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Resistance training in adults with Crohn's disease

Submission date 11/12/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/12/2017	**Overall study status** Completed	
Last Edited 12/08/2022	**Condition category** Digestive System	

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 resistance exercise programme in people suffering from CD.

Who can participate?
People aged 16 years or older who have mildly active or inactive Crohn's disease.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive usual care only. Those in the second group receive usual care plus a six-month resistance training programme involving a combination of supervised and unsupervised exercise sessions. Each session begins with a five-minute warm up, then approximately 45 minutes of whole-body resistance training (using body weight and elastic bands for resistance), and a three-minute cool down. At the start of the study, and then again at three and six months, participants complete a number of questionnaires and physical tests in order to find out if there has been any change to their muscle function, fatigue and quality of life. At the start of the study and at six months, participants are asked to provide a stool (faeces) sample so that the level of inflammation in their intestines can be assessed, as well as undertaking a bone scan to assess changes in bone mineral density.

What are the possible benefits and risks of participating?
Potential benefits of participating include improvements in muscle function, bone strength, fatigue levels and quality of life. There are no direct risks of participating, as the exercise

programmes have been found to be safe and participants' progress will be closely overseen by a study investigator.

Where is the study run from?
1. Northumbria University (UK)
2. Freeman Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2016 to September 2019

Who is funding the study?
1. Northumbria University (UK)
2. PROCARE ApS (UK)

Who is the main contact?
Dr Garry Tew

Study website
N/A

Contact information

Type(s)
Scientific

Contact name
Dr Garry Tew

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

35164

Study information

Scientific Title
Effects of a 6-month practical resistance training programme on muscle function and bone mineral density in adults with inactive or mildly active Crohn's disease: Study protocol for a randomised controlled trial

Study objectives
The main aim of this study is to investigate the effects of a 6-month resistance training programme on muscle function and bone mineral density in adults with inactive or mildly-active Crohn's disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East - Tyne & Wear South Research Ethics Committee,17/11/2017, ref: 17/NE/0308

Study design
Randomised; Interventional; Design type: Treatment, Physical, Rehabilitation

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
Specialty: Gastroenterology, Primary sub-specialty: Gastroenterology; UKCRC code/ Disease: Oral and Gastrointestinal/ Other diseases of the digestive system

Interventions
Participants are randomly allocated to one of two groups. Those in the first group receive usual care only. Those in the second group receive usual care plus a six-month resistance training programme involving a combination of supervised and unsupervised exercise sessions. Each session will begin with a five-minute warm up, then approximately 45 minutes of whole-body resistance training (using body weight and elastic bands for resistance), and a three-minute cool down. At the start of the study, and then again at three and six months, participants complete a

number of questionnaires and physical tests in order to find out if there has been any change to their muscle function, fatigue and quality of life. At the start of the study and at six months, participants are asked to provide a stool (faeces) sample so that the level of inflammation in their intestines can be assessed, as well as undertaking a bone scan to assess changes in bone mineral density.

Intervention Type
Other

Primary outcome measure
1. Bone mineral density at the femoral neck, greater trochanter and lumbar spine (L2- L4) is measured using dual energy X-ray absorptiometry at baseline and 6 months
2. Maximum voluntary isometric and isokinetic strength of the elbow flexor and knee extensor muscles is measured using isokinetic dynamometry at baseline, 3 months and 6 months
3. Handgrip strength is measured using a handgrip dynamometer at baseline, 3 months and 6 months
4. Lower-limb muscle endurance is measured using the 30-second chair sit-to-stand test at baseline, 3 months and 6 months
5. Upper-limb muscle endurance is measured using the 30-s arm bicep curl test at baseline, 3 months and 6 months

Secondary outcome measures
1. Quality of life is measured using the Inflammatory Bowel Disease Quality of Life Questionnaire (IBDQ) at baseline, 3 months and 6 months
2. Health status is measured using the EuroQol 5-dimensions, 5-level questionnaire (EQ-5D-5L) at baseline, 3 months and 6 months
3. Fatigue is measured using the Inflammatory Bowel Disease Fatigue Scale (IBD-F) at baseline, 3 months and 6 months
4. Body mass is measured using balance beam scales at baseline and 6 months
5. Stature is measured using a stadiometer at baseline and 6 months
6. Disease activity is measured using the Crohn’s Disease Activity Index (CDAI) at baseline and 6 months
7. Bowel inflammation is determined by measuring faecal calprotectin at baseline and 6 months
8. Blood markers of inflammation (e.g. C-reactive protein) are measured at baseline and 6 months
9. Physical activity is measured using the Scottish Physical Activity Questionnaire (SPAQ) at baseline, 3 months and 6 months
10. Feasibility and acceptability outcomes will include rates of recruitment, retention, attrition, missing data, intervention adherence and adverse events, which will all be calculated once follow-up is complete

Overall study start date
01/10/2016

Completion date
31/10/2019

Eligibility

Key inclusion criteria

1. Age 16 years or older
2. Clinical diagnosis of Crohn's disease for at least 4 weeks before screening visit
3. Inactive (<150 on Crohn's Disease Activity Index [CDAI]) or mildly active (150-219 on CDAI) Crohn's disease assessed no greater than 4 weeks before screening visit
4. Faecal calprotectin <250mcg/g recorded no greater than 4 weeks before screening visit
5. Stable medications for at least 4 weeks before 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: 50; UK Sample Size: 50

Total final enrolment
47

Key exclusion criteria
1. Absolute contraindications or co-morbidities to exercise testing and training as defined by the American College of Sports Medicine
2. Deemed unsuitable to undertake resistance exercise (assessed by gastroenterologist /physician)
3. Planned major surgery within the first 6 months after randomisation
4. Female planning pregnancy within the first 6 months after randomisation
5. Pregnant
6. Current participation in > 2 sessions/week of resistance exercise (self-reported)
7. Participation in another clinical trial for with concurrent participation is deemed inappropriate

Date of first enrolment
08/01/2018

Date of final enrolment
28/02/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northumbria University
Northumberland Road
Newcastle upon Tyne
United Kingdom
NE1 8ST

Study participating centre
Freeman Hospital
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
Northumbria University Newcastle

Sponsor details
Research and Innovation Services
Northumberland Building, 056
Newcastle
England
United Kingdom
NE1 8ST

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/049e6bc10

Funder(s)

Funder type
Government

Funder Name
Northumbria University

Alternative Name(s)

Northumbria University, Newcastle

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
PROCARE ApS

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal within one year of the trial end date.

Intention to publish date
27/09/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Garry Tew, Email: garry.tew@northumbria.ac.uk, anonymised participant level data.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2020	30/10/2020	Yes	No
Protocol file	version 2.1	28/01/2019	12/08/2022	No	No
HRA research summary			28/06/2023	No	No