

# A study comparing cancer patients randomly assigned to be offered either genetic testing 'at home' or in hospital

<b>Submission date</b> 21/07/2023	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/07/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 22/01/2026	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Patients who are diagnosed with womb, bowel, or ovarian cancer that fulfill NHS genetic testing criteria are recommended to have genetic testing to see if their cancer was related to an inherited gene alteration. Identifying carriers of alterations allows novel personalised cancer treatments, prevention of second cancers, and testing of family members for cancer screening and prevention. Genetic testing requires pre-test counselling to ensure patients are informed about the impact of having a genetic test and managing the result. This 'genetic counselling' has traditionally been provided by genetics services. However, it is now routinely being offered by cancer-treating teams in an approach called "mainstreaming". Currently, the demand for genetic counselling and testing is swiftly increasing and capacity constraints requires the development of new scalable cost and resource-efficient implementation models. This study will assess if pre-test counselling and genetic testing can be done using a direct-to-patient model. Participants will receive genetic testing information on a smartphone app or website that they can access at home along with counselling support through a study telephone helpline. Those who agree to testing can consent via the app and perform testing at home with a saliva genetic testing kit delivered and returned by post. In the study this direct-to-patient approach is directly compared to the standard mainstreaming approach.

### Who can participate?

Patients aged 18 years and over diagnosed with bowel, womb, or ovarian cancer who are eligible for NHS genetic testing

### What does the study involve?

This study compares and evaluates the uptake of genetic testing using both approaches. The researchers also assess patient satisfaction, quality-of-life, and psychological outcomes following testing, using standardized or customized questionnaires over 1 year of follow-up. Clinician opinions will be elicited. Some patients will also be interviewed to assess attitudes, experiences, and impact on emotional wellbeing. An economic analysis will be undertaken to assess the cost-effectiveness of this approach for the NHS.

What are the possible benefits and risks of participating?

Patients that take part in the study will be offered genetic testing. Everyone who is offered genetic testing is given information about the potential risks or benefits of genetic testing. This may have implications for patients' cancer treatment, as they can be offered novel treatments which can improve outcomes. They can also opt for cancer prevention options to prevent other (second) cancers for themselves. Family members can also be tested and opt for screening or cancer prevention options.

Patients may be assigned to receive genetic testing information and genetic testing at home. They will not have to attend a hospital for this to take place. Taking part in this study will also help determine if this direct-to-patient approach of offering genetic testing is as acceptable for patients as standard genetic testing in clinics. Genetic testing is offered as part of standard NHS cancer care. Some people who receive positive genetic test results may feel frightened, sad or upset about their test result. A positive result may mean that patients find out that they have an increased risk of developing other cancers. This may be a result that they were not expecting.

Where is the study run from?

Wolfson Institute of Population Health, Queen Mary University of London (UK)

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

January 2022 to October 2028

Who is funding the study?

1. GlaxoSmithKline (UK)
2. Barts Charity (UK)
3. North East London Cancer Alliance (UK)
4. North Central London Cancer Alliance (UK)

Who is the main contact?

Prof. Ranjit Manchanda, bartsctu-detect-2@qmul.ac.uk

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-two-different-ways-of-carrying-out-genetic-testing-for-people-with-cancer-detect>

## Contact information

### Type(s)

Principal investigator

### Contact name

Prof Ranjit Manchanda

### ORCID ID

<https://orcid.org/0000-0003-3381-5057>

### Contact details

Room 131, Centre for Prevention, Detection & Diagnosis  
Wolfson Institute of Population Health  
Charterhouse Square  
London  
United Kingdom  
EC1M 6BQ

+44 (0)7979884575  
r.manchanda@qmul.ac.uk

## **Additional identifiers**

**Clinical Trials Information System (CTIS)**  
Nil known

**Integrated Research Application System (IRAS)**  
319066

**Central Portfolio Management System (CPMS)**  
57783

## **Study information**

**Scientific Title**  
Direct-to-patient testing at cancer diagnosis for precision prevention-2

**Acronym**  
DETECT-2

**Study objectives**  
Patients at colorectal, endometrial, or ovarian cancer diagnosis have equal genetic testing uptake when offered direct-to-patient genetic testing at cancer diagnosis when compared to standard of care (mainstream genetic testing by members of cancer-treating teams)

**Ethics approval required**  
Ethics approval required

**Ethics approval(s)**  
approved 29/08/2023, London - Brighton & Sussex Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8202; brightonandsussex.rec@hra.nhs.uk), ref: 23/LO/0677

**Study design**  
National multicentre two-arm interventional randomized control trial

**Primary study design**  
Interventional

**Study type(s)**  
Efficacy, Quality of life, Other

**Health condition(s) or problem(s) studied**  
Patients diagnosed with colorectal, endometrial, or ovarian cancer eligible for genetic testing for cancer susceptibility gene variants

**Interventions**

Eligible patients undergo block randomisation (1:1, stratified by cancer type) at recruitment to one of the two study arms:

1. Direct-to-patient testing: Patients will be provided information about genetic testing on a web-app decision aid. This decision aid will be accessible on smartphones, tablets, and web browsers and provide information about genetic testing, how it is performed, the possible results, and potential impacts. The web app will include the consent form for genetic testing allowing patients to accept or decline genetic testing electronically.

Patients consenting to genetic testing will receive a sample collection kit in the post, provide their sample at home using the saliva-collection kit, and post it back to the genetic testing laboratory to perform the testing.

Results will be returned by post and email, and patients will be supported throughout the entirety of this pathway by a telephone helpline staffed by study counsellors experienced in genetic counselling. Patients with positive or uncertain results from genetic testing will be given post-test counselling. Participating sites will refer these patients to their local genetics service(s) as per standard NHS practice/care followed.

2. Standard of care: Patients will receive pre-test counselling from a non-genetics clinician with consent for genetic testing, blood sample collection, and return of results undertaken in clinic as per routine hospital practice.

## **Intervention Type**

Other

## **Primary outcome(s)**

Uptake of genetic testing between the direct-to-patient genetic testing arm versus standard mainstreaming. Uptake of genetic testing will be assessed by equivalency at the end of the study (each event is recorded at decision to test and equivalence is calculated at the end of the study).

## **Key secondary outcome(s)**

1. Decision satisfaction or regret assessed by the 5-item Decision Regret Scale (O'Connor) assessed up to 1 year following return of genetic test results
2. Mental health and emotional outcomes measured by the Hospital Anxiety and Depression Scale, 1-item "I am satisfied with the decision I have made" 5-point Likert scale, Impact of Events Scale, and Multidimensional Impact of Cancer Risk Assessment measured at baseline (if relevant) and up to 1 year following the return of genetic test results.
3. Participant quality-of-life assessed by EuroQol EQ-5D-5L questionnaire, validated cancer-specific and general cancer EORTC questionnaires at baseline and after genetic testing up to 1 year following the return of genetic test results
4. Attitudes, experiences, and impact on emotional health assessed by semi-structured qualitative interviews at 1-6 months after receiving the genetic testing result
5. Decision aid and telephone helpline use in direct-to-patient testing pathway assessed by participant usage statistics collected by the web app and telephone helpline usage case report forms for all participants in the DTP arm at decision to test, 21 days post result and 6 months post result
6. Variant prevalence measured by the number of pathogenic/likely-pathogenic variants/variant of uncertain significance detected divided by the number of people undergoing genetic testing at the end of the study

7. Cost-effectiveness of both testing approaches will be assessed by incremental cost-effectiveness ratio (ICER/QALY) between the two study arms assessed against the willingness-to-pay threshold stipulated by NICE (£20,000-30,000/QALY) at the end of the study
8. Clinician experience of direct-to-patient testing pathway measured using a bespoke clinician questionnaire administered to participating clinicians once a site is set up and operating

**Completion date**

01/10/2028

## Eligibility

**Key inclusion criteria**

1. Adults diagnosed with endometrial cancer or colorectal cancer fulfilling NHS clinical genetic testing criteria for mismatch repair genes based on clinical or histo-pathological molecular profile  
or
2. Adults diagnosed with high-grade epithelial ovarian cancer fulfilling NHS clinical genetic testing criteria

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

100 years

**Sex**

All

**Total final enrolment**

0

**Key exclusion criteria**

Current exclusion criteria as of 09/05/2024:

1. Patients who have had previous genetic testing for Lynch Syndrome, OC, or CRC genes
  2. Patients whose family has a known pathogenic variant in a cancer susceptibility gene, which is part of the panel the patient is eligible for undergoing testing.
  3. Unable to provide informed consent
-

Previous exclusion criteria:

1. Patients who have had previous genetic testing for Lynch Syndrome, or OC genes
2. Patients whose family has a known pathogenic variant in one of the following genes: BRCA1, BRCA2, RAD51C, RAD51D, BRIP1, PALB2, MLH1, MSH2, MSH6, PMS2
3. Unable to provide informed consent

**Date of first enrolment**

25/04/2024

**Date of final enrolment**

30/11/2026

## **Locations**

**Countries of recruitment**

United Kingdom

England

Northern Ireland

Scotland

**Study participating centre**

**Barts Health NHS Trust**

The Royal London Hospital

80 Newark Street

London

England

E1 2ES

**Study participating centre**

**University College London Hospitals NHS Foundation Trust**

250 Euston Road

London

England

NW1 2PG

**Study participating centre**

**London North West University Healthcare NHS Trust**

Northwick Park Hospital

Watford Road

Harrow  
England  
HA1 3UJ

**Study participating centre**  
**Nottingham University Hospitals NHS Trust**  
Trust Headquarters  
Queens Medical Centre  
Derby Road  
Nottingham  
England  
NG7 2UH

**Study participating centre**  
**University Hospitals Bristol and Weston NHS Foundation Trust**  
Trust Headquarters  
Marlborough Street  
Bristol  
England  
BS1 3NU

**Study participating centre**  
**Imperial College Healthcare NHS Trust**  
The Bays  
St Marys Hospital  
South Wharf Road  
London  
England  
W2 1BL

**Study participating centre**  
**Barking, Havering and Redbridge University Hospitals NHS Trust**  
Queen's Hospital  
Rom Valley Way  
Romford  
England  
RM7 0AG

**Study participating centre**  
**University Hospital Southampton NHS Foundation Trust**  
Southampton General Hospital

Tremona Road  
Southampton  
England  
SO16 6YD

**Study participating centre**  
**Sandwell and West Birmingham Hospitals NHS Trust**  
City Hospital  
Dudley Road  
Birmingham  
England  
B18 7QH

**Study participating centre**  
**Norfolk & Norwich University Hospitals NHS Foundation Trust**  
Colney Lane  
Colney  
Norwich  
England  
NR4 7UY

**Study participating centre**  
**University Hospitals Sussex NHS Foundation Trust**  
Worthing Hospital  
Lyndhurst Road  
Worthing  
England  
BN11 2DH

**Study participating centre**  
**University Hospitals Dorset NHS Foundation Trust**  
Management Offices  
Poole Hospital  
Longfleet Road  
Poole  
England  
BH15 2JB

**Study participating centre**  
**Portsmouth Hospitals University NHS Trust**  
Queen Alexandra Hospital

Portsmouth  
England  
PO6 3LY

**Study participating centre**  
**East Kent Hospitals University NHS Foundation Trust**  
Kent & Canterbury Hospital  
Ethelbert Road  
Canterbury  
England  
CT1 3NG

**Study participating centre**  
**Oxford University Hospitals NHS Foundation Trust**  
John Radcliffe Hospital  
Headley Way  
Headington  
Oxford  
England  
OX3 9DU

**Study participating centre**  
**Manchester University NHS Foundation Trust**  
Cobbett House  
Oxford Road  
Manchester  
England  
M13 9WL

**Study participating centre**  
**NHS Lothian**  
Waverley Gate  
2-4 Waterloo Place  
Edinburgh  
Scotland  
EH1 3EG

**Study participating centre**  
**Somerset NHS Foundation Trust**  
Trust Management  
Lydeard House

Musgrove Park Hospital  
Taunton  
England  
TA1 5DA

**Study participating centre**  
**University Hospitals of Derby and Burton NHS Foundation Trust**  
Royal Derby Hospital  
Uttoxeter Road  
Derby  
England  
DE22 3NE

**Study participating centre**  
**Cardiff and Vale NHS Trust**  
Cardigan House  
University Hospital of Wales  
Heath Park  
Cardiff  
Wales  
CF14 4XW

**Study participating centre**  
**University Hospitals of Leicester NHS Trust**  
Leicester Royal Infirmary  
Infirmary Square  
Leicester  
England  
LE1 5WW

**Study participating centre**  
**South Tees Hospitals NHS Foundation Trust**  
James Cook University Hospital  
Marton Road  
Middlesbrough  
England  
TS4 3BW

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

Barrack Road  
Exeter  
England  
EX2 5DW

**Study participating centre**  
**East Suffolk and North Essex NHS Foundation Trust**  
Colchester Dist General Hospital  
Turner Road  
Colchester  
England  
CO4 5JL

**Study participating centre**  
**Milton Keynes University Hospital NHS Foundation Trust**  
Standing Way  
Eaglestone  
Milton Keynes  
England  
MK6 5LD

**Study participating centre**  
**Cardiff & Vale University Lhb**  
Woodland House  
Maes-y-coed Road  
Cardiff  
Wales  
CF14 4HH

**Study participating centre**  
**North West Anglia NHS Foundation Trust**  
Peterborough City Hospital  
Bretton Gate  
Bretton  
Peterborough  
England  
PE3 9GZ

**Study participating centre**  
**Lancashire Teaching Hospitals NHS Foundation Trust**  
Royal Preston Hospital

Sharoe Green Lane  
Fulwood  
Preston  
England  
PR2 9HT

**Study participating centre**

**Leeds Teaching Hospitals NHS Trust**

St. James's University Hospital  
Beckett Street  
Leeds  
England  
LS9 7TF

**Study participating centre**

**Homerton Healthcare NHS Foundation Trust**

Homerton Row  
London  
England  
E9 6SR

**Study participating centre**

**Gateshead Health NHS Foundation Trust**

Queen Elizabeth Hospital  
Sheriff Hill  
Gateshead  
England  
NE9 6SX

**Study participating centre**

**St George's University Hospitals NHS Foundation Trust**

St George's Hospital  
Blackshaw Road  
Tooting  
London  
England  
SW17 0QT

**Sponsor information**

**Organisation**

Queen Mary University of London

**ROR**

<https://ror.org/026zzn846>

**Funder(s)****Funder type**

Industry

**Funder Name**

GlaxoSmithKline

**Alternative Name(s)**

GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

**Funding Body Type**

Government organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

United Kingdom

**Funder Name**

Barts Charity

**Alternative Name(s)****Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

**Funder Name**

North East London Cancer Alliance

**Funder Name**

North Central London Cancer Alliance

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be available upon request from Prof. Ranjit Manchanda (bartsctu-detect-2@qmul.ac.uk)

**IPD sharing plan summary**

Available on request, Stored in non-publicly available repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes