



IBD BOOST

Living well with
Crohn's & Colitis

IBD-BOOST TRIAL				
SITE ID:				
PARTICIPANT ID:				
CRF BOOKLET NUMBER:				

CONSENT FORM (ONLINE)

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

Chief Investigator: Professor Christine Norton

Please read the following statements carefully and tick YES if you agree. We will not collect your information or ask you to participate in this trial without your consent.

- | | YES | NO |
|---|--------------------------|--------------------------|
| 1. I confirm that I have read and understood the information sheet [Standard or shortened PIL to be referenced depending on randomisation Version: X.X XX/XX/XXXX] for the above trial. I have had the opportunity to consider the information, ask questions using the contact details on the information sheet and have had these answered satisfactorily. | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. I understand that my participation is voluntary (my choice) and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. I understand that relevant information from my medical records and data that I have provided as part of this trial may be accessed by individuals from King's College London, the sponsor, the Pragmatic Clinical Trials Unit at Queen Mary University of London, from relevant regulatory authorities or from the NHS trust, where it is relevant to my taking part in this research. Only information relevant and necessary for my participation in this research will be accessed. I give permission for these individuals to have access to my records. | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. I understand that my IBD healthcare team may be notified of my involvement in this trial. | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. I consent to completing a stool sample that will be processed at a Laboratory at King's College Hospital. I understand this will not be required if I participated in the IBD-BOOST Optimise study. | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. I understand that the information collected about me may be used to support other research in the future and may be shared anonymously with other researchers. | <input type="checkbox"/> | <input type="checkbox"/> |

APPENDIX 8

IBD-BOOST: TRIAL Consent Form (Online Copy)

Version: 2.0 07.06.19

IRAS: 258725

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7. I agree to the identifiable data that I have completed for the previous IBD-BOOST Survey and, if applicable, the IBD-BOOST Optimise study, being used for this trial.

Yes No

8. Please tick yes if you agree to being in the trial.

YES NO

‘By typing my first name and last name below, I give consent to participating in the IBD-BOOST TRIAL’.

First Name of Participant
Last Name of Participant
Date

As part of the trial, we would like to conduct interviews either by phone or face-to-face with some of the people taking part. This will help us understand more about their experience of symptoms and the self-management programme.

The following statement is optional. Please tick YES if you agree.

I agree to the research team contacting me about taking part in interviews.

YES NO

If you need more information to help you decide, please contact: *[insert name & role]*

Email: *[inset name]*, **Tel:** *[insert number]*

