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Early DETECTion of ColoRectal Cancer in Yorkshire (DETECT-CRC): Feasibility study assessing active case finding of colorectal cancer in socio-economically deprived areas.

Submission date
25/03/2024

Recruitment status
Recruiting

Registration date
02/04/2024

Overall study status
Ongoing

Last Edited
12/06/2025

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Colorectal cancer (CRC) is the fourth most common cancer in the UK and the second leading cause of cancer deaths. Early detection is crucial, as it drastically increases the chances of successful treatment. However, people living in areas with higher poverty levels (socio-economically deprived areas) often have lower rates of CRC screening and thus receive later diagnoses, leading to poorer outcomes.

High street pharmacists are easily accessible to most people. Nearly 90% of people in England live within a 20 minute walk of a pharmacy. About 84% of the UK population visits a pharmacy at least once a year. People in highly deprived areas have even better access to pharmacies (99.8%) than those in more affluent areas (90.2%). This shows that pharmacies are in a unique position to promote cancer awareness and early detection, especially in disadvantaged communities.

The main aim of the study is to assess the feasibility of active case finding (ACF) in high street pharmacies to identify patients with colorectal cancer.

Who can participate?
Pharmacies within South Yorkshire that fall into areas categorised as deciles 1 and 2 of the Index of Multiple deprivation.

What does the study involve?
People presenting at active case finding pharmacies who fulfil the at-risk criteria for bowel cancer will be offered a consultation with a trained pharmacist. Where applicable, they will be provided with a faecal immunochemical test (FIT) kit to perform at home and advised to return the sample by post. Patients will complete the FIT according to the instructions provided and post the sample to the central laboratory for processing. The laboratory will process the sample. Test results will be shared directly with the patient and their GP, and results recorded on currently adopted reporting systems. Positive results will be managed in accordance with the

hospital clinic under “consider further testing” (colonoscopy, CT colonography). The testing of the sample and any follow up care is as per routine practice.

Where is the study run from?
University of Sheffield (UK)

When is the study starting and how long is it expected to run for?
January 2024 to June 2026

Who is funding the study?
Yorkshire Cancer Research (UK)

Who is the main contact?
Co-chief Investigator: Dr Matthew Kurien, matthew.kurien@nhs.net

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-diagnosing-bowel-cancer-earlier-in-yorkshire-detect-crc

Study website
https://www.sheffield.ac.uk/ctru/current-trials/detect-crc

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Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
339557

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Funding reference: RA/2023/R2/108, Protocol number: 178543

Study information

Scientific Title
'Open-label', cluster randomised controlled trial, randomly allocating pharmacies in lower super output areas (LSOAs) to compare active case-finding of bowel cancer versus usual care alone with an equal allocation ratio.

Acronym
DETECT-CRC

Study objectives
To assess the feasibility of active case finding (ACF) in high street pharmacies to identify patients with colorectal cancer.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/08/2024, Yorkshire & The Humber - South Yorkshire Research Ethics Committee (NHSBT Newcastle Blood Donor Centre Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 207 104 8021; southyorks.rec@hra.nhs.uk), ref: 24/YH/0144

Study design
Open-label parallel group cluster randomized controlled feasibility trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Pharmacy

Study type(s)
Diagnostic

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Colo-rectal cancer

Interventions
Open-label, parallel group, cluster randomised controlled feasibility trial, randomly allocating geographical areas defined by one or more adjacent lower super output areas (LSOAs) to compare active case-finding of bowel cancer facilitated by pharmacies versus usual care alone with an equal allocation ratio. The trial will take place in approximately 40 pharmacies located within these clusters in South Yorkshire LSOAs in Deciles 1 and 2 of Multiple Deprivation over a 12 month period. Each cluster contains one or more pharmacies. The trial aims to distribute 1000 FIT kits over a 12 month period.

For pharmacies randomised to the intervention arm, they will be trained in active case finding of colo-rectal cancer (CRC). People presenting at active case finding pharmacies who fulfil the at-risk criteria for bowel cancer will be offered a consultation with a trained pharmacist. Where applicable, they will be provided with a faecal immunochemical test (FIT) kit to perform at home and advised to return the sample by post. Patients will complete the FIT according to the instructions provided and post the sample to the central laboratory for processing. The laboratory will process the sample. Test results will be shared directly with the patient and their GP, and results recorded on currently adopted reporting systems. Positive results will be managed in accordance with the hospital clinic under “consider further testing” (colonoscopy, CT colonography). The testing of the sample and any follow up care is as per routine practice. For pharmacies randomised to the control arm, there will be no change to their practice.

Intervention Type
Other

Primary outcome measure
Feasibility of recruitment to main trial: Number of people who were given a FIT kit from pharmacies delivering the active case finding service (measured using screening log data collected by participating pharmacies) over 12 months.

Secondary outcome measures
1. Intervention adherence - defined objectively as the number of FIT samples performed after dissemination in pharmacy settings - (measured using a unique identifier to enable tracking when the test is received by the central lab) over 12 months.
2. Patients’ views on acceptability of research procedures and intervention measured using semi structured qualitative interviews after at least 3 months of ACF service being delivered.
3. Pharmacists’ views on intervention/research protocol acceptability measured using semi structured qualitative interviews after at least 3 months of ACF service being delivered.
4. General Practitioners’ views on intervention/research protocol acceptability measured using semi structured qualitative interviews after at least 3 months of ACF service being delivered.

5. Feasibility of recruiting community pharmacies - measured using field notes to record problems with project approvals and set-up at participating pharmacy sites; target sites for the main trial.

Overall study start date
01/01/2024

Completion date
30/06/2026

Eligibility

Key inclusion criteria
Pharmacy inclusion criteria:
1. South Yorkshire pharmacies in LSOAs in Deciles 1 and 2 of the Index of Multiple Deprivation.
2. Willing to be randomised to active case finding or usual care.
3. Willing to distribute FIT kits to people attending pharmacy as per the details in protocol.
4. Have read the study-specific SOP and can follow all the elements laid out therein.
5. Have access to PharmOutcomes online system.
6. Have completed the required ACF training associated with the service.
7. Able to offer face to face consultations in a private room.

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Upper age limit
90 Years

Sex
Both

Target number of participants
40 high-street pharmacies

Key exclusion criteria
Pharmacy exclusion criteria:
1. Unable to meet the trial requirements for storing and distributing FIT kits

Date of first enrolment
01/01/2025

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Vantage Pharmacy
2 Ridgeway Road
Manor Top
Sheffield
United Kingdom
S12 2SS

Study participating centre
Wicker Pharmacy
55-67 Wicker
Sheffield
United Kingdom
S3 8HT

Sponsor information

Organisation
University of Sheffield

Sponsor details
School of Medicine and Population Health
The University of Sheffield
Barber House
387 Glossop Road
Sheffield
England
United Kingdom
S10 2HQ
+44 (0) 114 222 1443
l.v.unwin@sheffield.ac.uk

Sponsor type
University/education

Website

http://www.sheffield.ac.uk/

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Charity

Funder Name
Yorkshire Cancer Research

Alternative Name(s)
YCR

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results of the study will be disseminated through peer reviewed scientific journals and at clinical and academic conferences, as well as submission of a final report to the funder, which will be made available online.

Details of the study will also be made available on the Sheffield CTRU website. Summaries of the research will be updated periodically to inform readers of ongoing progress.

The results will be published on a freely accessible database within one year of completion of the trial.

Intention to publish date
30/06/2026

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

IPD sharing plan summary

Data sharing statement to be made available at a later date