ISRCTN58613962 https://doi.org/10.1186/ISRCTN58613962

Current public title as of 28/02/2019: Physical activity for people recovering from bowel cancer, or with inflammatory bowel disease who have a stoma Previous public title: Physical activity for people recovering from bowel cancer who have a stoma

Submission date	Recruitment status	[_] Prospectively registered
14/09/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/12/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/02/2020	Cancer	

Plain English summary of protocol

Background and study aims
Many people recovering from bowel cancer require surgery. If a section of the bowel is removed, the surgeon may temporarily divert the faeces by bringing a loop of bowel out through the abdominal wall and attaching it to the skin – this is called a stoma. A bag is worn over the stoma to collect the faeces. The formation of a stoma has many repercussions for the patient including low energy, tiredness, poor body image, fears of leakage, and fears of a hernia. These problems affect patient quality of life, and can be a barrier to being physically active. Activity levels might be improved in this patient group by addressing the concerns they have about their stoma, and by offering them input from a physical activity specialist. The aim of this study is to look at whether bowel cancer patients with a stoma enjoy a physical activity programme, and if it is beneficial.

Who can participate?
Currently as of 28/02/2019:
Patients with bowel cancer undergoing surgery with the formation of a temporary or permanent stoma. The trial also includes people who have had their stoma formed as a result of inflammatory bowel disease.
Previously:
Patients with bowel cancer undergoing surgery with the formation of a temporary or permanent stoma

What does the study involve?
About 6 weeks after their surgery, the participants are offered a 12-week programme of physical activity intervention from exercise specialists. They record their activities in a diary, and are also

given a device to measure their daily step counts. This study assesses how many patients participate, what activities they do each week; patients, clinicians and physical activity specialists' opinions on the intervention; and if there are improvements in quality of life, function and fatigue.

What are the possible benefits and risks of participating?
This is the first study to find out whether bowel cancer patients with a stoma enjoy a physical activity programme, and if it beneficial to them. There is great potential to improve quality of life by addressing the stoma-related barriers to being physically active. Participants may expect to see improvements in their day to day activity by doing more steps each day. Previous studies of a similar nature have also seen improvements in quality of life and in confidence to be more active. The main risk of taking part is the risk of hernia formation at the site of the stoma, but this can be avoided by not putting undue pressure on the abdomen. Recent guidelines suggest that some exercises, and being active, can reduce the risk of a hernia forming.

Where is the study run from?
1. NHS Highland (UK)
2. University College London Hospitals NHS Foundation Trust (UK)
3. London North West Healthcare NHS Trust (UK)

When is the study starting and how long is it expected to run for?
September 2017 to August 2018

Who is funding the study?
Bowel and Cancer Research (UK)

Who is the main contact?
Mrs Julie Munro

Contact information

Type(s)
Public

Contact name
Mrs Julie Munro

Contact details
School of Health, Social Care and Life Sciences
University of the Highlands and Islands (UHI)
Centre for Health Sciences, Old Perth Road
Inverness
United Kingdom
IV2 3JH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1109JH_UHI_ALL

Study information

Scientific Title
A physical activity intervention to improve the quality of life of bowel cancer patients with a stoma: a feasibility study

Study objectives
This is the first study to look at whether bowel cancer patients with a stoma enjoy a physical activity programme, and if it is beneficial. This is a feasibility trial, so there is no hypothesis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North of Scotland Research Ethics Committee, 11/07/2017, ref: 17/NS/0065, IRAS ID: 219548

Study design
Multi-centre feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Bowel cancer patients with a stoma

Interventions
This study is testing the feasibility of a physical activity intervention. This will be offered to patients following their surgery for bowel cancer, where a stoma has been created. Patient will be offered to take part in a 12 week programme of physical activity intervention from exercise specialists. Participants will undergo initial assessment, and will be given an exercise

prescription once a week for 12 weeks. They will record their activities in a diary, and will also be given a device to measure their daily step counts. Physical activity prescription will either be given face-to-face or via video conference.

Intervention Type
Behavioural

Primary outcome measure
The feasibility and potential benefit of a physical activity intervention for bowel cancer patients with a stoma:
1. How many patients participate, and what and how much physical activity they do each week. They will record their activities in a diary, and will also be given a device to measure their daily step counts
2. Opinions of all those involved in the trial, namely patients, stoma nurses, and exercise specialists about the intervention, collected by semi-structured interviews at the end of the 12 week intervention. All semi-structured interviews will be audio recorded (as included in patient consent form), and transcribed. Transcriptions will be examined by 2 members of the research team for thematic analysis
3. Any improvements made in quality of life, physical function, and fatigue (see below)

Measured at baseline and at 12 weeks:
1. Quality of life, assessed using the Stoma Quality of Life scale
2. Fatigue, assessed using FACIT fatigue
3. Body image, assessed using FACT-C
4. Physical activity levels, measured by accelerometry for 7 consecutive days through waking hours
5. Physical function, measured using the following:
5.1. 6-minute walk test
5.2. Sit to stand test
5.3. Arm curl
5.4. Sit and reach test

Secondary outcome measures
1. Screening, eligibility, consent and intervention completion rates:
1.1. Screening and eligibility will be collected throughout the 6-month recruitment period by clinical nurse specialists. Patient screening forms have been provided for this purpose
1.2. Verbal consent for contact will be obtained by a member of the direct healthcare team. A verbal consent form will be passed on to one of two researchers for initial contact. Initial contact will be no sooner than 6 weeks post-surgery. Informed consent will be obtained by one of two trial researchers. This involves a fully informed consent and after a period of discussion around what is involved for the participant. A patient information sheet is given in advance to ensure the participant has all the information required, and can make an informed decision about their potential involvement
1.3. Intervention completion will be recorded by the trial exercise specialists who will be providing the intervention. This will be recorded through attendance records throughout the 12-week intervention (this includes recording completed teleconference calls, which are considered as an ‘attended’ session). Data completion will consist of baseline measures (taken at baseline), and completion measures (taken after the 12-week intervention). Data collection involves accelerometer data (device worn for 7 days, pre- and post-intervention); questionnaire completion (pre-and post-intervention)
2. The number of consultations taking place between patients and exercise specialists. The trial

intervention is 12 weeks long, and consultations are weekly. These may be face to face, or via video call, or a combination of both. Number of consultations will be recorded for each participant, along with length of time of each consultation
3. The acceptability of this intervention for this patient population, recorded through semi-structured interview at the end of the intervention, along with consent rates and intervention completion rates to indicate the acceptability of the intervention with this patient population

Overall study start date
01/09/2017

Completion date
30/08/2019

Eligibility

Key inclusion criteria
Current inclusion criteria as of 28/02/2019:
1. Patients diagnosed with bowel cancer or inflammatory bowel disease.
2. Undergoing elective colorectal resections including open and laparoscopic procedures
3. The formation of a temporary or permanent stoma
4. Patients undergoing pre and post radiotherapy, and chemotherapy
5. WIth and without parastomal hernia

Previous inclusion criteria:
1. Patients diagnosed with bowel cancer
2. Undergoing elective colorectal resections including open and laparoscopic procedures
3. The formation of a temporary or permanent stoma
4. Patients undergoing pre and post radiotherapy, and chemotherapy
5. WIth and without parastomal hernia

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30

Total final enrolment
30

Key exclusion criteria
1. Patients who have undergone emergency surgery for bowel cancer
2. The patient's clinician deems the patient unsuitable for engaging in any sort of physical activity. Clinician may be surgeon, consultant gastroenterologist, oncologist, or nurse specialist

Date of first enrolment
01/11/2017

Date of final enrolment
30/08/2019

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
NHS Highland
United Kingdom
IV2 3JH

Study participating centre
University College London Hospitals NHS Foundation Trust
United Kingdom
NW1 2PG

Study participating centre
London North West Healthcare NHS Trust
United Kingdom
HA1 3UJ

Sponsor information

Organisation
Bowel and Cancer Research

Sponsor details
National Bowel Research Centre
1st Floor, Abernethy Building
2 Newark Street

London
United Kingdom
E1 2AT

Sponsor type
Charity

Website
http://www.bowelcancerresearch.org/

Organisation
NHS Highland

Sponsor details
CfHS
Old Perth Road
Inverness
United Kingdom
IV2 3JH

Sponsor type
Other

Organisation
Bowel and Cancer Research

Sponsor details

Sponsor type
Not defined

Website
http://www.bowelcancerresearch.org/

ROR
https://ror.org/030y35h40

Funder(s)

Funder type
Charity

Funder Name

Bowel and Cancer Research

Alternative Name(s)
Bowel & Cancer Research, B&CR

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Study protocol is available on request. High impact peer reviewed journals will be targeted. Following completion of the trial, the intention is to share and disseminate the findings in a range of clinical conferences and networks (e.g. health and physical activity; stoma care; bowel cancer).

Intention to publish date
31/01/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Gill Hubbard (gill.hubbard@uhi.ac.uk).
Data: quantitative – questionnaires (raw data can be provided), Actigraph physical activity data (raw format). Qualitative data will not be available
Any data provided through data sharing will be fully anonymised. Participants will be led through fully informed consent stating that anonymised data may be shared outwith the organisation following their completion of the trial. Qualitative data will not be available for sharing on the premise that it may lead to identification of a participant, trial site, or health professional involved. Data will be shared at the discretion of the principal investigator, who will comply fully with the ethical obligations for data protection as set out during trial IRAS registration.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	17/06/2019	10/02/2020	Yes	No
Results article	results	01/12/2020	10/02/2020	Yes	No
HRA research summary			28/06/2023	No	No