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Measuring patient preferences for the treatment of rectal cancer

Submission date 02/10/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/10/2020	**Overall study status** Completed	
Last Edited 12/06/2023	**Condition category** 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
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Study website
https://complete-response.com/prefcore/

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIHR200500

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

Study design
Observational

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Internet/virtual

Study type(s)
Quality of life

Participant information sheet
https://completeresponse.files.wordpress.com/2020/10/full-pis-prefcore_bowel-cancer-uk-2.docx

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 measure
Participant treatment preference recorded during the DCE at a single timepoint

Secondary outcome measures
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

Overall study start date

02/03/2020

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
600

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
England

United Kingdom

Study participating centre
The University of Manchester
Oxford Rd

Manchester
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Sponsor information

Organisation
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Sponsor type
University/education

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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

Publication and dissemination plan
In addition to the published Dynamic Computer Interactive Decision Application (DCIDA), we are aiming for publication in high-impact, peer-reviewed journals once the results are available.

Intention to publish date
01/03/2022

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?
Protocol file	version 1	16/03/2022	12/06/2023	No	No