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Patient acceptability of FIT stool test and analysing a colorectal cancer risk tool

Submission date 29/12/2022	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 16/01/2023	**Overall study status** Completed	
Last Edited 13/11/2024	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Previous studies have investigated if the faecal immunochemical test (FIT), a non-invasive test which measures blood in stools, could be used to investigate patients with colorectal cancer symptoms. Addressing patient barriers to using FIT is important in maximising uptake if FIT is recommended as a colorectal cancer rule-out test. Previous studies have allowed over 1000 patients to feedback on their experience of using FIT, however, researchers would like to have feedback from patients who decided not to use FIT or respond to the questionnaire.
As well as using faecal haemoglobin alone as a triage tool to help rule out colorectal cancer in patients, the researchers would also like to investigate to determine if a colorectal cancer risk tool using more patient parameters would allow better individualised risk categorisation of patients. The proposed study would use a risk tool for colorectal cancer, developed using previous study data, and use this developed tool to look at colorectal cancer outcomes compared to calculated cancer risk in patients.

Who can participate?
Study 1: Patients aged 18 to 110 years who have been offered but have not used FIT as part of their referral from primary to secondary care
Study 2: Patients who have been referred to Croydon University Hospital under the FIT Implementation pathway

What does the study involve?
Study 1: Patients have a recorded telephone discussion about their experiences of being offered the FIT kit.
Study 2: Patients who have used a stool test called FIT (faecal immunochemical test) in 2019 or 2020 will be identified. This is usually offered to patients when they are referred from their GP to Croydon Hospital because of bowel symptoms. To determine if FIT could be improved for patients in the future, by combining the test result with further information to create a risk score for bowel (lower gut) pathology, the research team will record patients' FIT test results and blood test results at the time FIT was used, along with age and gender and outcome of the referral to Hospital, and then anonymise this information (remove all personal details from it) so

that a FIT risk score can be calculated. The anonymised information will not be associated with patient medical records, no changes will be made to patient medical records and this will not affect any clinical care patients receive at Croydon University Hospital.

What are the possible benefits and risks of participating?
Taking part in the telephone interview does not affect patients directly but it may help improve the test process in the future. Whether patients chose to take part in the discussion has no bearing on their current or future treatment. There are no risks to having the telephone interview.

Where is the study run from?
Croydon University Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2021 to October 2023

Who is funding the study?
Croydon University Hospital (UK)

Who is the main contact?
1. Muti Abulafi, muti.abulafi@nhs.net
2. Theo Georgiou Delisle, t.georgioudelisle@nhs.net

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
290890

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
21/PR/1006, IRAS 290890

Study information

Scientific Title
Understanding reasons why patients with colorectal symptoms do not use the faecal immunochemical test when offered and analysing a risk tool for colorectal cancer

Study objectives
Study 1: There are barriers to using the faecal immunochemical test (FIT) for patients who have declined to use the test when offered it as part of their investigations for potential colorectal cancer symptoms

Study 2: A risk score using individualised patient parameters including faecal haemoglobin (FHb) be more accurate than FHb alone in categorising patient risk of colorectal cancer (CRC).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/08/2021, London - Surrey Research Ethics Committee (Nottingham Centre, The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8372; surrey.rec@hra.nhs.uk), ref: 21/PR/1006

Study design
Study 1: Qualitative research; Study 2: Database analysis

Primary study design
Observational

Secondary study design
Qualitative research and database analysis

Study setting(s)

Hospital

Study type(s)
Diagnostic

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Colorectal cancer

Interventions
An observational study in two parts:
Part 1: Patients who have been referred to Croydon University Hospital from primary care within Croydon
CCG under the colorectal 2-week wait pathway which uses this FIT with potential colorectal cancer symptoms but who did not complete a FIT will be identified. These patients will be contacted by telephone and invited to take part in the study which would involve a recorded telephone interview which would explore their reasons for choosing not to use FIT.

Part 2:
This is a retrospective study of patient outcomes. Patients who have been referred to Croydon University Hospital from Primary Care under the 2-week wait will have their demographics (gender, age), investigations (faecal haemoglobin, serum haemoglobin, CRP, ferritin) recorded along with radiographic/endoscopic investigations and diagnosis outcomes. This data is routinely recorded already as part of the 2-week wait pathway at Croydon University Hospital. Once data collection is complete, patient data will be anonymised and two colorectal cancer risk tools (one using CRP and one not using CRP) will be used to calculate potential colorectal cancer risk scores for patients and this score compared to patient outcomes.

Intervention Type
Other

Primary outcome measure
Study 1: Perceived barriers to using the faecal immunochemical test (FIT) for patients who have declined to use the test when offered it as part of their investigations for potential colorectal cancer symptoms, measured using qualitative interviews, completed after patient investigations and diagnosis completed. Analysis through grounded theory analysis.
Study 2: Factors that would increase the likelihood of patients using FIT when offered as an initial investigation for suspected colorectal cancer symptoms, measured using qualitative interviews, completed after patient investigations and diagnosis completed. Analysis through grounded theory analysis.

Secondary outcome measures
Study 1: Diagnostic accuracy of colorectal cancer risk tool compared to faecal haemoglobin alone, measured through predicted % risk of colorectal cancer using risk tool and % risk of colorectal cancer using faecal haemoglobin alone, compared to diagnostic cancer outcomes of patients following completion of two weeks wait investigations.
Study 2: Sensitivity and specificity of risk tool for colorectal cancer measured by selecting % of patients predicted to have colorectal cancer at set risk thresholds compared to diagnostic cancer outcomes of patients following completion of two-week wait investigations.

Overall study start date
25/03/2021

Completion date
01/10/2023

Eligibility

Key inclusion criteria
Study 1:
1. Patients who have been offered but have not used FIT as part of their referral from primary to secondary care colorectal department within Croydon CCG but who have not completed a FIT (Referral via FIT Implementation pathway).
2. Adults (aged 18 to 110 years)
3. Patients will be able to read, understand and communicate their understanding of the patient information form and complete the consent form
4. Patients will be able to conduct telephone interviews in English

Study 2:
1. Patients who have been referred to Croydon University Hospital under the FIT Implementation pathway
2.1. Patients who have recorded: FHb, serum Hb, ferritin, age, gender and CRP as well as 2-week wait pathway diagnosis in electronic medical notes or:
2.2. Patients who have recorded: FHb, serum Hb, ferritin, age and gender as well as 2-week wait pathway diagnosis in electronic medical notes

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
110 Years

Sex
Both

Target number of participants
Study 1: 15-30. Study 2: Maximum target is number of patients referred on the 2-week wait pathway over study period (10 months)

Key exclusion criteria
Study 1:
1. Patients not offered FIT as part of 2-week wait referral

2. Patients not able to read, understand and communicate their understanding of the patient information form and consent form
3. Patients not able to conduct telephone interviews in English

Study 2:
1. Patients not referred under 2-week wait pathway to hospital
2. Patients without recorded faecal haemoglobin recorded
3. Patients with inadequate biochemical parameters recorded

Date of first enrolment
19/11/2022

Date of final enrolment
19/11/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Croydon University Hospital
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
http://www.croydonhealthservices.nhs.uk/patients-visitors/Croydon-University-Hospital.htm

ROR
https://ror.org/04e2jep17

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Croydon University Hospital

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/01/2025

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are/will be available upon request from Michael Chang (michael.chang@nhs.net)
Types of data shared:
Study 1: Publication of interview analysis will anonymise patient identifiable information. Care will be taken that when specific
patient experiences are presented, incidental details that in combination might identify a patient are carefully removed
where necessary.
Study 2: Quantitative analysis will use anonymised data only. When publishing data will be anonymised.
There are no ethical or legal restrictions

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	19/08/2021	16/01/2023	No	Yes
HRA research summary			28/06/2023	No	No