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Identifying potential medical causes of fatigue, pain and urgency in inflammatory bowel disease and optimising medical management of these causes

Submission date
05/02/2020

Recruitment status
No longer recruiting

Registration date
12/02/2020

Overall study status
Completed

Last Edited
17/01/2025

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Inflammatory Bowel Disease (IBD) affects 300,000 people in the UK causing unpredictable bouts of gut inflammation, with acute illness, diarrhoea, and pain. In remission, many people with IBD live with fatigue, chronic pain, and bowel urgency/incontinence. There is no current cure for IBD, which usually starts in childhood or as a young adult. Most previous IBD research has focused on controlling inflammation. However, many people report continuing IBD-related fatigue (41%), abdominal pain (62%) and difficulty with continence (up to 75%) even when IBD is in remission. These symptoms limit peoples' quality of life and ability to work and socialise. This study is stage three of IBD-BOOST, a National Institute of Health Research (NIHR) Programme Grant for Applied Research (PGfAR) funded programme. The overall aim of the Programme Grant is to improve the quality of life of people with IBD by reducing the burden of IBD-related fatigue, pain, and urgency/incontinence. This interventional study of a non-randomised (cohort) study is stage 3 of the IBD-BOOST programme and will test a checklist and clinical management algorithm (step by step guide for health professionals), which we have developed for identifying and managing the most common medical causes of these IBD-related symptoms. We will then address any medical issues detected. These symptoms of fatigue, pain and urgency/incontinence have a major impact on quality of life in people with IBD, but have been largely ignored by clinicians and researchers. Our programme, shaped by the concerns of our patient and clinician stakeholders, focuses on a supported online self-management intervention for these symptoms. This study will help identify participants who will be suitable for a self-management intervention and ensure that anyone displaying "red-flag" symptoms (indicating an urgent or serious medical issue) is identified for prompt treatment. It is currently unclear how useful it is to investigate these symptoms and whether symptoms will respond to correcting biomedical abnormalities. It is currently unclear how best to manage these common symptoms of fatigue, pain and urgency /incontinence in people with inflammatory bowel disease. Many patients do not report these symptoms at all, or if they do are offered little beyond investigation and treatment of active disease. We have found in previous work that many patients do not receive what are considered "standard care" investigations or management for these symptoms. Our previous systematic

literature reviews have identified many potentially reversible causes for these symptoms. Many of these, particularly the psycho-social elements, will be addressed in our online self-management programme which follows on from the current proposal within our programme grant. However, there are also "medical" causes (such as anaemia as a cause of fatigue), which could be addressed before patients enter a self-management programme.

Who can participate?
Patients aged 18 years or older, with IBD, who have completed the IBD-BOOST survey (stage 2).

What does the study involve?
Patients participating in this study will be sent a checklist to complete about their IBD-related symptoms and any tests that they have had recently. They will also be asked to compete faecal calprotectin sample sent to them with stamped addressed packaging to send to lab. Once received, a nurse or doctor from the patient's IBD hospital will then review the completed checklist and the results of the faecal calprotectin test and use a care pathway developed by experts to decide if a phone call and possibly further tests are necessary. If the nurse or doctor feels that more information is needed, a phone call or appointment will be arranged. During this consultation, the nurse will run through a series of questions relating to the patient's fatigue, pain and/or urgency plus any other important symptoms they may be experiencing. After the consultation, it may be suggested that the completes further tests such as a blood test. If offered any management or advice, patients will be asked to complete a questionnaire about their symptoms after 3 months to see if there has been any improvement.

What are the possible benefits and risks of participating?
Through benefiting in this study patients will be checked to see if any of their symptoms have any common medically treatable underlying causes and treated through standard care. Patients will asked to complete a faecal calprotectin sample and will receive the result. It is unlikely that participating in this study would cause any harm. Potential side effects of any interventions that you are offered by an IBD Care Team as a result of participation in this study will be discussed with the patient beforehand and should be packaged with an information sheet.

Where is the study run from?
Northwick Park Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2017 to March 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Prof. Christine Norton (public and scientific contact)
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Contact information

Type(s)
Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
249845

Protocol serial number
RP-PG-0216-20001, IRAS 249845, CPMS 41698

Study information

Scientific Title
Identifying potential medical causes of fatigue, pain and urgency in inflammatory bowel disease and optimising medical management of these causes. The IBD-BOOST OPTIMISE Study

Acronym
IBD-BOOST OPTIMISE

Study objectives
Of those people with IBD who experience fatigue, pain and/or faecal urgency/incontinence and express an interest in intervention for one or more of these symptoms, what proportion have patho-physiological contributors which are potentially medically treatable?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/04/2019, West Midlands - Black Country Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; +44 (0)207 104 8284; nrescommittee.westmidlands-blackcountry@nhs.net), ref: 19/WM/0107

Study design
Non-randomized interventional study

Primary study design

Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Inflammatory Bowel Disease

Interventions
The OPTIMISE Study will test a checklist and algorithm designed to find any medical issues which may be causing IBD-related symptoms of fatigue, pain or urgency and to ensure these are being treated as well as they can be ("Optimised") by a patient's NHS IBD care team.

Patients participating in this study will be sent a checklist to complete about their IBD-related symptoms and any tests that they have had recently. They will also be asked to compete faecal calprotectin sample sent to them with stamped addressed packaging to send to lab. Once received, a nurse or doctor from the patient's IBD hospital will then review the completed checklist and the results of the faecal calprotectin test and use a care pathway developed by experts to decide if a phone call and possibly further tests are necessary. If the nurse or doctor feels that more information is needed, a phone call or appointment will be arranged. During this consultation, the nurse will run through a series of questions relating to the patient's fatigue, pain and/or urgency plus any other important symptoms they may be experiencing. After the consultation, it may be suggested that the completes further tests such as a blood test. If offered any management or advice, patients will be asked to complete a questionnaire about their symptoms after 3 months to see if there has been any improvement.

Intervention Type
Other

Primary outcome(s)
Proportion of participants with any of the following detected via the OPTIMISE checklist, faecal calprotectin test or by the nurse/clinician following the algorithm
1. "Red flags" (indicating an urgent or serious medical issue) on checklist which require investigation
2. Active disease (defined as faecal calprotectin 200 or over and/or IBD control score 13 or under)
3. Abnormalities detected on blood test in people with fatigue
4. Irritable Bowel Syndrome or functional dyspepsia diagnosed in people with pain (by responses on checklist)
5. Untreated loose stool detected in people with urgency

Key secondary outcome(s))
1. Proportion of participants for whom a clinical intervention was indicated using the OPTIMISE checklist
2. Proportion of participants who declined a suggested clinical intervention
3. Proportion of participants starting a clinical intervention for these 3 symptoms
4. For those starting a clinical optimisation intervention, the cost of implementing the algorithm (clinical tests or intervention and nurse/clinician time to implement the algorithm)
5. The checklist also includes the following measures, which will be repeated at 3 months:
5.1. PROMIS Short Form v1.0 – Fatigue 4a; 4 item validated scale to measure fatigue
5.2. PROMIS Scale v1.0 - Pain Intensity 3a; 3 item validated scale to measure pain
5.3. PROMIS Scale v1.0 – Gastrointestinal Bowel Incontinence 4a; 4 item validated scale to

measure bowel control
5.4. IBD-Control score; 8-item self-reported score to measure disease control from the patient's perspective
5.5. EQ-5D-5L (Quality of Life measurement); a 5-item standardised measure of health
6. Only those participants needing interventions as indicated by the algorithm, will be sent the outcome questionnaire at 3 months after return of the initial checklist and stool sample. This questionnaire will also include a free text feedback option at follow up to capture qualitative comments about the experience of completing the checklist and algorithm, and how onerous or helpful this was.
7. In addition, the nurse/clinician will complete the Optimisation CRF for each participant, this will include number of visits or telephone contacts, all tests and results and all management initiated within the algorithm. Qualitative comments on taking the participant through the process of using the checklist and algorithm will be collected here.
8. Feasibility outcomes will include number consenting but then discontinuing (with reasons if possible), completion of outcome measures, completion of CRFs.

Completion date
31/03/2023

Eligibility

Key inclusion criteria
1. Diagnosis of IBD (including patients with an ileo-anal pouch or stoma)
2. 18 years and over
3. Lives in UK and attends one of the IBD-BOOST NHS clinical sites for routine IBD care
4. Has completed the IBD-BOOST survey (stage 2) and indicated that they would like further support to help manage their symptoms
5. Ability to give informed consent and sufficient command of English to understand study documents and procedures will be assumed from response to previous survey

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
201

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/09/2020

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Northwick Park Hospital
London North West University Healthcare NHS Trust
Watford Road
Harrow
United Kingdom
HA1 3UJ

Sponsor information

Organisation
London North West Healthcare NHS Trust

ROR
https://ror.org/04cntmc13

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/12/2024	17/01/2025	Yes	No
HRA research summary			20/09/2023	No	No
Protocol file	version 7.0	16/08/2022	21/08/2023	No	No
Statistical Analysis Plan	version 1.0	27/04/2023	21/08/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes