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Can a mindfulness-based stress-reduction course improve symptoms and wellbeing in young people aged 15-24 years with inflammatory bowel disease?

Submission date
04/02/2019

Recruitment status
No longer recruiting

Registration date
12/09/2019

Overall study status
Completed

Last Edited
26/02/2020

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Inflammatory bowel disease (IBD), namely Crohn's disease (CD) and ulcerative colitis (UC), is a complex inflammatory disease accompanied by pain and distress. 1 in every 250 people in the UK has IBD, which means there are about 240,000 patients in the UK. The incidence of IBD in young people is increasing, with one in four new cases now diagnosed under the age of 16. Adolescence is a time of great physical, social and emotional change and having IBD during this time can be devastating.
Flare-ups of IBD can happen during times of stress, so finding ways of helping people with IBD manage stress is essential. Mindfulness-Based Stress Reduction (MBSR) is the most well-recognised approach for the management of stress and long-lasting illness. It consists of an 8-week group programme, in which participants are taught about the relationship between stress and illness and trained in mindfulness meditation practices. A number of studies have shown that MBSR may be useful in people with IBD. Research in adults has shown that MBSR helped to reduce flare-ups in people with high levels of stress and also it improved quality of life in those who did experience flare-ups. There needs to be more research investigating MBSR in adolescents and young adults.
This study aims to investigate whether taking part in an 8-week MBSR group programme can improve symptoms (e.g. pain and flare-ups) and quality of life in young people who have IBD. In this course, participants will be taught a range of techniques that have been shown to help people manage the stress associated with pain and physical symptoms and promote emotional well-being.

Who can participate?
People aged between 15 and 24 who have a diagnosis of Crohn's disease or ulcerative colitis (two types of IBD) can participate in this study.

What does the study involve?
This is a waiting list control trial. This means that participants will be randomly assigned to one

of two groups. Group 1 will start the course immediately after recruitment and Group 2 will participate in the programme about 8 to 10 weeks later. The course itself will be the same for both groups.
Group 1:
• A member of the research team will questions about physical symptoms, stress and emotional well-being. Patients who are interested in the research will then be asked to complete a consent form and some questionnaires. The researcher will also ask for consent to view the participant's medical information, including blood test results. This will take place during the usual gastroenterology outpatient clinic appointment.
• People allocated to Group 1 will then be invited to attend the 8-week course (one session per week for 1.5 hours), which will be delivered in a group format with other young people.
• Once the course has finished, participants will be asked again about physical symptoms, stress and emotional well-being again . Once again this will take place at the usual gastroenterology outpatient clinic appointment.
• The above assessments will be repeated again 10-12 weeks later at the next outpatient appointment.

Group 2:
• A member of the research team will ask questions about physical symptoms, stress and emotional well-being. People who are interested in the research will then be asked to complete a consent form and some questionnaires. The researcher will also ask for consent to view the participant's medical information including blood test results. This will take place during the usual gastroenterology outpatient clinic appointment.
• The above assessments will be repeated 10-12 weeks later at the next outpatient appointment, before the 8-week course begins.
• Participants will then be invited to attend the 8-week course which will be delivered in a group format with other young people. This will begin approximately 2 months later than Group 1. The content of the course will be the same as Group 1.
• Once the course has finished, participants will be asked again about physical symptoms, stress and emotional well-being, again at the next gastroenterology outpatient appointment.

What are the possible benefits and risks of participating?
The programme aims to reduce stress, reduce symptoms associated with Crohn’s disease and ulcerative colitis and improve overall emotional well-being and quality of life. There are unlikely to be any risks involved in taking part in the research. The group sessions are led by an experienced clinical psychologist who will be available to meet with anyone should they experience any difficulties and give advice about what to do.

Where is the study run from?
University College London Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
June 2015 to December 2018

Who is funding the study?
Crohn’s in Childhood Research Association (CICRA)

Who is the main contact?
1. Dr Jacqueline Doyle, Clinical Psychologist
Jacqueline.doyle3@nhs.net
2. Prof. Deborah Christie
deborah.christie2@nhs.net

Contact information

Type(s)
Scientific

Contact name
Prof Deborah Christie

Contact details
Child and Adolescent Psychological Medicine
Level 6
250 Euston Road
London
United Kingdom
NW1 2PG
0203 447 9086
deborah.christie2@nhs.net

Type(s)
Scientific

Contact name
Dr Jacqueline Doyle

Contact details
GI Division, Ground Floor West, 250 Euston Road,
London
United Kingdom
NW1 2PG
0203 447 9419
jacqueline.doyle3@nhs.net

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
207335

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 207335, protocol 16/503

Study information

Scientific Title

An evaluation of mindfulness-based stress reduction groups for adolescents and young adults with Crohn's disease and ulcerative colitis

Acronym
MBSR-AH

Study objectives
1. A mindfulness-based psychological intervention can improve inflammatory-related symptoms in adolescents with inflammatory bowel disease (IBD) rated by by self-reported symptom measures.
2. Psychological stress correlates with the activation of cellular immune and inflammatory responses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/03/2017, Yorkshire and The Humber Bradford Leeds Research Ethics Committee of the Health Research Authority (nrescommittee.yorkandhumber-bradfordleeds@nhs.net, 0207 104 8088), ref: 17/YH/0050

Study design
Randomised waiting-list-controlled trial

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 contact details to request an information sheet.

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

Interventions
Participants will be randomly assigned to one of two groups. Group 1 will start the MBSR course immediately after recruitment and Group 2 will participate in the programme about 8 to 10 weeks later. The course itself will be the same for both groups. The process for each group is outlined below:
1. Group 1:
1.1. A member of the research team will ask questions about any gastro-intestinal symptoms and about current emotional well-being. People who are eligible for the research will be asked to complete a consent form and some additional questionnaires. This will all take place during the

routine outpatient gastroenterology appointment.
1.2. Participants will then be invited to attend an 8-week Mindfulness-Based Stress-Reduction (MBSR) course (one session per week for 1.5 hours), which will be delivered in a group format with other young people. In this course people will be taught a range of mindfulness practices that have been shown to help people manage the stress associated with pain and physical symptoms and promote emotional well-being. In addition to this participants will be given a CD of a variety of different mindfulness practices and asked to do these at home for approximately 20 minutes each day.
1.3. After the group sessions have ended, participants will be asked the questions about gastrointestinal symptoms, stress and well-being again at the next gastroenterology outpatient appointment. These assessments will be repeated again 10-12 weeks later at the next outpatient appointment.

2. Group 2:
2.1. A member of the research team will ask questions about any gastrointestinal symptoms and about current emotional well-being. People who are eligible for the research will be asked to complete a consent form and some additional questionnaires. This will all take place during the routine outpatient gastroenterology appointment. These assessments will be repeated 10-12 weeks later at the next outpatient appointment, before the Mindfulness Based Stress Reduction (MBSR) course has started.
2.2. Participants will then be invited to attend an 8-week MBSR course which will be delivered in a group format with other young people. This will begin approximately 2 months later than Group One. The content of the course will be the same as in Group 1.
2.3.Finally, after the group sessions have ended, group 2 will be asked the questions about gastrointestinal symptoms, stress and well-being again at the next gastroenterology outpatient appointment.

Intervention Type
Behavioural

Primary outcome measure
For CD patients:
1. Patient-reported symptoms assessed using the Harvey-Bradshaw Index (HBI) at T0 (at recruitment), T1 (10 -12 weeks after recruitment) and T2 (10-12 weeks after T1)

For UC patients:
2. Patient-reported symptoms assessed using the Paediatric Ulcerative Colitis Activity Index (PUCAI) at T0 (at recruitment), T1 (10 -12 weeks after recruitment) and T2 (10-12 weeks after T1)
3. Patient-reported symptoms assessed using the Simple Clinical Colitis Activity Index (SCCAI) at T0 (at recruitment), T1 (10 -12 weeks after recruitment) and T2 (10-12 weeks after T1)

For all patients:
4. Haematological parameters, including full blood count and erythrocyte sedimentation rate, assessed before and after the intervention
5. C-reactive protein (CRP, a marker of inflammation) level in blood assessed before and after the intervention
6. Intestinal inflammation assessed using faecal calprotectin level before and after the intervention

Secondary outcome measures

1. Health-related quality of life specific to IBD assessed using the IMPACT-III Quality of Life Questionnaire at T0 (at recruitment), T1 (10 -12 weeks after recruitment) and T2 (10-12 weeks after T1)
2. Mindfulness assessed using the Mindful Attention Awareness Scale at T0 (at recruitment), T1 (10 -12 weeks after recruitment) and T2 (10-12 weeks after T1)
3. Mental wellbeing assessed using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at T0 (at recruitment), T1 (10 -12 weeks after recruitment) and T2 (10-12 weeks after T1)
4. Perception of stress assessed using the Perceived Stress Scale (PSS) at T0 (at recruitment), T1 (10 -12 weeks after recruitment) and T2 (10-12 weeks after T1)

Overall study start date
19/03/2016

Completion date
25/12/2018

Eligibility

Key inclusion criteria
1. Aged 15-24 years
2. Diagnosed with Crohn's disease (CD) or ulcerative colitis (UC)

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
86

Total final enrolment
58

Key exclusion criteria
1. Severe IBD
2. Currently experiencing severe psychological difficulties (e.g. psychosis, substance abuse or suicidality)

Date of first enrolment
21/03/2017

Date of final enrolment
26/06/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London Hospitals
GI Division
Ground Floor West
250 Euston Road
London
United Kingdom
NW1 2PG

Sponsor information

Organisation
University College London Hospitals

Sponsor details
Joint Research Office
UCL
Gower St
London
England
United Kingdom
WC1E 6BT
+44 (0) 20 3447 5199
randd@uclh.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.ucl.ac.uk/jro

ROR
https://ror.org/042fqyp44

Funder(s)

Funder type
Charity

Funder Name
Crohn's in Childhood Research Association

Alternative Name(s)
CICRA

Funding Body Type
Government organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The data is currently being analysed and will be published in a high-impact peer-reviewed journal in approximately October 2019.

Intention to publish date
01/03/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mark Shevlin (m.shevlin@ulster.ac.uk).
Type of data: Deidentified data on main study variables T0, T1, & T2.
When the data will become available and for how long: data will be made available on publication of main study findings.
By what access criteria data will be shared including with whom: brief research proposal will be requested that outlines the (1) aims of the proposed analysis, (2) details of variables that are required, (3) proposed analysis, (4) dissemination strategy.
For what types of analyses: requests for data must include detailed specification of proposed analysis and justification.
By what mechanism: de-identified data will be made available in password protected and encrypted file and sent using secure email system (Tutanota).
Whether consent from participants was obtained: consent obtained to support other research in the future, and may be shared anonymously with other researchers.
Comments on data anonymization: potentially identifying information (DoB, study site, postcode) will not be provided. Age, gender, and 4-category ethnicity are the only demographic variables that will be provided.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		05/02/2020	05/02/2020	No	No
HRA research summary			28/06/2023	No	No