

# CRIB (Cancer Rehabilitation In Bowel cancer): the use of cardiac rehabilitation services to aid the recovery of colorectal cancer patients: a pilot randomised controlled trial (RCT) with embedded feasibility study

<b>Submission date</b> 12/12/2012	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 21/03/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/09/2016	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://www.cancerresearchuk.org/cancer-help/trials/a-trial-looking-exercise-programme-after-bowel-cancer-surgery-crib>

## 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**

12/5001/09

## **Study information**

### **Scientific Title**

The use of cardiac rehabilitation services to aid the recovery of colorectal cancer patients: a pilot randomised controlled trial (RCT) with embedded feasibility study

### **Acronym**

CRIB

### **Study objectives**

Is existing cardiac rehabilitation service an acceptable model of rehabilitation to aid the recovery of cancer patients?

More details can be found at: <http://www.nets.nihr.ac.uk/projects/hsdr/12500109>

Protocol can be found at: [http://www.nets.nihr.ac.uk/\\_\\_data/assets/pdf\\_file/0019/81217/PRO-12-5001-09.pdf](http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0019/81217/PRO-12-5001-09.pdf)

### **Ethics approval required**

Old ethics approval format

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

NHS Research Scotland (NRS), 22/02/2013, REC ref: 13/NS/0004

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

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

Not specified

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

Quality of life

### **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

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

Colorectal cancer

## **Interventions**

Patients will be randomised to the intervention or control group after they have consented to participating in the study and after baseline primary and secondary measures have been collected. Randomisation with stratification by centre will be conducted by Tayside Clinical Trials Unit.

Participants will either receive rehabilitation (intervention group) or a 'Staying healthy after bowel cancer' booklet by Bowel Cancer UK (control group). However, we may make slight modifications to the intervention based on the findings of the feasibility study, which will be documented. To optimise intervention fidelity, interventionists will be expected to follow the cancer patient rehabilitation pathway for this study and their site-specific rehabilitation programme. A researcher will contact participants randomised to the rehabilitation group each week by telephone in order to complete an intervention record log to document, for example, type and duration of exercises completed and content of educational classes attended for participants receiving the intervention. A researcher will also contact participants randomised to the control group to record, for example, any advice given about exercising.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

Physical activity levels using an accelerometer measured at T0 - before patients are randomised to the intervention or control group, T1 - at the end of the intervention (data will be collected 12 weeks after baseline for patients in the control arm) and T2 - 3 months later.

## **Secondary outcome measures**

Quality of life measures

## **Overall study start date**

01/03/2013

## **Completion date**

31/12/2014

## **Eligibility**

### **Key inclusion criteria**

Adults (male and female) who have been:

1. Diagnosed with primary colorectal cancer
2. Are in the recovery period following surgery and may or may not be receiving adjuvant chemotherapy

### **Participant type(s)**

Patient

### **Age group**

Adult

**Sex**

Both

**Target number of participants**

The sample size in Phase 1 is 12 cancer patients and their nominated family member, 6 cardiac patients and 12 clinicians. In Phase 2 the estimated sample size is 66 colorectal cancer patients.

**Key exclusion criteria**

Adults who:

1. Have advanced disease
2. Fail clinical/risk assessment for rehabilitation and therefore deemed by clinicians as unsafe to participate in exercise classes
3. Have a severe cognitive impairment and are therefore unable to give informed consent to participate in the study
4. Are unable to communicate in English

**Date of first enrolment**

31/07/2013

**Date of final enrolment**

31/07/2014

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

Scotland

United Kingdom

**Study participating centre**

School of Nursing, Midwifery and Health

Inverness

United Kingdom

IV3 3JH

**Sponsor information****Organisation**

University of Southampton (UK)

**Sponsor details**

Health Services and Delivery Research Programme

National Institute for Health Research

Evaluation, Trials and Studies Coordinating Centre

Alpha House

Southampton  
England  
United Kingdom  
SO16 7NS

**Sponsor type**

University/education

**Website**

<http://www.netscc.ac.uk/hsdr/index.html>

**ROR**

<https://ror.org/01ryk1543>

## Funder(s)

**Funder type**

Government

**Funder Name**

National Institute for Health Research (NIHR) (UK) - Health Services and Delivery Research Programme (ref: 12/5001/09)

## 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?
<a href="#">Protocol article</a>	protocol	18/02/2014		Yes	No
<a href="#">Results article</a>	results	01/12/2015		Yes	No
<a href="#">Results article</a>	results	04/01/2016		Yes	No
<a href="#">Results article</a>	results	01/08/2016		Yes	No

