

# A bowel management intervention for individuals following rectal cancer treatment: assessing feasibility, acceptability and potential effectiveness

<b>Submission date</b> 24/05/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/05/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 29/03/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-study-looking-at-way-of-helping-people-cope-with-bowel-problems-after-treatment-for-rectal-cancer>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

9931

## **Study information**

### **Scientific Title**

A bowel management intervention for individuals following rectal cancer treatment: assessing feasibility, acceptability and potential effectiveness

### **Study objectives**

A bowel management intervention will be tested upon a cohort of up to 40 patients who have been diagnosed with curative rectal cancer and will be treated by sphincter-saving surgery +/- other cancer treatments. The intervention will have two parts: the first is the delivery of written information and appropriate contact numbers/web-sites and the second is a specific bowel intervention for those with change in bowel habit which consists of one face-to-face appointment and two telephone follow-up calls. Bowel function and quality of life measures will be administered to the sample pre and post these interventions which are orientated to their treatment schedule: pre-treatment, 6 weeks, five months and ten months post-treatment.

Evaluation will be through use of both quantitative and qualitative outcomes including the ICIQ-B Bowel Assessment Instrument (Cotterill et al, 2008), Quality of Life Short Form SF36 and the My Caw tool. There will also be qualitative interviews with members of the cohort who are willing to participate in this additional evaluative feature of the study and a survey of healthcare professionals involved in the follow up care of rectal cancer patients. Assessment of process and other study effects will also be made.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

First Medical Ethics Research Committee Ref: 10/H0709/65; approval date 02/11/2010

### **Study design**

Non-randomised, interventional

### **Primary study design**

Interventional

### **Secondary study design**

Non randomised study

### **Study setting(s)**

Hospital

### **Study type(s)**

Quality of life

### **Participant information sheet**

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

### **Health condition(s) or problem(s) studied**

Colorectal cancer

### **Interventions**

1. Bowel management - the planned intervention is based on the current method of Biofeedback therapy offered at St Mark's for patients referred with bowel symptoms of urgency and incontinence
2. It will be given by the researcher with support from the Biofeedback team
3. To ensure all patients receive consistent pre-operative care, they will all be offered relevant written information about their treatments prior to treatment
4. This information provides necessary preparation for what to expect following treatment
5. Follow Up Length: 10 months
6. Study Entry: Registration only

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

ICIQ-B; Timepoint(s): pre treatment, 6 weeks post treatment, 5 months, 10 months

### **Secondary outcome measures**

1. Bowel assessment and QOL
2. Timepoint(s): 1) the ICIQ-B Bowel Assessment Instrument (Cotterill et al, 2008)
3. Quality of Life Short Form (SF)

### **Overall study start date**

02/03/2011

### **Completion date**

30/03/2012

## **Eligibility**

### **Key inclusion criteria**

1. Diagnosis of curative rectal cancer
2. Consents to sphincter saving surgery
3. Over 18
4. Able to speak and read English
5. Patients having pre-op radiotherapy (RT) will be included which may be a short or long course of treatment. Occasionally the RT will be so effective that surgery will not be required can still be included.
6. Patients may also have post-operative radiotherapy and chemotherapy treatments
7. Male & Female
8. Lower Age Limit 18 years

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

UK Sample Size: 40

**Total final enrolment**

28

**Key exclusion criteria**

1. Unable to articulate their diagnosis of cancer due to denial, confusion, learning disability
2. Local excision surgery
3. Surgery involving formation of permanent stoma
4. Under 18
5. Unable to read study measures and/or has a level of spoken English which requires a translator.
6. Patients who do not want to participate in the intervention

**Date of first enrolment**

02/03/2011

**Date of final enrolment**

30/03/2012

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

Florence Nightingale School of Nursing and Midwifery

London

United Kingdom

SE1 8WA

**Sponsor information**

**Organisation**

North London Cancer Research Network (UK)

**Sponsor details**

Stephenson House  
158-160 North Gower Street  
London  
United Kingdom  
NW1 2ND

**Sponsor type**

Research organisation

**Website**

<http://www.nlcn.nhs.uk/>

**Funder(s)****Funder type**

Research organisation

**Funder Name**

National Cancer Survivorship Initiative (UK)

**Results and Publications****Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan**

Not provided at time of registration

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Plain English results</a>		20/05/2016	29/03/2022	No	Yes