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

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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

Type(s) Scientific

Contact name Dr Kinta Beaver

### **Contact details**

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# 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?
<u>Results article</u>	results	01/02/2011		Yes	No