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MODIFY Fatigue: a cognitive-behavioral therapy intervention study to improve fatigue in inflammatory bowel disease patients

Submission date
02/09/2016

Recruitment status
No longer recruiting

Registration date
06/09/2016

Overall study status
Completed

Last Edited
02/01/2020

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
Inflammatory bowel disease (IBD) is a term used to describe conditions which cause long-term inflammation (swelling) in the gut. The two main forms of IBD are Crohn's disease (CD) and ulcerative colitis (UC). Crohn's disease can affect any part of the gut, but is most commonly at the end of the ileum (the last part of the small intestine) or the colon (the large intestine). Ulcerative colitis generally affects the colon and rectum (the last part of the large intestine). There is currently no cure for these conditions, and so the main aim of treatment is to reduce the symptoms (remission) and prevent the disease from "flaring up" and becoming active again. Even when the disease is in remission, many patients still experience 'irritable bowel syndrome-like' symptoms, such as bloating, diarrhoea and abdominal (tummy) pain. Fatigue (extreme tiredness) is one of the most common and difficult to cope with symptoms for patients with IBD. However currently there are very few ways of managing IBD-fatigue effectively. There is some evidence that cognitive behavioural therapy (a type of talking therapy which helps people to manage their problems by changing the way they think and behave) could be a good way of managing IBD-fatigue. This study aims to find out whether conducting a large study looking at the effectiveness of cognitive behavioural therapy (CBT) for the treatment of IBD-fatigue is feasible, but conducting a small-scale study to see if the study procedures are acceptable.

Who can participate?
Adults with IBD who are not currently experiencing a disease flare up and are currently experiencing fatigue.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive a CBT manual about the management of fatigue, as well as a 60-minute session and seven 30-minute telephone/Skype sessions with a therapist over an eight week period. Those in the second group receive the Crohn's and Colitis UK (IBD charity) Fatigue in IBD" Information Sheet to use without therapist help. At the start of the study and then again after 3, 6 and 12 months, participants in

both groups complete a number of questionnaires to measure their fatigue, disease activity and quality of life. A small sub-set of 7 patients, therapists and healthcare professionals are also invited for interviews after 3 months in order to evaluate their opinions about the CBT program.

What are the possible benefits and risks of participating?
There is a possibility that some participants may benefit from an improvement to their fatigue levels. There is a small risk that some participants may become a little distressed when completing the study questionnaires, talking to the therapist or when reading the Fatigue Information Sheet alone, or being interviewed, because thinking about their IBD could be upsetting.

Where is the study run from?
IBD Centre, Guy's and St Thomas's NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2016 to August 2018

Who is funding the study?
Florence Nightingale Faculty of Nursing & Midwifery (Walpole Legacy), Kings College London (UK)

Who is the main contact?
Miss Micol Artom

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.2

Study information

Scientific Title
Management of inflammatory bowel disease-fatigue: a pilot cognitive-behavioural therapy interventional study

Acronym
MODIFY Fatigue

Study objectives
The aims of the study are:
1. To determine the feasibility and initial estimates of efficacy of a therapist-supported CBT intervention vs. a fatigue Information Sheet in managing fatigue in people with IBD
2. To evaluate patients', therapists' and healthcare professionals' working with IBD perspectives of experience, acceptability and feasibility of the intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
United Kingdom National Research Ethics Service - North West - Liverpool Central Committee, 08/12/2016, ref: 16/NW/0791

Study design
Two-arm pilot randomised controlled trial with nested qualitative study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Inflammatory bowel disease

Interventions

Pilot randomised controlled trial:
Consenting participants will be randomised to CBT manual plus therapist support or Fatigue Information Sheet only using an online random number generator with a 1:1 ratio. All baseline information will be collected prior to randomisation. Participants will be randomised at the individual level. Owning to the nature of the study the participants, the researchers and the therapist will not be blinded to treatment allocation after randomisation.

Arm 1: Participants will receive a CBT manual for the management of fatigue and have one 60-minute session and seven 30-minute telephone/Skype sessions with a therapist over an eight week period. All sessions will be over the telephone or Skype according to patient preference. During the intervention participants will have access to all usual care, including the nurse-led helpline.

Arm 2: Participants will receive the Crohn's and Colitis UK "Fatigue in IBD" Information Sheet to use without therapist help. CC UK is the UK's leading charity for patients with CD and UC. CC UK provides patients with free online information sheet and guides to help those affected by IBD.

All participants will complete outcome measures at 3, 6 and 12-months follow-up. At 12 months, participants in Group 2 (Fatigue Information Sheet) will be provided with the CBT manual received by Group 1 if they wish. They will not receive any therapist support with the manual.

Nested qualitative study:
A subset of participants from the RCT will be invited for qualitative interviews (n = 7), after they have completed the 3-month post-randomisation outcome measures. This interview sub-sample will be purposely sampled to include both genders, a range of ages, both IBD diagnoses and those successful and not successful in showing an initial improvement in IBD-fatigue, to better understand patient perspectives on the intervention. Participants will be asked about the process of recruitment and randomisation, their experience of the intervention itself, their reasons for dropping out or not completing (where appropriate) and areas for improvement in the design of future fatigue interventions for patients with IBD. The therapist supporting patients during the intervention will be interviewed to understand their experience of delivering the intervention and to inform future adaptation and delivery of the intervention in clinical practice. Healthcare professionals working with patients with patients with IBD at GSTT will be interviewed to obtain their views on the intervention and its implementation within existing IBD service at a roll out stage. Approximately 3 healthcare professionals will be interviewed until apparent data saturation is reached.

Intervention Type
Behavioural

Primary outcome measure
Self-reported IBD-fatigue is measured using the Inflammatory Bowel Disease –Fatigue Scale (IBD-F) at baseline, 3, 6 and 12-months post-randomisation.

Secondary outcome measures
Pilot randomised controlled trial:
Self-reported IBD-quality of life is measured using the United Kingdom Inflammatory Bowel Disease Questionnaire (UK IBDQ) at baseline, 3, 6 and 12-months post-randomisation.

Explanatory variables:
1. Disease activity is measured using Disease activity indexes, Harvey Bradshaw Index (HBI) and

the Simple Clinical Colitis Activity Index (SCCAI) at baseline, 3, 6 and 12-months post-randomisation
2. Illness perceptions are measured using the Brief Illness Perceptions Questionnaire (BIPQ) at baseline and 3-months post-randomisation
3. Daytime sleepiness is measured using the Epworth Sleepiness Scales (ESS) at baseline and 3-months post-randomisation
4. Anxiety is measured using the 7-item Generalized Anxiety Disorder Scale (GAD7) at baseline and 3-months post-randomisation
5. Depression is measured using the 9-item Patient Health Questionnaire (PHQ9) at baseline and 3-months post-randomisation

Nested qualitative study:
Experience and acceptability of the intervention will be evaluated by conducting post-intervention interviews with a subset of 7 participants from the intervention group.

Overall study start date
01/09/2016

Completion date
08/08/2018

Eligibility

Key inclusion criteria
1. Patients who are currently experiencing fatigue
2. Proof of diagnosis of IBD (record of diagnostic endoscopy in patient clinical notes); patients without this test will not be included
3. Aged 18 year old and over
4. No current flare-ups of disease (experiencing usual bowel symptoms when disease not in active flare)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Total final enrolment
31

Key exclusion criteria

1. Current flare-up of disease (experiencing bowel symptoms usually associated with active flare)
2. Course of CBT for any reason in the last year
3. Currently enrolled in another trial involving a novel pharmacological intervention
4. Current or planned pregnancy
5. Inability to give informed consent (for example, due to reduced mental capacity)
6. Insufficient command of written and spoken English to understand study documents or procedures

Date of first enrolment
07/04/2017

Date of final enrolment
24/07/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
IBD Centre
Guy's and St Thomas's NHS Foundation Trust
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
King's College London

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Sponsor type
University/education

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
University/education

Funder Name
Florence Nightingale Faculty of Nursing & Midwifery (Walpole Legacy)

Results and Publications

Publication and dissemination plan
1. Planned submission of results for publication in multidisciplinary academic journals (such as Gut, Inflammatory Bowel Diseases and Journal of Crohn's & Colitis) to disseminate to professional audiences
2. Planned submission to key IBD conferences, including the UK British Society of Gastroenterology, the European Crohn's & Colitis Organisation and the USA Digestive Diseases Week

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. Data will be held at King's College London.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/05/2017		Yes	No
Results article	results	10/12/2019	02/01/2020	Yes	No
HRA research summary			26/07/2023	No	No