ISRCTN10641791 https://doi.org/10.1186/ISRCTN10641791

Redesigning a faster pathway to inflammatory bowel disease (IBD) diagnosis

Submission date 25/07/2025	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 25/07/2025	**Overall study status** Ongoing	
Last Edited 25/07/2025	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Inflammatory Bowel Disease (IBD) is a long-term condition that affects the gut. Many people with IBD experience symptoms like diarrhoea, stomach pain, and bleeding for over a year before they get a diagnosis. This delay can happen because people feel embarrassed or worried about having invasive tests. This study aims to find out whether offering a simple stool test directly to the public—without needing to see a doctor first—could help people get diagnosed sooner.

The study has two parts. The first part looks at how long it takes people to get diagnosed after symptoms begin, and what might stop them from seeking help. The second part tests whether sending stool kits directly to people with symptoms can help identify those who may have IBD earlier.

Who can participate?
In the first part of the study (RAPID-1), people aged 16 and over who have been diagnosed with IBD in the past 30 days can take part.
In the second part (RAPID-2), people aged 16 to 49 who live in the Royal Devon area and have had lower tummy symptoms for more than two weeks can request a free stool test kit online.

What does the study involve?
In RAPID-1, participants will complete questionnaires about their health, mood, and quality of life. Some will also be invited to take part in an interview to talk about their experience of getting diagnosed.
In RAPID-2, participants will receive a stool test kit by post, collect a sample at home, and send it back to the lab. If the test shows signs of inflammation or blood, they will be offered a follow-up phone call and further tests. Everyone will be followed up for a year to see what happens next with their health.

What are the possible benefits and risks of participating?
Taking part may help improve how IBD is diagnosed in the future. Participants may also get earlier access to care if their test shows signs of IBD. Risks are low, but some people may feel uncomfortable collecting a stool sample or discussing personal health issues.

Where is the study run from?
Royal Devon University Healthcare NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

Who is funding the study?
National Institute for Health and Care Research (NIHR).

Who is the main contact?
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Contact information

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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
343084

Protocol serial number
CPMS 62918

Study information

Scientific Title
Redesigning a faster pathway to IBD diagnosis: can direct-to-public stool biomarker testing reduce the time to diangosis of IBD?

Study objectives
1. Quantify diagnostic delay in IBD
1.1. Measure time from symptom onset to diagnosis in newly diagnosed IBD patients.
1.2. Subdivide delay into:
1.2.1. Time from symptom onset to first GP contact.
1.2.2. Time through primary and secondary care services.
2. Identify barriers to early presentation
2.1. Use patient questionnaires to explore reasons for delayed presentation.
2.2. Conduct semi-structured interviews to investigate:
2.2.1. Emotional and practical barriers (e.g. embarrassment, fear of tests).
2.2.2. Preferences for test delivery and communication strategies.
3. Assess acceptability of direct-to-public stool testing
3.1. Evaluate public willingness to use FIT or calprotectin tests without healthcare professional involvement.
4. Pilot direct-to-public testing strategy
4.1. Offer stool tests to 5,000 individuals aged 16–49 years with lower GI symptoms.
4.2. Determine positivity rates of FIT and calprotectin in this population.
5. Evaluate impact on diagnostic timeliness
5.1. Compare proportion of patients diagnosed within 4 months in the pilot group to RAPID-1 cohort.
5.2. Assess whether direct-to-public testing reduces diagnostic delay.
6. Inform future implementation
6.1. Use findings to guide marketing, distribution, and integration of direct-to-public testing into healthcare pathways.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/06/2024, North East - Newcastle & North Tyneside 2 Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8055; newcastlenorthtyneside2.rec@hra.nhs.uk), ref: 24/NE/0114

Study design
Interventional non-randomized

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Inflammatory bowel disease

Interventions
RAPID-1

Exploring lived experience of diagnostic delay in IBD and optimising the acceptability of a direct-to-public diagnostic pathway.

We will recruit 200 people who have been recently diagnosed with Inflammatory Bowel Disease. Participants will complete a questionnaire using validated measures of fatigue (IBD-F), psychological well-being (PHQ-8 and GAD-7), and quality of life (EQ-5D-5L). The questionnaire will also include questions related to health, lifestyle, diagnostic delay, and preferred method of communication.

We will collect data on demographics (age, sex, ethnicity, highest educational attainment, comorbidities, height and weight, smoking status, and postcode), mode of presentation (emergent vs elective, dates and numbers of primary and secondary care contacts), and IBD type (family history, disease activity [PRO2], stool testing [calprotectin vs FIT], phenotype according to Montreal classification).

Participants will be followed up over 12 months. Researchers will access electronic health records to collect data on clinical outcomes related to IBD, including treatment, hospitalisation, complications, and surgeries.

A subset of patients will be invited to participate in a semi-structured interview within 4 weeks of diagnosis. These patients will be selected to represent a broad spectrum of IBD presentations, including those with known risk factors for diagnostic delay (e.g. no rectal bleeding, depression, Crohn’s disease). Sampling will continue until thematic saturation is reached; approximately 20 interviews are expected. These interviews will explore barriers to presentation with gastrointestinal symptoms and the acceptability and distribution of a direct-to-public stool test. This patient and public involvement and engagement exercise will inform the marketing strategy for RAPID-2.

RAPID-2
We will release 5,000 direct-to-public stool biomarker testing kits. Members of the public will be able to consent and register for a free kit via an online portal.

Participants will complete e-consent and a purpose-designed e-case record form. Eligible individuals will receive a stool collection pack and be instructed to collect a sample using a picker stick, transferring a small amount into a pre-labelled testing tube, which is returned via Royal Mail pre-paid post. Both calprotectin (a marker of gut inflammation) and FIT (a measure of microscopic blood in stool) will be measured on all samples.

Using pre-specified calprotectin and FIT cut-offs, individuals with positive results will be offered a telephone appointment with a member of the research team within two weeks, and secondary

care tests will be arranged. Those with negative results will receive them electronically, along with safety netting advice.

All participants who test negative or undergo further investigation without a significant GI pathology will be followed up. Their electronic health records will be reviewed over the 12 months following testing to determine whether a subsequent diagnosis was made that could explain their symptoms. Participants will also be contacted up to twice at 6-month intervals to check for diagnoses made elsewhere.

If a participant is diagnosed with IBD via this pathway, they will be asked to complete the same questionnaire used in RAPID-1. Their electronic health record will also be reviewed over the following year for IBD outcomes, including treatment, hospitalisation, complications, and surgery.

Analysis

We will compare the proportion of patients who wait more than 4 months to be diagnosed with IBD between those diagnosed through routine care (RAPID-1) and those diagnosed via the direct-to-public pathway (RAPID-2).
We will also compare the RAPID-1 and RAPID-2 groups in terms of:
1. The interval from symptom onset to diagnosis of IBD, stratified by:
- Time from symptom onset to first GP presentation (patient delay)
- Time from first GP presentation to GP referral (primary care delay)
- Time from GP referral to IBD diagnosis (secondary care delay)
2. Identification of barriers and facilitators to early diagnosis of IBD, using in-depth semi-structured interviews with people recently diagnosed.
3. The impact of IBD on patient-reported outcome measures at diagnosis, including quality of life, mood, and fatigue.
4. Rates of emergency admission and surgery in the 12 months following diagnosis.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
RAPID 2: Proportion of patients diagnosed with IBD >4 months from symptom onset measured using patient records

Key secondary outcome(s))
1. Time from symptom onset to IBD diagnosis is measured using patient self-report and electronic health record review at baseline (RAPID 1)
2. Time from symptom onset to first GP presentation (patient delay) is measured using patient self-report at baseline (RAPID 1)
3. Time from first GP presentation to GP referral (primary care delay) is measured using electronic health record review at baseline (RAPID 1)
4. Time from GP referral to IBD diagnosis (secondary care delay) is measured using electronic health record review at baseline (RAPID 1)

5. Barriers and facilitators to early diagnosis are measured using semi-structured qualitative interviews conducted within 4 weeks of diagnosis (RAPID 1)
6. Quality of life is measured using EQ-5D-5L at baseline (RAPID 1)
7. Mood is measured using PHQ-8 and GAD-7 at baseline (RAPID 1)
8. Fatigue is measured using IBD-Fatigue Scale at baseline (RAPID 1)
9. Emergency admission is measured using electronic health record review at 12 and 24 months post-diagnosis (RAPID 1)
10. Surgery is measured using electronic health record review at 12 and 24 months post-diagnosis (RAPID 1)

11. Uptake of direct-to-public stool testing is measured using registration and kit return rates via the online portal during the recruitment period (RAPID 2)
12. Positivity rates of calprotectin and FIT are measured using laboratory analysis of returned stool samples at baseline (RAPID 2)
13. Diagnostic accuracy of calprotectin and FIT is measured using comparison with clinical diagnosis of IBD confirmed by electronic health record review over 12 months (RAPID 2)
14. Cost-effectiveness is measured using health economic modelling based on testing costs, diagnostic yield, and downstream healthcare utilisation over 12 months (RAPID 2)
15. Resource utilisation is measured using electronic health record review of healthcare contacts, investigations, and treatments over 12 months (RAPID 2)
16. Time from symptom onset to IBD diagnosis is measured using patient self-report and electronic health record review at baseline (RAPID 2)
17. Time from symptom onset to first GP presentation (patient delay) is measured using patient self-report at baseline (RAPID 2)
18. Time from first GP presentation to GP referral (primary care delay) is measured using electronic health record review at baseline (RAPID 2)
19. Time from GP referral to IBD diagnosis (secondary care delay) is measured using electronic health record review at baseline (RAPID 2)
20. Quality of life is measured using EQ-5D-5L at baseline (RAPID 2)
21. Mood is measured using PHQ-8 and GAD-7 at baseline (RAPID 2)
22. Fatigue is measured using IBD-Fatigue Scale at baseline (RAPID 2)
23. Emergency admission is measured using electronic health record review at 12 months post-diagnosis (RAPID 2)
24. Surgery is measured using electronic health record review at 12 months post-diagnosis (RAPID 2)

Completion date
31/08/2027

Eligibility

Key inclusion criteria
RAPID 1
1. Aged over 16 years
2. Able to give informed consent
3. Diagnosed with inflammatory bowel disease (IBD) within 30 days of study recruitment

RAPID 2 (Clinical Cohort)
1. Aged over 16 years
2. Willing and able to give informed consent
3. Diagnosed with likely inflammatory bowel disease within 30 days of study recruitment at

Royal Devon University Healthcare NHS Foundation Trust (Exeter and Barnstaple sites), as identified by the clinical care team

RAPID 2 (Direct-to-Public Testing Cohort)
1. Aged over 16 years
2. Willing and able to give informed consent
3. Residing within the population served by Royal Devon University Healthcare NHS Foundation Trust
4. Reporting lower gastrointestinal symptoms for more than 2 weeks (including lower abdominal pain below the umbilicus, diarrhoea, or rectal bleeding)
5. No flexible sigmoidoscopy or colonoscopy within the 2 years preceding testing

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

Key exclusion criteria
1. Those who are under 16 years old
2. Those who are unwilling to consent to the study accepting that researchers will have ongoing access to their primary and secondary care medical record for 1-year after the test for the purpose of follow up.

Date of first enrolment
12/06/2024

Date of final enrolment
01/09/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Devon University Healthcare NHS Foundation Trust
Royal Devon University NHS Ft

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Sponsor information

Organisation
Royal Devon University Healthcare NHS Foundation Trust

ROR
https://ror.org/05e5ahc59

Funder(s)

Funder type
Government

Funder Name
CROHN'S & COLITIS UK; Grant Codes: M2023-6 Ahmad

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date