

# BRCA-DIRECT- Is digitally delivered information about genetic testing feasible, effective and acceptable to women with breast cancer?

<b>Submission date</b> 22/01/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 28/01/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/11/2024	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-giving-information-about-genetic-testing-online-brca-direct#undefined> (added 20/10/2021)

### Background and study aims

Compared to the general population, women who have a fault in their BRCA1, BRCA2 or PALB2 gene (a pathogenic\_variant) have a higher risk of developing breast and ovarian cancer.

Currently, within the National Health Service (NHS), women with breast cancer are not routinely tested for these genes unless they have a strong family history of cancer. The results of a BRCA-gene test can be of value in any woman with breast cancer as it can provide useful information on: (i) how to best treat the cancer, (ii) the risk of this, or other cancers returning, (ii) whether family members are at high risk of cancer.

Before having a BRCA-gene test, women currently have a lengthy one-to-one consultation with a doctor or a genetic counsellor, who explains what the test results could mean for them and their families. Recent advances in technology for this test have brought down the cost and time taken to run it, but it is not being used widely within the NHS due to a lack of doctors and genetic counsellors available to provide genetic counselling.

This study will examine the feasibility, effectiveness and acceptability of delivering digital (online) information about BRCA gene testing to breast cancer patients at two UK hospital Trusts. 1000 women with breast cancer will be randomised to receive digital information about genetic testing via the 'BRCA-DIRECT' system or by a standard genetic counselling telephone appointment. Following this, participants will then decide whether to proceed with the BRCA-gene test.

### Who can participate?

Women aged 18 years or above, with diagnosis of invasive breast cancer or high grade Ductal Carcinoma in Situ (DCIS) and access to a smartphone.

What does the study involve?

Participating in the study will take 4-6 weeks and during this time participants will provide a saliva or blood sample for the BRCA-gene test, receive pre-test information, complete eight questionnaires and a feedback survey. Test results will be provided to each participant.

What are the possible benefits and risks of participating?

**Benefits:** Participants will have the option to receive a BRCA-test for which participants may not have been eligible through standard NHS care. The results of this test may give participants useful information about their future risk of cancer and that of their family. We hope this study will tell us whether digital delivery is an acceptable way of giving breast cancer patients information about genetic testing. Participants will be helping us gain knowledge to answer that question.

**Risks:** Participants will be allocated to an information delivery method by randomisation, so participants may not receive the one participants prefer. Participants will also be asked to complete some questionnaires which will require some of their time.

Where is the study run from?

Institute of Cancer Research (UK)

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

January 2021 to January 2023

Who is funding the study?

Cancer Research UK

Who is the main contact?

Prof. Clare Turnbull (scientific), [Clare.Turnbull@icr.ac.uk](mailto:Clare.Turnbull@icr.ac.uk)

Bethany Torr (public), [BRCA-DIRECT@icr.ac.uk](mailto:BRCA-DIRECT@icr.ac.uk)

**Study website**

<https://www.brca-direct.org/>

## Contact information

**Type(s)**

Scientific

**Contact name**

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**Type(s)**

Public

**Contact name**

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**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number**

278052

**ClinicalTrials.gov number**

NCT04842799

**Secondary identifying numbers**

CPMS 47406, IRAS 278052

**Study information****Scientific Title**

BRCA-DIRECT: randomised evaluation in women diagnosed with breast cancer of digitally-delivered pre-test information for BRCA-testing

**Acronym**

BRCA-DIRECT

**Study objectives**

This study will examine the feasibility, effectiveness and acceptability of delivering digital (online) information about BRCA gene testing to breast cancer patients at two UK hospital Trusts. 1000 women with breast cancer will be randomised to receive digital information about genetic testing via the 'BRCA-DIRECT' system or by a standard genetic counselling telephone appointment. Following this, participants will then decide whether to proceed with the BRCA-gene test.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 04/01/2021, London - Chelsea Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)207104 8064; chelsea.rec@hra.nhs.uk), 20/LO/1200

**Study design**

Interventional randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

See additional files

**Health condition(s) or problem(s) studied**

Breast Cancer

**Interventions**

Participants will be sent a link to the BRCA-DIRECT online system at least 24 hours after the signed consent form was received. They will be asked to complete a medical family history questionnaire, three baseline quality of life questionnaires.

Participants will be randomised 1:1 to receive information about genetic testing either online or via a telephone appointment with a genetic counsellor. Following this, patients can choose whether to proceed to genetic testing of their saliva sample.

One week after activating the test, participants will be asked to complete one quality of life questionnaire and a study specific knowledge questionnaire.

All patients with a test result indicating that they have a pathogenic\_variant BRCA gene will receive their result from a genetic counsellor. Patients with normal BRCA genes will be randomised to receive results by telephone appointment or genetic counsellor appointment. All participants will also receive a letter giving their results in detail. This letter will be copied to their medical team and GP.

One week after receiving their results, participants will be asked to complete one quality of life questionnaire and a feedback survey, asking about their experience of using the BRCA-DIRECT online system. During the pilot phase (first 120 participants recruited) participants will also have the option to register for a telephone interview with a researcher to provide more detailed feedback (capped at 50 participants).

One month after receiving their results, participants will be asked to complete a final quality of life questionnaire with a reminder to complete a feedback survey, if not already done.

### **Intervention Type**

Other

### **Primary outcome measure**

The proportion of patients proceeding to genetic testing following delivery of pre-test information measured using case report forms

### **Secondary outcome measures**

1. Knowledge about genetic testing for BRCA genes measured using the Knowledge Questionnaire 7 days after the BRCA-test consent has been signed
2. Anxiety following delivery of pre-test information, and test results, in the two allocated groups (State Trait Anxiety Inventory scores and intolerance of uncertainty questionnaire)
3. Uptake of digital genetic testing (decline rates and reasons will be assessed by expression of interest forms throughout the study)
4. 'Test-offer-to-results' time (Audit of study timelines vs current SOC within service)
5. Uptake of telephone helpline (Central log retained throughout the study)
6. Healthcare professional satisfaction with BRCA-DIRECT digital model (survey at 7 days)
7. Patient satisfaction with BRCA-DIRECT digital model (satisfaction survey at 7 days and detailed interviews within pilot phase)

### **Overall study start date**

01/01/2021

### **Completion date**

16/01/2023

## **Eligibility**

### **Key inclusion criteria**

1. Diagnosis of invasive breast cancer or high grade Ductal Carcinoma in Situ (DCIS)
2. Aged 18 years or over
3. Access to smartphone or email and internet
4. Good comprehension of the English Language

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Female

**Target number of participants**

Planned Sample Size: 1,000; UK Sample Size: 1,000

**Total final enrolment**

1140

**Key exclusion criteria**

Previously tested for any of BRCA genes BRCA1, BRCA2, PALB2

**Date of first enrolment**

01/06/2021

**Date of final enrolment**

15/08/2022

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre****The Royal Marsden Hospital**

Royal Marsden NHS Foundation Trust

Downs Road

Sutton

United Kingdom

SM2 5PT

**Study participating centre****The Royal Marsden Hospital**

Fulham Road

Chelsea

London

United Kingdom

SW3 6JJ

**Study participating centre****The Nightingale Centre**

Manchester University NHS Foundation Trust

Wythenshawe Hospital

Southmoor Road

Manchester  
United Kingdom  
M23 9LT

**Study participating centre**

**The Royal Marsden Hospital, Sir William Rous Unit**  
Galsworthy Road  
Kingston upon Thames  
United Kingdom  
KT2 7QB

**Study participating centre**

**Manchester University NHS Foundation Trust**  
North Manchester General Hospital  
Delaunays Road  
Crumpsall  
Manchester  
United Kingdom  
M8 5RB

## **Sponsor information**

**Organisation**

The Institute of Cancer Research

**Sponsor details**

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barbara.pittam@icr.ac.uk

**Sponsor type**

Research organisation

**Website**

<https://www.icr.ac.uk/>

**ROR**

<https://ror.org/050g6df85>

# Funder(s)

## Funder type

Charity

## Funder Name

Cancer Research UK; Grant Codes: C61296/A29423

## Alternative Name(s)

CR\_UK, Cancer Research UK - London, CRUK

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Other non-profit organizations

## Location

United Kingdom

# Results and Publications

## Publication and dissemination plan

The study results will be published in peer reviewed journals and presented at scientific conferences. It will not be possible to identify any individuals. Links to publications will also be available via the ICR and SHORE-C websites.

## Intention to publish date

01/05/2024

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from the BRCA-DIRECT Management Committee (BRCA-DIRECT@ICR.AC.UK). At the end of the study, the BRCA-DIRECT platform and study databases will be dismantled. All electronic data will be securely transferred to the Institute of Cancer Research for secure storage and archiving. A copy of the selected raw data will also be transferred securely to Sussex Clinical Trial Unit (CTU)/ Sussex Health Outcomes Research & Education in Cancer (SHORE-C) for analysis of psychosocial outcomes.

All study data and documentation will be archived at the Institute of Cancer research for 5 years beyond the end of the study. Study data will be stored and accessible by PIN only. Following this period, data will be destroyed according to Institute of Cancer Research policy. Following analysis and publication of main trial results, data analysis files created at Sussex Clinical Trial Unit (CTU)/ Sussex Health Outcomes Research & Education in Cancer (SHORE-C) will be transferred to ICR for archiving and all copies of raw data and analysis files at Sussex CTU /SHORE-C will be destroyed. Any requests from external parties for data collected for BRCA-DIRECT will be considered by the BRCA-DIRECT Management Committee (MC). The final decision will rest with the Custodian of the data.



**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Other publications</a>	Results of internal pilot	22/07/2022	25/07/2022	Yes	No
<a href="#">Protocol file</a>	version 0.61	17/03/2023	04/05/2023	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Results article</a>		01/10/2024	20/11/2024	Yes	No