ISRCTN13021107 https://doi.org/10.1186/ISRCTN13021107

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

Submission date
02/12/2015

Recruitment status
No longer recruiting

Registration date
02/12/2015

Overall study status
Completed

Last Edited
04/01/2023

Condition category
Digestive System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Study website
http://www.crohnsandcolitis.org.uk/research/projects/exercise-and-ibd

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Other

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
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 measure
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

Secondary outcome measures
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 dertermined 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

Overall study start date
01/01/2016

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

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 45; UK Sample Size: 45

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
England

United Kingdom

Study participating centre
University of East London
University Way
London
United Kingdom
E16 2RD

Sponsor information

Organisation
University of Hertfordshire

Sponsor details
College Lane
Hatfield
England
United Kingdom
AL10 9AB

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0267vjk41

Funder(s)

Funder type
Charity

Funder Name
Crohn's and Colitis UK

Alternative Name(s)
Crohn's & Colitis UK

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The dissemination strategy for this research will be to inform a wide range of local, national and international audiences about the results and conclusions. It must, however, be remembered as part of this strategy that the current project is preliminary work aimed at informing a subsequent definitive clinical trial.

Health professionals:
We aim to publish our research in journals that cover the relevant medical specialities and with preference for those that deposit publications in open access databases to increase free dissemination. In addition, we aim to present this research at appropriate national and international conferences.

Users:
From this perspective, we aim in the first instance to collaborate with our patient's representatives and local experts in the patient and public involvement to best facilitate user dissemination. We plan to write a specific news piece that will be forwarded to appropriate groups and organisations.

Service managers:
As an exploratory study, it is unlikely that results from this study will directly influence commissioning processes in the short term. Moreover, we will engage with appropriate primary and secondary care groups to discuss support for our proposed definitive study leading on from this research.

Intention to publish date
30/06/2018

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?
Protocol article	protocol	03/04/2017		Yes	No
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