ISRCTN71618461 https://doi.org/10.1186/ISRCTN71618461

A supported online self-management for symptoms of fatigue, pain and urgency /incontinence in people with inflammatory bowel disease: the IBD-BOOST trial

Submission date 02/09/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol
Registration date 09/09/2019	**Overall study status** Completed	[X] Statistical analysis plan [_] Results
Last Edited 18/06/2025	**Condition category** Digestive System	[_] Individual participant data [X] Record updated in last year

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 abdominal 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. Patients feel that these symptoms are not taken seriously by health professionals and report that little help is given. However, the James Lind Alliance IBD research priority-setting consensus put fatigue, pain, and continence in the top 10 issues that IBD patients and clinicians want to be addressed by research.

The current application is stage four 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, abdominal pain, and urgency/incontinence. The current application is for the final part of the project, a 2-arm randomised controlled trial (RCT) of a facilitator supported online intervention for people who have expressed a desire for intervention for fatigue, pain and /or urgency/incontinence, compared to care as usual.

Who can participate?

Patients 18 years old or over with a diagnosis of IBD, living in England, Scotland or Wales, and have participated in Stage 2 of the programme (IBD-BOOST) survey

What does the study involve?

This trial is testing whether an online self-management programme can improve symptoms and quality of life. Participants who consent to take part will complete an online questionnaire. An

automated computer system will then put participants into one of two groups by chance (randomly).
One group will receive a password to access an online self-management programme. It has 11 sessions, depending on the participant's symptoms and can be completed over a few weeks or up to 6 months. The sessions can be done at any time, with some exercises in between, and should take a total of 1-2 hours per week. Participants will also have a professional facilitator who will support the participant with an initial telephone call and then via in-website messaging, during the first 3 months, if they wish.
The other group will not have access to the online programme at first, but will receive care as usual. Twelve months after taking part, this group will have access to the online programme, but without the facilitator support.
We will ask both groups to complete the questionnaires again at 6 and 12 months after signing up and they will receive a £5 gift voucher each time.

What are the possible benefits and risks of participating?
Benefits: For participants who haven't taken part in the IBD-BOOST Optimise study (Stage 3 of the IBD-BOOST programme), the faecal calprotectin stool sample results combined with the participant's checklist results may raise medical issues that their healthcare team can potentially help to manage. Participants could potentially then benefit from symptom (fatigue, pain and urgency/incontinence) relief. PPI indicated that people want to be reassured that "nothing has been missed" when they experience these symptoms. Participants who are randomised to the online self-management programme of the study, may find the programme beneficial as the aim is to address symptoms such as faecal urgency/incontinence, pain and fatigue utilising cognitive behavioural therapy components. Participants who have been randomised to the control arm (care as usual) group, will be offered access to the online intervention (but no facilitator support) at 12 months so that they have the potential benefit of the online self-management platform in future.
Risks: This is a low-risk study, although there is potential for participants to become distressed when thinking about their symptoms. The online intervention site will include a link/website address to CCUK who provide support via their helpline, and contact details are included in the Participant Information Leaflet. The outcome measures include questions on anxiety and depression. At the end of the questionnaire, there are helplines listed that can offer support and there is a protocol risk assessment. We recognise the potential burden on participants of these multiple outcome measures (Just under 150 questions). However, as we are assessing multiple symptoms and are keen to include potentially explanatory variables, we feel that these are necessary. We will send an unconditional £5 incentive to participants for both the 6 and 12 months follow-up. For participants who did not take part in the previous stage of the study (Stage 3 of the IBD-BOOST programme, the IBD-BOOST Optimise study), they may feel burdensome to send a faecal/stool sample for the calprotectin test, however this will be balanced by the benefit of knowledge regarding whether inflammation has been detected in a participant's sample, indicating active disease (flare). Patients with IBD are routinely asked to complete this test at many of their routine NHS clinic visits so this will not be a novel test.

Where is the study run from?
Trial study centres:
1. London North West University Hospital NHS Trust, UK
2. Nottingham University Hospitals NHS Trust, UK
3. St Helens and Knowsley Teaching Hospitals NHS Trust
Trial run from:
1. King's College London, UK
2. London North West University Healthcare NHS Trust, UK
3. Barts and the London Pragmatic Clinical Trials Unit, UK

When is the study starting and how long is it expected to run for?
December 2019 to March 2023

Who is funding the study?
National Institute of Health Research (NIHR) Programme Grant for Applied Research (PGfAR), UK

Who is the main contact?
1. Prof. Christine Norton
christine.norton@kcl.ac.uk
2. Miss Laura Miller
l.miller@qmul.ac.uk

Study website
http://www.ibd-boost.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Christine Norton

ORCID ID
https://orcid.org/0000-0003-2259-0948

Contact details
Florence Nightingale Faculty of Nursing, Midwifery and Palliative Care
King’s College London
57 Waterloo Road
London
United Kingdom
SE1 8WA
+44 (0)20 7848 3864
christine.norton@kcl.ac.uk

Type(s)
Public

Contact name
Miss Laura Miller

Contact details
Barts and the London Pragmatic Clinical Trials Unit (PCTU)
Centre for Evaluation and Methods
Wolfson Institute of Population Health
Queen Mary University of London
Yvonne Carter Building
58 Turner Street
London

United Kingdom
E1 2AB
+44 (0)207 848 3318
l.miller@qmul.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
258725

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 258725, RP-PG-0216-20001

Study information

Scientific Title
A Randomised Controlled Trial of supported online self-management for symptoms of fatigue, pain and urgency/incontinence in people with inflammatory bowel disease: the IBD-BOOST trial.

Acronym
IBD-BOOST

Study objectives
Current study hypothesis as of 19/07/2022:
A facilitator-supported, online, tailored self-management programme for fatigue, pain and faecal urgency/ incontinence in people with IBD will result in better IBD-related quality of life and global rating of symptom relief compared to care as usual at six months after randomisation.

Previous study hypothesis:
A facilitator-supported, online, tailored self-management programme for fatigue, pain and faecal urgency/ incontinence in people with IBD will result in better quality of life compared to care as usual at six months after randomisation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/07/2019, London - Surrey Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8310; NRESCommittee.SECoast-Surrey@nhs.net), ref: 19/LO/0750

Study design
A pragmatic multi-centre two-arm parallel-group superiority randomized controlled trial with an internal pilot

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
https://www.kcl.ac.uk/nmpc/assets/boost-trial-pil.pdf

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

Interventions
Current intervention as of 19/07/2022:
A pragmatic multi-centre two-arm, parallel group superiority RCT, with an internal pilot, of facilitator-supported online self-management versus care as usual to manage symptoms of fatigue, pain, and faecal urgency/incontinence in IBD. One baseline assessment and two assessments at 6 and 12 months after randomisation. Primary outcome: IBD-related quality of life and global rating of symptom relief at 6 months.

This trial will compare a web-based programme, known as 'BOOST', for self-management of pain, fatigue and urgency/incontinence symptoms of IBD ('BOOST' is based on the principles of cognitive behavioural therapy with telephone and online messaging support) to standard care.

The content has been developed by health psychologists to be interactive and tailored to patients' needs. BOOST includes 11 online sessions which can be viewed on computer, smart phone or tablet.). Sessions 1-6, are core transdiagnostic sessions to be completed by participants experiencing fatigue, pain and faecal urgency/incontinence. Based on a Cognitive Behavioural model of IBD symptoms, the core sessions cover topics around: understanding IBD symptoms, balancing activity and exercise, sleep hygiene, changing negative thoughts, coping with stress and emotions, and making the most of social support. Sessions 7-11 are symptom-specific sessions to be completed by participants experiencing or with a specific interest in fatigue, pain and faecal urgency/incontinence, respectively. The symptom specific sessions provide participants with more in-depth psychoeducation on the interaction between medical and psychosocial factors contributing to the severity and impact of IBD symptoms, together with practical tips and exercises on how to better manage them.

Participants will be able to log into BOOST via a computer, tablet or smartphone, according to their preference, and complete approximately one session per week. Each session takes 30-60 minutes to complete. Participants will be able to complete the sessions at a time and place that is convenient to them and to pace themselves in a way that suits them and their lifestyle. In between sessions, participants will be asked to complete tasks which will help them to practice the skills acquired during the intervention sessions. Throughout the intervention, the participants will be supported via online messages by an assigned healthcare professional, who

will act as their facilitator. The facilitator will have access to information on how participants are using the intervention (sessions and task completed) and will monitor and help to promote participants' engagement with the intervention, together with supporting participants work towards achievement of their intervention goals.

Participants randomized to the intervention will have access to care as usual plus the online tailored self-management programme for six months, plus one individual telephone or Skype support session (for up to 30 minutes, training and a paper copy of the content will be provided for the facilitator), plus access to online messaging with their facilitator via the BOOST platform for the first three months after recruitment.

Participants randomised to the control have access to all usual care.

Participants in the intervention arm have access to the online self-management programme for six months, plus access to online messaging with their facilitator via the website platform for the first 3 months after recruitment.

Both the intervention and control group are followed up at 6 and 12 months,

Participants who consent, are eligible and return the baseline questionnaire will be randomised by the central research team using an online randomisation system developed for the study by the PCTU. The central team will then inform the participant which group they are in. Stratified central web-based randomisation to 2 groups. Stratified by diagnosis (Crohn's disease vs. other IBD) and whether or not participated in WP2c study (OPTIMISE: medical symptom optimisation). Allocation will be concealed until consent and baseline measurements completed

Previous intervention:
A pragmatic multi-centre two-arm, parallel group superiority RCT, with an internal pilot, of facilitator-supported online self-management versus care as usual to manage symptoms of fatigue, pain, and faecal urgency/incontinence in IBD. One baseline assessment and two assessments at 6 and 12 months after randomisation. Primary outcome: IBD quality of life at 6 months.

This trial will compare a web-based programme, known as 'BOOST', for self-management of pain, fatigue and urgency/incontinence symptoms of IBD ('BOOST' is based on the principles of cognitive behavioural therapy with telephone and online messaging support) to standard care.

The content has been developed by health psychologists to be interactive and tailored to patients' needs. BOOST includes 11 online sessions which can be viewed on computer, smart phone or tablet.). Sessions 1-7, are core transdiagnostic sessions to be completed by participants experiencing fatigue, pain and faecal urgency/incontinence. Based on a Cognitive Behavioural model of IBD symptoms, the core sessions cover topics around: understanding IBD symptoms, balancing activity and exercise, sleep hygiene, changing negative thoughts, coping with stress and emotions, and making the most of social support. Sessions 8-11 are symptom-specific sessions to be completed by participants experiencing or with a specific interest in fatigue, pain and faecal urgency/incontinence, respectively. The symptom specific sessions provide participants with more in-depth psychoeducation on the interaction between medical and psychosocial factors contributing to the severity and impact of IBD symptoms, together with practical tips and exercises on how to better manage them.

Participants will be able to log into BOOST via a computer, tablet or smartphone, according to their preference, and complete approximately one session per week. Each session takes 30-60

minutes to complete. Participants will be able to complete the sessions at a time and place that is convenient to them and to pace themselves in a way that suits them and their lifestyle. In between sessions, participants will be asked to complete tasks which will help them to practice the skills acquired during the intervention sessions. Throughout the intervention, the participants will be supported via online messages by an assigned healthcare professional, who will act as their facilitator. The facilitator will have access to information on how participants are using the intervention (sessions and task completed) and will monitor and help to promote participants' engagement with the intervention, together with supporting participants work towards achievement of their intervention goals.

Participants randomized to the intervention will have access to care as usual plus the online tailored self-management programme for six months, plus one individual telephone or Skype support session (for up to 30 minutes, training and a paper copy of the content will be provided for the facilitator), plus access to online messaging with their facilitator via the BOOST platform for the first three months after recruitment.

Participants randomised to the control have access to all usual care.

Participants in the intervention arm have access to the online self-management programme for six months, plus access to online messaging with their facilitator via the website platform for the first 3 months after recruitment.

Both the intervention and control group are followed up at 6 and 12 months,

Participants who consent, are eligible and return the baseline questionnaire will be randomised by the central research team using an online randomisation system developed for the study by the PCTU. The central team will then inform the participant which group they are in. Stratified central web-based randomisation to 2 groups. Stratified by:
- Diagnosis (Crohn's disease vs. other IBD)
- Whether or not participated in WP2c study (OPTIMISE: medical symptom optimisation)
Allocation will be concealed until consent and baseline measurements completed

Intervention Type
Behavioural

Primary outcome measure
UK Inflammatory Bowel Disease Questionnaire (UK-IBDQ) and global rating of symptom relief at six months after randomisation.

Secondary outcome measures
1. UK Inflammatory Bowel Disease Questionnaire (UK-IBDQ) at 12 months
2. Rating of satisfaction with results of BOOST programme (simple 0-100 visual analogue scale) at 6 and 12 months only
3. Global rating of symptom relief at 12 months
4. Numerical (0-10) pain rating scale at baseline, 6 and 12 months after randomisation
5. Vaizey (faecal) incontinence score, reflecting patients' perceptions of severity at baseline, 6 and 12 months after randomisation
6. IBD-Fatigue score at baseline, 6 and 12 months after randomisation
7. IBD-Control score; 8-item self-reported score to measure disease control from the patient's

perspective at baseline, 6 and 12 months after randomisation
8. EQ-5D-5L general health-related quality of life at baseline and 6 and 12 months after randomisation

Overall study start date
01/11/2017

Completion date
24/03/2023

Eligibility

Key inclusion criteria
1. Diagnosis of IBD (self-reported as having been medically diagnosed with IBD including patients with an ileo-anal pouch or stoma)
2. 18 years old or over
3. Living in England, Scotland or Wales
4. Have participated in Stage 2 of the programme (IBD-BOOST survey) and have self-scored one or more symptoms of fatigue, pain or urgency/incontinence as having an impact on their life of 5 or more on a 0-10 scale when completing Stage 2 (IBD-BOOST survey) or Stage 3 (medical symptom optimisation) (whichever is the more recent)
5. No “red flags”– see below
6. Access to the online intervention via a computer or mobile device

Screening for 'red flags':
Following consent, we will screen patients for ’red flags’ (such as new bleeding, rapid weight loss or vomiting that has not been previously reported to a health care practitioner) self-reported on a screening checklist. Note: The “red flags” criteria have been developed in consultation with 5 consultant gastroenterologists who are either co-applicants or part of our wider advisory group: they have each confirmed that they feel that participants who meet the criteria will be safe to enter an online self-management programme. If ineligible because of a red flag, a participant may be re-assessed if they contact the research team and report the information they have provided has changed such as the symptom has been adequately investigated or managed, in which case the participant can be included.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
At least 740 participants

Total final enrolment
780

Key exclusion criteria
1. One or more “red flags” identified on pre-randomisation screening, (such as new bleeding, rapid weight loss or vomiting that has not been previously reported to a health care practitioner) self-reported on a screening checklist. Note: The “red flags” criteria have been developed in consultation with 5 consultant gastroenterologists who are either co-applicants or part of our wider advisory group: they have each confirmed that they feel that participants who meet the criteria will be safe to enter an online self-management programme. If ineligible because of a red flag, a participant may be re-assessed if they contact the research team and report the information they have provided has changed such as the symptom has been adequately investigated or managed, in which case the participant can be included.
2. Inability to give informed consent (for example, due to reduced mental capacity)
3. Insufficient command of English to understand study documents and procedures

Date of first enrolment
18/12/2019

Date of final enrolment
31/07/2022

Locations

Countries of recruitment
England

United Kingdom

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

Study participating centre
Nottingham University Hospitals NHS Trust
Queen’s Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
St Helens and Knowsley Teaching Hospitals NHS Trust
Whiston Hospital
Warrington Road
Prescot
United Kingdom
L35 5DR

Sponsor information

Organisation
London North West University Healthcare NHS Trust

Sponsor details
Research and Development
Northwick Park Hospital
Watford Road
Harrow
England
United Kingdom
HA1 3UJ
+44 (0)20 8869 5829
LNWH-tr.Research@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://www.lnwh.nhs.uk/research/

ROR
https://ror.org/04cntmc13

Funder(s)

Funder type
Government

Funder Name
Programme Grants for Applied Research

Alternative Name(s)
NIHR Programme Grants for Applied Research, PGfAR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
We will submit results for publication in multidisciplinary academic journals (such as Inflammatory Bowel Diseases and Journal of Crohn's & Colitis) to disseminate to professional audiences. We will submit 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
31/12/2024

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 risk of patient identification.

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		03/08/2021	03/09/2021	Yes	No
Other publications	Describing intervention development	18/05/2022	20/05/2022	Yes	No
Participant information sheet	version 5.0	17/06/2021	19/07/2022	No	Yes
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan	version 1.0	18/08/2023	21/08/2023	No	No
Other files	Health economics analysis plan (HEAP) version 1.0	01/10/2023	02/10/2023	No	No
Statistical Analysis Plan	version 2.0	21/03/2024	26/03/2024	No	No
Other	risk assessment protocol	12/07	16/07		

publications		/2024	/2024	Yes	No
Other publications	cross-sectional analysis of baseline data	06/03/2025	10/03/2025	Yes	No
Other publications	What is the impact on recruitment of a shortened compared with a standard-length participant information leaflet? PROMETHEUS in IBD-BOOST: study within a trial, a decentralised UK randomised controlled trial	18/06/2025	18/06/2025	Yes	No