

**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**

Participant Information Sheet

We invite you to take part in this research trial. Before you decide, it is important that you know why we are doing the trial and what is involved. Please read the following information carefully.

What is the purpose of this trial?

Many people with Inflammatory Bowel Disease (including Crohn's disease and ulcerative colitis) have troublesome symptoms of tiredness (fatigue), pain and/or urgency to use the toilet. This trial will test an online self-management programme to see if it can improve one or more of these three symptoms and your quality of life.

Why me?

You are invited to participate in this trial because you have a diagnosis of Crohn's disease, ulcerative colitis or another type of IBD. You have also completed the IBD-BOOST Survey and indicated that you have one or more IBD related symptoms of fatigue, pain and/or urgency and that you would be interested in receiving support. **Please note that if since completing the IBD-BOOST Survey your symptoms have significantly improved and are no longer impacting you, the IBD-BOOST Trial may not be suitable for you- if in doubt please contact the Trial team.**

If I take part what will happen?

After you have had all your questions answered by the research team (using the contact details listed below) and have agreed to take part, we will send you an online consent form via our secure and confidential trial website. You will be unable to proceed further until you have completed the consent form.

- If you have previously completed the IBD-BOOST survey ***and participated*** in the IBD-BOOST (Optimise) study, we will ask you to complete a confidential online questionnaire providing details about yourself and your symptoms.

Or

- If you have previously completed the IBD-BOOST survey ***and not participated*** in the IBD-BOOST (Optimise) study, we will ask you to:
 - Complete a short questionnaire on your general health (the questions help identify anything that may need to be checked before you can participate in the trial).

- Provide a sample of your stool (poo). You will be sent a stool sample kit with instructions by post. Further details about this are provided below under ‘Do I have to provide a stool sample?’
- Finally, we will then ask you to complete a confidential online questionnaire providing details about yourself and your symptoms.

When you have completed the questionnaire and provided a sample (if necessary), an automated computer system will put you into **one of two groups by chance** (randomly).

- **One group will** receive a password to access an online self-management programme for IBD related fatigue, pain and urgency.
 - The self-management programme will be available online and has been designed using elements of cognitive behavioural therapy (CBT). CBT is a therapy that can help you better manage your symptoms by making positive changes in the ways you think, feel and behave.
 - The programme will take you through a series of sessions with online activities. The sessions can be completed over a few weeks or up to 6 months and can be done at any time on a laptop, tablet or smart phone, however using a laptop or tablet may be easier to view the programme. We estimate that you would spend on average 1-2 hours per week completing the sessions and associated tasks.
 - The programme is supported by a specially trained professional who will support you with an initial telephone call and then via in-website messaging, during the first 3 months, if you wish. Messages sent via the in-website messaging system will be anonymised and viewed by a member of the research team for quality, training and evaluation purposes.
- **The other group will** not have access to the online programme at first, but will receive care as usual. This group is very important, as we will be able to compare the two groups in order to see whether there are any benefits to having access to the online programme. Twelve months after taking part, **this group** will have access to the online programme, but without the facilitator support.

We will ask people in both groups to complete online questionnaires again at 6 and 12 months after signing up. This is to see how things have been for you since joining the trial.

Will you compensate me for the time this takes?

You will receive a £5 gift voucher after 6 months, when you are sent the follow up online questionnaire and a further a £5 gift voucher after 12 months when you are sent the final online questionnaire.

Do I have to complete a stool sample?

You will only be asked to complete a stool sample if you have not already completed one as part of a previous study (IBD-BOOST Optimise). This tests for active inflammation (faecal calprotectin).

If you do need to complete it you will be sent a stool sample kit in the post. There will also be instructions and contact details included in the kit, in case you are unsure of anything. The package will contain a pot for the sample and a pre-paid plastic envelope. Once you have completed your sample, you will need to seal it in the plastic envelope and put it in the post. Your test will then arrive at our laboratory and be processed. When the sample has been analysed, it will be destroyed and we will send you a letter or email with the result information on the test and contact details if you would like to discuss the result. If you receive your routine IBD care from a hospital that is participating in the IBD-BOOST programme your IBD team will also be advised of the results of your stool sample.

Do I have to take part?

You do not have to take part. It is entirely up to you whether you would like to take part in this trial. If you choose **not** to take part, your medical care and your legal rights will not be affected.

What will happen if I want to withdraw from this trial?

You are free to withdraw yourself from the trial at any time without giving a reason. If you choose to withdraw, your medical care and your legal rights will not be affected.

What if there is a problem?

It is unlikely that participating in this trial would cause you any harm. However, if you have any concerns or a complaint about any aspect of this trial, please speak to us and we will do our best to answer your questions. Please contact IBD-BOOST Research Team on 020 7848 3318 and ibd-boost@kcl.ac.uk. If you remain unhappy, you can make a formal complaint through the NHS complaints procedure. Details can be obtained through the Patient Advisory Liaison Service at your hospital or at London North West University Healthcare NHS Trust who can be contacted at LNWH-tr.PALS@nhs.net.

What organisations are involved?

King's College London (KCL) and the Pragmatic Clinical trials Unit (PCTU) Queen Mary University of London are working in partnership with London North West University Healthcare NHS Trust (LNWUH). LNWUH is the sponsor for this trial based in the United Kingdom.

Will my taking part in this trial be kept confidential?

The research team will keep your name and contact details confidential and secure. The research team will use this information as needed, to contact you about the research trial, to make sure that relevant information about the trial is recorded for your care, and to oversee the quality of the trial. Certain individuals from LNWUH and regulatory organisations may look at your medical and research records to check the accuracy of the research trial. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

How will my personal information be managed?

We will be using information from you in order to undertake this trial and we will be responsible for looking after your information and using it properly. KCL and the PCTU on behalf of LNWUH will securely collect identifiable information for the purpose of this trial. KCL and the PCTU will pass these details to LNUWH at the end of the study along with the information collected from you for archiving. The only people in LNWUH who will have access to information that identifies you will be people who need to audit the data collection process. LNWUH will keep identifiable information about you for 10 years after the trial has finished (likely to be 2023).

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the trial, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information at <https://www.lnwh.nhs.uk/privacy>.

Will you share my data?

The information collected about you may be used to support other research in the future, and may be shared anonymously (without using your name) with other researchers. In addition, if you receive your routine IBD care from a hospital that is participating in the IBD-BOOST programme your IBD team will be advised of your participation in the trial, the results of your general health questionnaire and of your stool sample (if applicable), and the group that you have been put into. Your IBD team can also advise us if there have been any changes to the information in your general health questionnaire.

What will happen to the results of the research trial?

The results will be published in a scientific journal so that other people know about it. A summary of the results will be published on the Crohn's & Colitis UK website <https://www.crohnsandcolitis.org.uk/>.

Will I be able to access the BOOST Self-management programme after the trial?

Twelve months after signing up to the trial we will contact you to ask if you wish to have access to the programme. This is for people in both groups. We also aim to make the BOOST self-management programme available free of charge to the public on the Crohn's & Colitis UK website after the trial has finished in October 2023.

Who is organising and funding the research?

Professor Christine Norton is leading an experienced team of doctors, nurses and researchers. The trial is being funded by the National Institute of Health Research (NIHR) through their Programme Grants for Applied Research.

Who has reviewed this research?

This trial has been reviewed and given favourable opinion by London - Surrey Research Ethics Committee (Reference: 19/LO/0750) and has approval from the Health Research Authority.

If you would like further information before deciding to participate, please contact:

IBD-BOOST Research Team

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Appendix 5a

IBD-BOOST TRIAL: Participant Information Sheet (Standard)

Version: 5.0 17.06.2021

IRAS: 258725

FUNDED BY

NIHR | National Institute
for Health Research