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Improving patient understanding of GEP test results (IMPARTER4): an RCT

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ABSTRACT

Objective Explaining gene expression profiling (GEP) test results to patients can be challenging. We examined the utility of two 8 min films about Oncotype DX and Prosigna to aid the knowledge and decision-making of women with early-stage oestrogen receptor positive (ER+) breast cancer.

Methods and analysis Patients awaiting GEP test results completed an anxiety questionnaire and the intolerance of uncertainty scale (IUS) before randomisation and divided into Group A (standard verbal and/or written hospital information) or Group B (standard information plus GEP film). Prior to results, they were interviewed about their GEP test knowledge and how the recurrence risk helps determine treatment options. After the results consultation, participants answered two further questionnaires. Participating clinicians completed IUS scales and reported their satisfaction with the results discussions.

Results 230/251 patients completed the study (Group A (n=106) and Group B (n=124)). The total knowledge score was higher in Group B (estimated between groups mean difference of 2.5 (95% CI:1.7 to 3.4) p<0.001). Most treatment decisions adhered to recommended risk of recurrence thresholds, although patients with higher trait anxiety were more likely to make less apparently rational decisions OR=0.93 (95%CI 0.88 to 0.97) p=0.002 (163/230; 70.8% received ET alone; 65/230; 28% ET plus chemotherapy, and two sought second opinions). Clinicians reported slightly longer consultations for Group A participants who tended to ask more difficult and unexpected questions.

Conclusion Patients who received standard verbal and written information plus film had increased knowledge about GEP tests compared with standard information alone.

Trial registration number ISRCTN28497350.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Gene expression profiling (GEP) test results can be difficult for healthcare professionals to explain, and when set against a backdrop of fear and anxiety, many patients find test results hard to understand. Patient information leaflets may help but often demand high literacy and numeracy, and a crossover study with women showed that knowledge was significantly higher following viewing of a short film.

WHAT THIS STUDY ADDS

⇒ An appropriately designed film provided more comprehensive, understandable information to aid the discussion about GEP test results, and the extra knowledge conveyed permits more educated decision-making about the addition of adjuvant chemotherapy to endocrine therapy in oestrogen receptor positive early breast cancer.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ There are many efforts to help patients make more educated, informed decisions about treatments. Although patient information leaflets may help, they are rarely tested robustly to examine if the format used does assist patients. Short, well-designed film formats with simple graphics that are easy to access on smartphones or computers should be considered.

INTRODUCTION

Not all patients with early-stage, hormone-receptor-positive, human epidermal growth factor receptor 2 (HER2) negative breast cancer will benefit from the addition of chemotherapy to endocrine treatment alone. As the iatrogenic harms of chemotherapy can be substantial and exert a deleterious impact on quality of life, determining how likely chemotherapy is to reduce the risk of recurrence (RoR) is important. Often, clinico-pathological features of the tumour (size, histological grade, type, nodal status, etc) together with a patient's age will provide sufficient information to guide adjuvant therapy management. For patients in whom the benefits of chemotherapy are less certain, gene expression profiling (GEP) tests have an increasingly significant role in aiding decision-making. There are a variety of GEP tests available including Mammaprint, Oncotype DX, EndoPredict and Prosigna,[1–7] all of which offer predictive and certain prognostic information.

Some doctors consider GEP to be a tool that enhances confidence in their clinical risk assessments, while others view it as critical to resolving their own reservations about recommending chemotherapy.[8] Discussions about GEP testing and the RoR results, which

involve explaining risk and uncertainty to patients with potentially life-threatening disease, can be challenging,[9] as people find it difficult to reason about uncertainty.[10] One of the aims of the GEP tests is to help remove some of that uncertainty and aid decision-making.

A discrete choice experiment to elicit preferences and estimate the value of GEP testing information in treatment decisions for early-stage breast cancer showed that the most important attribute was the GEP test score indicating the likely benefit from chemotherapy. However, trust in the doctor and his/her clinical estimate of the risk of the cancer returning, plus the side effects of chemotherapy, also influenced decisions.[11] Another study explored how women received and incorporated results of the Oncotype DX test into decisions about adjuvant treatments. Although 71% accurately recalled their risk score, a third felt they did not understand the GEP test results discussion.[12] Almost half (46%) of the patients said the doctor used words and numbers to explain the result; 38% words, numbers and graphs; 14% words only; 4% words and graphs; 1% numbers and graphs; and 1% numbers only.[12] Later research examining women's understanding about the Oncotype DX test revealed that few (22%) realised the RoR estimate calculation includes the impact of endocrine treatment.[13] Predictably, knowledge scores correlated positively with higher literacy and numeracy skills, which is an important consideration in risk communication and potentially limits the usefulness of GEP information leaflets.[14]

The industry Oncotype DX and Prosigna leaflets each employ quite complex language and concepts, which would be incomprehensible for the majority of patients that they were trying to help. Consequently, we designed two 8 min patient information films about these commonly used GEP tests. We compared the ability of the films to convey basic information about GEP tests and recurrence risk with that achieved after reading an information leaflet in a cross-over study with 120 women without breast cancer aged 45–75.[15] Findings showed that providing information about either Oncotype DX or Prosigna in the film format significantly improved participants' knowledge compared with that achieved from reading the relevant information leaflets (mean difference 4.1; p<0.001; 95% CI 3.2, 5.0).[15] Importantly, a majority also preferred the films, citing their clarity, the simple graphics and reassuring tone and pace of the voice-over. Most found the leaflets quite difficult to understand, due to the medical terminology used, extraneous information and layout.

In the IMPARTER Phase 4 randomised controlled trial (RCT) reported here, we assessed the films' utility in a clinic setting. Eligible patients were those diagnosed with early-stage oestrogen receptor (ER+)-positive and HER2-negative breast cancer and identified by their clinical team as benefiting from having their tumour samples sent for GEP analysis to help determine the necessity of adjuvant chemotherapy alongside endocrine treatment. The primary research question was to see if the provision of GEP films improved the knowledge needed by patients to inform their decision-making compared with standard information alone.

MATERIALS AND METHODS

The films

The films were developed by the authors (LJ & VJ) following discussions with healthcare professionals who had attended educational workshops to help improve communication about risk and uncertainty when discussing GEP results, and patient representatives who had experience of the tests. The two 8 min films (Oncotype DX or Prosigna) complement the industry-produced leaflets and explain what the tests are, why they are used in breast cancer, how results help determine risks of recurrence and whether or not chemotherapy is recommended as a treatment option. They are conversational in style, with a generic introduction incorporating simple explanatory graphics and engaging visual materials of test laboratories and doctors with patients. Following this introduction, separate sections explain the tests and recurrence risk results in more detail.[15]

Links to YouTube Playlists for the original English versions of each film plus translations in French, Spanish, Italian, Urdu, Hindi, Punjabi, Gujarati and Bengali are freely available here:

OncotypeDX:

https://www.youtube.com/playlist?list=PLMFkHw5PDllAKNUw2VdqxcJ5k4-KVoO_K

Prosigna:

https://www.youtube.com/playlist?list=PLMFkHw5PDllABS19LMl9jKZxyaf3uMcPL

Study design

IMPARTER4 was a multi-centred randomised trial open to all patients eligible for an Oncotype DX or Prosigna GEP test. Randomisation was stratified by hospital sites using Sealed Envelope with 5000 codes and conducted following the online completion of informed consent and baseline questionnaires for each patient. Participants were randomised to either:

Group A

Standard GEP test information as per individual hospital policy, which could be leaflets and/or verbal information provided by members of the clinical breast teams.

Group B

Standard hospital information plus a link to view the relevant GEP patient information film on either smartphones, tablets, laptops or computers.

Primary outcome

Comparison of knowledge and understanding of GEP testing and RoR scores between patients randomised to standard information policy (verbal and/or leaflet) or standard policy plus the relevant patient information film.

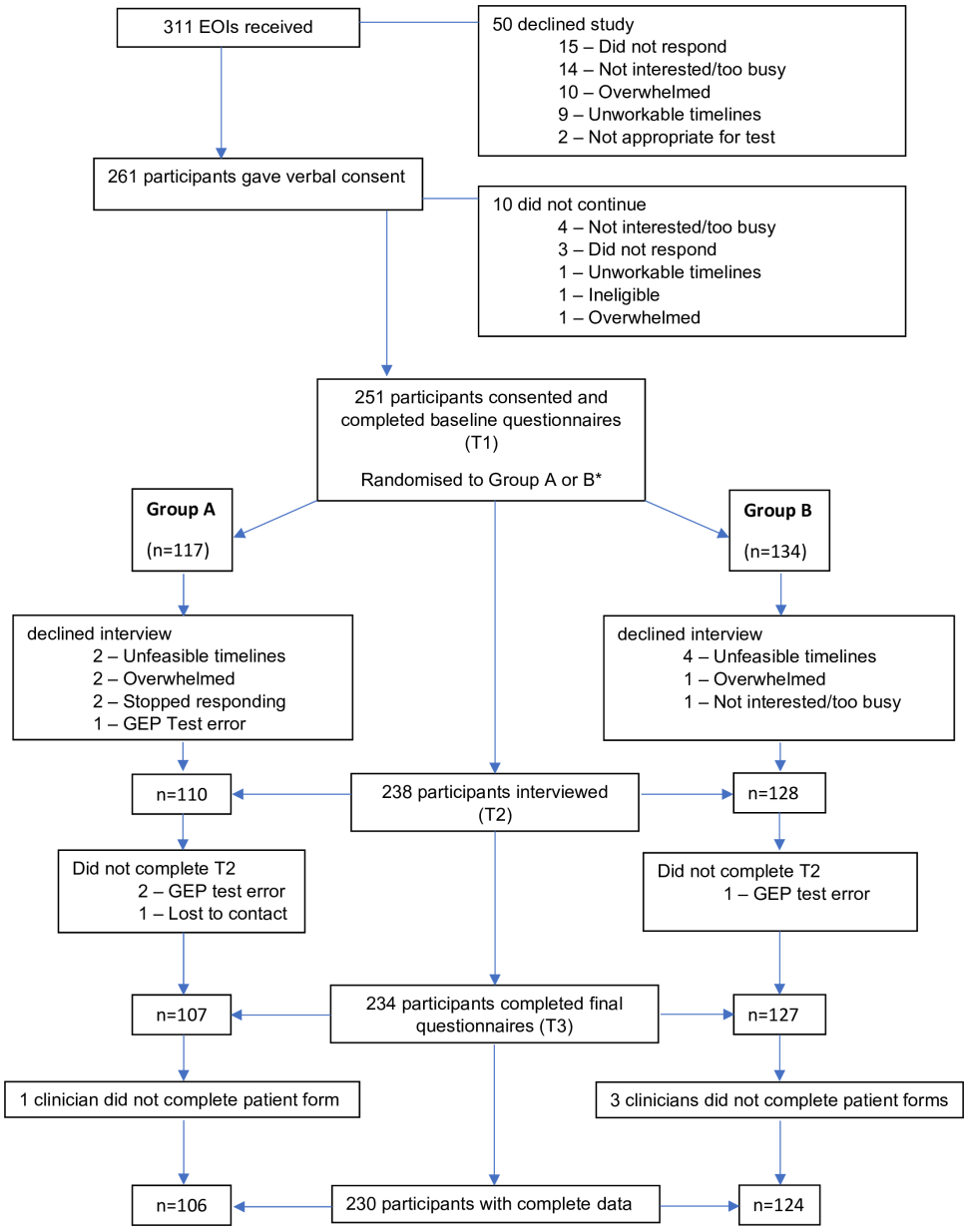

Figure 1 Consort diagram.*Participants were not informed of randomisation allocation until baseline questionnaires were completed.

Secondary outcomes

1. Impact of patient anxiety and intolerance of uncertainty and decisional conflict on decision-making.
2. Confidence/satisfaction with GEP test result consultations (clinician).
3. Agreement between clinician and patient on the treatment decision and influence of clinician's satisfaction with interview and intolerance of uncertainty scale (IUS) scores, patient's recurrence risk or pre-existing characteristics (trait anxiety, uncertainty) and if GEP knowledge/understanding mitigate these.

Recruitment

The study ran from April 2022 to January 2024, and 18 breast cancer units in England and Northern Ireland participated. Eligible patients received information from their clinical teams explaining the study together with an 'expression of interest' (EOI) form. Exclusion criteria included an inability to read and speak English and having no access to internet connections or devices on which to view the film. The EOI contained the patient's name, contact details, type of GEP test (Oncotype DX or Prosigna) and likely date of the results consultation. These were sent via secure email to study researchers who contacted the patient 24 hours later to answer any further questions.

The sponsor was the University of Sussex (IRAS 094FAL / 304561), was approved by London–Bromley REC (IRAS project ID: 304561), Belfast Health and Social Care Trust (22 036LF-S) and by HRA and Health and Care Research Wales (HCRW) (21/PR/1576). IMPARTER4 was

Table 1 Participants' baseline characteristics

	A (n=106)	B (n=124)	Total (n=230)
Test type			
OncotypeDX	54 (50.9%)	66 (53.2%)	120 (52.2%)
Prosigna	52 (49.1%)	58 (46.8%)	110 (47.8%)
Age, yrs			
Mean	58.6	57.8	58.2
SD	10.7	10.5	10.6
Median	58.0	58.0	58.0
Q1, Q3	50.9, 66.9	50.1, 65.4	50.3, 65.8
Range	32.1–81.4	29.9–76.9	29.9–81.4
***Partner**			
No	25 (23.6%)	21 (16.9%)	46 (20.0%)
Yes	81 (76.4%)	103 (83.1%)	184 (80.0%)
****Educational level**			
Low	52 (49.1%)	58 (46.8%)	110 (47.8%)
Medium	12 (11.3%)	26 (21.0%)	38 (16.5%)
High	42 (39.6%)	40 (32.3%)	82 (35.7%)
Employed			
No (inc. sick leave)	60 (56.6%)	68 (54.8%)	128 (55.7%)
Yes	46 (43.4%)	56 (45.2%)	102 (44.3%)
STAI trait anxiety			
Mean	40.2	39.7	39.9
SD	10.4	10.1	10.2
Median	39.0	39.5	39.0
Q1, Q3	33.0, 46.0	33.0, 45.2	33.0, 46.0
Range	20.0–78.0	20.0–66.0	20.0–78.0
STAI state anxiety			
Mean	41.4	41.8	41.6
SD	12.5	12.6	12.5
Median	40.0	40.5	40.0
Q1, Q3	32.0, 51.0	33.0, 51.0	32.0, 51.0
Range	20.0–72.0	20.0–80.0	20.0–80.0
Intolerance of uncertainty total			
Mean	29.5	28.2	28.8
SD	9.0	8.6	8.8
Median	28.0	27.0	28.0
Q1, Q3	23.0, 34.8	21.0, 34.0	22.0, 34.0
Range	13.0–60.0	14.0–53.0	13.0–60.0

*Partner: No – Single/Divorced/Widowed; Yes – Partnered/Married

**Education levels: - Low = O levels/GCSEs/Scottish equivalent or trade/technical/vocational training, Medium = A levels/Scottish Highers or teacher training/nursing, and High= university degree or further post-graduate/professional

registered with the International Standard Randomised Controlled trial register (ISRCTN: 28497350).

Participant time points and randomisation

Assessments were conducted at Time 1 (T1) prior to randomisation, Time 2 (T2) between 1 and 7 days prior to receiving their GEP RoR results and Time 3 (between 1 and 7 days) post results discussion.

Questionnaires

At T1, patient participants and clinicians completed online consent and the IUS, which measures responses to uncertainty, ambiguous situations and the future.[16] Individuals with high intolerances attempt to make seemingly less risky choices, so the scale has utility when examining HCPs' and patients' decision-making behaviours. Patient participants also completed the Spielberger (STAI) trait and state anxiety inventories.[17] Trait anxiety was measured at baseline only and reflects an individual's underlying predisposition towards anxiety. State anxiety measures how a person feels right now and was measured at T1 and T3.

Experienced researchers (LM, RS) conducted study-specific structured telephone interviews at T2 to gauge participants' knowledge and understanding of GEP testing. The interviewers asked nine key facts developed for a previous study[15] about the nature and purpose of GEP testing and the meaning of different recurrence risk results. The maximum possible score was 18, with higher scores indicating better understanding. Additional questions explored what other information resources participants had used (leaflets/websites) and who else they had sought for advice (see online supplemental files A,B).

Those in Group B were asked how many times and on which type of device they had viewed the film (smartphone/laptop/tablet). They were also encouraged to provide feedback about the film, what they valued and what they had found helpful or unhelpful.

Following the results discussion at T3, participants completed the online 10-item low literacy decisional conflict scale (DCS).[18] The DCS comprises four subscales: uncertainty, informed, values clarity and supported. The total score ranges from 0 (no decisional conflict) to 100 (high decisional conflict). The clinicians reported their level of confidence/satisfaction with each GEP results consultation via a study-specific six-item scale. They also stated the RoR score and treatment decision for each patient. The clinicians and breast cancer teams did not have access to the films, and they were not informed which patients had received it.

Statistical methods

The sample size calculation was based on the knowledge scores collected from 120 participants in the previous study[15]; 200 patients (100 per group) would allow estimation of the mean difference in knowledge scores with an accuracy of one unit with 95% CI. Specifically, by constructing a two-sided 95% CI for the difference between two means such that its width is no greater than two units, assuming equal allocation and equal SD of 3.5. To allow for 20% missing data, 250 patients would be required.

Patient characteristics, STAI trait and state scores, IUS total and sub-scores were described through means (SD) or medians (interquartile ranges) for non-symmetric distributions, overall and by randomisation group.

Three linear regression models were fitted to the GEP knowledge scores. An unadjusted model included a binary variable for randomisation group (A or B) as explanatory factor, and a second model adjusted for the patient's age, education and recruitment site. Additionally, the effects of test type (Oncotype DX or Prosigna) and the interaction term between the randomisation group and test type were assessed in the adjusted model. A third model added

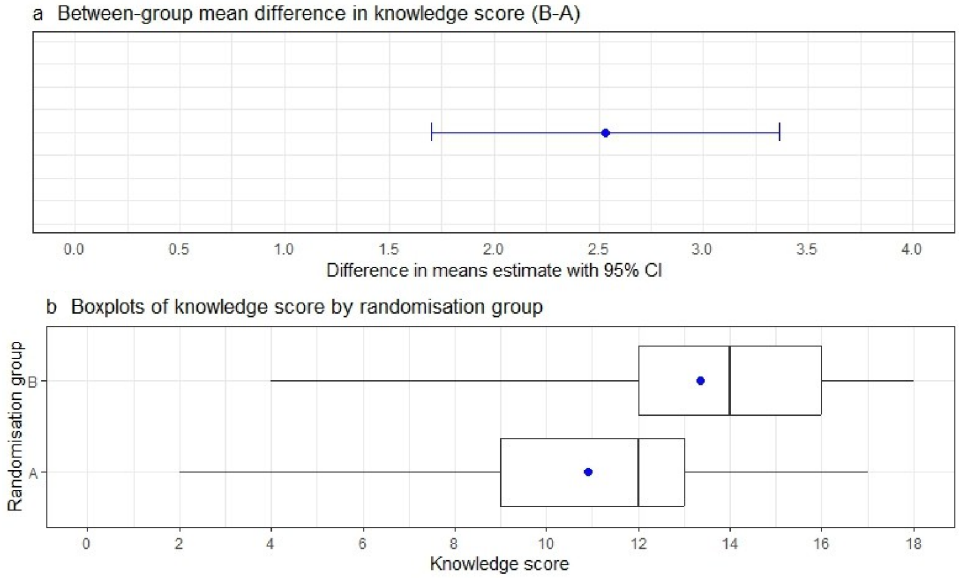

Figure 2 Estimated group mean difference in knowledge score and boxplot of knowledge score by group.

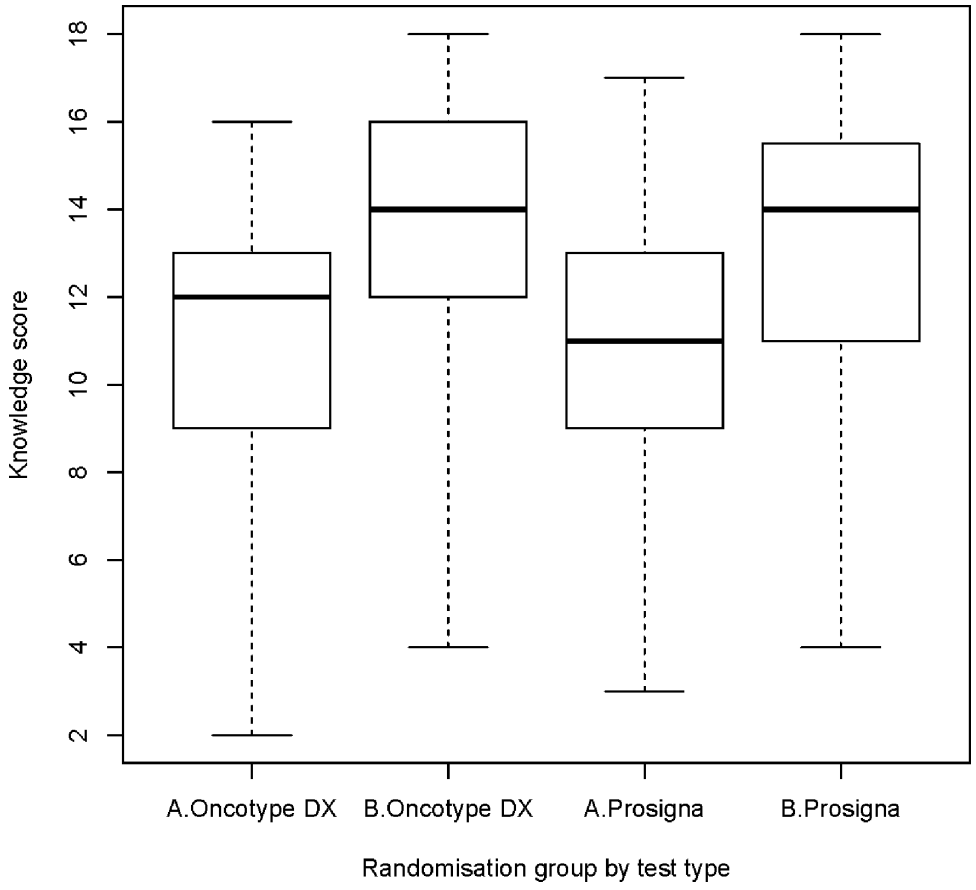

Figure 3 Boxplot of knowledge score by group and test type.

IUS and STAI trait anxiety as potential effect modifiers to the adjusted model. Over half of the clinicians treated only one (51%) or two (16%) participants; however, we estimated the intra-class correlation (ICC) and tested for a potential clustering effect by comparing the above linear regression models with a mixed-effects linear model with a random intercept using a likelihood ratio test.

Most participants (60%) had a decisional conflict score of equal to zero. Therefore, a binary variable indicating scores greater than zero was analysed using binomial regression with randomisation group, GEP knowledge score and their interaction as explanatory variables. A binary variable for 'rational treatment decision' was created by dichotomising treatment decisions, that is, endocrine/hormone therapy (ET) alone or ET and chemotherapy as '*rational*' if they appeared to be logical and followed recommended threshold guidance, or '*not rational*' if thresholds were not adhered to and/or there were no apparent explanations as to why a contrary decision had been made. A logistic regression model was fitted to this variable in terms of GEP knowledge score, patient's STAI trait and clinician's IUS total scores. As there was not enough variability in the sample to conduct a formal analysis of agreement between clinicians and patients on the treatment decision, this was summarised descriptively.

The IUS total and sub-scores completed by patients were standardised with respect to community norms and analysed using linear regression models with STAI state and STAI trait scores as explanatory variables.

Diagnostic plots, including plots of residuals, and Q–Q plots were used to check the model assumptions. The goodness of fit was assessed through the model's R-squared statistic for linear regression models and the deviance statistic for logistic regression models. The analyses were carried out using the statistical software R.[19]

Patient and public involvement

Patients were not directly involved in the design of this RCT, but the GEP films were produced with input from patients living with breast cancer and members of the public who reviewed the films in an earlier phase of the study.[15]

Role of the funding source

The funder had no role in the study design, data collection, analysis, interpretation or writing of the manuscript.

RESULTS

Eighty-two clinicians (56 oncologists, 12 surgeons, 11 nurses and three others) from 18 UK hospital sites participated. Figure 1 shows that 251/311 (81%) of referred patients consented, completed based questionnaires and were randomised to either Group A (standard hospital information) or Group B (standard information plus

Table 2 Descriptive statistics of primary and secondary outcomes

	A (n=106)	B (n=124)
Knowledge score		
Mean	10.9	13.4
SD	3.6	3.1
Median	12	14
Q1, Q3	9.0, 13.0	12.0, 16.0
Range	2.0–17.0	4.0–18.0
STAI state anxiety post consultation		
Mean	40.5	40.2
SD	13	14.4
Median	41	37.5
Q1, Q3	29.2, 49.0	29.0, 48.0
Range	20.0–76.0	20.0–77.0
Decisional conflict scale total		
Mean	12.5	9.8
SD	20.7	18.5
Median	0	0
Q1, Q3	0.0, 20.0	0.0, 10.0
Range	0.0–80.0	0.0–95.0
Uncertainty DCS subscore		
Mean	16.5	13.5
SD	32.9	26.6
Median	0	0
Q1, Q3	0.0, 0.0	0.0, 6.2
Range	0.0–100.0	0.0–100.0
Informed DCS subscore		
Mean	10.2	8.6
SD	21.9	20
Median	0	0
Q1, Q3	0.0, 0.0	0.0, 0.0
Range	0.0–100.0	0.0–100.0
Values clarity DCS subscore		
Mean	12.7	11.1
SD	22.4	23.3
Median	0	0
Q1, Q3	0.0, 25.0	0.0, 0.0
Range	0.0–100.0	0.0–100.0
Support DCS subscore		
Mean	12.1	7.8
SD	23.4	18.6
Median	0	0
Q1, Q3	0.0, 16.7	0.0, 0.0
Range	0.0–100.0	0.0–83.3
Clinician six-item self-report responses		
1. How knowledgeable did the patient seem to be about the GEP test result?		
Very	31 (29.2%)	33 (26.6%)
Moderately	63 (59.4%)	74 (59.7%)
Not very	12 (11.3%)	17 (13.7%)
2. Did the patient ask any difficult questions?		
Yes	11 (10.4%)	3 (2.4%)
Can't recall	8 (7.5%)	11 (8.9%)
No	87 (82.1%)	110 (88.7%)
3. Did the patient ask any unexpected questions?		
Yes	8 (7.5%)	4 (3.2%)
Can't recall	4 (3.8%)	10 (8.1%)
No	94 (88.7%)	110 (88.7%)
4. How long did the consultation take?		
Longer than usual	13 (12.3%)	10 (8.1%)
Same as usual	75 (70.8%)	94 (75.8%)
Shorter than usual	18 (17.0%)	20 (16.1%)
5. How confident do you feel about the decision made about whether or not to prescribe chemotherapy?		
Very	87 (82.1%)	101 (81.5%)
Moderately	17 (16.0%)	23 (18.5%)
Not very	2 (1.9%)	0 (0.0%)
6. How satisfied were you personally with the consultation overall		
Very	75 (70.8%)	93 (75.0%)
Moderately	29 (27.4%)	30 (24.2%)
Not very	2 (1.9%)	1 (0.8%)

DCS, decisional conflict scale; GEP, gene expression profiling.

relevant GEP film). Complete data were available for 230/251 (92%) (n=106 Group A, and n=124 Group B) (see figure 1). The 21 participants whose partial data are not included in the analyses were from Group A (n=11; 7 OncotypeDX, 4 Prosigna) and Group B (n=10; 7 OncotypeDX, 3 Prosigna).

Baseline patient characteristics including GEP test type are shown in table 1. There was no difference between the groups in terms of age, education, state or trait anxiety or intolerance of uncertainty. Nine centres used Oncotype DX, six Prosigna and three worked with both GEP tests, which may account for the slight difference in proportions overall (Oncotype DX 52.2% (n=120); Prosigna 47.8% (n=110)).

Two-thirds (66%; 152/230) of participants said they received both verbal and written GEP test information, 23% (52/230) verbal information alone and 9% (21/230) leaflets alone (two in Group A did not recall being given/told anything and three in Group B said they only received the film). More Group A patients (75%; 80/106) had verbal and written information compared with Group B (59%; 73/124). Some participants accessed the internet for further information (95/230; 41%) (see online supplemental table S1).

Primary outcome

Mean knowledge scores for Group A were 10.9 (SD 3.6, range 2–17) and 13.4 (SD 3.1, range 4–18) for Group

B. Both the unadjusted and the adjusted linear regression models showed that patients in Group B (film) had higher knowledge scores than those in Group A. The linear regression models of the knowledge score are shown in online supplemental table S2. The estimated mean difference based on the model adjusting for age, education and recruitment site was 2.5 units (95% CI: 1.7 to 3.4, p<0.001) (figure 2). The coefficients for test type (Oncotype DX and Prosigna) and the interaction term for group by test type were not statistically significant. As shown in the boxplots in figure 3, the median knowledge scores for Group B were higher than those for Group A, for each test type. The inclusion of the IUS total score and Trait anxiety showed significant association with the knowledge score and slightly increased group effect of 2.6 units (95% CI: 1.8 to 3.4). The knowledge questions that elicited significantly greater understanding for Group B participants were knowledge about the GEP report and the potential treatment decisions attributed to the different scores (low, medium, high risk). Model comparisons with a mixed-effects linear model indicated that the ICC was negligibly small for each of the three models (ICC=0.007, 0.049 and 0.078 respectively), and both the linear and mixed-effects linear models produced equivalent results.

Treatment decisions

The range of GEP RoR scores was 0–62 for Oncotype DX and 0–86 for Prosigna. Following the results discussions, 163/230 (70.8%) patients were prescribed endocrine therapy (ET) alone, and 65/230 (28.3%) ET and chemotherapy. Most treatment decisions appeared to be rational and followed guidance around thresholds determining risk categories. However, 17/230 decisions (11/120; 9.1% OncotypeDX; 6/110; 5.4% Prosigna) differed from the recommendations; three participants with low RoR scores opted to have chemotherapy plus ET, and 12 patients with medium/high risk scores declined chemotherapy and opted for ET alone (two of these patients were unhappy with treatment recommendations and sought second opinions). Ten patients were in Group A and 7 in Group B.

Secondary outcomes

Descriptive statistics of the primary and secondary outcomes are shown in table 2.

A logistic regression model showed an association of a patient's STAI trait anxiety with the probability of a rational decision: OR=0.93 (95%CI 0.88 to 0.97), p=0.002.

Those patients with higher trait anxiety were more likely to make less apparently rational decisions.

Linear regression analyses of patients' total IUS and subscales (PA and IA) scores showed significant association with baseline STAI trait anxiety (online supplemental table S3), with those reporting higher levels of STAI trait anxiety also reporting higher levels of intolerance of uncertainty (online supplemental figure S1). Patients' decisional regret scores were uniformly low irrespective of the group or GEP test type.

Clinicians' IUS total scores did not impact on treatment decisions (online supplemental table S4). They were satisfied overall with their GEP test result consultations (168/230; 73% 'very' and 59/230; 26% 'fairly'). Clinicians reported that Group A patients compared with those in Group B asked more difficult (11/106,10.4% v 3/124, 2.4%) and unexpected questions (8/106, 7.5% v 4/124, 3.2%). They also felt that Group A consultations had taken longer (13/106, 12.3% v 10/124, 8.1%).

The probability of a decisional conflict total score of greater than zero did not differ between Groups A and B and was not associated with the knowledge score (online supplemental table S5).

The GEP information films

Patients viewed the films mainly on smart phones (63/124; 50.8%), followed by laptops (24/124; 19.4%), tablets (22/124; 17.7%) and computers (15/124; 12.1%). The mean number of viewings was 1.75 (range 1–5). Feedback regarding the films was provided by 110/124 (89%) patients who made 120 comments; of which (n=93/120; 78%) were positive and (n=27/120; 22%) more negative or constructive. Some of the positive feedback reflected participants' preference for learning, that is, visual/auditory compared with reading leaflets. For example: -

> *I had more confidence about the test after watching the film. It was helpful to my understanding.* Id 0105

> *Felt that it was just the right amount of information and not too long. I didn't come away from it feeling scared or worried about anything. I also didn't come away with any questions as the video was really informative and really clear.* Id 0715

The more critical but constructive comments mainly referred to the background music and length of introduction.

> *The introduction is far too long. 30 seconds of music when you just want information is too much. The film was short enough and explained everything in layman's terms. Keeping in mind all the different people who get breast cancer, it seemed to cater for.* Id 1804

DISCUSSION

Shared decision-making is now an imperative in most countries and preferred by a majority of patients,[20] but this is an illusory concept unless they are able to truly comprehend the rationale and logic for different treatment recommendations. The findings from this study show that providing patients with well-designed, short, user-friendly information films can significantly improve knowledge and understanding about GEP test results. Irrespective of the GEP test, those who received standard hospital information and viewed the film exhibited superior knowledge about the GEP test and recurrence risk results compared with patients provided with standard

verbal and written information alone. The value of audio-visual interventions to enhance patient understanding and ultimately decision-making has focused mainly on clinical trial information. A Cochrane systematic review involving data from 1884 participants was inconclusive about its influence on trial participation but did note a trend towards improvements in patient knowledge and satisfaction.[21]

Unlike previous research, we did not find a significant relationship between a patient's or clinician's intolerance to uncertainty and treatment decision-making.[19] There was an association of a patient's IUS score with rational decisions, but this diminished when controlling for anxiety trait. The majority were satisfied by the decisions made, which were logical and followed protocol, that is, low RoR score and hormone treatment alone prescribed. There were, however, 17 decisions that did not follow protocol, seven of which are explained by the patient's aversion to chemotherapy. It is, of course,a matter for debate as to whether or not it is worth the time and expense of GEP testing if a patient has no intention of accepting chemotherapy. The reasons for ten other apparently irrational treatment choices are unknown and cannot be easily explained by the predicted variables. In seven Oncotype DX test patients, one might speculate that as these women had RoR scores ranging from 17 to 23 but were aged between 46 and 49 years their clinicians felt comfortable omitting chemotherapy, but the other decisions were less clear.

The interviews revealed that patients valued the films, the contents of which enabled them to understand the reason for the test and the impact of the result on a decision regarding the need for chemotherapy. Potentially this enabled patients to have more informed discussions with their clinicians. The high proportion of positive comments made was similar to those found in feedback from women without breast cancer in the earlier study.[15]

Strengths

The primary strength of this study was the evaluation of the intervention via an RCT in 18 different hospital sites. The clinical teams were unaware who had viewed the films unless patients revealed this to them.

Weakness

The main weakness was a lack of objective evidence as to what was actually discussed during GEP test results consultations. Recordings of these might have provided greater insight into reasons for the few incongruous treatment decisions.

Unlike an earlier study,[22] we did not compare clinicians' treatment choices based on clinico-pathologic features with the decisions made. The clinician perceptions of consultation times being 'longer', 'the same' or 'shorter' than usual were not measured objectively, so the finding that they found those of patients who had the information films shorter were subjective and could be biased.

Although the GEP films were not available to the clinical breast teams, we did not record if the doctor knew whether their patient had watched a film. Knowledge of this might have biased the clinicians' perceptions of the GEP test result discussions. It was impossible to blind our interviewers as to randomisation group as questions were specifically asked about the value of the film.

CONCLUSIONS

This randomised trial produced strong evidence for a benefit in terms of patient understanding of GEP tests and breast cancer treatment recommendations based on RoR scores. Some clinicians reported shorter discussions with patients asking fewer challenging questions; this suggests potential benefits for busy clinical teams. The low decisional regret of the majority of patients indicated overall satisfaction with shared decision-making about their treatment choices.[23]

Improving written and visual information about GEP testing can help patients make more educated and informed decisions about their treatments, but clinicians still need an increased repertoire of communication skills when explaining risks and benefits.[10] Employing plain, non-patronising language and describing the absolute rather than relative risks with and without chemotherapy can be improved through attendance at evidence-based workshops to help with this.[9]

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Contributors LF is the guarantor for the study. LF and VJ designed the study, SM designed the online database to collect participants' consent and questionnaire data, and LM and RS recruited sites, performed day to day management of participants and interviewed them. IST conducted the analyses and wrote the statistical section of the manuscript. LF and VJ wrote the first draft of the manuscript with contributions from all authors on subsequent and final version.

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Patient and public involvement Patients and/or the public were involved in the design, conduct, reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by the University of Sussex (IRAS 094FAL/304561), was approved by London-Bromley REC (IRAS project ID: 304561), Belfast Health and Social Care Trust (22036LF-S) and by HRA and Heath and Care Research Wales (HCRW) (21/PR/1576). IMPARTER4 was registered with the International Standard Randomised Controlled trial register (ISRCTN: 28497350). Participants gave informed consent to participate in the study before taking part.

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