### IMPARTER:4 IMproving PAtient undeRstanding of Gene Expression Profiling TEst Results: Phase 4



Lucy Matthews, Rachel Starkings, Valerie Jenkins, Shirley May, Lesley Fallowfield Sussex Health Outcomes Research and Education in Cancer (SHORE-C), Brighton and Sussex Medical School, UK

# Background

Treatments given after breast cancer (BC) surgery, may include:

- Radiotherapy
- Hormone treatment
- Chemotherapy

All aim to reduce the risk of the BC recurring.

Patients with early stage oestrogen receptor positive, Her2

### Aims

IMPARTER:4 is an RCT exploring the usefulness of the films compared to standard information with BC patients in a clinical setting.

Primary outcome: to determine if provision of a patient

information film improves patients' knowledge and understanding

about GEP tests and recurrence scores.

Secondary outcomes: variables influencing patient knowledge,

clinician satisfaction with decision to give chemo or not, impact of

negative BC may not need chemotherapy.

Gene Expression Profiling (GEP) tests help estimate the risk of recurrence and likely benefit of chemotherapy.

Two main GEP tests used in the UK are:

- Oncotype DX
- Prosigna

Both produce a recurrence score from low to high risk which helps inform doctor-patient discussions about the usefulness of adding chemotherapy to endocrine/hormone treatment alone.

Conversations can be complex and patient information sheets often contain medical terminology which is problematic for people with low health literacy and numeracy. film on consultation time, clinician satisfaction with consultation.

### **Methods**

Patients consenting to an Oncotype DX / Prosigna test identified by clinical teams at 18 recruiting hospitals

Complete online consent form and baseline questionnaires (anxiety trait/state + intolerance of uncertainty (IoU))

Randomised to receive standard information provided by the hospital (Group A) or standard information plus the relevant GEP test film (Group B)

Patients interviewed about key facts producing a knowledge score

SHORE-C produced 8-minute patient information films about Oncotype DX and Prosigna. The films use patient friendly language, visuals and voiceovers explaining the GEP testing process and meaning of the results.

In previous research, 120 women without BC had an improvement in knowledge after watching the films compared to reading leaflets & preferred the film (Fallowfield et al., 2022).





After GEP test results patients complete online questionnaires measuring anxiety and decisional conflict

Clinicians giving the GEP test result complete IoU once and a satisfaction with the consultation questionnaire for each patient

## **Planned analysis**

Recruitment ended December 2023, 251 consented, 225 have complete data.

Independent statistician to analyse differences in knowledge scores between Group A and B.

Secondary outcomes mapped alongside knowledge scores using linear regressions.

Clinician IoU scores, confidence & satisfaction with the GEP



results appointment modelled with the patient's GEP test result score.

#### Conclusions

Shared decision making demands that patients understand complex information.

If study findings are positive, hopefully the film can be made available to all patients.

Versions of the film are available in, Urdu, Bengali, Gujarati, Hindi, Spanish, French and Italian.

Acknowledgments: Patients, clinicians and nurses. Breast Cancer Research Foundation for funding the study

Reference: Fallowfield, L. J., Farewell, D., Jones. H., May. S., Catt. S., Starkings, R., and Jenkins, V. (2022) 'IMPARTER, Phase 1 of an intervention to improve patients' understanding of gene expression profiling tests in breast cancer'. Breast Cancer Research and Treatment, 192:265-271 <a href="https://doi.org/10.1007/s10549-021-06491-2">https://doi.org/10.1007/s10549-021-06491-2</a>