

Improving patient information about recovery after bowel surgery

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| Submission date 02/10/2023 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 10/10/2023 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 10/04/2025 | Condition category Cancer | <input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year |

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

<https://orcid.org/0000-0003-2413-5690>

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

325201

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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 \geq 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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**

United Kingdom

England

Study participating centre

St James University Hospital

Gledow Wing

Beckett Street

Leeds

United Kingdom

LS9 7TF

Sponsor information**Organisation**

University of Leeds

ROR

<https://ror.org/024mrx33>

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

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 |