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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

Submission date 12/12/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/03/2013	**Overall study status** Completed	
Last Edited 02/09/2016	**Condition category** Cancer	

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

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Additional identifiers

Protocol serial number
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

Ethics approval required
Old ethics approval format

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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Quality of life

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(s)
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.

Key secondary outcome(s)
Quality of life measures

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

Scotland

Study participating centre
School of Nursing, Midwifery and Health
Inverness
United Kingdom
IV3 3JH

Sponsor information

Organisation
University of Southampton (UK)

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

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	01/12/2015		Yes	No
Results article	results	04/01/2016		Yes	No
Results article	results	01/08/2016		Yes	No
Protocol article	protocol	18/02/2014		Yes	No
HRA research summary			28/06/2023	No	No