

Supplementary Table –S1: Knowledge Questionnaire

<i>Knowledge about BRCA1/2</i>	True	False
Even if a woman has an alteration in the <i>BRCA1</i> or <i>BRCA2</i> gene she may not develop cancer.	<input type="checkbox"/>	<input type="checkbox"/>
If a woman carries a <i>BRCA</i> gene alteration but does not develop cancer, her child may still have the alteration.	<input type="checkbox"/>	<input type="checkbox"/>
Men carrying a <i>BRCA</i> gene alteration are at an increased risk of developing cancer.	<input type="checkbox"/>	<input type="checkbox"/>
A woman who has a <i>BRCA1</i> / <i>BRCA2</i> gene alteration has an increased risk of developing ovarian cancer.	<input type="checkbox"/>	<input type="checkbox"/>
Removal of tubes and ovaries in women carrying a <i>BRCA</i> gene alteration can prevent cancer arising in the tubes or ovaries.	<input type="checkbox"/>	<input type="checkbox"/>
Women carrying a <i>BRCA</i> gene alteration have a 50% chance of passing it on to their children.	<input type="checkbox"/>	<input type="checkbox"/>
Screening trials for early detection of breast and ovarian cancer are available for women who carry a <i>BRCA</i> gene alteration.	<input type="checkbox"/>	<input type="checkbox"/>
Screening for early detection of prostate cancer is available for men who carry a <i>BRCA</i> gene alteration.	<input type="checkbox"/>	<input type="checkbox"/>
<i>BRCA</i> gene alterations are more common in Ashkenazi Jews than in other, Non-Ashkenazi individuals.	<input type="checkbox"/>	<input type="checkbox"/>
Roughly 1 in 40 Ashkenazi Jews carries a <i>BRCA</i> gene alteration.	<input type="checkbox"/>	<input type="checkbox"/>

Supplementary Table-S2: DVD Evaluation Questionnaire

Genetic Counselling Decision Tool Evaluation Questionnaire					VRN-	
1)	How satisfied were you with the information provided in the presentation?					
	Very Satisfied	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2)	Was the amount of information provided in the presentation:					
	Too little		About right		Too much	
	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
3)	Was the amount of time it took to watch the presentation:					
	Too short		About right		Too long	
	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
4)	Did any parts of the presentation need to be explained in more detail?					
	Yes	<input type="checkbox"/>		No	<input type="checkbox"/>	
5)	If yes, please write which part or parts in the space provided.					
6)	Were there any parts of the presentation that could be left out?					
	Yes	<input type="checkbox"/>		No	<input type="checkbox"/>	
7)	If yes, please write which part or parts in the space provided.					
8)	How much did the presentation improve your understanding of:					
		Not at all	Not very much	Somewhat	Quite a bit	A lot
	The purpose of genetic testing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The risks of genetic testing in your situation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The benefits of genetic testing in your situation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The implications of a positive result	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9)	How much did the presentation make you feel:					
		Not at all	Not very much	Somewhat	Quite a bit	A lot
	Worried or concerned	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Reassured	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Upset	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10)	What about the video, if anything, made you feel worried, reassured or upset?					
11)	Would you recommend the presentation to others in the same situation					
	Yes, I would	<input type="checkbox"/>	I'm not sure	<input type="checkbox"/>	No, I would not	<input type="checkbox"/>

Satisfaction, relevance and adequacy were assessed with a structured likert scale covering satisfaction with information, amount of information and length of the DVD; two closed and open ended questions on whether any parts needed more explanation or could be left out; and whether participants would recommend the DVD to others in their situation (yes/no options). Four specific items were used to assess perceived improvement of understanding (of purpose, benefits, risks and impact of genetic testing) using response options on a 1 to 5 Likert-scale ranging from 1= 'not at all' to 5 = 'a lot'. Emotional impact was assessed by 3 items asking whether the DVD made them feel 'worried or concerned', 'reassured', or 'upset' using the same 1 to 5 Likert-scale response options above, as well as an open ended question asking 'what, if anything, made you feel worried, reassured or upset'. Space for free text and open ended comments was provided.

Supplementary Table S3: Development of Knowledge Questionnaire

Knowledge Questionnaire Development

No single published knowledge questionnaire evaluated[6, 7, 8, 9, 10, 11, 12, 13, 14] was comprehensive/suitable enough to cover all issues related to BRCA1/BRCA2 testing in AJ men-&-women. Hence, a new questionnaire was developed for the trial,

The stages of development of the Knowledge Questionnaire are as under-

1) Literature Review:

Relevant questionnaires[6, 7, 8, 9, 10, 11, 12, 13, 14] were identified following a literature review. Of these, the National Institutes of Health (NIH) scale had been used with AJ individuals in two previous studies,[11, 15] and the Knowledge and Belief scale[7] was developed in consultation with, and for use in the Ashkenazi population. Some were minor modifications[10, 11, 13, 14] of the original NIH Cancer Genetic Studies Consortium Questionnaire.[8, 12] Scales developed[16] prior to those listed above mainly covered knowledge related to breast cancer risk rather than genetic testing.

2) Initial 'consensus group' assessment:

Available questionnaires were reviewed, tabulated and evaluated by a consensus group of six including a clinician (one), psychologists (two), genetic counsellor (one), clinical geneticist (one) and a lay representative. Each question was systematically discussed and debated by this group.

Existing questionnaires focused mainly on issues of inheritance, risk and breast cancer, while ovarian cancer and prostate cancer were less sufficiently covered. In addition they were limited by having been developed from and for high-risk populations. These scales contain a number of items that reflect relatively detailed level of knowledge expected within specific high-risk populations, rather than the more general knowledge which may be of greater relevance to a well lower-risk population. As no single published questionnaire was entirely suitable for the study, these were adapted and a new questionnaire developed for the trial.

3) Initial draft questionnaire:

All available items from reviewed questionnaires (avoiding duplication) were tabulated. The wording of questions was modified slightly if it was felt that doing so would improve its applicability to the study. A set of 21 new questions were also added to this list to cover relevant aspects which the group felt had not been adequately covered leading to a revised draft knowledge questionnaire of 84 questions.

4) Questionnaire piloting:

In the next stage this was piloted amongst 10 health professionals, and required a relevance score (from 1 to 4) to be given to each item. Respondents scored items based on their knowledge and experience in cancer genetics and/or working with high risk families and were also asked to identify any additional questions which they considered to be important for a finalised questionnaire.

5) Second 'consensus group' meeting:

This was held to review responses to the initial questionnaire and delete low relevance items, to optimise questionnaire length and facilitate compliance. The initial draft was reduced to 16 questions.

6) Final Questionnaire:

The 16-item questionnaire was further debated by the group and questions rationalised by omitting ones which appeared repetitive, simplifying the language of questions where necessary, and combining questions to create a single question where appropriate. All items were adapted so that they were suitable for use with both men and women, and to address prostate cancer, as well as breast and ovarian cancer. Excessive details, such as on precise figures of risk, were omitted. A True / False close ended questionnaire format used previously by others[8] was preferred to a likert scale with 4-5 response options. Our aim was to develop an easy to use, short questionnaire. The list of 16 items was rationalised to a questionnaire of 10 items (supplementary table-1)

7) Additional Analysis

Face and content validation was conducted throughout the development process, which was guided by expert input including geneticists, gynaecological oncologists, psychologists, nurses, genetic counsellors, questionnaire designers and lay people. Consensus group review and feedback from health professionals further validated the content of the knowledge items. Results of the ratings of the questionnaire items indicated high levels of content validity. Kuder-Richardson(KR-20)(software version-1.2)[17, 18] was used to measure internal consistency/reliability as it is more appropriate (than Cronbach's- α) for dichotomous (True/False) option scales. The KR-20 value was 0.457 and item-rest correlation was 0.183, suggestive of moderate internal reliability. Although this might be considered problematic for scales measuring a single trait or content domain, a high KR statistic cannot be expected for a multidimensional knowledge scale such as ours, where the items are not very similar, but cover a broad range of the underlying continuum. Criterion validation was not attempted as there is no gold-standard knowledge questionnaire. The scale's ability to detect changes in knowledge in response to educational interventions (sensitivity-to-change) was evaluated in this study. Test-retest validity could not be evaluated as the outcome (knowledge) is not stable and changes following intervention (genetic-counselling) in the study.

Supplementary Table S4: Development of DVD

Development of DVD

The DVD was developed to serve as an audio-visual decision aid to facilitate informed decision making by conveying balanced information about benefits and harms and issues related to genetic testing and participation in the study.

Face and content validity was ensured at each stage of this process. This was based on the Ottawa decision support framework,[1, 2, 3] which separates evaluation of quality of decision making from the decision outcomes. Decisions are dependent on participants' values and cannot be considered right/wrong. However, decisions which are informed, consistent with personal values, involve satisfaction with the decision making process and are acted upon, are considered optimum.[2, 4]

1) Literature Review and content preparation:

The first stage of development comprised a comprehensive review of available literature and national and international guidelines for genetic testing to prepare the content. Detailed 'participant information', and 'educational' booklets, containing relevant information were meticulously developed with inputs from experts, lay people, consumer representatives and community organisations. The initial draft of the content for the script was prepared by a small group comprising a clinician, two psychologists and a genetic counsellor.

2) Larger consensus group review:

This initial draft was reviewed by a larger consensus group consisting of gynaecological oncologists (two), psychologists (three), a nurse, clinical geneticists (three), genetic counsellors (two), and consumer representatives (three).

3) Next stage:

After a number of iterations the next draft was piloted with lay people and health professionals not involved in the study as well as the wider Trial Management Team and feedback used to incorporate changes. The material developed was kept to a Flesch-Kincaid grade of less than 8.0, which corresponds to a UK reading age of 11-13 years.

4) Community group feedback:

In the subsequent stage the content was circulated to Jewish charities and representative groups. A consensus meeting between community representatives and the study team from the community was held in July 2008 and further changes to design and content incorporated following this. Feedback provided was incorporated within narrative script for the DVD and study information materials.

5) DVD Script:

This covered detailed information on concepts of genes, mutations, inheritance, levels of cancer risk, lifestyle factors, advantages/ benefits of genetic testing, disadvantages of genetic testing, issues related to insurance, employment and marriage-ability, confidentiality, implications and management options of a positive result, implications of a negative result, support provided, contact details and other sources of information. It also provided information on background, aims, study design, processes and pathways involved in the study, study duration, eligibility, options, principle of randomisation, withdrawal, sample collection and storage, study investigators, collaborators (community and scientific), funders, and ethics review.

6) Illustrations:

Visual figures, diagrams and pictures were developed using power point to highlight and illustrate the script.

7) Power-point version:

The script and visual material developed was used to prepare a power-point presentation. This was reviewed by a consumer representative and the wider study team and piloted and validated in 30 initial volunteers in the DVD-group counselling arm.

8) Preliminary DVD format evaluation:

The next stage involved preliminary shooting of the DVD. Different formats of the DVD were evaluated during this process, including (a) continuous voice-over with no visual depiction of the narrator, (b) narrator as a permanent inset at the corner of the picture and (c) the narrator presenting the script with the camera at times showing a full screen picture of the narrator and at other times zooming away to show the visual graphics, diagrams and material linked to the script. These three formats were reviewed by the consensus group after initial prototypes were developed and format (c) chosen as it was more visually appealing, interactive and engaging for the viewer. Subsequent developments of the DVD were undertaken using format (c).

9) First DVD prototype:

The first DVD prototype was 30 minutes long. This was reviewed by the wider study team, a consumer representative and piloted among 10 individuals undergoing group counselling in the study. Feedback indicated that the DVD though very informative was too long and a shorter version would be preferred. The speed of narration was also slow in places. This is consistent with a recent Cochrane review suggesting that decision aids with more detail compared to simpler decision aids showed smaller improvements.[5]

10) Final DVD:

The script and visual material were shortened and narrative speed slightly increased in places, to produce a 15 minute DVD. This final version of the DVD was used within the study from Feb-2009.

Supplementary Table- S5: Patient / Community involvement

The study was preceded by an extensive broad based consultation / engagement with all sections of the Jewish community which lasted almost a year. This involved numerous meetings, presentations, lectures and correspondence with community groups, charities, organisations, leaders, Rabbis and stake holders across all sections of the London Jewish community. Community feedback influenced protocol development and was incorporated into the design, logistics, preparation of study materials (participant information sheets/posters/ flyers), as well as study acronym. Some community charities provided support and premises for recruitment to the study. This helped increase awareness about the study and facilitated recruitment. Results of the study will be disseminated through supporting charities and community groups as well as websites. The study outcomes assess the impact of the intervention (genetic counselling) on participants. Supporting charities and individuals are acknowledged and thanked in the acknowledgement section of the manuscript.

Supplementary table-S6: Parts of the DVD requiring more details or which could be left out

Parts Requiring More Detail		n (%)
BRCA	BRCA1/2 genes	3 (1%)
Risks, inheritance	Risks of children, siblings, family	3 (1%)
	AD inheritance	1 (0.3%)
	Cancer risks, risks of other cancers	3 (1%)
	statistics, diagrams	1 (0.3%)
Insurance	Insurance, moratorium details	8 (2.5%)
Prostate cancer	Prostate cancer details	2 (0.6%)
Breast cancer risk management	Breast cancer screening	1 (0.3%)
	RRSO to prevent breast ca	1 (0.3%)
Study Design	Testing for SJ / mixed SJ, AJ parentage	2 (0.6%)
	FH arm study results	4 (1.3%)
	Randomisation	6 (1.9%)
	Time of genetic test	1 (0.3%)
	Follow up	1 (0.3%)
	International use of data	1 (0.3%)
Presentation	Pausing before each section	2 (0.6%)
Parts which can be omitted		n
Genetic testing Information	Details about genes	1 (0.3%)
	gender specific elements	1 (0.3%)
	lot of info is in booklet	1 (0.3%)
Study Details	organisations and people involved	1 (0.3%)
	About Boots	1 (0.3%)

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