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Exploring the use of information films to improve patient understanding of genomic expression profiling (GEP) tests in the breast cancer setting

Submission date
02/02/2022

Recruitment status
No longer recruiting

Registration date
11/02/2022

Overall study status
Completed

Last Edited
12/08/2025

Condition category
Cancer

[_] Prospectively registered
[_] 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-to-improve-peoples-understanding-of-a-test-for-gene-faults-in-breast-cancer-imparter

Background and study aims
The results from Gene Expression Profiling (GEP) tests in breast cancer are used to determine whether additional chemotherapy has a role in reducing a patient's risk of recurrence. Healthcare Professionals can find discussing GEP test results challenging and many breast cancer teams provide patients with information leaflets to aid their understanding of the tests. Unfortunately, these are often written by either academic or commercial sponsors and designed to meet certain ethical and regulatory guidelines and are often hard to understand by the public user.

Two gene expression profiling tests used in breast cancer in the UK are Oncotype DX and Prosigna. We examined the ease of readability of patient information leaflets describing these tests. Both employed complex language and concepts. We therefore designed 2 short (8 minute) patient information films, one for Oncotype DX and one for Prosigna. We compared the ability of these to convey basic information about GEP testing and recurrence risk results with that achieved after reading an information leaflet.

Results from the IMPARTER (Phase 3) cross-over study, showed that providing information about Oncotype DX or Prosigna in film format, significantly improved the knowledge of 120 women aged 45-75 (without breast cancer) compared with that achieved after reading the information leaflets. A majority of participants preferred the films for reasons including clarity, simple graphics, and reassuring tone and pace. The leaflets proved difficult for most participants to understand, often due to the medical terminology used, irrelevant extra information, and the layout.

IMPARTER Phase 4 takes place in a clinic setting with patients identified by their breast cancer multidisciplinary team as benefiting from having their tumour sample sent for GEP analysis. We wish to examine if providing a patient information film about either Oncotype DX or Prosigna, 1) improves the knowledge needed to inform decision-making, and 2) enhances satisfaction with patient–clinician discussions.

Who can participate?
Adult women over 18 years, who have had successful surgery to remove breast cancer.

What does the study involve?
Participants will be randomly allocated to receive standard information (usual practice/leaflets) plus or minus the patient information film.
Later their knowledge and understanding of GEP will be assessed.
The outcomes will show if the film provides additional value to patients over the standard information alone (usual practice/leaflet), in terms of knowledge and satisfaction with the consultation and decision-making.

What are the possible benefits and risks of participating?
There are no direct benefits in taking part. However, the study will show if the film is an additional useful source of information for patients considering GEP tests. This may help people with breast cancer in the future. The main disadvantage of taking part will be the time it takes to complete the assessments. Some people may feel uncomfortable answering questions about their understanding of GEP tests.

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

When is the study starting and how long is it expected to run for?
December 2021 to January 2024

Who is funding the study?
Breast Cancer Research Foundation (USA)

Who is the main contact?
IMPARTER@sussex.ac.uk

Study website
https://shore-c.sussex.ac.uk/imparter4.html

Contact information

Type(s)
Scientific

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Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
304561

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 51297, IRAS 304561

Study information

Scientific Title
IMproving PAtient undeRstanding of GEP TEst Results: Phase 4

Study objectives
1. Those patients viewing the information film will have higher GEP knowledge scores than those having standard information alone
2. Increased knowledge (and better understanding of recurrence risk results) is associated with less decisional conflict
3. The clinicians' satisfaction with the risk results consultations will be higher in patients randomised to standard information plus film

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/12/2021, London- Bromley Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 207 104 8105; bromley.rec@hra.nhs.uk), ref: 21/PR/1576

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
https://shore-c.sussex.ac.uk/imparter4.html

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

Interventions
This is a randomised trial using quantitative methods. Participants will complete questionnaires and take part in a verbal knowledge assessment with a researcher in relation to GEP testing.

Patient online assessments
The research team will e-mail participants with a link to complete their online consent form, demographic questions, the STAI trait (20 items) and state inventories (20 items) and an intolerance of uncertainty measure (12 items).

The online STAI state inventory will be completed again, along with the Decisional Conflict Scale (10 items), within a week of a patient having their GEP test result consultation.

Patient randomisation
Once participants have completed their initial online assessments they will be randomised to groups - group A will not receive any additional information to that which they receive from their clinical team as per standard of care. Group B will be sent an additional link to watch a video on the GEP test they're having - either Oncotype DX or Prosigna. Group randomisation will be stratified by site.

Patient knowledge assessment
All participants will take part in a telephone interview prior to receiving their GEP results. This will comprise of knowledge items plus additional questions to gather feedback on what

resources participants used, whether they sought advice from anyone else, what they liked and what they did not find helpful.

Clinician assessments
Clinicians will be asked to complete the intolerance of uncertainty scale. This will be done at the time of site set-up.
Following each patient consultation, clinicians will also complete a 6 item confidence /satisfaction scale.

Intervention Type
Behavioural

Primary outcome measure
Patients' knowledge and understanding about GEP tests and risk of recurrence results measured by a knowledge interview prior to a patient receiving their GEP test results

Secondary outcome measures
1. The impact of anxiety, intolerance of uncertainty and decisional conflict on decision-making (patient) assessed by the state (baseline and T2) and trait STAI measures (baseline), intolerance of uncertainty (T1) and decisional conflict measure (T2)
2. The confidence/satisfaction with GEP test result consultations (clinician) completed following the test result consultation
3. The agreement between clinician and patient on their treatment decision and whether this is influenced by the clinician's satisfaction with interview about recurrence risk and IoU scores (clinician completes once per study prior to seeing patients), the patient's recurrence risk, or pre-existing characteristics (trait anxiety, uncertainty) and whether GEP knowledge/understanding mitigate these

Overall study start date
21/12/2021

Completion date
31/01/2024

Eligibility

Key inclusion criteria
1. First presentation of early stage breast cancer with all known disease surgically removed
2. Oestrogen Receptor (ER+ve) and HER-2 negative (female patients only)
3. No clear decision as to whether chemotherapy should be given as adjunct based on current prognostic criteria
4. Consented to GEP tests
5. Able to give full informed consent to IMPARTER:4
6. Good comprehension of the English language
7. Access to internet connection and compatible devices

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 250; UK Sample Size: 250

Total final enrolment
251

Key exclusion criteria
1. Other breast cancer diagnosis e.g. DCIS, metastatic
2. Unable to give fully informed consent
3. Under 18 years of age
4. Unable to understand and speak English
5. No access to internet connection and/or compatible devices

Date of first enrolment
01/02/2022

Date of final enrolment
05/12/2023

Locations

Countries of recruitment
England

United Kingdom

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

Study participating centre
Poole Hospital
University Hospitals Dorset NHS Foundation Trust
Longfleet Road
Poole

United Kingdom
BH15 2JB

Study participating centre
Ashford and St Peter's Hospital NHS Foundation Trust
London Road
Ashford
United Kingdom
TW15 3AA

Study participating centre
Royal Free Hospital
Royal Free London NHS Foundation Trust
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
Royal Devon & Exeter Hospital
Royal Devon and Exeter NHS Foundation Trust
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
The Maidstone Hospital
Maidstone and Tunbridge Wells NHS Trust
Hermitage Lane
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ME16 9QQ

Study participating centre
Basingstoke and North Hampshire Hospital
Hampshire Hospitals NHS Foundation Trust
Aldermaston Road
Basingstoke
United Kingdom
RG24 9NA

Study participating centre
The Royal Marsden NHS Foundation Trust
Fulham Road
London
United Kingdom
SW3 6JJ

Study participating centre
The Princess Alexandra Hospital NHS Trust
Hamstel Road
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United Kingdom
CM20 1QX

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

Study participating centre
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Sponsor information

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Sponsor type
University/education

Website
http://www.sussex.ac.uk/

ROR
https://ror.org/00ayhx656

Funder(s)

Funder type
Charity

Funder Name
Breast Cancer Research Foundation

Alternative Name(s)
BREAST CANCER RESEARCH FOUNDATION INC, The Breast Cancer Research Foundation, BCRF

Funding Body Type
Government organisation

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

Location
United States of America

Results and Publications

Publication and dissemination plan
We plan to analysis all results following the end of study for publication in peer reviewed journals, conference presentations, and participant/public facing materials.

Intention to publish date
31/01/2025

Individual participant data (IPD) sharing plan

Data are available upon reasonable request. Requests should be sent to Prof Dame Lesley Fallowfield (l.j.fallowfield@sussex.ac.uk). The data would be anonymised, non-personal questionnaire response data.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Results article		21/03/2025	11/08/2025	Yes	No