

Developing a safe and effective exercise programme for people with Crohn's Disease

Submission date 02/12/2015	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 02/12/2015	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 04/01/2023	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Crohn's disease (CD) is one of the main types of inflammatory bowel disease (IBD), a name given to long-term conditions which causes inflammation (swelling) in the digestive system (gut). Although it can affect any part of the gut, it is most common at the end of the ileum (the last part of the small intestine) or the colon (the large intestine). It is characterised by different phases of disease activity, alternating between remission (when the disease is not active) and flare-ups (when the disease is active and causing symptoms). Currently, there is no cure for Crohn's disease, and so treatments tend to be geared towards ensuring the disease remains in remission. Currently, little is known about the effects of exercise in CD; however it could have several beneficial effects such as reducing fatigue and inflammation, increasing muscle and bone strength, and improving overall quality of life. The aim of this study is to look into the effects of a high-intensity exercise programme and a moderate-intensity exercise programme on people suffering from CD.

Who can participate?

People between 16 and 65 who have mildly active or inactive Crohn's disease.

What does the study involve?

Participants are randomly allocated to one of three groups. Those in the first group are invited to attend 3 high-intensity exercise sessions a week for 12 weeks, using an exercise bike. The sessions begin with a five-minute warm up, and then alternating one-minute bouts of hard cycling with one-minute bouts of easy cycling, for 20 minutes, before a three-minute cool down. Those in the second group are invited to attend 3 moderate-intensity exercise sessions a week for 12 weeks, using an exercise bike. The sessions begin with a five-minute warm up, and then 30 minutes of cycling at moderate intensity, before a three-minute cool down. In both groups, the resistance level (how hard it is) is increased at 4 and 8 weeks. Those in the third group do not take part in any additional exercises. At the start of the study, and then again at 13 and 26 weeks, participants complete a number of questionnaires and physical tests in order to find out if there has been any change to their health and mental well-being. At the start of the study and week 13, participants are asked to provide a stool (faeces) sample and a blood sample, so that their body's level of inflammation can be assessed.

What are the possible benefits and risks of participating?

Potential benefits of participating include improved physical fitness and reduced fatigue which can improve general health. There are no direct risks of participating, as the exercise programmes have been found to be safe and all sessions will be closely monitored by a clinical co-investigator.

Where is the study run from?

University of East London (UK)

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

January 2016 to December 2017

Who is funding the study?

Crohn's and Colitis UK (UK)

Who is the main contact?

Dr Lindsay Bottoms

Contact information

Type(s)

Scientific

Contact name

Dr Lindsay Bottoms

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Additional identifiers

Protocol serial number

19920

Study information

Scientific Title

A randomised controlled trial investigating the feasibility and acceptability of high--intensity interval training and moderate--intensity continuous training in adults with inactive or mildly active Crohn's disease

Study objectives

The aim of the study is to explore the feasibility, acceptability and possible benefits of high-intensity interval training and moderate-intensity continuous training on people with Crohn's disease.

Ethics approval required

Old ethics approval format

Ethics approval(s)

London - Camden & Kings Cross Research Ethics Committee, 24/11/2015, ref: 15/NW/0813

Study design

Multi-centre randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Gastroenterology; Subtopic: Gastroenterology; Disease: All Gastroenterology

Interventions

Participants are randomly allocated to one of three groups.

High-intensity training group: Participants will be invited to complete three exercise sessions each week for 12 consecutive weeks. All exercise will be performed on a stationary upright cycle ergometer. Each session will begin with a 5-minute warm-up of easy cycling. The main body of each session will involve ten, 1-minute bouts of hard cycling, interspersed with 1-minute bouts of easy cycling. The session will end with a 3-minute cool-down of easy cycling. The resistance level on the cycle ergometers will be progressed after 4 and 8 weeks of training.

Moderate-intensity training group: Participants will be invited to complete three exercise sessions each week for 12 consecutive weeks. All exercise will be performed on a stationary upright cycle ergometer. Each session will begin with a 5-minute warm-up of easy cycling. The main body of each session will involve 30 minutes of cycling at a moderate intensity. The session will end with a 3-minute cool-down of easy cycling. The resistance level on the cycle ergometers will be progressed after 4 and 8 weeks of training.

Control group: Participants continue as normal, and do not undertake any additional activity.

All exercise sessions will be supervised in a university sports science laboratory or a hospital rehabilitation facility. Data will be collected in order to assess the feasibility of conducting a future large-scale study of exercise training in CD. In addition, possible benefits of the exercise programmes to be explored include reduced inflammation (measured using blood and stool samples), increased fitness (assessed using a cycling exercise test), and improved fatigue levels, mental health and quality of life (using standardised questionnaires). Participants will be assessed at 13 and 26 weeks after joining the study.

Intervention Type

Other

Primary outcome(s)

1. Recruitment rates are calculated when the recruitment period is complete
2. Intervention adherence rates are calculated when intervention delivery period is complete
3. Missing data rates are calculated when follow-up is complete
4. Retention rates are calculated when follow-up is complete

Key secondary outcome(s)

1. Blood markers of inflammation (e.g. IL-6, CRP) are measured at baseline and 13 week in all participants, and week 7 in exercise group participants
2. Body mass is determined at baseline and 13 weeks
3. Cardiorespiratory fitness (ventilatory threshold and peak oxygen uptake) is determined at baseline and 13 weeks
4. Disease symptoms are measured using the Crohn's Disease Activity Index at baseline and 13 weeks
5. Health status is measured using the EuroQol EQ-5D-5L questionnaire at baseline, 13 and 26 weeks
6. Bowel inflammation is determined by measuring faecal calprotectin at baseline and 13 weeks
7. Anxiety and depression are measured using the Hospital Anxiety and Depression Scale at baseline, 13 and 26 weeks
8. Fatigue is measured using the Inflammatory Bowel Disease Fatigue Scale at baseline, 13 and 26 weeks
9. Quality of life is measured using the Inflammatory Bowel Disease Quality of Life Questionnaire at baseline, 13 and 26 weeks
10. Physical activity is measured using the International Physical Activity Questionnaire at baseline, 13 and 26 weeks
11. Resting blood pressure is measured at baseline and 13 weeks
12. Resting heart rate is measured at baseline and 13 weeks
13. Waist circumference is measured at baseline and 13 weeks

Completion date

31/12/2017

Eligibility

Key inclusion criteria

1. Aged between 16 and 65 years
2. Clinical diagnosis of CD for at least 4 weeks before the screening visit
3. Mildly active (150 to 219 on Crohn's Disease Activity Index [CDAI]) or inactive (<150 on CDAI) CD assessed no greater than 4 weeks before the screening visit
4. Faecal calprotectin <250 mcg/g recorded no greater than 4 weeks before the screening visit
5. Stable medications for at least 4 weeks before the screening visit
6. Able to provide written informed consent and complete the study questionnaires
7. Able to travel to the research centre for assessment visits and exercise sessions

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

36

Key exclusion criteria

1. Absolute contraindications to exercise testing and training as defined by the American College of Sports Medicine
2. Coexistent serious autoimmune disease such as rheumatoid arthritis or systemic sclerosis
3. Planned major surgery within the first 3 months after randomisation
4. Pregnant
5. Female planning pregnancy within the first 3 months after randomisation
6. Poor tolerability of venepuncture
7. Lack of adequate venous access for required blood sampling
8. Current participation in more than 90 min/week of purposeful exercise, such as jogging or swimming
9. Participation in another clinical trial for with concurrent participation is deemed inappropriate

Date of first enrolment

01/04/2016

Date of final enrolment

31/03/2017

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

University of East London

University Way

London

United Kingdom

E16 2RD

Sponsor information**Organisation**

University of Hertfordshire

ROR

<https://ror.org/0267vjk41>

Funder(s)

Funder type

Charity

Funder Name

Crohn's and Colitis UK

Alternative Name(s)

Crohn's & Colitis UK, CrohnsandColitisUK, NACC

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2019	20/08/2020	Yes	No
Results article	Affective and enjoyment responses	20/09/2019	04/01/2023	Yes	No
Protocol article	protocol	03/04/2017		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes