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

Submission date
22/01/2021

Recruitment status
No longer recruiting

Registration date
28/01/2021

Overall study status
Completed

Last Edited
20/11/2024

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Bethany Torr (public), BRCA-DIRECT@icr.ac.uk

Contact information

Type(s)
Scientific

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Public

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Miss Bethany Torr

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
278052

ClinicalTrials.gov (NCT)
NCT04842799

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

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
United Kingdom

England

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

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, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

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?
Results article		01/10/2024	20/11/2024	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Results of internal pilot	22/07/2022	25/07/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 0.61	17/03/2023	04/05/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes