

# Nutrition support in inactive Crohn's disease

<b>Submission date</b> 24/01/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 31/01/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/10/2020	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

People with Crohn's disease (a long-term condition causing inflammation of the lining of the digestive system) may experience a number of nutritional deficiencies even at times when their disease is not active. This study aims to look at the feasibility of carrying out a study to compare dietary counselling to standard written information to manage under-nutrition in people with Crohn's disease.

### Who can participate?

Patients aged 18-65 with Crohn's disease in its inactive state attending outpatient appointments at Guy's and St Thomas' NHS Trust.

### What the study involve?

Participants are randomly allocated to one of two groups. Both groups receive standard care in the form of written dietary information increasing portion size, meal frequency, food choice, nutrient density and food fortification. One group also receives dietary counselling tailored to provide an additional 600 kcal/d for a period of two months. At the end of the study, interviews are conducted to measure participant acceptability.

### What are the possible benefits and risks of participating?

The participants may view the opportunity to receive well-established dietary counselling as a benefit of the study. The main disadvantages are the burden of participating in a study, the need to make dietary changes and the need to visit the research centre to carry out measurements on two occasions.

### Where is the study run from?

Guy's and St Thomas' NHS Trust (UK)

### When is the study starting and how long is it expected to run for?

February 2014 to May 2014

### Who is funding the study?

King's College London (UK)

Who is the main contact?  
Sheena Visram  
sheena.visram@kcl.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Kevin Whelan

**Contact details**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
1

## Study information

**Scientific Title**  
Detecting and managing undernutrition in adults with inactive Crohn's Disease: feasibility randomised comparative trial of oral nutritional support

**Study objectives**  
The feasibility study will allow methodology, study design and outcome measures to be tested and a key outcome will be to measure patients' perceptions of the interventions, design and outcomes. This will provide essential information to inform the design of an adequately powered multicentre trial of oral nutritional support.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
NRES Committee North West Liverpool East, ref: 13/NW/0854 - approval pending

**Study design**

Feasibility randomised comparative trial: single centre two-armed parallel groups

**Primary study design**

Interventional

**Secondary study design**

Randomised parallel trial

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please contact [sheena.visram@kcl.ac.uk](mailto:sheena.visram@kcl.ac.uk) to request a patient information sheet

**Health condition(s) or problem(s) studied**

Nutritional support for inactive Crohn's disease

**Interventions**

Participants will be randomised to two groups:

1. Intervention group: Receives standard care in the form of written information. In addition, they will receive dietary counselling individually tailored to increase dietary intake by 600 kcal /day over a period of two months.
2. Comparison group: Standard care only

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

1. Recruitment rate, retention, attrition and feasibility
2. Eligibility criteria including screening for under-nutrition, study design and methodology
3. Qualitative interviews on experience of participation

Measured by Interview Acceptability Interview at at baseline and two months

**Secondary outcome measures**

1. Nutritional outcome measures (measured by anthropometry and food record charts)
2. Clinical Outcomes (markers of disease activity and a Stool and Symptom Diary)
3. Patient centred outcome measures (measured by questionnaires)

All completed at baseline and after two months

**Overall study start date**

01/02/2014

**Completion date**

30/09/2014

## **Eligibility**

**Key inclusion criteria**

1. Men and women aged  $\geq 18$  years
2. Diagnosis of Crohn's disease for duration of at least 6 months confirmed by standard clinical, histological and radiological criteria
3. Crohn's disease in remission as defined by Harvey Bradshaw score of  $< 5$
4. Stable medications (see exclusion criteria), no recent surgery (see exclusion criteria) and stable symptoms for at least 2 months
5. BMI  $< 20$  kg/m<sup>2</sup>
6. A willingness to participate
7. Individuals able to give informed consent

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

24 participants. Each group will aim to recruit 12 participants.

**Total final enrolment**

7

**Key exclusion criteria**

1. Patients with active Crohn's disease
2. Use of the following treatments: antibiotics, non-steroidal anti-inflammatory drugs (NSAIDs) during the preceding week
3. Currently taking steroids
4. Recent changes in dose to the following treatments: azathioprine, 6-mercaptopurine, methotrexate or  $\alpha$ -TNF agents during the preceding 12 weeks, oral 5-aminosalicylate (5-ASA) or steroids during the preceding 4 weeks
5. Previous pan-proctocolectomy, pure perianal disease or short bowel syndrome
6. Stenotic disease
7. Sepsis or fever
8. Diabetes or coeliac disease (by serology and/or duodenal biopsy)
9. Other concomitant serious comorbidity e.g. significant hepatic, renal, endocrine, respiratory, neurological or cardiovascular disease

- 10. Pregnancy or lactation
- 11. Taking any medications with the potential to influence gastrointestinal symptoms unless taking a long-term stable dose that is unlikely to change or stop during the trial
- 12. Currently receiving oral nutritional supplements, enteral or parenteral nutrition, or having received dietary counselling or oral nutritional supplements, enteral or parenteral nutrition, in the previous 3 months prior to study commencement
- 13. Non fluent English

**Date of first enrolment**

01/02/2014

**Date of final enrolment**

01/05/2014

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**King's College London**

London

United Kingdom

SE1 9NH

## **Sponsor information**

**Organisation**

King's College London (UK)

**Sponsor details**

c/o Keith Brennan

Room 1.8 Hodgkin Building

Guys Campus

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England

United Kingdom

SE1 4UL

**Sponsor type**

University/education

**ROR**

## Funder(s)

### Funder type

University/education

### Funder Name

King's College London

### Alternative Name(s)

Collegium Regale Londiniense, King's, KCL

### Funding Body Type

Government organisation

### Funding Body Subtype

Universities (academic only)

### 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="#">HRA research summary</a>			28/06/2023	No	No