

Feasibility of a personalised, distance-based lifestyle intervention in colorectal cancer patients

Submission date 02/11/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/11/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/03/2016	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-study-looking-lifestyle-changes-after-treatment-bowel-cancer>

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

The feasibility of a personalised, distance-based lifestyle intervention in colorectal cancer (CRC) patients who have recently completed treatment, focusing on increasing fruit and vegetable (F&V) intake, reducing red and processed meat consumption, and increasing physical activity

Study objectives

This is a pilot study to examine the feasibility and acceptability of a distance-based intervention to increase physical activity and fruit and vegetable consumption and reduce red and processed meat consumption in patients who have recently completed treatment for bowel cancer.

Ethics approval required

Old ethics approval format

Ethics approval(s)

UCLH NHS Foundation Trust Ethics Committee, 14/10/2009, ref: 09/H0715/44

Study design

Multicentre non-randomised interventional pilot study

Primary study design

Interventional

Secondary study design

Non randomised study

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

Topic: National Cancer Research Network; Subtopic: Colorectal Cancer; Disease: Colon, Rectum

Interventions

This is a feasibility study without a control group, therefore all participants will receive the same intervention. Participants will be provided with written information regarding the benefits of changes in physical activity, F&V, red and processed meat consumption following bowel cancer. They will then receive 6 personalised telephone consultations over the course of 3 months (1 call every 2 weeks). These sessions, based on self-regulation theory, will take into account baseline levels of each behaviour and introduce goal setting with the aim of gradually improving behaviour and a rate that is sustainable. Participants will also be educated regarding behaviour

change skills, such as self-monitoring and evaluation of behavioural goals. Participants will be given logbooks and a pedometer in order to record their behaviour.

Intervention Type

Behavioural

Primary outcome measure

Feasibility, measured on trial completion

Secondary outcome measures

All measured on trial completion:

1. Acceptability
2. Blood samples to measure vitamin C, E and plasma carotene
3. Change in physical activity
4. Fatigue
5. Fruit and vegetable consumption
6. Insulin-like growth factor 1 (IGF-1)
7. Physical function
8. Quality of life (Functional Assessment of Cancer Therapy-Colorectal [FACT-C])
9. Red and processed meat consumption

Overall study start date

01/04/2011

Completion date

29/07/2011

Eligibility**Key inclusion criteria**

1. Patients within 6 months of treatment completion for M0 colorectal cancer
2. Can speak and read in English
3. Aged over the age of 18 years but with no maximum age limit, either sex

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned sample size: 30

Key exclusion criteria

1. Any contraindications preventing participation in unsupervised physical activity
2. Those who have ileostomy/colostomy bags

Date of first enrolment

01/04/2011

Date of final enrolment

29/07/2011

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University College London

London

United Kingdom

WC1E 6BT

Sponsor information

Organisation

University College London Hospitals NHS Foundation Trust (UK)

Sponsor details

The Hatter Institute for Cardiovascular Studies

25 Grafton Way

London

England

United Kingdom

WC1E 6DB

Sponsor type

Hospital/treatment centre

Website

<http://www.wcrf.org/>

ROR

<https://ror.org/042fqyp44>

Funder(s)

Funder type

Research organisation

Funder Name

World Cancer Research Fund

Alternative Name(s)

World Cancer Research Fund UK, WCRF, WCRF UK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

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	01/02/2015		Yes	No