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# Measuring patient preferences for the treatment of rectal cancer

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| **Submission date**<br>02/10/2020 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>30/10/2020 | **Overall study status**<br>Completed | |
| **Last Edited**<br>12/06/2023 | **Condition category**<br>Cancer | |

## Plain English summary of protocol

Background and study aims
In the UK, there are over 16,000 new cases of rectal cancer per year. Treatment includes chemotherapy and radiotherapy, followed by major surgery, especially in those patients deemed as 'high-risk'. There are risks of surgical complications, long-term side-effects, and about a third of patients require a permanent colostomy (a 'bag').

In the past 5-8 years, researchers have found that rectal tumours may totally disappear after chemo-radiotherapy in 25% patients (known as a clinical complete response), avoiding the need for surgery. This is a new type of rectal cancer management known as 'organ preservation'. Instead of surgery, patients are actively monitored, 'watch-and-wait', to ensure tumours have not returned.

Initially, doctors were nervous that not giving patients surgery might compromise long-term survival. However, one of the largest studies in the world addressing this question and based in NW England (the OnCoRe project; lead: Renehan), showed that this approach is safe. There is a common perception among cancer doctors that organ preservation is a good thing, but there is little research addressing patient preferences. Specifically, no research has investigated how people balance the characteristics of these treatments and make decisions.
There are no decision aids for this complex treatment; yet it is known that decision aids have a positive effect on patient-clinician communication and enhance quality of patient decision-making.

Study aims:
1. To understand the factors taken into account by patients when making a decision on rectal cancer treatments
2. To develop an electronic patient decision aid based on these factors, which will be able to directly benefit patients facing this decision within the next few years.

Who can participate?
The online survey will be open to both people with a previous diagnosis of rectal cancer and members of the general public.

What does the study involve?
The completion of a survey which is expected to take around 20 minutes. In this survey, participants will first be shown information on different types of treatment options available for rectal cancer. Participants will then be asked some questions about their preferences for the treatment of rectal cancer. Following this, there will be some questions about how health information is used to make decisions and participants views about treating rectal cancer. Finally, optional questions will be asked regarding the participant.

What are the possible benefits and risks of participating?
There is a small risk that participants may find reading about cancer distressing. Links to further information about rectal cancer will be included in the survey. There are no direct benefits to participants for participating in the study, but we hope to use the information gathered from this study to improve the care received by rectal cancer patients within the National Health Service (NHS).

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

When is the study starting and how long is it expected to run for?
March 2020 to July 2023

Who is funding the study?
National Institute for Health Research (NIHR)

Who is the main contact?
Mr Lee Malcomson, lee.malcomson@manchester.ac.uk
Prof. Andrew Renehan, andrew.renehan@manchester.ac.uk

# Contact information

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Scientific

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Public

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# Additional identifiers

**National Institute for Health and Care Research (NIHR)**
200500

# Study information

**Scientific Title**
Quantifying and implementing patient preferences for the treatment of high-risk rectal cancer, including the new strategy of organ preservation: The PrefCoRe Study

**Acronym**
PrefCoRe

**Study objectives**
This study is taking place to investigate and understand factors taken into account by patients (current & future) when making a key decision on rectal cancer treatment. Specifically, patients who have a complete clinical response to (chemo)radiotherapy and have the choice of either major resection surgery or a watch & wait (active surveillance) pathway. In addition, we aim to develop an user-friendly patient decision aid informed by these factors and conduct preliminary tests of the tool to understand its acceptability.

**Ethics approval required**
Old ethics approval format

**Ethics approval(s)**
Approval pending. The application is currently in progress and is to be submitted for review by the University of Manchester Ethics Board by 09/10/2020

**Primary study design**
Observational

**Study design**
Observational

### Study type(s)
Quality of life

### Health condition(s) or problem(s) studied
Rectal cancer

### Interventions
An online survey comprising a discrete choice experiment (DCE) will be designed to elicit preferences of a sample of patients and members of the public for the treatment of high-risk rectal cancer. The DCE will ask respondents to choose between three labelled alternatives: watch-and-wait, surgery and wait-and-see (no surgery or follow-up visits). The experimental design of the DCE will be informed using Ngene. The online survey will consist of a consent form, followed by an animated narrative storyline (that will be produced in collaboration with SciAni), the choice sets, questions about respondents' personal views on decision-making in healthcare, questions regarding their attitude towards risk, their current health status, socio-demographic questions about themselves and questions to gauge their understanding of probabilities.

### Intervention Type
Procedure/Surgery

### Primary outcome(s)
Participant treatment preference recorded during the DCE at a single timepoint

### Key secondary outcome(s)
Usability score recorded for the designed Dynamic Computer Interactive Decision Application (DCIDA) measured using the System Usability Scale (SUS) at a single timepoint immediately after the intervention

### Completion date
01/07/2023

## Eligibility

### Key inclusion criteria
1. Age 18+ years
2. Previous diagnosis of rectal cancer (for ~50% of participants)
3. Able to complete and submit an online DCE

### Participant type(s)
All

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

**Sex**
All

**Key exclusion criteria**
Does not meet inclusion criteria

**Date of first enrolment**
04/11/2020

**Date of final enrolment**
30/06/2023

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**The University of Manchester**
Oxford Rd
Manchester
United Kingdom
M13 9PL

# Sponsor information

**Organisation**
University of Manchester

**ROR**
https://ror.org/027m9bs27

# Funder(s)

**Funder type**
Government

**Funder Name**
National Institute for Health Research (RfPB Award, ref NIHR200500)

### 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 current data sharing plans for this study are unknown and will be available at a later date

### IPD sharing plan summary
Data sharing statement to be made available at a later date

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Protocol file | version 1 | 16/03/2022 | 12/06/2023 | No | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |