

Nutrition support in inactive Crohn's disease

Submission date 24/01/2014	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 31/01/2014	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 05/10/2020	Condition category Digestive System	☐ Individual participant data ☐ 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

Diabetes and Nutritional Sciences Division

King's College London

4th Floor Franklin-Wilkins Building

150 Stamford Street

London

United Kingdom

SE1 9NH

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

Completion date

30/09/2014

Eligibility

Key inclusion criteria

1. Men and women aged ≥ 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/m²
6. A willingness to participate
7. Individuals able to give informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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 α -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**

United Kingdom

England

Study participating centre

King's College London

London

United Kingdom

SE1 9NH

Sponsor information

Organisation

King's College London (UK)

ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

University/education

Funder Name

King's College London

Alternative Name(s)

King's, Collegium Regium apud Londinenses, Collegium Regale Londinense, Collegium Regale Londiniense, KCL

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

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?
HRA research summary			28/06/2023	No	No