

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

<b>Submission date</b> 02/02/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/02/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/08/2025	<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-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

**Contact name**

Dr Imparter Study team

**Contact details**

University of Sussex

Brighton

United Kingdom

BN1 9RH

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imparter@sussex.ac.uk

### **Type(s)**

Principal Investigator

### **Contact name**

Prof Lesley Fallowfield

### **ORCID ID**

<https://orcid.org/0000-0003-0577-4518>

### **Contact details**

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SHORE-C, Brighton and Sussex Medical School  
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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  
Maidstone  
United Kingdom  
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  
Harlow  
United Kingdom  
CM20 1QX

**Study participating centre****Kent & Canterbury Hospital**

East Kent Hospitals University NHS Foundation Trust  
Ethelbert Road  
Canterbury  
United Kingdom  
CT1 3NG

**Study participating centre****Darent Valley Hospital**

Dartford and Gravesham NHS Trust  
Darent Wood Road  
Dartford  
United Kingdom  
DA2 8DA

## **Sponsor information**

**Organisation**

University of Sussex

**Sponsor details**

Sussex House  
Falmer  
Southern Ring Road



Brighton  
England  
United Kingdom  
BN1 9RH  
+44 1273872748  
researchsponsorship@sussex.ac.uk

**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?
<a href="#">HRA research summary</a>			26/07/2023	No	No
<a href="#">Results article</a>		21/03/2025	11/08/2025	Yes	No