Investigating the follow-up care needs of people with colorectal cancer and piloting a telephone intervention

Submission date	Recruitment status	Prospectively registered
28/09/2007	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
28/09/2007	Completed	[X] Results
Last Edited	Condition category	Individual participant data
05/10/2011	Cancer	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Kinta Beaver

Contact details

Professor of Nursing

School of Nursing, Midwifery & Social Work

University of Manchester & Central Manchester and Manchester Children's University Hospitals

NHS Trust

University Place (Block 3)

5th Floor (Room 5.309)

Oxford Road

Manchester

United Kingdom

M13 9PL

+44 0161 306 7779

kinta.beaver@manchester.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0301182420

Study information

Scientific Title

Study objectives

What are the follow-up care needs of people with colorectal cancer? Can a telephone intervention, currently being evaluated for people with breast cancer, have wider applicability and be relevant for people with colorectal cancer?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 05/11/08: Cumbria and Lancashire A, 13/03/06, REC reference 05/Q1308/46.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

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: Colorectal

Interventions

Interviews with patients, postal administration of questionnaire and exploratory trial with a small randomised controlled trial. For the RCT part, patients recruited to the telephone pare will be given a hospital card with the date and time when a trained specialist colorectal cancer nurse will call them. This will be compared to patients being seen at the hospital in the normal way.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Patients views and preferences on follow-up care after treatment for colorectal cancer.

Added 05/11/08:

- 2. Satisfaction with information received
- 3. Satisfaction with follow-up service provision
- 4. Psychological morbidity

Secondary outcome measures

Added 05/11/08: Cost effectiveness

Overall study start date

01/06/2006

Completion date

01/10/2007

Eligibility

Key inclusion criteria

Interviews with outpatients at surgical and oncology clinics, 30 patients; questionnaires with patients on follow-up treatment, 150-200 patients; RCT with outpatients at surgical and oncology clinics, 60 patients.

Inclusion criteria for RCT participants:

- 1. Adults >18
- 2. Aware of diagnosis of colorectal cancer
- 3. Complete treatment for colorectal cancer
- 4. No evidence of local or regional recurrence
- 5. No current clinical problems
- 6. In addition for RCT stage: access to a telephone

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

60

Key exclusion criteria

- 1. Not aware of diagnosis of colorectal cancer
- 2. Treatment ongoing
- 3. Evidence of recurrent disease
- 4. Clinical problems that warrant hospital visits
- 5. Patient already taking part in a clinical trial
- 6. Hard of hearing/deaf with no telephone adaptation system in operation. No telephone access

Date of first enrolment

01/06/2006

Date of final enrolment

01/10/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Professor of Nursing

Manchester United Kingdom M13 9PL

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details

The Department of Health, Richmond House, 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name

Blackpool Fylde & Wyre Hospitals NHS Trust (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	01/02/2011		Yes	No