

# Protein acetylation as a diet-modifiable biomarker of colorectal cancer risk

<b>Submission date</b> 08/04/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 04/08/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/01/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N12017

# Study information

## Scientific Title

Protein acetylation as a diet-modifiable biomarker of colorectal cancer risk: an interventional single-centre cross-section trial

## Acronym

The FACT study

## Study objectives

We hypothesise that the reduced risk of colorectal cancer through increased fibre intake is mediated in part through changes in global protein acetylation.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

North Sheffield Ethics Committee gave approval on the 11th October 2006 (ref: 06/Q2308/93)

## Study design

Interventional single-centre non-randomised non-controlled cross-section trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## 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

Colorectal cancer/bowel health

## Interventions

Volunteers with a low habitual consumption of non-starch polysaccharides (NSP) and resistant starch (RS) will be recruited to an 8-week high fibre intervention trial. Volunteers will be provided with a range of high-fibre food options, with the goal of reaching 20 g per day fibre intake.

## Intervention Type

Other

**Phase**

Not Applicable

**Primary outcome measure**

Altered faecal short chain fatty acid (SCFA) production.

In the cross-sectional arm there is a single sampling timepoint and all primary and secondary measures are made at this point. For the intervention arm sampling is performed at baseline and after 8 weeks of intervention.

**Secondary outcome measures**

1. Altered bowel crypt cytokinetics (proliferation, apoptosis and apoptosis regulators)
2. Identification of candidate biomarker acetylations

In the cross-sectional arm there is a single sampling timepoint and all primary and secondary measures are made at this point. For the intervention arm sampling is performed at baseline and after 8 weeks of intervention.

**Overall study start date**

01/07/2006

**Completion date**

30/09/2009

**Eligibility****Key inclusion criteria**

1. Aged 40 years and above, either sex for interventional arm and male only for cross-sectional arm
2. Adenoma, normal or cancer colon (30 of each group)
3. Body mass index (BMI) between 20 and 29 kg/m<sup>2</sup>

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

140

**Key exclusion criteria**

1. Severe medical or psychiatric illness
2. Unable to understand or communicate effectively

**Date of first enrolment**

01/07/2006

**Date of final enrolment**

30/09/2009

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Human Nutrition Unit

Sheffield

United Kingdom

S10 2RX

## **Sponsor information**

**Organisation**

University of Sheffield (UK)

**Sponsor details**

Research Office

Research Services

New Spring House

231 Glossop Road

Sheffield

England

United Kingdom

S10 2GW

**Sponsor type**

University/education

**Website**

<http://www.sheffield.ac.uk/>

**ROR**

<https://ror.org/05krs5044>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Food Standards Agency (UK) (ref: N12017)

**Alternative Name(s)**

The Food Standards Agency, FSA

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

**Funder Name**

Biotechnology and Biological Sciences Research Council (BBSRC) (UK) (ref: BB/D 004187/1)

**Alternative Name(s)**

UKRI - Biotechnology And Biological Sciences Research Council, BBSRC UK, BBSRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**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?
<a href="#">Protocol article</a>	protocol	18/09/2009		Yes	No
<a href="#">Results article</a>	results	17/04/2015		Yes	No