

# Yorkshire Cancer Research Bowel Cancer Improvement Program

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<b>Registration date</b> 31/01/2019	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/09/2024	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Bowel cancer affects 3,300 people a year within Yorkshire and the Humber. Over the next five years over 6,000 people in Yorkshire and the Humber will die of bowel cancer. This study wants to greatly reduce this number, decrease the number of deaths and improve the patients' experience of their care. The management of bowel cancer and outcomes for patients across Yorkshire and the Humber differs. This study wants to understand why there is a difference and then improve outcomes by addressing these issues. The study will use data collected during the diagnosis and treatment of patients with bowel cancer in the NHS. This data has been linked together by the National Cancer Registration and Analysis Service (NCRAS) and provides basic information about bowel cancer care across the region. This study will improve this information by consenting patients and collecting new data via patient reported outcome measures (PROMS) and will also collect additional data from radiology and pathology to improve the data that is held. The study team will analyse this data to find areas that can be improved and work with the clinical teams to provide educational events and improvements. The study team will assess the differences made to the care and outcome of bowel cancer patients across the region. The overall aim of this programme of work is to work out how much bowel cancer outcomes can be improved by working with bowel cancer multidisciplinary teams (MDTs), collecting and feeding back to them high quality information and providing training and supervision for specialists where a need is found.

### The primary aims of the study are:

1. To develop high quality cancer information to evaluate the outcomes for patients with bowel cancer across Yorkshire and the Humber
2. To describe the quality of life of newly diagnosed bowel cancer patients close to the time of diagnosis. This will provide a starting point to measure differences in quality of life across Yorkshire and Humber.
3. To explore the issues that may be able to predict the quality of life of patients 12 months after diagnosis.
4. To collect tissue for testing to show whether certain chemotherapy drugs can be used to improve outcomes.

5. To support the introduction of NICE recommended Lynch testing in the region. Lynch Syndrome is an inherited disorder that increases the risk of many types of cancer, particularly bowel cancer.

**Who can participate?**

Patients over the age of 18 with bowel cancer who live in the Yorkshire and Humber region of the UK and who are treated at one of the 14 participating hospital trusts

**What does the study involve?**

The study involves asking patients to agree to complete two questionnaires; one shortly after diagnosis but before they have had their first treatment, and the second questionnaire 12 months after their diagnosis. These questionnaires can be completed online or on paper. The study also asks for agreement for some of the tissue that has been removed during the patient's surgery for bowel cancer to be sent to the University of Leeds study teams so that additional tests can be performed on the tissue.

**What are the possible benefits and risks of participating?**

For most of the participants there will be no obvious benefit for participating in the study. However, some of the tissue testing may identify information that could be used to discover where some treatments will be most effective and benefit future patients. Some participating patients may directly benefit from the project by being referred to a clinical trial, giving them the chance to receive treatments which are not usually available. The research team know that some of the questions included in the questionnaires included sensitive issues about sex, bladder and bowel function as well as the financial impact of cancer. All of the questions are optional so patients do not have to answer questions that make them uncomfortable.

**Where is the study run from?**

The study is run from the University of Leeds and the lead NHS site is Leeds Teaching Hospital NHS Trust. There are 14 hospital trusts participating in the study, all of which are based in the Yorkshire and Humber region of the UK.

**When is the study starting and how long is it expected to run for?**

April 2016 to December 2026

**Who is funding the study?**

Yorkshire Cancer Research (UK)

**Who is the main contact?**

Hannah Rossington

H.L.Rossington@leeds.ac.uk

**Study website**

[www.ycrbcip.leeds.ac.uk](http://www.ycrbcip.leeds.ac.uk)

## Contact information

**Type(s)**

Public

**Contact name**

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**Type(s)**

Scientific

**Contact name**

Prof Phil Quirke

**ORCID ID**

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**Contact details**

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**Additional identifiers**

EudraCT/CTIS number

IRAS number

227673

ClinicalTrials.gov number

Secondary identifying numbers

CPMS 35830, IRAS 227673

**Study information****Scientific Title**

Does intensive multidisciplinary team intervention improve bowel cancer outcomes in Yorkshire?  
The Yorkshire Cancer Research Bowel Cancer Improvement Programme (YCR BCIP)

## **Acronym**

YCRBCIP

## **Study objectives**

This study hypothesises that there is variation in the management of, and outcomes from bowel cancer in Yorkshire and the Humber region and that in some areas reduction in this variation may benefit patients. It is proposed that quantifying the variation and working with bowel cancer multidisciplinary teams to identify key areas for change will lead to significant gains for patients and their clinical teams.

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

Approved 12/12/2018, West Midlands – Solihull Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 207 104 8269; solihull.rec@hra.nhs.uk), ref: 17 /WM/0374

## **Study design**

Observational; Design type: Cohort study

## **Primary study design**

Observational

## **Secondary study design**

Cohort 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 cancer

## **Interventions**

This study has two key elements; an observational, population-based study (data work stream) and a prospective cohort study (for the tissue and patient reported outcome measures (PROMS)).

The data work stream of the study is an observational population-based study. This means that the study team will follow the complete patient pathways from diagnosis to treatment for patients diagnosed with bowel cancer. The population included in this study are people who live within the Yorkshire and Humber region and who have been diagnosed and treated by one of 16

bowel cancer multi-disciplinary teams based in the region. A dataset will be developed using existing data routinely collected by the NHS during the diagnosis and management of patients with bowel cancer.

The data will provide diagnostic, staging and treatment information in addition to basic information such as age, gender and deprivation. These datasets are all routinely linked within the secure environment of Public Health England National Cancer Registration and Analysis Service (NCRAS) who already have approval to work with patient identifiable data. The study will use extracts of this data that cover the population of Yorkshire and the Humber. The Health Service (Control of Patient Information) Regulations have specific provisions for Confidential Patient Information to be disclosed, without patient consent, for defined medical purposes, including the specific support offered (under Regulation 2) to cancer registration. The National Cancer Registration and Analysis Service has Regulation 2 support and this is reviewed annually by the Health Research Authority Confidentiality Advisory Group (Reference: PIAG 03(a)/2001).

Additional data from participants in the PROMS and Tissue parts of the study will be linked to these routine datasets within the secure environment of NCRAS. The data collected from the tissue and PROMS parts of the study will be stored within a secure electronic environment within the University Leeds. All data will be stored under the participants specific study identifier to maintain confidentiality of the data. This anonymised form of the data will be securely electronically transferred to NCRAS via the arrangements specified in the System Level Security Policy. Identified individuals within NCRAS will be given specific authorisation to the study "link table" this will enable them to perform the necessary linkages to the existing datasets. The data linkage will take place within the secure Public Health England within NCRAS.

The research team has taken steps to ensure patient confidentiality of the data is maintained. Before the dataset is released to the research team at the University of Leeds all patient identifiers (such as NHS number, name and date of birth) will be removed. As the analysis team will not have access to hospital systems it will not be possible to identify individual patients within this integrated dataset. The study team have also obtained consent of the bowel cancer clinical teams to use this data to support audit and service evaluation as part of this programme.

The baseline data and subsequent data analyses will be presented to the multidisciplinary teams. This will be used to identify areas of weakness that are appropriate educational interventions. The interventions will take place in years 2, 3, 4 of the study and will usually be study days for the region focused on a specific aspect of care e.g. risk-stratification and optimisation for major surgery. The aim of these interventions will be to develop regional consensus and quality improvements within the NHS hospital trusts across the Yorkshire and Humber region.

The PROMS and tissue aspects of the study will include patients diagnosed who live in Yorkshire and the Humber who have been diagnosed and treated by one of the 16 participating bowel cancer MDTs. Once it has opened, patient who meet the eligibility criteria will be asked whether they would consent to be involved in the study.

Participants will be asked to complete a PROMs questionnaire at two timepoints; before their treatment for bowel cancer and at 12 months following their diagnosis. Participants will also have tissue samples of their cancer, which are surplus to diagnosis, tested for novel biomarkers that may influence future treatments and selection for clinical trials. Any clinically significant results will be passed back to their local clinical team for discussion with the participant.

The study will also undertake where necessary free of charge the testing of patients for Lynch syndrome until it is routinely introduced across Yorkshire and the Humber. Lynch Syndrome is an inherited disorder that increases the risk of many types of cancer, particularly bowel cancer. The NICE guidelines issues in February 2017 recommended that all patients diagnosed with bowel cancer should be offered testing when they are first diagnosed, using immunohistochemistry and this would guide further testing for Lynch syndrome. There are not currently arrangements for testing all bowel cancer patients in Yorkshire and the Humber. To encourage early adoption of the NICE guidance the research team has offered free of charge testing for all patients who are diagnosed and managed by one of the 14 hospital trusts participating in the study for twelve months to allow commissioners time to develop commissioning plans to embed this testing into standard commissioned pathways. The results from the immunohistochemistry tests will be passed back to the patient's clinical teams for discussion with the patient and if appropriate onward referral to NHS genetics services. As this is a NICE recommended pathway and should form part of standard care for bowel cancer patients it, therefore, does not require specific consent as part of this research study. The details of the immunohistochemistry testing for mismatch repair proteins is not included in the consent processes for this study.

## **Intervention Type**

Other

## **Primary outcome measure**

Bowel cancer survival across Yorkshire and Humber in context of treatment and socio-demographics, assessed using datasets from the Public Health England National Cancer Registration and Analysis Service (NCRAS) covering 2014-2021.

## **Secondary outcome measures**

Quality of life, measured using standardised and tested questionnaires including EORTC, EQ-5D-5L, Social Difficulties Inventory, The Short Warwick-Edinburgh Mental Well-being Scale, Self Efficacy for Managing Chronic Disease scale, The Brief Illness Perceptions Questionnaire measured at diagnosis and 12-months following diagnosis.

## **Overall study start date**

01/04/2016

## **Completion date**

30/12/2026

# **Eligibility**

## **Key inclusion criteria**

For the observational, population-based aspects of the study:

1. A diagnosis of bowel cancer (ICD 10 code C18, 19 or C20)
2. Resident in the Yorkshire and Humber region and managed by one of the sixteen bowel cancer MDTs who are participating in the study.

For prospective cohort aspects of the study:

1. A diagnosis of bowel cancer (ICD 10 code C18, 19 or C20)
2. Close to the time of diagnosis and before primary treatment commences (unless the individual presents urgently and undergoes an emergency resection)

3. Considered suitable for treatment

4. English literate

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 2000; UK Sample Size: 2000

**Key exclusion criteria**

1. Patients under 18 years of age
2. Patients with a diagnosis of anal cancer (ICD-10 code C21)
3. Patients who are not-resident within Yorkshire and the Humber study region and who have not been diagnosed and managed by one of the sixteen bowel cancer MDTs who participating in the study
4. In addition for the prospective cohort aspects will exclude patient who lacks the capacity to give informed consent (this may be due, for example, to psychopathology, cognitive dysfunction or learning difficulties)

**Date of first enrolment**

31/03/2018

**Date of final enrolment**

30/12/2025

**Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Airedale General Hospital**

Skipton Road

Steeton

Keighley

United Kingdom

BD20 6TD

**Study participating centre**  
**Bradford Royal Infirmary**  
Duckworth Lane  
Bradford  
United Kingdom  
BD9 6RJ

**Study participating centre**  
**Calderdale Royal Hospital**  
Salterhebble  
Halifax  
United Kingdom  
HX3 0PW

**Study participating centre**  
**Huddersfield Royal Infirmary**  
Acre Street  
Lindley  
United Kingdom  
HD3 3EA

**Study participating centre**  
**Chesterfield Royal Hospital**  
Calow  
Chesterfield  
United Kingdom  
S44 5BL

**Study participating centre**  
**Doncaster Royal Infirmary**  
Armthorpe Road  
Doncaster  
United Kingdom  
DN2 5LT

**Study participating centre**  
**Harrogate District Hospital**  
Lancaster Park Road  
Harrogate



United Kingdom  
HG2 7SX

**Study participating centre**

**Rotherham Hospital**

Morrgate Road  
Rotherham  
United Kingdom  
S60 2UD

**Study participating centre**

**St James's University Hospital**

Beckett Street  
Leeds  
United Kingdom  
LS9 7TF

**Study participating centre**

**Scarborough Hospital**

Woodlands Drive  
Scarborough  
United Kingdom  
YO12 6QL

**Study participating centre**

**York Hospital**

Wigginton Road  
York  
United Kingdom  
YO31 8HE

## **Sponsor information**

**Organisation**

University of Leeds

**Sponsor details**

c/o Clare Skinner  
Faculty Research Office

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**Sponsor type**

University/education

**ROR**

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

## Funder(s)

**Funder type**

Charity

**Funder Name**

Yorkshire Cancer Research; Grant Codes: L394

**Alternative Name(s)**

YCR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Current publication and dissemination plan as of 09/09/2024:

Baseline results PROMs aspect of the study to be published in 2025

Full study results to be published in 2027

Previous publication and dissemination plan as of 14/09/2023:

Planned publication of baseline results by 2024. Planned publication of the full study in 2026 in a high-impact peer-reviewed journal.

Previous publication and dissemination plan as of 30/10/2020:  
Planned publication of baseline results by 2022. Planned publication of the full study in 2025 in a high-impact peer-reviewed journal.

Previous publication and dissemination plan:  
Planned publication in a high-impact peer-reviewed journal.

**Intention to publish date**  
30/12/2027

**Individual participant data (IPD) sharing plan**  
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Philip Quirke (P.Quirke@leeds.ac.uk). Data will be available for sharing after primary outputs have been presented and published (after 2026). The type of data/ types of analyses will be reviewed by the project steering group before release of data. Consent has been obtained from participants during the consent process to anonymous data being shared with other researchers. Only anonymised data will be available for sharing with all patient identifiers removed (this includes NHS number, dates of birth/death and postcode).

**IPD sharing plan summary**  
Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	26/11/2019	16/09/2020	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No