

Open-IBD

A long-term study of human cells and gut microbes in people with newly diagnosed Crohn's and Colitis

You have been referred to the hospital to diagnose symptoms that may be related to a condition called Inflammatory Bowel Disease (IBD). We understand that waiting for a diagnosis while experiencing unpleasant symptoms can be distressing.

We would like to invite you to take part in a research study where you will be seen quickly in a rapid access clinic run by specialists in gastroenterology. By taking part you would be seen soon by these specialists for assessment and if needed, would be followed up regularly long term by this expert team.

Although participating in research may not be your immediate priority, we hope you will benefit by early access to specialist care and that you will find being involved in this study of your human cells, gut microbes and diet interesting. We would therefore like to invite you to participate in the Open-IBD research study.

Nearly 1 in 100 people across the UK suffer with Crohn's or Colitis

There are two common types of Inflammatory Bowel Disease (IBD): Crohn's Disease ("Crohn's") and ulcerative colitis ("Colitis"). Crohn's and Colitis are long-term conditions that cause inflammation of the digestive tract, often leading to challenging and debilitating symptoms. These include diarrhoea (with or without blood), abdominal pain, weight loss and fatigue. Crohn's and Colitis are common and are becoming more common each year.

The early and long-term symptoms can vary significantly from person to person and over time. The exact causes of Crohn's and Colitis, as well as what influences this behaviour in different people, remains unknown.

There are many treatments available to help manage Crohn's and Colitis, which can work very well. However,

1. They do not work for everyone
2. They may become less effective over time
3. Later treatments may work less well after a poor response to initial treatments

This can all make life difficult for people living with Crohn's or Colitis, as it may take time to find the right treatment and it may mean changing medication multiple times in a trial-and-error approach. During this period, people may experience uncontrolled symptoms and unnecessary side effects which can negatively impact their quality of life.

Our goal is to improve the treatment journey

We are doing research to better understand why Crohn's and Colitis first starts and why they behave differently for each person. We want to understand why certain treatments work for some people and not for others. The more we understand this, the better we can personalise treatments in the future, ensuring people receive the medication most likely to effectively treat their condition early in their journey and reduce the risk of side effects.

What the research involves

If you are part of our research study you will be seen in a specialist research clinic. If you are diagnosed with Crohn's or Colitis, then you will begin a treatment plan with regular check-ups and tests. This study is a two-year project incorporating more tests and checks along the way, giving you easy and continued access to your healthcare team and to information about your health.

Up front tests

- We will collect a stool sample, blood sample and you will complete some questionnaires about your lifestyle, diet and the impact of your symptoms.
- We will take additional biopsy samples during the colonoscopy (an exploration of the bowel with a flexible camera) you will have as part of your standard hospital care.

If you are not diagnosed with Crohn's or Colitis

- No further research visits are needed, though your ongoing medical data will still support the study (you don't need to do anything to make this happen).
- You will continue to be seen by the hospital for any NHS tests or follow up you need.

If you are diagnosed with Crohn's or Colitis

- We will collect stool samples and blood samples every three months for the first year and you will be given health questionnaires to complete.
- We will repeat the above every six months for the second year.
- You will have a follow up colonoscopy after one year to check on the health of your bowel.

Please note, if you are not diagnosed with Crohn's or Colitis, we won't ask for any more samples or visits as part of the study, but you would be fully supported in the usual way from your healthcare team with whatever follow on care or investigation is needed.

How does Open-IBD compare to the typical Crohn's and Colitis journey?

We have a number of patient advisers on the study who themselves are living with Crohn's and Colitis and have helped to write this information sheet. They believe this research study provides valuable support by ensuring each person is monitored regularly, which they see as a big benefit to anyone who takes part. The additional monitoring is seen as a feature of high-quality care.

Treatment plan	Upfront	1 st year follow up	Annual check	2 nd year follow up
Typical Crohn's and Colitis journey	<ul style="list-style-type: none"> • Stool sample • Blood sample • Colonoscopy • Health questionnaires 	Varies from persons to person, typically involves check-ups every 3 to 6 months	Will vary but typically discussion with Crohn's and Colitis nurse/doctor	Varies from persons to person, but typically annual check-ups from here
Open-IBD journey	As above but with additional tissue samples taken during the colonoscopy	Visits every three months, including: <ul style="list-style-type: none"> • Stool sample • Blood sample • Health questionnaires 	Colonoscopy to check for any change since diagnosis	Visits every six months, including: <ul style="list-style-type: none"> • Stool sample • Blood sample • Health questionnaires

Understanding the risks

As with any medical procedure, there may be risks. Blood tests can cause minor discomfort and bruising. The biopsies, which involve taking a small tissue sample, carry a minimal risk of bleeding or perforation (causing a tear in the bowel wall). All procedures will be performed by qualified and trained medical professionals to minimise these risks.

You will be given high street shopping vouchers to compensate you for your time. You will receive a £50 voucher for completing the first study visit questionnaires. If diagnosed with Crohn's or Colitis, you will be given a £25 voucher on completion of study questionnaires at each of the subsequent three or six-monthly visits, and a £50 voucher at the annual check as a thank you for completing the study questionnaires.

In addition, up to £60 in travel costs will be reimbursed. The total value over 2 years is up to £285.

Those who can take part

In order to take part in the study:

- You must be aged 16 or over and have suspected Crohn's or Colitis.
- You must not have had a Crohn's or Colitis diagnosis confirmed previously.
- You must never have been treated previously for Crohn's or Colitis.

For more information

Please visit the Open-IBD website here: <https://www.open-ibd.org/>
(or use the QR code to access more participant information)

Alternatively, please speak to your gastroenterology care team.



Further information about Crohn's and Colitis is available at: <http://www.crohnsandcolitis.org.uk/>

To take part

The research relies on thousands of participants giving their consent to take part. However, we understand you need to decide what is right for you.

If you are interested in taking part, please read the full participant information sheet for further details. This can be found using the QR code above or by contacting your local research team using the below details:

[Please ask your local Open-IBD hospital site for contact details]

Data privacy

If you opt to take part in the study, we will use information from you and your medical records as well as data analysed from the samples you provide. We will only use information that we need for the research study, and everyone involved in this study will keep your data safe and secure.

At the end of the study, we will save some of the data (which cannot be linked to you) for future research. We will also ask for your consent to access your medical records in future to retrieve information relevant to this study. We will make sure no-one can work out who you are from the reports we write. The full participant information sheet tells you more about this.