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

Submission date
24/05/2011

Recruitment status
No longer recruiting

Registration date
24/05/2011

Overall study status
Completed

Last Edited
29/03/2022

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Non-randomised, interventional

Study type(s)
Quality of life

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

Key secondary outcome(s)
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)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United Kingdom

England

Study participating centre
Florence Nightingale School of Nursing and Midwifery
London
United Kingdom
SE1 8WA

Sponsor information

Organisation
North London Cancer Research Network (UK)

Funder(s)

Funder type
Research organisation

Funder Name

Results and Publications

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?
Plain English results		20/05/2016	29/03/2022	No	Yes