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The development and evaluation of an individualised information package for patients with rectal cancer

Submission date 22/11/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/01/2009	**Overall study status** Completed	
Last Edited 27/11/2015	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The development and evaluation of an individualised information package for patients with rectal cancer: a randomised controlled trial

Study objectives
Does a tailored information package for people with rectal cancer affect anxiety, length of consultation and number of follow-up consultations with the Stoma Care Nurse Specialist (SCNS)? Does a tailored information package help to prepare patients for survivorship following a diagnosis of rectal cancer?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office for Research Ethics Committees in Northern Ireland (ORECNI), approved on 09/07/2008 (ref: 08/NIR01/36)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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
Cancer of the rectum

Interventions
The intervention group will receive a series of leaflets from the newly designed information pack depending on their condition, treatment plan and choice of information. To assist people with literacy difficulties and to ensure that the leaflets' content is understood the SCNS will go through a "guided tour" of the information leaflets with each patient in the intervention group.

The intervention group will also receive the usual care that they would receive at any appointment with the Nurse Specialist. The nurse will discuss their condition, treatment options and concerns. The patients will also have an opportunity to ask questions. The control group will

receive usual care and will receive the generic colorectal cancer leaflets currently used in usual care. The length of the consultations for both the intervention and control groups will be recorded.

The total duration of the study and follow-up is approximately seven months with data collection at time 1 (at diagnosis) time 2 (just before discharge from hospital after surgery) and time 3 (six months after time 2).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Satisfaction with information, assessed using Patient Satisfaction with Cancer Treatment Education (PS-Ca-TE) at T1, T2 and T3
2. Anxiety will be measured using the Hospital Anxiety and Depression Scale at T1, T2 and T3
3. Health behavioural style, assessed by the Monitor-Blunter style scale at T1 only
4. Preparation for Survivorship will be measured using Reintegration to Normal Living Index at T1, T2 and T3

Length of consultation with the Stoma Care Nurse Specialist and number of follow-up appointments with the Stoma Care Nurse Specialist will be recorded by the Stoma Care Nurse Specialist for the duration of the study for each participant.

Timepoints for data collection:
T1: At diagnosis
T2: Just before discharge from hospital after surgery
T3: Six months after T2

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/12/2008

Completion date
31/08/2010

Eligibility

Key inclusion criteria
1. Both males and females, no age limits
2. Patients with a new diagnosis of rectal cancer

Participant type(s)
Patient

Age group

Other

Sex
Both

Target number of participants
94

Key exclusion criteria
Patients at an advanced stage of illness who are under the care of the palliative care team or who are considered to have a prognosis of less than six months.

Date of first enrolment
01/12/2008

Date of final enrolment
31/08/2010

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Altnagelvin Hospital
Londonderry
United Kingdom
BT47 6SB

Sponsor information

Organisation
Western Health and Social Care Trust (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.westerntrust.hscni.net/

ROR
https://ror.org/00sb42p15

Funder(s)

Funder type
Government

Funder Name
Northern Ireland Health and Social Services Central Services Agency, R&D Office (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2014		Yes	No