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Can mindfulness-based cognitive therapy (a group self-help program) improve the quality of life for inflammatory bowel disease patients?

Submission date
02/08/2013

Recruitment status
No longer recruiting

Registration date
09/08/2013

Overall study status
Completed

Last Edited
26/08/2015

Condition category
Digestive System

[_] 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 an incurable long-term condition affecting 250,000 sufferers in the UK and 28 million people worldwide. The disease affects the gut and the two main types are Crohn's disease and ulcerative colitis. The IBD disease course is highly unpredictable and symptoms include pain (due to inflammation of the gut), diarrhoea, vomiting and other symptoms that cause great distress for the individual. Rates of anxiety and depression among people with IBD are higher than the general population. Previous studies suggested that experiencing the prolonged effects of pain, anxiety, distress and low mood could have a harmful effect on quality of life. Mindfulness-based cognitive therapy (MBCT) is a psychological group programme based on the concept that the participants of an eight-week MBCT course will experience reduced negative effects from pain and psychological factors such as distress, anxiety and low mood at completion of the course. In this study, we are aiming to test the group MBCT programme for IBD patients and collect information that will inform a future full-scale study.

Who can participate?
All adults aged 18 or over with a confirmed diagnosis of Crohn's disease or ulcerative colitis.

What does the study involve?
Participants will be randomly allocated to one of two groups. Both groups will go through the same MBCT programme, but the second group will start approximately six months later than the first group (after the six months follow-up data has been collected). This will allow comparison between the two groups in the six months. The second group will be given a leaflet 'Staying Well with IBD' as soon as they are randomly allocated and informed that they are in the second group. Both groups will be asked to complete questionnaires at the start of the study, at two months and at six months and will be invited to a group chat.

What are the possible benefits and risks of participating?
We believe that going through the MBCT programme, IBD patients will become empowered with non-drug-related strategies and tools to reduce daily stress, anxiety and low mood which

could help improve their quality of life. This could potentially benefit all Crohn's and colitis patients who are enrolling, but also can benefit any future patients diagnosed with IBD. No side effects are known.

Where is the study run from?
The study has been set up by University of Stirling in collaboration with NHS Highland and NHS Grampian, UK.

When is the study starting and how long is it expected to run for?
Recruitment of the study started in May 2013 and the completion of the study is anticipated for the end of 2015. Participants will be recruited for up to a year.

Who is funding the study?
University of Stirling, UK.

Who is the main contact?
Ms Mariyana Schoultz
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Contact information

Type(s)
Scientific

Contact name
Ms Mariyana Schoultz

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The use of mindfulness-based cognitive therapy for improving quality of life for inflammatory bowel disease patients: a pilot randomised controlled trial with embedded process evaluation

Study objectives
The aim of the study is to pilot a group mindfulness-based cognitive therapy program in inflammatory bowel disease patients.
The study objectives are:
1. To adapt an intervention manual based on MBCT manual developed by Segal et al (Segal et al, 2013), outlining how to carry out an MBCT program for IBD patients.
2. To determine the feasibility of conducting a definitive RCT of group MBCT for improvement of quality of life for IBD patients.
3. To use data arising from differences between MBCT and control arm to inform a power calculation for sample size of a definitive RCT.
4. Estimate trial recruitment (percentage of IBD patients who consent to the trial) and completion/retention rates (percentage of participants completing the trial).
5. To embed a process evaluation within the pilot trial to assess the acceptability of the intervention and trial procedures for IBD patients :
5.1. Assess acceptability of recruitment, randomisation and consent procedure
5.2. Assess acceptability and feasibility of collecting reliable and valid data on primary and secondary outcomes
5.3. Assess the fidelity of protocol
5.4. Assess acceptability of length of intervention
5.5. Assess appropriateness/suitability of the intervention used
5.6. Assess barriers to attendance
5.7. Assess expectations about intervention
5.8. Assess perceived impact on quality of life

On 13/11/2013 the sources of funding field was updated; the previous source of funding was University of Stirling (UK).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee for North of Scotland, 08/04/2013. REC ref: 13/NF/0018

Study design
Exploratory randomised controlled trial with embedded process evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Inflammatory bowel disease

Interventions
There are two arms to this study: an active intervention group (8-week mindfulness-based cognitive therapy group) and a waiting list control group

The mindfulness-based cognitive therapy involves eight weekly sessions, each one lasting for approximately 120 minutes. The sessions are led by mindfulness facilitators (professionals delivering mindfulness groups with different patient groups within the NHS, who have attended an initial 8-week mindfulness based cognitive therapy program, a further mindfulness teacher training course and who receive regular supervision). The intervention is manualised to ensure consistency across the different venues where it is being delivered.
Mindfulness-based cognitive therapy (MBCT) is a psychological group intervention based on the concept that the participants of an eight week MBCT course will experience reduced negative effects from pain and psychological factors such as distress, anxiety and depression at completion of the 8-week course.

Those participants allocated to the waiting list control arm of the study will have an opportunity to receive the same MBCT program after six months, once the follow up data has been collected.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Quality of life - IBDQ inflammatory bowel disease specific quality of life questionnaire at baseline, two months and six months follow up.

Secondary outcome measures
1. Anxiety - state and trait anxiety (STAI)
2. Depression - Becks depression inventory (BDI)
3. Disease activity - Crohn's disease activity Index - (CDAI) or Simple clinical colitis activity index (SCCAI)
4. Attention Awareness - Mindful attention awareness scale (MAAS)
All assessed at baseline, two months and six months follow up
Evaluation Survey at two months

Overall study start date
01/05/2013

Completion date

01/05/2015

Eligibility

Key inclusion criteria
1. Be able to verbally communicate and write in English (English language does not have to be first language)
2. Able to give informed consent
3. Age of 18 or over (no upper limit)
4. Confirmed diagnosis of Crohn's disease or Ulcerative Colitis (by clinician)
5. Ability to do light exercise (for example to lift arms above the head or bend knees)
6. To be able to commit to at least 6 sessions out of 8
7. To be able to commit to do home practice of up to 45 minutes daily over the 8 weeks of the study
8. No change of antidepressants (dose or type) within the last three months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Unable to give informed consent
2. Major psychiatric illness
3. Active alcohol or drug dependency
4. Scheduled for major surgery in the next three months
5. Participation in pharmacological study or psychological intervention study within the last six months or intention to participate in pharmacological study during the duration of this study
6. Have recently (within the last three months) been prescribed antidepressants
7. With exacerbated symptoms

Date of first enrolment
01/05/2013

Date of final enrolment
01/05/2015

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre
University of Stirling (Highland Campus)
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Sponsor information

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University of Stirling (UK)

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Sponsor type
University/education

ROR
https://ror.org/045wgfr59

Funder(s)

Funder type
University/education

Funder Name
University of Stirling (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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

Funder Name
R&D Highland (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	17/12/2013		Yes	No
Results article	results	25/08/2015		Yes	No