

INTERCEPT-C: weight loss and colorectal cancer risk

Submission date 16/10/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/12/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/01/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Obesity is a significant health concern and is associated with an increased risk of developing certain types of cancer. However, less is known about how obesity and cancer are linked, and there is little evidence that standard dietary methods of weight loss reduce cancer risk. The aim of this study is to explore the effects of diet-induced weight loss on biomarkers for colorectal cancer risk.

Who can participate?

Men and women, aged 18-60, non-smokers, fluent in English, with body mass index BMI ≥ 30

What does the study involve?

Participants attend weekly sessions with a Psychologist/Dietitian at University College London where they receive a complete meal replacement plan and support. Participants are asked to have a flexible sigmoidoscopy (a procedure used to see inside the sigmoid colon and rectum) to obtain colon tissue samples from their colon at baseline and follow-up (8 weeks). At the start of the study and after 8 weeks, participants complete a questionnaire on psychological wellbeing and eating habits, have a blood test, and have their body measurements taken (height, weight, body fat, waist and hip circumference).

What are the possible benefits and risks of participating?

If the diet is adhered to, participants will lose weight and they should benefit from the effects of weight loss. In addition, they will be provided with the tools to manage their lifestyle in the longer term to help them successfully maintain the weight loss. Participants will be under the care of a specialist in obesity medicine while on the meal replacement programme. As with all medical procedures there are risks involved, however they are small. The flexible sigmoidoscopy will be carried out by a Consultant Colorectal Surgeon at University College London with a great deal of experience and who is equipped to deal with any issues should they arise. Perforation through the bowel wall or bleeding from biopsy sites are the main risks, but both complications are very rare and only happen in about 1 in every 1,500 examinations. If these occur the Surgeon is experienced in dealing with them. A small proportion of participants may experience anxiety

or mild discomfort during the procedure. Experienced medical professionals will monitor participants throughout. Participants will also be provided with feedback on the flexible sigmoidoscopy results. All participants will have their travel expenses reimbursed.

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
July 2013 to July 2014

Who is funding the study?
Cancer Research UK

Who is the main contact?
Dr Rebecca Beeken
r.beeken@ucl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Jane Wardle

Contact details
University College London
Health Behaviour Research Centre
Department of Epidemiology and Public Health
1-19 Torrington Place
London
United Kingdom
WC1E 6BT

Additional identifiers

Protocol serial number
A14133

Study information

Scientific Title
Intervening to reduce colorectal cancer risk (INTERCEPT-C): a feasibility study to explore the impact of diet-induced weight loss on biomarkers for colorectal cancer

Study objectives
Diet-induced weight loss will be associated with changes in the serum and tissue markers related to colorectal cancer risk.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee London, Harrow, 07/03/2013

Study design

Non-randomised single arm exploratory interventional treatment trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Colon cancer, obesity

Interventions

The trialists have designed a weight loss intervention that combines an low calorie diet (LCD~800 calories per day) using the Cambridge Weight Plan products with additional behaviour change techniques from the Shape Up weight management programme developed by the charity Weight Concern. The trialists believe this combined approach will help maximise sustained weight loss and participant well-being. Participants will be on the complete meal replacement programme for 8 weeks this will be followed by 4 weeks in which real food is re-introduced alongside the meal replacement products. Participants will get support and advice on behaviour change on a weekly basis from a Research Psychologist/Dietitian at UCL. Participants will also be weighed at these appointments.

Intervention Type

Behavioural

Primary outcome(s)

The following tissue and serum samples will be analysed to measure changes in the levels of cancer-related molecular risk markers:

1. Serum insulin, glucose, total IGFI, IGFBP3, leptin, adiponectin and CRP.
2. Colon epithelial cell mRNA levels (as a measure of gene expression) of insulin/IGF/mTOR and adipokine/inflammatory signaling pathways
3. Colon epithelial cell protein levels of activated (phosphorylated) components of the insulin /IGF/mTOR and inflammatory signalling pathways

Measured at baseline and 8 week follow up.

Key secondary outcome(s)

1. Weight
2. Waist and hip circumference
3. Body mass index
4. Body fat (estimated using a Tanita Body Fat Scale)
5. Blood pressure
6. General health (General Health Questionnaire; GHQ28,Goldberg & Hillier, 1979)
7. Self-esteem (Rosenberg Self Esteem; RSE Scale, Rosenberg, 1965)
8. Body dissatisfaction (Body Shape Questionnaire; BSQ, Evans & Dolan, 1993)
9. Cognitive restraint over eating, disinhibited eating, and susceptibility to hunger (ThreeFactor

Eating Questionnaire; TFEQ, Stunkard & Messick, 1985)

10. Binge eating (Binge Eating Scale; BES, Gormally, Black, Daston, & Rardin, 1982)

11. Depression (Centre for Epidemiologic Studies Depression Scale; CESD, Devins, Orme, Costello, & Binik, 1998)

Measured at baseline and 8 week follow up.

Completion date

14/07/2014

Eligibility

Key inclusion criteria

1. Body mass index (BMI) ≥ 30
2. Aged 18-60
3. Non-smoker
4. Fluent in English

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

60 years

Sex

All

Key exclusion criteria

1. History of major depression
2. History of cardiovascular disease (CVD)
3. Pregnant
4. Taking medication prescribed by a general practitioner over the past month (excluding oral contraceptives)
5. Diabetic
6. Has a disease of the liver, kidney, heart, lung, blood or skin
7. Has had intestinal surgery
8. History of malabsorption
9. Regularly use drugs with anti-inflammatory or antidiabetogenic properties
10. Previous diagnosis of cancer
11. Known food allergies (including lactose intolerance)

Date of first enrolment

15/07/2013

Date of final enrolment

14/07/2014

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University College London

London

United Kingdom

WC1E 6BT

Sponsor information

Organisation

University College London (UK)

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (UK); Ref: A14133

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Funder Name

Cambridge Weight Plan (UK) are providing the meal replacement products for the study

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	01/11/2017	22/01/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes