What does the study involve?
Patients will be given the booklet and a link to the video before their operation. They will be asked to complete some questionnaires about their care, and how useful the booklet was. Some patients and staff will also be asked to give feedback in interviews with a researcher, and the researcher will visit hospital wards to see how the goal boards are used. The findings will help improve the Recover Together information, and tell us whether a large trial is worthwhile.

What are the possible benefits and risks of participating?
There are no serious anticipated risks of taking part in the study. Whilst the researchers cannot be certain about the benefit of the information resources right now, this work will may benefit those taking part and in the future.

Where is the study run from?
University of Leeds (UK)

When is the study starting and how long is it expected to run for?
October 2022 to July 2025

Who is funding the study?
National Institute for Health and Care Research (UK)

Who is the main contact?
Dr Steve Chapman, s.chapman@leeds.ac.uk

Contact information

Type(s)
Principal Investigator

Contact name
Dr Stephen Chapman

ORCID ID
http://orcid.org/0000-0003-2413-5690

Contact details
Clinical Sciences Building
St James's University Hospital
Leeds
United Kingdom
LS9 7TF
-
s.chapman@leeds.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
325201

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 58103, IRAS 325201

Study information

Scientific Title

Improving recovery after bowel cancer surgery: Mixed-method feasibility study of a co-produced information intervention (Recover Together)

Acronym
Recover Together

Study objectives
Feasibility hypothesis 1: The Recover Together intervention can be feasibly delivered in NHS practice
Feasibility hypothesis 2: A definitive study of the Recover Together intervention can be feasibly delivered in the future

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/08/2023, West of Scotland Research Ethics Service (Ground Floor Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 3140212; WoSREC3@ggc.scot.nhs.uk), ref: 23/WS/0136

Study design
Interventional non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Colorectal surgery

Interventions
Recover Together intervention comprising of:
1. Recover Together booklet
2. Recover Together video
3. Recover Together goal board

The total duration of the intervention is 3 months.

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
Intervention feasibility measures:
1. Time taken for intervention set up across participating sites measured according to time from HRA approval to first enrolment
2. Compliance with core processes per resource measured according to the proportion of core processes satisfied per resource
3. Compliance with all core processes per participant measured according to the proportion of all core processes satisfied

Study method feasibility measures:
1. Return rate per measurement instrument measured according to the rate of return per instrument
2. Return rate of all instruments per participant measured according to the overall rate of return per participant
3. Rate of missing cost/resource utilisation data measured according to the rate of missing data points

All of the feasibility endpoints are measured once at the end of the study

Secondary outcome measures
Clinical instrument measures:
1. Patient satisfaction measured using the Bauer Patient Satisfaction Questionnaire on Day 1 after surgery
2. Patient well-being measured using the Quality of Recover-15 survey at baseline and on Day 3 after surgery
3. Health-related quality of life measured using the EQ-5D-5L at baseline, Day 30, and 6 months after surgery
4. Functional status measured using the WHO Disability Assessment Schedule 2.0 at baseline and 6 months after surgery
5. Resource use using a bespoke resource-use questionnaire measured at baseline and 6 months after surgery

Overall study start date
01/10/2022

Completion date
31/07/2025

Eligibility

Key inclusion criteria
To be eligible for the study, patients must satisfy all of the following inclusion criteria:
1. Aged >= 18 years
2. Able to provide written informed consent
3. Planned to undergo elective colorectal surgery (with or without a stoma)
4. Indication for surgery is for suspected or confirmed colorectal cancer

For the staff interviews, we will include staff who have experience of introducing the video and booklet in outpatient clinics, and/or delivering the goal board on the ward, as well as staff who have trained other staff in how to deliver the intervention.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 105; UK Sample Size: 105

Key exclusion criteria
No further exclusion criteria will apply although participants will be required to understand either English or Urdu language. There will be no exclusions based on literacy or disability.

Date of first enrolment
01/11/2023

Date of final enrolment
01/11/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St James University Hospital
Gledow Wing
Beckett Street
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
University of Leeds

Sponsor details
Woodhouse Lane
Leeds
England
United Kingdom
LS2 9JT
+44 (0)113 3437587
governance-ethics@leeds.ac.uk

Sponsor type
Hospital/treatment centre

Website
http://www.leeds.ac.uk/

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study will be published in a peer-reviewed journal approximately 12 years after the final study end date. It will also be disseminated at professional conferences and through networks of doctors, nurses, surgeons, and patients.

Intention to publish date
01/04/2026

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request and following consideration of a statistical analysis plan. These requests should be sent to the main contact (Dr Steve Chapman; s.chapman@leeds.ac.uk). If approved, data will be provided in anonymised form.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		04/11/2024	06/11/2024	Yes	No