

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

Submission date 02/11/2010	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 02/11/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 03/03/2016	Condition category Cancer	☐ 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

Protocol serial number

9281

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

Primary study design

Interventional

Study design

Multicentre non-randomised interventional pilot study

Study type(s)

Treatment

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(s)

Feasibility, measured on trial completion

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

Study participating centre

University College London
London
United Kingdom
WC1E 6BT

Sponsor information

Organisation

University College London Hospitals NHS Foundation Trust (UK)

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, World Cancer Research Fund International, WCRF International, WCRF, WCRF UK

Funding Body Type

Government organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2015		Yes	No