

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

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

### Contact name

Dr Chloe Grimmett

### Contact details

Department of Epidemiology and Public Health

Gower Street

London

United Kingdom

WC1E 6BT

-

c.grimmett@ucl.ac.uk

## 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

### **Study design**

Multicentre non-randomised interventional pilot study

### **Primary study design**

Interventional

### **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?
<a href="#">Results article</a>	results	01/02/2015		Yes	No