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RESEARCH ARTICLE

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Patient decision aids in mainstreaming genetic testing for women with ovarian cancer: A prospective cohort study

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Abstract

Objective: To evaluate patient preference for short (gist) or detailed/extensive decision aids (DA) for genetic testing at ovarian cancer (OC) diagnosis.

Design: Cohort study set within recruitment to the Systematic Genetic Testing for Personalised Ovarian Cancer Therapy (SIGNPOST) study (ISRCTN: 16988857).

Setting: North-East London Cancer Network (NELCN) population.

Population/Sample: Women with high-grade non-mucinous epithelial OC.

Methods: A more detailed DA was developed using patient and stakeholder input following the principles/methodology of IPDAS (International Patients Decision Aids Standards). Unselected patients attending oncology clinics evaluated both a pre-existing short and a new long DA version and then underwent mainstreaming genetic testing by a cancer clinician. Appropriate inferential descriptive and regression analyses were undertaken.

Main outcome measures: Satisfaction, readability, understanding, emotional well-being and preference for long/short DA.

Results: The mean age of patients was 66 years (interquartile range 11), and 85% were White British ethnicity. Of the participants, 74% found DAs helpful/useful in decision-making. Women reported higher levels of satisfaction (86% versus 58%, $p < 0.001$), right amount of information provided (76.79% versus49.12%, $p < 0.001$) and improved understanding ($p < 0.001$) with the long DA compared with the short DA. There was no statistically significant difference in emotional outcomes (feeling worried/concerned/reassured/upset) between 'short' and 'long' DA; 74% of patients preferred the long DA and 24% the short DA. Patients undergoing treatment (correlation coefficient (coef) = 0.603; 95% CI 0.165–1.041, $p = 0.007$), those with recurrence (coef = 0.493; 95% CI 0.065–0.92, $p = 0.024$) and older women (coef = 0.042; 95% CI 0.017–0.066, $p = 0.001$) preferred the short DA. Ethnicity did not affect outcomes or overall preference for long/short DA.

Monika Sobocan, Dhivya Chandrasekaran and Michail Sideris contributed equally to this work.

Conclusions: A longer DA in OC patients has higher satisfaction without increasing emotional distress. Older women and those undergoing treatment/recurrence prefer less extensive information, whereas those in remission preferred a longer DA.

KEYWORDS
Decision aids, genetic testing, mainstreaming, ovarian cancer

1 | INTRODUCTION

Ovarian cancer (OC) is the leading cause of mortality from gynaecological malignancies and around 15–20% of OCs are associated with germline pathogenic or likely pathogenic variants in moderate to high penetrance Cancer Susceptibility Genes (CSGs).[1–5] The British Gynaecological Cancer Society and British Association of Gynaecological Pathologists consensus document recommends parallel germline and tumour *BRCA1/BRCA2* testing for all non-mucinous epithelial high-grade OCs, at the earliest opportunity in a patient's cancer diagnosis/treatment pathway.[6] It also underlines the necessity for provision of appropriate information for consenting patients for genetic testing. *BRCA* testing is also recommended by other international guidelines.[6–9] A wide range of clinical benefits, including poly-ADP ribose polymerase inhibitor treatment for patients and cascade testing in family members with opportunities for screening and prevention, underpins this rationale.[5,6,10,11] Existing resource/capacity constraints in genetics services have enabled newer scalable models like mainstreaming genetic testing by cancer clinicians at OC diagnosis to become part of routine clinical practice.[5]

Several factors may affect the uptake of genetic testing, including socioeconomic background, access to and infrastructure of the testing pathway, and quality of pre-test information and counselling. The clinical genetics community and patient groups/charities have highlighted the need for women to be adequately counselled, with appropriate patient education about the pros/cons/consequences before undergoing testing.[12] Patient decision aid (PDA, henceforth synonymous with DA) tools improve the quality of informed decision making, reduce clinician time and improve cost-efficiencies in clinical pathways.[13–15] DA tools improve knowledge, information and value-congruent decision making.[16] Although DAs are helpful, there is uncertainty around the extent and depth of information women with OC would prefer or need while undergoing routine mainstreaming genetic testing in clinical practice.[17] Additionally, the vast majority of evidence for DAs comes from cancer genetics clinics, where high-risk populations (usually unaffected) with a strong family history (FH) of breast cancer (BC) or OC or a known familial pathogenic variant are offered *BRCA1/BRCA2* testing.

We evaluate use of a more extensive 'long' patient DA and compare this to a pre-existing standard 'short' (genetics version) DA during pre-test counselling within mainstreaming genetic testing at OC diagnosis.

2 | METHODS

2.1 | Inclusion criteria and recruitment

Women diagnosed with high-grade epithelial non-mucinous OC within the North-East London Cancer Network (NELCN) multidisciplinary team and eligible for genetic testing were invited to participate. All eligible women attending oncology clinics within the NELCN between June and December 2017 were recruited prospectively. Recruitment included patients presenting at OC diagnosis, undergoing treatment (primary or for recurrence) and those attending follow-up appointments and in remission. Genetic testing included a parallel five-gene germline panel (*BRCA1/BRCA2/RAD51C/RAD51D/BRIP1*) and a two-gene somatic panel (*BRCA1/BRCA2*). Mainstreaming genetic counselling and testing were conducted by members of the gynaecological oncology multidisciplinary team, including medical oncologists, surgical gynaecological oncologists and Clinical Nurse Specialists.[5] Genetic test results were returned by the treating cancer clinicians. Women with germline pathogenic variants were also referred to the regional genetics service for follow up, and cascade testing of family members. We recorded demographics and clinical data including age, ethnicity, FH of cancer and clinical status (newly diagnosed OC; in remission/surveillance; or recurrence) at recruitment.

2.2 | Development of a long patient DA

First, patients' representatives and charity leads reviewed a pre-existing two-page short DA (Appendix S1). This was deemed to have inadequate amounts of pre-test information for counselling. Following that, a more comprehensive 12-page long pre-test counselling DA (Appendix S2) was developed.

The DA was developed using a multistep process in accordance with published guidance, as illustrated in Figure 1.[13] The first step (scoping and design) defined the scope of the DA (women with OC deciding on whether to have genetic testing). We then formed a steering group of major stakeholders including patients, clinicians (regional clinical geneticists, genetic counsellors, surgical and medical oncologists, Clinical Nurse Specialists, clinical scientists), patient representatives and charity leads. We undertook a comprehensive literature review including national/international guidelines for genetic testing to inform content. The steering group composed the primary content, which was discussed in an iterative process

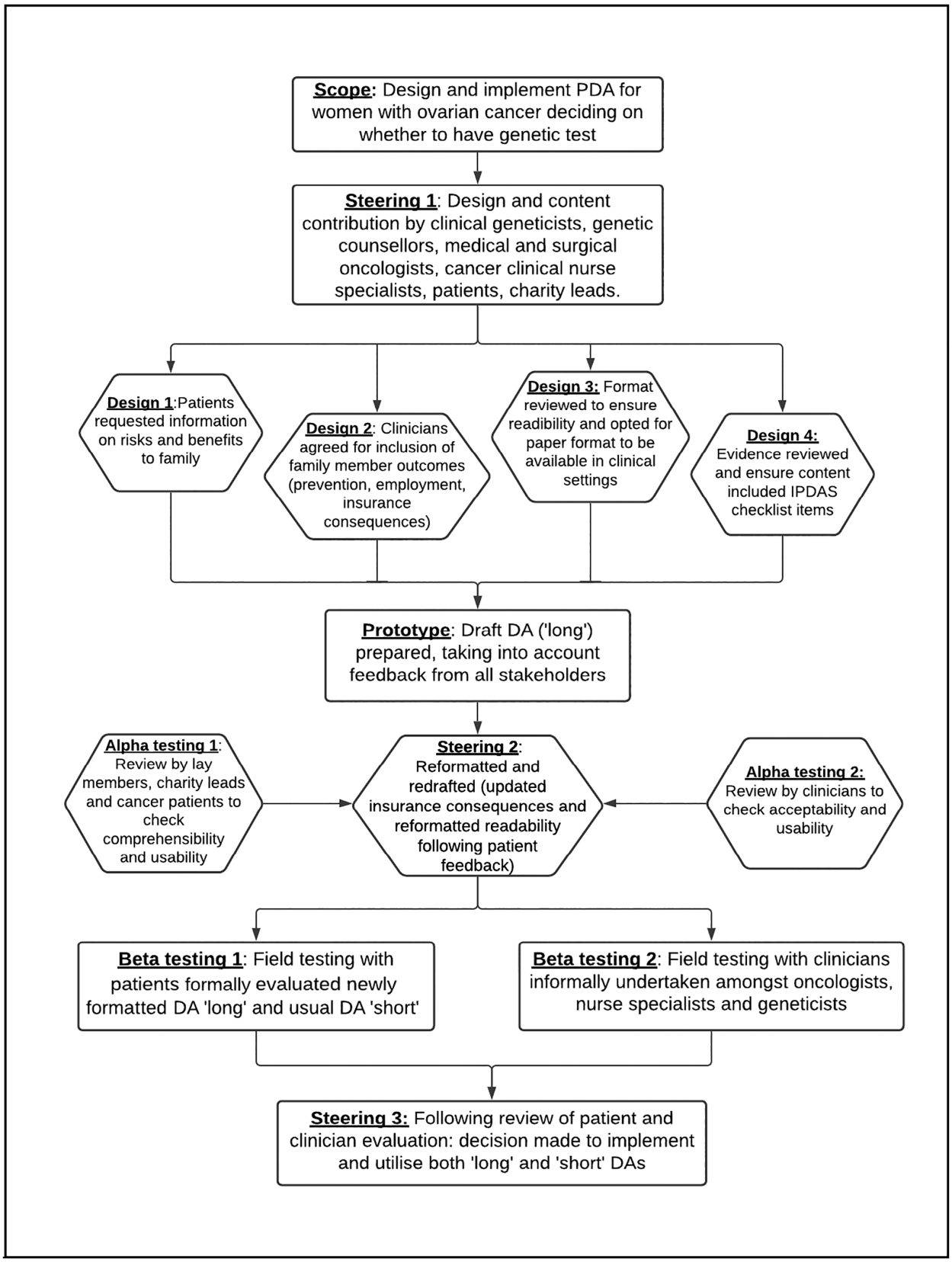

FIGURE 1 Summary of the development process of the extended patient decision aid and assessment of its content.

with stakeholders including patients and clinicians. Patients requested the addition of information on risks and benefits of genetic testing to family (Design 1); Clinicians agreed on inclusion of implications for family members (e.g. screening/prevention, employment, insurance consequences) (Design 2). The DA was reviewed and formatted to ensure readability and the steering committee opted for paper format (Design 3). The DA content was reviewed for evidence base and to ensure content included the International Patients Decision Aids Standards (IPDAS) checklist items (Design 4). This prototype DA was further evaluated for comprehensibility and usability (Alpha-testing 1). Following this, the steering group reformatted readability and updated insurance and employment consequences for unaffected family members (Steering 2). The updated draft of DA was then reviewed by clinicians to check acceptability and usability (Alpha-testing 2).

The pre-final long DA content underwent field testing with patients who evaluated long and short DAs (Beta-testing 1) and clinicians (Beta-testing 2). Subsequently the steering committee finalised and implemented the long and short DAs.

2.3 | DA assessment questionnaires (pre- and post-counselling)

To evaluate the DA we adapted an assessment questionnaire based on previously published reports assessing pre-counselling genetic information.[6,11] Each question was discussed and reviewed by senior clinicians in gynaecological oncology and clinical genetics, and by statisticians. A pilot DA assessment questionnaire was developed based on an earlier customsied DA assessment questionnaire used by us for a genetic-testing study.[18] This was distributed among clinicians and lay members for readability, ease of use and assessment of the layout and format. This helped to develop content and face validation. The updated pre-final version was further reviewed, reaching consensus on a final 15-item pre-counselling questionnaire and a five-item post-counselling questionnaire. The pre-counselling 15-item questionnaire (Table S1); assessed both the long and short DAs for (a) 'satisfaction with information content', (b) 'amount of information', (c) 'time taken to read through content', (d) 'need for further information' (e) 'need for leaving out information' (f) 'improvement in understanding' (g) 'ease of understanding' and (h) 'emotional impact' (Table S1). Patients were also asked whether they preferred the long or short DA version.

All patients were given the long and short DA together followed by the pre-counselling DA evaluation questionnaire (Table S1). This was followed by mainstreaming counselling and testing by the cancer clinician. Following face-to-face counselling by the cancer clinician, participants completed a five-item after mainstream counselling evaluation questionnaire (Table S2). A five-point Likert scale evaluated whether DA was useful in decision-making about genetic testing; whether seeing their cancer clinician had made their decision easier/clearer; whether they changed their decision about genetic testing after seeing their clinician; and whether they would have been able to make this decision without seeing their clinician. Finally, post-consultation, patients were asked which DA (short or long) would they prefer (Table S2).

2.4 | Patient and public involvement

As highlighted above, patients' representatives and charity leads were involved in study development, co-development of the long DA and the evaluation process and dissemination of findings.

2.5 | Statistical analysis

Inferential descriptive statistics were used to provide a primary summary of the baseline characteristics and questionnaires' data (usefulness and preference of each DA version). Multiple logistic regression was used to model the effect of several variables on information and satisfaction with the DA, post-counselling evaluation of usefulness of DA and face-to-face consultation. Linear regression was used to model the effect (correlation coefficient (coef)) of variables on understanding, DA length and emotional impact. Analyses were adjusted for age, stage at diagnosis (reference: Stage 1 to 2 versus Stage 3 to 4), ethnicity (reference: White versus non-White ethnicity), FH of OC or BC/personal history of BC (reference negative versus positive FH), treatment status (reference: remission versus on treatment) and recurrence status (reference: no recurrence versus history of recurrence). McNemar–Bowker test was used to test difference in proportions. This hypothesis testing was done on contingency tables. Two-sided p values are reported for all statistical tests. Statistical analysis used R version-3.5.1 and SPSS version-25.

3 | RESULTS

From a total of 143 women who were offered and underwent genetic testing, 114 (79.7%) consented to participate in this study. The mean age at OC diagnosis was 63 years (interquartile range 12) and the age at the time of mainstreaming pre-test counselling was 66 years (interquartile range 11). Our cohort included predominantly women of White ethnicity ($n = 97$, 85%), 9 (8%) were Black, 5 (4%) were Asian and 3 (3%) were of 'other' ethnicity. Sixteen (14%) women had a first-degree relative with OC or BC (positive FH), 89/114 (78%) were diagnosed at advanced stage (Stage 3/4) disease, 59/114 (52%) were undergoing treatment at the time of genetic counselling/testing and 55 (48%) were in remission. Of the 114 women, 58 (51%) had been diagnosed with recurrent disease (28 first recurrence, 16 second recurrence, 12 third recurrence and 2 fourth recurrence).

3.1 | Pre-counselling evaluation of long and short DA

We found significantly higher levels of satisfaction for the information provided in the long DA (45.61% versus 15.79%, $p < 0.001$, were 'very satisfied') (Table 1), 77% rated the amount of information in the long DA as 'about right' compared with 49% in the short DA ($p < 0.001$) and 49% found the information in the short DA too little. However, 21% felt the long DA took too long to read versus 2% for short DA ($p < 0.001$), and 26% found the short DA took too little time to read.

Nine of the 114 patients felt that parts of the long DA needed to be explained in more detail but 24 felt that parts of the short DA required more detailed explanation. In contrast, 16/114 felt that parts of the long DA needed to be left out compared with 2/114 patients feeling parts of the short DA needed to be left out.

Patients reported that the long version, compared with the short version, provided a significantly ($p < 0.001$) greater improvement in understanding of what the genetic test involves, treatment benefits, disadvantages, and implications of carrying an OC CSG for the family (Table 2). There was no significant difference in feeling emotionally worried or concerned between the two DAs (Table 2). However, 66.7% of women felt somewhat or a-lot reassured with the long DA compared with 54.3% with the short DA ($p = 0.042$). There was a 5.4% (6/114) difference between number of women feeling upset following reading the long or short DAs.

Before mainstreaming genetic counselling/testing by the cancer clinician, when asked which DA they preferred, 58% (66/114) of women chose 'probably/definitely' long DA, 16% (18/114) were 'not sure' and 26% (30/114) preferred 'probably/definitely' short DA.

3.2 | Post-counselling evaluation

Eighty-four of the 114 patients (74%) reported that the DAs were 'probably/definitely' useful in helping decision-making about genetic testing. Following cancer clinician consultation, 74% (84/114) preferred the long DA (definitely/probably) and 21% (24/114) the short DA ($p < 0.001$). Following consultation, 32% (36/114) of women changed their initial decision about genetic testing. The majority of patients (91%, 104/114) reported that the mainstreaming consultation 'definitely/probably' made the decision easier/clearer to make. However, 23% (26/114) indicated that they could have made their decision regarding genetic testing without seeing a cancer clinician (Table 3).

3.3 | Factors affecting DA preference

We explored the potential impact of variables of age, stage, disease status (treatment, recurrence, remission), FH and ethnicity on outcome variables of DA preference through regression modelling (Table S3).

With each incremental year in age, patients were more likely to report the long DA to be 'too long' in terms of length (odds ratio [OR] = 1.1, 95% CI 1.04–1.2; $p = 0.004$). Older women were more likely to prefer the short DA in both pre-consultation (coef = 0.035; 95% CI 0.009–0.061; $p = 0.009$) and post-consultation (coef = 0.042, 95% CI 0.017–0.066; $p = 0.001$) settings. Patients of White ethnicity were more likely to find the DA easy to understand for both the long (coef = −0.61, 95% CI −1.15 to −0.07; $p = 0.027$) and short (coef = −0.584, 95% CI −1.07 to −0.10; $p = 0.02$) versions. However, ethnicity did not affect other outcomes or overall preference for the long DA. Further correlations are presented in Table S3. The responses did not differ significantly between women with or without a positive FH.

Exploring the association of disease stage/treatment status suggested that women with advanced (Stage 3/4) disease may be less likely to report the DA useful following their genetic consultation (coef = −0.456, 95% CI −0.835 to −0.076; $p = 0.019$), and overall preferred the short DA (coef = 0.572, 95% CI 0.097–1.047, $p = 0.019$).

TABLE 1 Pre-counselling questionnaire comparing long and short DA for satisfaction, amount of information provided and time taken to read.

Question	Likert scale	Long DA frequency (%)	Short DA frequency (%)	*p* value (McNemar–Bowker test)
Satisfaction with information provided	Very satisfied	52/114 (45.61)	18/114 (15.79)	<0.001
	Satisfied	46/114 (40.35)	48/114 (42.11)	
	Neither satisfied or dissatisfied	10/114 (8.77)	32/114 (28.07)	
	Dissatisfied	0/114 (0)	12/114 (10.53)	
	Very dissatisfied	6/114 (5.26)	4/114 (3.51)	
Amount of information	Too little	2/112 (1.79)	56/114 (49.12)	<0.001
	About right	86/112 (76.79)	56/114 (49.12)	
	Too much	24/112 (21.43)	2/114 (1.75)	
Time taken to read through DA	Too short	2/113 (1.77)	30/114 (26.32)	<0.001
	About right	87/113 (76.99)	82/114 (71.93)	
	Too long	24/113 (21.24)	2/114 (1.75)	

TABLE 2 Pre-counselling questionnaire comparing understanding and emotional reaction between long and short DA.

Question		Long DA ($n=114$)			Short DA ($n=114$)			p value
		Not at all	Somewhat	A lot	Not at all	Somewhat	A lot	
Improvement in understanding	What the genetic test involves	0	8 (7.02)	106 (93.0)	0 (0)	50 (43.9)	64 (56.1)	<0.001
	Treatment benefits	4 (3.5)	34 (29.8)	76 (66.7)	18 (15.8)	60 (52.6)	36 (31.6)	<0.001
	Disadvantages of the test	4 (3.5)	22 (19.3)	88 (77.2)	36 (31.6)	54 (47.4)	24 (21.1)	<0.001
	Implications of carrying an ovarian cancer gene	2 (1.8)	32 (28.1)	80 (70.2)	22 (19.3)	68 (59.7)	24 (21.1)	<0.001
How did the information sheet make you feel?	Worried or concerned	90 (78.95)	22 (19.3)	2 (1.8)	96 (84.2)	18 (15.8)	0	0.289
	Reassured	38 (33.3)	50 (43.9)	26 (22.8)	52 (45.6)	42 (36.8)	20 (17.5)	0.042
	Upset	98 (86.0)	14 (12.3)	2 (1.8)	104 (91.2)	8 (7.0)	2 (1.8)	0.041

TABLE 3 Post-counselling evaluation of DA and face-to-face consultation.

Question	Likert scale	Frequency (%)
Do you think the information sheets were useful in helping you make the decision about genetic testing?	Definitely not	0
	Probably not	6 (5.3%)
	Not sure	24 (21.1%)
	Probably yes	42 (36.8%)
	Definitely yes	42 (36.8%)
Following your consultation, which information sheet do you prefer?	Definitely the long version	30 (26.3%)
	Probably the long version	54 (47.4%)
	Not sure	6 (5.3%)
	Probably short version	18 (15.8%)
	Definitely the short version	6 (5.3%)
Did having a face-to-face consultation with the doctor make the decision easier/ clearer to make?	Definitely not	0
	Probably not	0
	Not sure	10 (8.8%)
	Probably yes	62 (54.4%)
	Definitely yes	42 (36.8%)
After your face-to-face conversation, did you change your decision about genetic testing?	Definitely not	28 (24.6%)
	Probably not	38 (33.3%)
	Not sure	12 (10.5%)
	Probably yes	22 (19.3%)
	Definitely yes	14 (12.3%)
Looking back, do you think you could have made the decision regarding genetic testing without seeing a doctor?	Definitely not	34 (29.8%)
	Probably not	36 (31.6%)
	Not sure	18 (15.8%)
	Probably yes	20 (17.5%)
	Definitely yes	6 (5.3%)

Women on treatment were more likely to report the long DA as 'too long' for time taken to read (OR = 3.6, 95% CI 1.2–11.6; $p=0.023$) and less likely to request more detail in the short DA (OR = 0.29 95% CI 0.1–0.9; $p=0.031$). Both pre-counselling (coef = 0.621 95% CI 0.152–1.091; $p=0.01$), and after mainstreaming counselling (coef = 0.603, 95% CI 0.165–1.042, $p=0.007$) women on treatment reported a preference for the short DA. However, they were also more likely to report feeling 'somewhat worried' reading the short DA (OR = 15.9 95% CI 3.71–15.0; $p=0.001$).

Women with recurrent disease are more likely to rate the amount of information as 'about right' in the short DA (OR = 0.30 95% CI 0.12–0.70; $p=0.006$); and expressed a preference for the short DA both before (coef = 0.72; 95% CI 0.263–1.178; $p=0.002$) and after (coef = 0.493; 95% CI 0.065–0.92; $p=0.024$) counselling.

4 | DISCUSSION

4.1 | Summary of findings

Over seven out of ten women in our study showed a preference for more detailed information as in the long DA. The use of the long version DA was associated with significantly higher satisfaction, was perceived to provide the right level of information, and offered greater improvement in patients' understanding of the process, potential implications, benefits and disadvantages related to genetic testing. The shorter DA was, however, preferred by women who were older, had advanced-stage disease, a history of recurrence or were on active treatment at the time of the study. The longer DA was mostly preferred by younger women, women with early-stage disease or in remission. FH of BC/OC and background ethnicity did not appear to influence most outcomes. Neither the long or short DA made patients feel emotionally worried or concerned. Over one-third of women changed their decision to undergo testing after seeing their clinician and over one-quarter declared that they would have made this decision without seeing their clinician.

4.2 | Interpretation

Decision aids are tools to facilitate patient decision-making by providing information about options and the associated risks and benefits, and helping clarify decisions in relation

to personal values.[16] As genomics-driven personalised OC treatment is now available, there is an increasing need for streamlined genetic counselling and consent. For this purpose, succinct coherent information delivery in a timely fashion is required for informed decision making.[19–21] DAs are critically important in situations when there is more than one reasonable option, with varying implications, and the optimal choice for each individual may differ as a result of variations in their values and preferences.[16,22] Pre-test counselling alone, in affected patients, has been shown to be insufficient in fulfilling all the information requirements of patients; specifically in communicating a patient's personal risk of developing a secondary cancer or the likelihood of family members being affected by familial cancers related to *BRCA* or other CSGs.[23,24] Given the need and importance of adequate counselling and education for an informed genetic-testing process, a pre-existing two-page short DA may not have adequately addressed patients' needs. Our study highlights that a large number of patients (up to 74%) wanted more detailed information and preferred the long DA. However, those undergoing active treatment may prefer more succinct/gist information. Our findings fit with existing guidelines that inclusion of detailed well-designed DAs into usual healthcare improves patients' knowledge, reduces decisional conflict and increases patient participation in decision-making.[15,16]

Pre-test information and counselling is aimed to increase knowledge without increasing anxiety or stress.[17] In this cohort, it was reassuring to find low rates (2%) of emotional upset or worry with either version of the DA. Over two-thirds of our cohort reported high levels of reassurance when using the long DA. The pre-test education information provided in the long DA, was perceived as being the right amount by three-quarters of respondents and probably contributed to higher levels of satisfaction and reassurance.

Our findings suggest that contrary to information pertaining to cancer treatment, in the context of genetic testing a number of cancer patients may want more detailed information. This is unlike testing in unaffected individuals, where we previously found no difference in outcomes between gist and detailed versions of DA in the context of genetic testing for ovarian cancer risk assessment.[25] It is possible that the level of information required for post-test counselling in cancer (affected) patients may also be different to that in unaffected individuals. This is an area that requires further research. Cancer patients who demonstrate a good understanding of potential burdens related to CSG pathogenic variants are more likely to engage in positive coping styles than avoidance tactics and more likely to engage with preventive strategies for themselves and at-risk family members.[26,27]

On the contrary, qualitative studies highlight some OC patients prefer brief personalised information without complicated statistics.[28] This is not inconsistent with our findings, as one-quarter of patients preferred the short DA. Explorative multivariate regression analyses in our cohort suggest that women undergoing active treatment and those with recurrent disease show a preference for the short DA. To the best of our knowledge, this observation has not been reported before. This may be because these women are primarily focused on and prioritising information related to completion of cancer treatment, rather than greater granular details of broader implications of genetic testing.

Our data indicate that older women too may favour more succinct information, may feel more worried and are also more likely to change their decision about genetic testing after a face-to-face consultation. It is possible that they may have a greater need for a traditional clinician-led consultation in order to reach a decision on genetic testing. However, age did not affect the uptake of genetic testing, and a mainstreaming clinician-led consultation may have contributed to this and easing their worries or uncertainties regarding genetic testing.

High rates of genetic-testing uptake (>95%) have been reported by our cancer network[5] as well as by other UK centres.[29] DAs improve knowledge, information and value-congruent decision-making.[16] That neither the long nor the short DA made patients feel emotionally worried or concerned was reassuring.

It is possible that the knowledge and expertise of the group of clinicians or health professionals providing counselling can influence some findings and potentially uptake of testing. An earlier analysis has found that the number of consultations needed when Clinical Nurse Specialists were undertaking mainstreaming genetic-testing counselling was significantly greater than numbers needed by cancer clinicians.[5] However, we do not think the issue above has directly impacted our study findings. We undertook assessments of the DA before counselling too. In the UK genetic testing in ovarian cancer is pretty well embedded in clinical practice and most teams are past their initial learning curve.

Several alternative forms of DAs have been evaluated in the context of genetic testing. These include both written/printed formats as well as audiovisual tools.[14,30,31] In our cohort, 32% of the patients opted to have genetic testing following clinical consultation, and may not have done so without it. This suggests that the counselling session helped to address queries that may have arisen following reading of the DA, and facilitated informed decision-making. Decision tools can also reduce counselling time and so facilitate a more cost-efficient testing pathway.[14]

Nevertheless, one-quarter of our cohort reported that they could have made the decision without the clinical consultation. This strengthens the argument that for selected patients who are well-informed and have a good command of English the DAs alone can serve as an alternative to face-to-face genetic counselling. This is consistent with findings from a number of studies that have investigated alternatives to face-to-face or traditional genetic counselling. These studies found pre-test communication in large groups, pre-test video/DVD or web-based information or written educational information to be non-inferior to traditional face-to-face consultations,[14,32,33] with high acceptability and satisfaction rates. We earlier demonstrated high acceptability and satisfaction with genetic testing for OC CSGs in

unaffected individuals using web-based DA and a telephone helpline, and found that only one in seven women needed clinician support for decision-making.[18] However, decision-making in affected women (such as those with OC) is a completely different context. Our findings indicate that women with cancer have different needs compared with unaffected at-risk individuals, with a number of them changing their decision following clinician counselling. Our data also highlight the fact that OC patients' profiles and needs vary significantly, subsequently requiring a combination of different levels of detailed written information and a face-to-face consultation within the mainstreaming pathway.

4.3 | Strengths and limitations

This study is the first to compare the use of a detailed DA versus a gist DA in women diagnosed with OC and demonstrate a preference for more detailed information for many cancer patients. Our study is the first to highlight that women on active treatment for primary or recurrent disease and older women may prefer less detailed information, unlike women who are currently in remission. This study is prospective, was undertaken in a real-world setting, and the DA development process followed robust IPDAS methodology.

We also recognise a series of limitations. Our results are based on a single cancer network experience, which may limit the reproducibility/generalisability of our findings. However, our network covers a 1.5–2 million population and five hospitals including ethnic minority and culturally diverse patients. It is likely that findings may be similar for other UK cancer centres/networks with similar population characteristics. It is difficult to be certain whether the same (or different) findings will be elicited in other health systems or whether there may be significant differences with hard-to-reach or ethnic minority populations. Around 15% of the UK population comprises non-White ethnicities who can have different sociocultural norms and different attitudes towards genetic testing as well as different information support needs. Although 15% of participants in our study were non-White or ethnic minority (self-defined ethnicity), these absolute numbers are small. Information needs and preferences for type of DA have been found to be different in Asian populations and low/middle-income countries like India.[34] Further research is warranted across different health settings and contexts. Arguably, well-developed DAs may have a more important and valuable role to play in resource-challenged and less genetics-aware settings. Differences in level of education and socio-economic status may also impact results and the lack of these data is a limitation. The UK DETECT-2 (ISRCTN57402067) multicentre randomised trial will evaluate information provision and development of a scalable model for implementing large-scale genetic testing at cancer diagnosis, using a Web-App DA and a Direct to Patient approach. Patients' information needs will form an important part of the evaluation.

Our regression modelling, may be exploratory and a larger sample size is needed to confirm stronger associations for some factors that influence preferences. Lack of qualitative analysis is also a limitation of this work. Additional qualitative research would provide rich insights into patients' experiences with respect to the DA and genetic testing. Qualitative data along with quantitative data are increasingly now used to inform development of care pathways as this offers further insights into the choices that patients make. Qualitative interviews are planned to be undertaken by the group in the future.

5 | CONCLUSION

This study shows that pre-test DAs used alongside pre-test counselling by cancer clinicians can result in high levels of satisfaction, improve decision-making and have low rates of being emotionally upset, within the context of a mainstreaming parallel germline and somatic testing pathway. Three-quarters of our cohort of patients preferred the longer comprehensive DA, but a minority (one-quarter) expressed preference for the gist/short DA. Our data suggest the need for a more personalised approach with women who are currently on active treatment or diagnosed with recurrent disease wanting less information and preferring the short DA, whereas those in remission favour the longer DA.

AUTHOR CONTRIBUTIONS

Conceptualisation, RM; methodology, RM, DC, RL and ML; formal analysis, RM, DC, MS and OB; implementation and investigation, RM, DC, REM, SMC, LAJ, NS, RL, AF, EB, AK and ML; resources, DC, MS, OB, REM, TMB, SMC, LS, OE, LAJ, MA, AK, ML, NS, AF, LC, EB, EB, SP, GT, CF, AK, JS, RL, RM; data curation, DC, RM, and OB; writing—original draft preparation, RM, MS, DC and MS; writing—review and editing, all authors; supervision, RM; project administration, RM, DC and MS; funding acquisition, RM. All authors have read and agreed to the published version of the manuscript.

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CONFLICT OF INTEREST STATEMENT

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DATA AVAILABILITY STATEMENT

Data available on reasonable request from the corresponding author

ETHICS APPROVAL STATEMENT

The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Ethics Committee of London Riverside Ethics Committee (reference number 17/LO/0405).

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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