**A non-inferiority randomised clinical trial of the use of the smartphone-based health applications IBDsmart and IBDoc® in the care of inflammatory bowel disease patients in New Zealand.**

Inflammatory bowel disease (IBD) is a chronic relapsing and remitting disease that can negatively affect quality of life (QoL) of its sufferers. In terms of IBD management, there are reports of inadequate access to IBD professionals, such as gastroenterologists and IBD nurses, and so there is a need for IBD care to be improved through cost-efficient means. This study aims to test the usability of two smartphone apps, namely IBDsmart and IBDoc®, and compare them to usual treatment in terms of IBD-related QoL and IBD symptom scores. IBDsmart is an app for monitoring the clinical symptoms of IBD and IBDoc® is an app for measuring the faecal calprotectin (an important biomarker) of IBD patients. The objectives are to see if (a) the information gathered by IBDsmart and IBDoc® are sufficient to replace an outpatient appointment, (b) if the apps are acceptable to patients and doctors, and (c) what the impact of the apps is on QoL and IBD symptoms. The participants will be recruited from outpatient clinics in Dunedin, Christchurch, and Auckland from June 2015 to November 2015; they will be randomized to the IBDsmart-IBDoc® group or the usual treatment group. It is expected that the smartphone apps (a) will be sufficient to replace an outpatient appointment, (b) will be acceptable to patients and doctors, and (c) will not have a negative impact on QoL or IBD symptoms.

**General information**

**Protocol title:**

A multicentre pilot study of the use of the smartphone-based health applications IBDsmart and IBDoc® in the care of Inflammatory Bowel Disease Patients in New Zealand. (17 March, 2015)

**Sponsor:**

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Ms Christine Ho 1

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**Research sites:**

University of Otago, Dunedin is the primary host of the study. Patients will be recruited from the Southern, Canterbury, and Waitemata District Health Boards.

**Rationale & background information**

The inflammatory bowel diseases (IBD) are chronic relapsing conditions that develop at the prime of life (mean onset age 29 years) and have a considerable negative affect on quality of life (QoL). The IMPACT study of nearly 5000 IBD patients in Europe in 2012 highlighted the problems of getting timely appropriate help and advice for their condition. It was found that 21% did not have adequate access to an IBD professional, with 74% having had time off work in the previous year; 48% for a doctor’s appointment and 44% due to hospital or emergency admission.1 The New Zealand Impact Survey, conducted by Crohn’s and Colitis New Zealand in 2012, canvassed over 200 patients with IBD and found that 26% of patients felt they had inadequate access to specialist care, and only 51% were in remission at the time of the survey.2

A recent review paper by eminent doctors, surgeons and nurses looking after IBD patients recently published in the September issue of Inflammatory Bowel Disease Journal has suggested that the future of IBD care should, amongst other things, be delivered in “Centres of Excellence” where there is access to telephone support lines and patients can be discussed at multidisciplinary virtual clinics. They encourage clinicians to “… *empower patients to actively participate in their disease management.*”3

Involvement of patients in their disease management via web-based education and care packages have been undertaken in a number of chronic relapsing diseases such as diabetes. Professor Pia Munkholm in a study on IBD patients in Denmark and Ireland, has demonstrated that such e-Health care can lead to increased compliance with maintenance medication, reduce time to remission of flares, reduce hospital presentations, outpatient appointments and save just under Euro200 per year in mild to moderately active ulcerative colitis patients.4 The belief is that this would also lead to better long term outcomes.

It is accepted that IBD activity is best assessed by direct inspection of the affected intestinal mucosa (e.g., by colonoscopy). This is impractical for many care scenarios and so various disease activity indices (DAIs) have been developed for both Crohn’s Disease (CD) and ulcerative colitis (UC). UC DAIs correlate reasonably well with both endoscopic scores and faecal calprotectin (FC), whereas CD DAIs correlate relatively poorly with endoscopic scoring systems and somewhat better with FC.5-8

A group of professionals within the Gut Health Network with expertise in Inflammatory Bowel Disease management and Health Technologies have developed a smart phone application which captures disease activity scores and communicates with the patients’ IBD carers remotely.

The DAIs collated are the Short CD Activity Index (sCDAI),9 the Harvey Bradshaw Index (HBI),10 a nursing-based problem index called the Dudley Intestinal Symptom Questionnaire (DISQ),11 and the Simple Clinical Colitis Activity Index (SCCAI).12 The application, called **IBDsmart,** has now been tested by 35 IBD patients in Southern DHB. Overall 74% of the responses were clearly positive with respect to the general usability of the system. There was also evidence of higher scores in terms of satisfaction (p=0.017), effectiveness (p=0.013), and speed (p=0.028) for those with UC compared to CD. This group also agreed more that IBDsmart could replace a visit to the specialist (p=0.022).13

FC is increasingly used not only to differentiate irritable bowel syndrome from IBD but more recently to help monitor IBD care.7 Traditionally a stool sample has had to be taken to the laboratory for testing, but now Bühlmann Laboratories have developed a reliable ELISA that can be performed at the patient’s convenience at home, and read by advanced smart phones, delivering an instant result to the patient and communicating it directly to their care team. The application and web portal together constitute **IBDoc®**. This system has now undergone testing for acceptability and validity in Europe 14, 15.

**Study goals and objectives**

**Aims:**

The overall aim of this study is to analyse the usability of **IBDsmart** with **IBDoc®** together in the outpatient management of patients with Inflammatory Bowel Disease and to study whether **IBDsmart/IBDoc®** has potential to replace outpatient clinic appointments.

**Objectives:**

*Primary*

* Are IBDsmart/IBDoc® acceptable to patients and doctors?
* Are IBDsmart/IBDoc® non-inferior to standard care delivered through outpatient clinic appointments only?

*Secondary*

* Is the information gathered by IBDsmart/IBDoc® sufficient to replace an outpatient appointment?
* Is IBDsmart/IBDoc® equivalent to normal outpatient management in terms of changes in QoL as measured by the inflammatory bowel disease questionnaire (IBDQ)16 and symptom scores as measured by the DAIs?
* What is the impact on disease burden as measured by DAI scores?
* How does the CDAI compare with the abbreviated sCDAI (which has no examination or blood test)?
* How well does IBDoc® FC correlate with DAI scores?
* What is the contribution of the DISQ to the traditional scoring systems?

**Study Design**

This will be a 52 week prospective, multi-centre, randomised intervention study comparing IBDsmart/IBDoc®-assisted virtual clinic appointments (Intervention Group) with routine face-to-face clinic appointments (Control Group). The participants will be recruited from the Southern, Canterbury, and Waitemata District Health Boards.

*Inclusion Criteria*

* Confirmed UC or CD
* At least 2 outpatient appointments in last 12 months.
* Willing and able to provide written consent
* 18 years of age or over

*Exclusion Criteria*

* Uncertain diagnosis; indeterminate colitis
* Severe disease with close monitoring
* Probable surgical intervention (e.g., colectomy, resection) upcoming
* Ileostomy, colostomy, or ileal pouch-anal anastomosis.
* Anyone for whom the SCCAI, HBI, or sCDAI are not valid
* Anyone for whom Faecal Calprotectin is not valid
* Pregnant
* Cannot provide written consent

**Methodology**

Figure 1 provides an overview of the study protocol. Participants in this study will be randomized to one of two groups: the IBDsmart/IBDoc® group or the usual care group. Randomization will occur by a computer program randomly allocating participants to one of the two groups. In the IBDsmart/IBDoc® group, the participants will be given access to the apps which the other group will not have access to. The IBDsmart app is a symptom monitoring app which contains validated questionnaires for measuring IBD symptoms. The symptom questionnaires available to UC patients will be the DISQ and SCCAI while the symptom questionnaires available to CD patients will be the DISQ, sCDAI, and HBI. The IBDoc® provides a means of patients measuring their FC levels at home by using a small piece of equipment that produces an output which the smartphone takes a picture of to give a score. The IBDoc® has been shown to be correlated with normal laboratory methods. 13

Figure 1: IBDsmart/IBDoc® Study Flow Diagram

Among patients in the IBDsmart/IBDoc® group, the resulting scores from both apps will be sent to the patient’s treating doctor on a regular basis. The group using the apps will not have routine outpatient appointments over the 52 weeks.

The other group, namely usual care, will not get access to the apps and will attend outpatient appointments as normally planned.

The sites for recruiting participants will be considered as receiving the same recruitment and intervention methods.

A number of outcomes will be measured during the course of the study, which are outlined as follows.

**Week 0, Baseline Assessment.**

* **Both Groups:**
	+ History & Examination.
	+ Patient & Doctor questionnaire
	+ FC (laboratory)
	+ IBDQ
	+ Blood tests as per discretion of the specialist for monitoring or surveillance.
	+ Disease-specific DAIs (physician completed; HBI and sCDAI for CD patients and SCCAI for UC patients)
* **Intervention Group**
	+ IBDsmart Disease-Specific DAI (HBI and sCDAI for CD patients and SCCAI for UC patients) & DISQ
	+ IBDoc® FC test

**Weeks 12, 24, 36.**

* **Both Groups**;
	+ Patient and Doctor Questionnaires
	+ IBDQ
* **Control Group**;
	+ History and Examination, Doctor-completed DAI, other investigation at discretion of provider.
* **Intervention Group**;
	+ IBDsmart DAI & IBDoc® FC.

**Week 52** – as per baseline assessment.

**NOTE:** If a patient experiences symptoms that they consider might be a flare during the study period then the Control group follow whatever they would normally do, e.g. ring their GP, ring the IBD nurse etc. The intervention group patients are encouraged to use their IBDsmart and IBDoc® apps to communicate with their care team. If a relapse is confirmed treatment alterations are made and then they will perform repeat assessments remotely (if deemed appropriate) weekly until in remission, and then monthly until the next scheduled routine assessment.

**Safety Considerations**

The biggest risk to participants is having to handle stool samples for the IBDoc® app. Participants will be provided gloves for this process, nonetheless.

**Follow-Up**

When participants are recruited, they will be in the study for 12 months.

**Data Management and Statistical Analysis**

The data will be managed by the study administrator and all patient information will be partially de-identified. Appropriate descriptive statistics will be provided for all measures of interest. Acceptability of IBDsmart/IBDoc® will be evaluated through descriptions of patient and doctor responses. Non-inferiority of the primary outcomes (IBDQ, sCDAI, SCCAI) will be investigated through linear mixed models of the follow-up scores (12, 24, 36, and 52 weeks) adjusting for baseline scores to estimate the difference between usual care and IBDsmart/IBDoc® at each time point. The primary outcome, non-inferiority at 52 weeks, will be established where the 90% two-sided CI for the between group effect (usual care-IBDsmart/IBDoc®) is strictly above the lower equivalence limits (-20, -70, and -3 respectively). Secondary analyses will be performed similarly using group differences at interim time points. If missing data rates exceed the expected 5% rate, multiple imputation will be used for sensitivity analyses. Correlations between the simple CDAI and full CDAI and between IBDoc® FC scores and DAI scores (sCDAI and SCCAI) will be investigated using Pearson’s correlation coefficients. All statistical analyses will be conducted using Stata 13.1 or a later version with tests performed at the 0.05 level (two-sided).

A sample size of 31 patients with CD per group (n=62) at follow-up will provide 80% power to detect non-inferiority (p<0.05) using sCDAI assuming a standard deviation of 110 and an equivalence limit of 70. A sample size of 17 patients with UC per group (n=34) at follow-up will similarly provide 80% power to detect non-inferiority (p<0.05) using SCCAI assuming a standard deviation of 3.5 and an equivalence limit of 3. Finally, a sample size of 45 patients with either CD or UC per group (n=90) at follow-up will provide 80% power to detect non-inferiority (p<0.05) using IBDQ assuming a standard deviation of 38 and an equivalence limit of 20. Thus, the study could be adequately powered with a total of 96 participants (62 with CD and 34 with UC) at follow-up. Allowing for 5% loss to follow-up, 102 participants (66 with CD and 36 with UC) will be enrolled at baseline.

**Expected Outcomes of the Study**

This study will provide information about whether IBD care can be improved through the use of smartphone apps. If the apps are shown to provide similar outcomes as usual care, a cost-effective means of IBD management will be uncovered. The results will be published in peer-reviewed literature.

**Duration of the Project**

Each participant will be in the study for twelve months.

Original Timeline

|  |  |  |
| --- | --- | --- |
| **Year** | **Month** | **Task** |
| 2014 | November | Agree protocol |
| 2015 | March | Submit to HDEC |
|  | June | Start recruitment |
|  | November | End recruitment |
| 2016 | November | Study completed |
|  | December | Statistical analysis |
| 2017 | February | Present at ECCO |
|  | October | Present results to UEGW |
|  | November | Present to NZSG ASM |

New timeline

|  |  |  |
| --- | --- | --- |
| **Year** | **Month** | **Task** |
| 2014 | November | Agree on protocol |
| 2015 | May | Ethics approval |
|  | August | Patient identification |
|  | September | Patient randomization |
| 2016 | February | Interim study management committee review |
| 2017 | February | Study completed |
|  | February | Statistical analysis |
|  | February | Present at ECCO |
|  | October | Present results UEGW |
|  | October | Present results NZSG ASM |

**Problems Anticipated**

Anticipated problems for this project include that the smartphones required for the IBDoc® app are of a high quality and price (iPhone 4s or above; Samsung 2 or above). For those without the required phone make and model, smartphones will be loaned to the participants; this will be funded through donations of smartphones from the general public and financially through the Gut Health Network. It is also anticipated that a few participants will refuse to use the IBDoc® app because of the need to handle stool.

**Project Management**

Associate Professor Michael Schultz is the co-ordinating investigator and will provide participants from his outpatient clinic.

Professor Murray Barclay is an investigator and will provide participants from his outpatient clinic.

Dr. Russell Walmsley is an investigator and will provide participants from his outpatient clinic.

Dr. Andrew McCombie is the study administrator and will be responsible for the recruitment and maintenance of all participants.

Associate Professor Holger Regenbrecht is responsible for the app development.

Dr. Tobias Langlotz is responsible for the app development.

Ms. Christine Ho is an IBD nurse involved providing a nurse’s perspective on the app development.

Ms. Nideen Visesio is an IBD nurse involved providing a nurse’s perspective on the app development.

**Ethics**

The most pertinent ethical concern is the use of smartphone technology to replace outpatient appointments. However, it is believed communication between patient and doctor will be enhanced and not hindered by the apps. In addition, the participants will be required to handle their stool for the IBDoc® app but they will be trained properly in how to do this and will be offered gloves for doing it.

The informed consent will be obtained by giving the participants an information sheet and consent form.

**Informed Consent Forms**

There is going to be an informed consent process undertaken wherein patients will read an information sheet about the study, have an opportunity to discuss this with an investigator, and then sign a consent form. The information sheet and consent form are on the following pages.

|  |  |
| --- | --- |
| **Participant Information Sheet** |  |
| Study title: | **A non-inferiority randomised clinical trial of the use of the smartphone-based health applications IBDsmart and IBDoc® in the care of inflammatory bowel disease patients in New Zealand** |
| Locality: | Southern, Canterbury, and Waitemata District Health Boards | Ethics committee ref.: |

|  |
| --- |
| **15/NTA/44** |

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| Lead investigator: | **Michael Schultz** | Contact phone number:  | 03 474 0999 |

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You are invited to take part in a study on the use of two smartphone apps for managing your inflammatory bowel disease (IBD). The name of the smartphone apps are “IBDsmart” and “IBDoc**®**.” Whether or not you take part is your choice. If you do not want to take part, you do not have to give a reason, and it will not affect the care you receive. If you do not want to take part now, but change your mind later you are welcome to join. If you want to take part now but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you would like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what will happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is six pages long, including the Consent Form. Please make sure you have read and understood all the pages.

**What is the purpose of the study?**

The overall aim of this study is to analyse the usability of IBDsmart with IBDoc**®** together in the outpatient management of patients with IBD and to study whether IBDsmart/IBDoc**®** has potential to replace outpatient clinic appointments. If it is shown to improve the care of IBD patients, it will help those with the disease in the future.

Part of the study protocol is a process called randomization. This is the process by which participants are randomly allocated (e.g., like flipping a coin) to one of two groups. These two groups are the *‘intervention’* or the *’control’* groups. Half of the participants will be randomly allocated to a group which will use the smartphone apps (called the ‘intervention’ group) while the other half will not use these apps but continue with their normal care (called the ‘control’ group). This is so we can test whether using the apps improves the overall care of IBD patients.

At this point, we do not know whether the apps will positively influence outcomes or not and so it is unknown which group is better to be a part of.

This study is funded by the Healthcare Otago Charitable Trust. The investigators have associations with the University of Otago, as well as the Canterbury, Southern, and Waitemata District Health Boards.

The study administrator is Dr. Andrew McCombie who can be contacted on ibdsmart@otago.ac.nz or 0272626111.

This study is commencing on 1/6/2015 and has approval from the Northern A Health and Disability Ethics Committee.

**What will my participation in the study involve?**

You have been approached to participate in the study because you have IBD either in the form of ulcerative colitis or Crohn’s disease. IBD patients with an uncertain diagnosis (e.g., indeterminate colitis) are not eligible to participate.

In this study, you will be randomly allocated to one of two groups (‘intervention’ or ‘control’). Those in the intervention group will be given access to the apps called IBDsmart and IBDoc**®**. IBDsmart is an app that assists you in recording your symptoms (e.g., pain, blood in stool, number of bowel motions) on a regular basis which can then be sent directly to your healthcare professionals and study administrator to assist them in making treatment decisions and managing the study, respectively.

IBDoc®, which will be linked to IBDsmart in your phone, is an app which includes a small piece of equipment for reading your faecal calprotectin (FC) levels from your stool in your own home. The equipment reads your FC levels and produces an output which can be read by the camera on your smartphone which then produces a number; this number indicates how much IBD activity is occurring in your intestines and may even assist in predicting future flare ups of your disease. The results from this are stored in a database held by BÜHLMANN Laboratories in Switzerland. Your healthcare team will access these results from BÜHLMANN Laboratories but not provide any of your medical information to them. You will have a unique patient ID on this database and your identity will not be visible to BÜHLMANN Laboratories. However, your email address will be visible to BÜHLMANN Laboratories so as to allow them to perform certain support activities, such as resetting a password, if need be. BÜHLMANN Laboratories will only access those patient data with the explicit consent of the treating physician if needed.

Those in the control group will not be given access to these apps and will keep seeing their gastroenterologist as usual. At this point, we are unsure if the intervention or control group will be advantaged.

The time required for being in this study is 52 weeks.

The study involves the following:

1. At the beginning of the study participants from both groups will complete a quality of life questionnaire, have a history and examination taken, have Doctor-completed disease activity indices completed, and have their doctor answer two brief questions about their health status. All participants will also be required to provide a stool sample for analysis (FC), and provide blood tests at the discretion of their specialist.
2. At weeks 12, 24, and 36 after entry into the study people from *both* groups will be required to fill out more questionnaires about quality of life. In addition:
	1. At the beginning and at weeks 12, 24, 36, and 52 the intervention group only will be required to use IBDsmart and IBDoc®. Some of the questions in the IBDsmart app may be of a sensitive nature (e.g., number of bowel motions, blood in stool, etc.). Their doctor will also answer two brief questions about their health status at each clinic visit.
	2. At weeks 12, 24, and 36, the control group only will have a history and examination taken, as well as Doctor-completed disease activity indices and two brief questions about their health status.
3. At week 52, participants from both groups will complete a quality of life questionnaire, have a history and examination taken, have Doctor-completed disease activity indices completed, and have their doctor answer two brief questions about their health status. Only those in the intervention group will complete usability questionnaires about IBDsmart and IBDoc® at 52 weeks.

If at any time participants feel they need to contact their specialist team (e.g., for a flare) they can do so either using the Smartphone apps (if in the intervention group) or by their normal method of communication (if in the control group).

Overall, participants from both groups will complete one quality of life questionnaire at 0, 12, 24, 36, and 52 weeks. In addition to these five questionnaires, the intervention group will complete one usability questionnaire for each app at 52 weeks as well as the disease activity indices on IBDsmart on a regular basis.

Some health data may also be collected by looking at your patient notes.

**What are the possible benefits and risks of this study?**

A potential inconvenience of taking part in this study is of having to collect stool samples but you will be given the choice of having gloves for this part of the study. In addition, you may have to learn how to use a Smartphone if you do not already know how to.

The potential benefits of this study are improved disease management for those allocated to the intervention group.

It is the responsibility of the research team, led by Associate Professor Michael Schultz, that optimal care is provided to all participants during the study.

**Who pays for the study?**

This study will be conducted at no financial cost to the participants involved. No payment or other form of reimbursement will be provided for your participation.

**What if something goes wrong?**

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study will not affect your cover.

**What are my rights?**

This study is purely voluntary. This means you can choose whether to participate or not without experiencing any disadvantage. You may also withdraw from the research at any time without experiencing any disadvantage.

You may access information collected about you for this study. Please contact Dr. Andrew McCombie at ibdsmart@otago.ac.nz or 0272626111 for this information.

You will be informed of any new information about adverse or beneficial effects related to the study that becomes available during the study that may have an impact on your health.

Your privacy and confidentiality will be ensured by secure storage of your health information and no private information being divulged to any third party.

**What happens after the study or if I change my mind?**

It is probable that the apps, namely IBDsmart and IBDoc®, will be available to all participants soon after the study. These will be available from the app stores.

Your study data will be securely stored for 10 years after which it will be destroyed by the lead investigator.

Biological specimens will be destroyed at the time of the study’s conclusion.

The results of this study will be communicated at scientific and medical conferences as well as in a peer reviewed medical journal.

**Who do I contact for more information or if I have concerns?**

If you have any questions, concerns or complaints about the study at any stage, you can contact:

 Dr. Andrew McCombie, Assistant Research Fellow

 Phone: 0272626111

 Email: ibdsmart@otago.ac.nz

If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

 Phone: 0800 4 ETHICS

 Email: hdecs@moh.govt.nz

For Maori health support please contact:

Maori Health Services

Nga Ratonga Hauora Maori

Christchurch Public Hospital

CDHB

03 364 0640 Ext 86160

|  |  |
| --- | --- |
| **Consent Form** | high resolution Otago logo |

**If you need an INTERPRETER, please tell us.**

**Please tick to indicate you consent to the following**

|  |  |  |
| --- | --- | --- |
| I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.  |  |  |
| I have been given sufficient time to consider whether or not to participate in this study. |  |  |
| I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study. |  |  |
| I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet. |  |  |
| I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care. |  |  |
| I consent to the research staff collecting and processing my information, including information about my health. |  |  |
| If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed. | Yes 🞏 | No 🞏 |
| I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study. | Yes 🞏 | No 🞏 |
| I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study. |  |  |
| I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study. |  |  |
| I understand the compensation provisions in case of injury during the study. |  |  |
| I know who to contact if I have any questions about the study in general. |  |  |
| I understand my responsibilities as a study participant. |  |  |
| I wish to receive a summary of the results from the study. | Yes 🞏 | No 🞏 |
| I understand my participation may involve handling my own stool samples (with optional gloves provided). |  |  |
| I understand I can be randomly allocated to the intervention or control group and what my participation in these groups would involve. |  |  |
| I understand there are two different apps used in the intervention group, namely IBDsmart and IBDoc®. |  |  |
| I understand I will be invited to fill out seven questionnaires over fifty-two weeks if I am in either group as well as regular symptom indices on IBDsmart if I am in the intervention group. |  |  |
| I understand the data from IBDoc® will be stored in a database held by a third party called BÜHLMANN Laboratories in Switzerland but they will not have access to my personal or medical information. |  |  |
| I understand my email address may be made available to BÜHLMANN Laboratories for the purpose of performing certain support activities such as resetting a password and they will only access those patients’ data with the explicit consent of my physician. |  |  |
|  |  |  |

**Declaration by participant:**

I hereby consent to take part in this study.

|  |
| --- |
| Participant’s name: |
| Signature: | Date: |

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it.

I believe that the participant understands the study and has given informed consent to participate.

|  |
| --- |
| Researcher’s name: |
| Signature: | Date: |

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