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From Observation to Intervention: Development of a Psychoeducational Intervention to Increase Uptake of *BRCA* Genetic Counseling Among High-Risk Breast Cancer Survivors

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Abstract

We describe the development of a psychoeducational intervention (PEI) to increase uptake of genetic counseling targeted to high-risk breast cancer survivors. Based on previous research, scientific literature, and a review of cancer education websites, we identified potential PEI content. We then assessed the initial acceptability and preference of two booklets of identical content but different layouts, by presenting the booklets to individuals with a personal or family history of breast cancer (n=57). The preferred booklet was evaluated by two focus groups of ten breast cancer patients who had not attended genetic counseling. The booklet was refined based on participants' feedback at each stage. Focus group participants generally found the booklet visually

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appealing, informative, and helpful, but some thought that it was too long. Final changes were made based on learner verification principles of attraction, comprehension, cultural acceptability, and persuasion. This project produced an interventional tool to present key constructs that may facilitate decision making about risk-appropriate genetic counseling uptake among high-risk breast cancer survivors. The process described for creating, testing, and adapting materials from a patient perspective can be used for developing other PEIs. This newly developed, unique PEI can be used in many clinical settings.

Keywords

Breast cancer; Genetic counseling; Educational intervention; Survivors

Introduction

Women with a personal history of breast cancer who carry a *BRCA* mutation are at substantially elevated contralateral breast [1] and ovarian cancer [2] risks compared with breast cancer patients without a *BRCA* mutation [3]. Thus, it is important to identify women who carry *BRCA* mutations so that they may avail themselves of the latest medical advances in prevention, early detection, and treatment [4, 5]. Referral to a cancer genetic professional for genetic counseling prior to genetic testing is strongly encouraged by health professional organizations [6, 7]. The model for providing comprehensive *BRCA* testing begins with an in-person, pretest genetic counseling session that includes a detailed risk assessment for hereditary cancer(s), education about hereditary breast and ovarian cancer, and counseling about the benefits and drawbacks of testing. This session is intended to increase knowledge, aid in psychosocial adjustment, and assist with decision making regarding testing [8, 9]. The National Comprehensive Cancer Network (NCCN) has published guidelines to facilitate referrals to genetic counseling in the oncology care setting [6]. NCCN criteria for appropriate referrals among individuals with a personal history of breast cancer include but are not limited to the following: breast cancer diagnosis of age ≤50, two or more close blood relatives diagnosed with breast cancer and/or pancreatic cancer, two primary breast cancers, triple-negative breast cancer, ovarian cancer, male breast cancer, and/or a previously identified *BRCA* mutation occurrence in the family.

There are multiple points in the cancer diagnosis, treatment, and survivorship continuum where genetic counseling can provide information for breast cancer patients meeting NCCN referral criteria. Newly diagnosed high-risk breast cancer patients are high-risk women who have not made a definitive decision about their surgical treatment for their current breast cancer treatment. These breast cancer patients may attend genetic counseling to seek specific information to inform their surgical decision (e.g., lumpectomy vs mastectomy, mastectomy of the affected breast vs mastectomy and contralateral prophylactic mastectomy) [10–14]. Studies in a variety of settings report that despite readily available referral criteria, integrating risk-appropriate referrals for and utilization of genetic counseling into breast cancer treatment planning is an ongoing challenge [15]. Thus, it is likely that numerous breast cancer survivors meeting genetics referral criteria (i.e., high-risk breast cancer survivors) have not been adequately informed about their genetic cancer risk(s).

For high-risk breast cancer survivors, genetic counseling can be important after treatment for the primary breast cancer. In this situation, the focus of information shifts from treatment decision making to prevention of future malignancies and, in some situations, information for at-risk family members. Breast cancer patients with a *BRCA* mutation are at substantially elevated risk of contralateral breast [1, 3, 16] and ovarian cancer [2], compared with patients without a *BRCA* mutation [3, 17]. Given the efficacy of contralateral, bilateral prophylactic mastectomy, and prophylactic oophorectomy [18–21] as well as the use of chemoprevention [22] in reducing the risk of cancer in mutation carriers, high-risk breast cancer patients could clearly benefit from information about their genetic risk for cancer. In addition, the optimal testing strategy is to test one or more affected relatives first. Then, if a mutation is identified, testing can be offered to unaffected individuals to determine whether they have inherited the cancer predisposition [23]. Therefore, *BRCA* genetic counseling for high-risk breast cancer survivors has the potential to inform a patient about her future cancer risk, as well as identify implications for her family members.

The Health Belief Model postulates that individuals will take action (e.g., attend genetic counseling) if they perceive the following: The illness is serious (perceived severity), they have a personal risk for the illness (perceived susceptibility), and that actions taken to control the illness are effective (perceived benefits) relative to the impediments (perceived barriers). Exposure to factors that prompt action (cues to action) [24] and the belief that they can successfully perform the actions to control the illness (self-efficacy) also facilitate behavior change [25]. Additional areas relevant to the development of the psychoeducational intervention (PEI) in the proposed study include addressing knowledge gaps, providing concrete skills to move from intention to behavior (e.g., implementation intention [26]), and the role of affect (e.g., distress) in behavior [9]. We describe our approach to the process of developing and evaluating the acceptability of a print-based PEI (booklet) to increase uptake of pretest genetic counseling among high-risk breast cancer survivors (i.e., breast cancer patients meeting ≥1 NCCN criteria for referral to a genetic professional), guided by a conceptual framework based on the Health Belief Model.

Methods

Our team used a multiphase approach to inform the PEI content and delivery mode. The first phase involved the PEI development, informed by published cancer education scientific literature and organizational websites, which took place in January 2009. In phase 2, the team assessed the initial acceptability of two versions of the PEI via feedback from conference attendees of an international advocacy support group (Facing Our Risk of Cancer Empowered [FORCE]) in May 2009. To assess the PEI's appropriateness, the chosen booklet was presented to the patients who were referred for, but did not attend, genetic counseling (phase 3) in November 2009. All study phases were approved by the University of South Florida institutional review board.

Phase 1: PEI Development

Content development was based on findings from a qualitative study that assessed barriers and facilitators to participation in genetic counseling among breast cancer patients. Details

about the study participants, procedures, and results were previously published [15]. In brief, the key findings that informed the PEI are discussed below, and the relevant theoretical constructs that are the basis for the proposed intervention are included in parentheses:

- Some women were surprised to learn about their risk for subsequent cancers and that the test results may lead them to have to consider prophylactic surgeries (of the currently healthy breast and/or ovaries) particularly related to ovarian cancer. These findings suggest that women already diagnosed with breast cancer may not perceive themselves at increased risk for future breast or ovarian cancer. (Health Belief Model perceived susceptibility)
- The majority of women who previously attended genetic counseling said that they did so because they wanted to help other family members learn about their cancer risks. (Health Belief Model perceived benefits)
- When asked if anything unexpected happened during the genetic counseling session, three positive and unanticipated outcomes emerged. Overall, patients who attended genetic counseling were very satisfied with their genetic counseling session. Specifically, they were satisfied with the detailed information that was relayed, that the information was provided in a manner relevant to their unique situation and history, and the amount of time spent by the counselors to cover this information. These findings indicate that the full range of benefits of genetic counseling may not be readily apparent to women at the time that they are referred for genetic counseling (Health Belief Model perceived benefits)
- Although all women in the study were referred for genetic counseling by a health care provider, less than half cited this as the primary influence in their decision to attend genetic counseling. Although physician recommendation has been found to be a strong predictor of uptake for hereditary breast and ovarian cancer genetic counseling and/or testing, our findings support the idea that there are other individuals (i.e., family members) whom women may also consult prior to attending genetic counseling (Health Belief Model cues to action)
- More than half of the women who received genetic counseling after completing treatment felt that they were too focused on treatment decisions or had too many other decisions to make to consider genetic counseling prior to treatment. From a clinical perspective, the optimal time for genetic counseling referral may be prior to definitive surgical treatment for breast cancer; however, our findings suggested that recently diagnosed patients may not uniformly be in the same psychosocial or emotional state to process and integrate the information from genetic counseling into their current treatment but may reconsider genetic counseling after completing treatment (psychosocial factors - cancer distress)
- The primary frustration reported by women was the insurance process. Some women mistakenly believed that authorization for genetic counseling also covered authorization for genetic testing (Health Belief Model perceived barriers).

The research team searched websites of major breast cancer advocacy, support, and education organizations that are providing patient education materials including the

American Cancer Society, CancerCare, Y-Me Breast Cancer Organization, National Breast Cancer Coalition, BreastCancer.org, Young Survival Coalition, Ribbon of Pink, Komen for the Cure Foundation, Avon Foundation, FORCE, and NCCN to assess whether any currently available materials addressed the issues identified in our prior work. These organizations provided information that was largely focused on the testing itself and did not adequately describe the importance of genetic counseling. None of the major breast cancer patient advocacy and educational organizations provided detailed information or psychosocial support related to genetic counseling specific to breast cancer patients. In examining available literature, we found a limited number of studies that describe the development of genetic education materials related to hereditary breast and ovarian cancer and *BRCA* testing for a variety of populations [27–32]. Of these studies, few specifically examined the impact of printed genetic education materials on outcomes including knowledge, interest in and uptake of genetic testing, and psychosocial factors (e.g., distress and decisional conflict) [28, 30, 31] among women who were either affected with or at increased risk for breast cancer. These studies have indicated that printed pre-genetic counseling interventions were effective in enhancing knowledge, increased awareness of the risk and limitations of testing, and resulted in more risk-appropriate interest in testing [28, 30]. However, to our knowledge, none of the printed genetic education materials available from advocacy and educational organizations or in the published literature have focused on developing or examining genetic counseling uptake among recently diagnosed high-risk breast cancer patients using a printed educational intervention. Thus, the team, which consisted of social/behavioral scientists, clinical genetics experts, and a patient advocate, used an iterative approach to developing and refining a draft version of the PEI.

Phase 2: Initial PEI Acceptability

To assess the initial acceptability, appeal, visual content, and format/layout of the two printed PEIs, feedback was sought from attendees at the 2009 FORCE conference. FORCE is the largest education, support, and advocacy organization for individuals at risk for hereditary breast and ovarian cancer (http://www.facingourrisk.org/). A flyer describing the study was included in the conference participants' registration packets. Women were eligible if they attended the conference and self-reported a personal and/or family history of breast cancer. A cover letter describing the study, both versions of the PEI, and a survey were available at a Moffitt Cancer Center table in the conference exhibit area. The survey questions focused on PEI esthetic quality/appeal, visual content, and format/layout, and also surveyed individual demographic and clinical characteristics. Completed surveys were returned to a box on the table. Survey participants could register for a drawing for one of four $20 gift cards. Because our target audience for the PEI was high-risk breast cancer survivors, booklet preferences were compared between women with a personal history of breast cancer versus those with a family history. A waiver of documentation of informed consent was obtained from the university's institutional review board for this phase.

Phase 3: Focus Groups

Learner verification [33, 34] is a useful framework for formative research to establish the appropriateness of communications, such as written materials, for the target population. Learner verification focuses on key elements: (1) attraction, (2) comprehension, (3) cultural

acceptability, and (4) persuasion. For learner verification, only small samples (six to ten individuals in a group at each iterative stage) are needed [33, 34]. Using records from the Moffitt Cancer Center cancer genetic counseling and testing program database, we recruited individuals who were diagnosed with invasive breast cancer and did not attend genetic counseling within 12 months of receiving a referral letter from a Moffitt physician. This time frame was selected to ensure that these women truly were nonattenders of genetic counseling rather than women who may have already scheduled and were waiting to attend an appointment. A review of clinical records showed that the range of time from referral to appointment was a few weeks to a year. The research team contacted only women who resided within the Tampa area to help ensure that travel time to the focus group location was less than 1 h.

Prospective participants were mailed an introductory letter signed by their Moffitt physician that briefly described the study and included a toll-free number to call if they did not wish to participate in the focus group. In addition, a copy of the preliminary PEI and a consent form were included in the initial mailing. All potential participants who had not called within 2 weeks since the letters were mailed were contacted by a research team member and provided a brief description of the study. The following additional eligibility criteria were confirmed or assessed: (1) age ≥18 years, (2) no documented/observable psychiatric or neurological disorders that would interfere with study participation, (3) capable of speaking and reading standard English, (4) have a mailing address and working telephone number, and (5) reside in the Tampa area. Participants who met all eligibility criteria and gave verbal consent were scheduled for one of two 90-min focus groups. Women received a reminder phone call the day before their scheduled focus group. Upon arrival, the participants were also asked to complete a brief written survey to collect demographic and clinical information. An experienced qualitative researcher served as the moderator for both focus groups (GQ). The focus group guide included 12 questions and was based on the key principles of learner verification. The focus groups were audio recorded and transcribed verbatim. The research team reviewed the transcripts for accuracy. The participants received a $25 gift card in appreciation of their participation.

Data Analysis

For phase 2, Fisher's exact test was conducted to compare booklet preferences between women with a personal history of breast cancer versus those with a family history. Data were analyzed using SAS 9.1 (Cary, NC). To assess the learner verification elements in phase 3, a simple tabular representation of responses to each question is considered a sufficient method for identifying key areas for improvement [34]. Transcribed texts from the focus groups and individual interviews were converted into tabular format according to question types in an Excel spreadsheet. Study team members reviewed these tabulations to identify areas for improvement in the PEI.

Results

Phase 1: PEI Development

Table 1 provides a summary of key constructs identified from previous research [35, 36] considered to be important factors to address in the PEI. The website review yielded educational resources concerning genetic risk assessment for individuals with a family history of breast cancer and treatment considerations in conjunction with genetic testing for individuals diagnosed with early-stage breast cancer, but we did not find materials that addressed the unique issues of high-risk breast cancer survivors as they relate solely to genetic counseling [8, 9]. Similarly, we reviewed the published scientific literature and identified several articles that discussed elements of the development of a printed genetic education tool, but none focused on our population of interest [27, 29, 31] or addressed the key issues identified in our prior pilot work [35, 36].

A booklet was selected as the modality for this intervention based on literature suggesting that printed materials are the most common way that cancer patients access information related to their diagnosis [37, 38], and previous research has demonstrated the efficacy and cost-effectiveness of printed PEI materials in influencing behavior change [39, 40]. In addition to including key constructs identified in our pilot studies [35, 36], we incorporated recommendations for the development of general and genetics-specific health education materials such as the use of pictures and pictographs to indicate quantitative information (e.g., risk), attention to general and genetics-specific health literacy (e.g., readability levels, use of a conversational narrative style, use of patient testimonials, “chunking” information into brief sections), and visual appeal (e.g., font size and color scheme) [33, 34, 41]. Table 1 provides examples of how key constructs from our previous work were operationalized for the PEI.

Content for the PEI was outlined by the team and provided to two graphic artists as the basis for developing the PEI according to graphic best practice. The two graphic artists were commissioned to individually develop one booklet each containing identical content yet, according to stylistic differences, had different designs, logos, and images while simultaneously covering the key constructs of interest. Selecting the booklet most preferred by our target audience was the main goal due to the importance of testing for patient-orientated appeal [42].

Phase 2: Initial PEI Acceptability

Fifty-eight women reviewed both versions of the PEI and completed the survey at the FORCE conference. The highest percentage of participants were white (84 %), married (71 %), between the ages of 25 and 50 years (64 %), and had attended genetic counseling (81 %). Approximately 53% indicated that they were either Catholic or Protestant, and 26 % were of Ashkenazi Jewish descent. Many women were college graduates (43 %), and approximately 36 % reported holding a postgraduate degree. The greatest percentage of women had a family history but not a personal breast cancer history (69 %), whereas 21%were diagnosed prior to age 50 and 9% after age 50. As shown in Table 2, booklet 1 was identified as having the more attractive cover, relevant photos, and preferred

illustrations compared with booklet 2. The responses for the two versions of the booklets did not indicate a significant difference in the overall booklet preference. The only statistically significant difference by personal breast cancer history pertained to overall preference for illustrations (p=0.005). Booklet 1 was selected to present to participants in phase 3.

Phase 3: Focus Groups

A total often women participated in the focus groups. Participants were from diverse racial/ethnic backgrounds (seven Caucasian, two Black, and one Hispanic), 50 % were married, and 80 % had children. All participants had at least a high school education and health insurance. The majority (90 %) was diagnosed with breast cancer prior to age 50 and did not have a first-degree relative with breast or ovarian cancer (60 %). As presented in Table 3, the PEI was well received by study participants and achieved major objectives related to learner verification. All participants reported that the PEI was easy to read, but some thought that it was too long; thus, sections that the women thought were irrelevant to genetic counseling decision making were deleted. Many women thought that having a family tree illustration was helpful and reported that the booklet helped them learn the difference between genetic counseling and genetic testing. One area in which respondents had additional questions was health insurance coverage for counseling and testing; this information was added to the final booklet. The majority of women conveyed an understanding that genetic counseling was available to aid the genetic testing decision making process. All women reported liking the booklet format and most described that, after reading the booklet, they learned that there are risk factors used to identify women eligible for genetic testing referral. Based on participant feedback, information was added to clarify the time frame in the breast cancer diagnosis and treatment process when genetic counseling is most useful. In addition to adding and deleting information, the PEI was modified to improve the information flow and implement suggestions for alternative wording. The current prototype is a 12-page booklet (8.5″ × 11″) written at a tenth-grade-reading level (Flesch–Kincaid Grade Level).

Discussion

Genetic counseling and/or testing remains underutilized, particularly in the breast oncology care setting [15, 43–46]. Through previous research and a website review, our team identified a previously unmet need for information about genetic counseling for high-risk breast cancer survivors. The development of a PEI to meet this need was an iterative process that entailed developing PEI content based on our team's previous work and theory and pilot testing the product with members of our targeted audience. As a result, a printed PEI was produced to provide current and reliable information about genetic counseling and genetic testing, with the goal of increasing genetic counseling uptake among these high-risk patients. Women from the targeted audience who found the PEI to be informative reported that the PEI would help patients understand the importance of genetic counseling. The PEI will be further evaluated as part of a multimedia intervention (video and booklet) that will be tested with breast cancer survivors in the context of a pilot randomized controlled trial where high-risk breast cancer survivors are randomized to receive study-related materials (n=40) versus usual care (n= 40). If shown to be effective, we will test the intervention in a

larger multisite trial that incorporates multiple oncology care settings with diverse patient populations.

Study Limitations

While this study provides an important step toward the development of a theoretically based educational intervention to increase uptake of genetic counseling among high-risk breast cancer survivors, the results should be considered in light of certain limitations. First, given their proactive efforts to engage in health-enhancing and health-related activities, FORCE conference attendees' PEI receptiveness and feedback could vary from women who did not attend the conference. Further, given that approximately 37 % of the participants had postgraduate degrees, they may be more likely to read an informative booklet similar to the PEI, and their preferred illustrations and concepts of what is “easy to understand” could be more advanced than what an underserved population might prefer. However, our focus groups, which consisted of women who were referred for genetic counseling but did not attend, also reported that the booklet was easy to read. Additionally, we did not specifically develop our focus group interview guide around Health Belief Model constructs; thus, we were unable to assess participant level change on Health Belief Model variables. However, we are currently assessing the impact of this PEI on Health Belief Model constructs as part of an ongoing study. Second, while we assessed overall preferences for the visual images in the booklets, we did not assess preferences for each visual separately. Thus, it is possible that specific visual images from the booklet that were not selected may have been preferred by our respondents, but we did not capture preferences with our questions. Third, our data were collected approximately 4 years ago and may raise questions about the relevance of this issue in current clinical practice. However, more recently published studies suggest that underutilization of genetic counseling and/or testing in the breast oncology care setting remains a continuing area of concern [15, 43–46]. Thus, the PEI developed in this study may still be very relevant in aiding women who have already undergone breast cancer treatment and erroneously believe that genetic counseling is unbeneficial for them.

Conclusions

This study demonstrates the development of a theoretically based PEI that was evaluated for acceptability using learner verification. Our findings demonstrate that the PEI was viewed as acceptable to our target population. To our knowledge, this is the first PEI developed specifically to increase genetic counseling uptake among high-risk breast cancer survivors. Our team was recently funded to further refine the booklet and create a companion video that will be pilot tested in a sample of high-risk breast cancer survivors who meet eligibility criteria for, but have not attended, genetic counseling. Future research should focus on assessing PEI acceptability and adapting the PEI for other populations.

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Table 1

Key PEI constructs identified in prior work and example intervention messages

Construct	Example findings from previous qualitative work [14, 15]	Examples of intervention messages
Perceived susceptibility	All breast cancer patients received referral for genetic counseling (i.e., the patients felt that there was nothing "unique" about their diagnosis that triggered the genetic counseling referral)	Heading: Why was I referred for genetic counseling? Sample text: "You are most likely to benefit from genetic counseling if: you were diagnosed with breast cancer before age 50, had a previous breast cancer diagnosis…"
Perceived benefits	Women who attended genetic counseling were pleasantly surprised by many aspects of the genetic counseling process	Heading: One patient's story Sample text: "Genetic counseling helped Sue understand why she developed breast cancer and also helped her weigh the options related to future risk reduction." (part of patient testimonial)
Perceived barriers	Concerns about the cost of testing	Heading: Does my insurance cover the cost of genetic testing? Sample text: "Many insurance companies cover the cost of testing for people who have a personal or family history of cancer…the out of pocket cost of testing is usually less than $400. …Even if you do not have insurance, your health care provider may be aware of other options for coverage."
Cues to action	Physician recommendation is an important way to prime women to consider genetic counseling	Heading: Introduction Sample text: "Only about 10–15 % of all women diagnosed with breast cancer are referred for genetic counseling."
Knowledge	Lack of awareness about genetic counseling and genetic testing process	Heading: What is genetic counseling? Sample text: "By the end of the session, you will likely have enough information to consider whether or not you want to proceed with genetic testing…"
Implementation intentions	Women who recalled receiving a referral letter intended to have genetic counseling at some point in the future	Heading: How can I make an appointment for genetic counseling? Sample text: "Call XXX to schedule an appointment." Provided space to fill in appointment date, time, and important documents to bring to session
Distress	Women felt that having genetic counseling during the diagnosis and treatment process would be overwhelming	Heading: I still have many emotions and feelings…I am not sure if I am ready to have genetic counseling

Table 2

Booklet preferences among FORCE conference attendees with and without a personal history of breast cancer (*n*=57)

Question	Total (*n*=57) *n* (%)	Personal history of breast cancer (*n*=17) *n* (%)	No personal history of breast cancer (*n*=40) *n* (%)	*p* value[a]
By looking at the covers, which booklet is more attractive?				
Booklet 1	31 (54.4)	8 (47.1)	23 (57.5)	0.599
Booklet 2	24 (42.1)	8 (47.1)	16 (40.0)	
No preference	2 (3.5)	1 (5.9)	1 (2.5)	
Which booklet has photos you can relate to?				
Booklet 1	28 (49.1)	6 (35.3)	22 (55.0)	0.249
Booklet 2	21 (36.8)	7 (41.2)	14 (35.0)	
No preference	8 (14.0)	4 (23.5)	4 (10.0)	
Overall, which illustrations do you prefer?				
Booklet 1	27 (47.4)	5 (29.4)	22 (55.0)	0.005*
Booklet 2	25 (43.9)	8 (47.1)	17 (42.5)	
No preference	4 (7.0)	4 (23.5)	0 (0.0)	
Which organizational style do you prefer?				
Booklet 1	26 (45.6)	4 (23.5)	22 (55.0)	0.068
Booklet 2	29 (50.9)	12 (70.6)	17 (42.5)	
No preference	2 (3.5)	1 (5.9)	1 (2.5)	
Which booklet has the right amount of text/writing relative to white space?				
Booklet 1	21 (36.8)	4 (23.5)	17 (42.5)	0.126
Booklet 2	24 (42.1)	7 (41.2)	17 (42.5)	
No preference	11 (19.3)	6 (35.3)	5 (12.5)	
Which booklet did you think was easier to read?				
Booklet 1	22 (38.6)	4 (23.5)	18 (45.0)	0.141
Booklet 2	27 (47.4)	9 (52.9)	18 (45.0)	
No preference	7 (12.3)	4 (23.5)	3 (7.5)	
Which booklet did you think was easier to understand?				
Booklet 1	19 (33.3)	2 (11.8)	17 (42.5)	
Booklet 2	27 (47.4)	12 (70.6)	15 (37.5)	
No preference	10 (17.5)	3 (17.6)	7 (17.5)	0.052

Data were analyzed for the 57 women who reported whether they had a personal or family history of breast cancer

The sum of percentages may not total 100 due to rounding error or missing data

*$p<0.05$

[a]Fisher's exact test comparing responses to questions by personal breast cancer history

Table 3

Focus group results and intervention modifications based on learner verification elements

Learner Verification Element	Summary	Sample quotes	Modification (if indicated; based on focus group data)
Attraction	Some women thought that the booklet was too long; Almost all of the women liked it and described it as "pretty," "informative," and "easy to read"	"I thought it was kinda long" "I think it's informative and it helps…" "I like the cover; you have a variety of ethnic groups and ages and little genetic gene things here and whatever and the breast cancer thing and the colors are nice." "My thought on page 2 is that it's kinda bland 'cause it is just two paragraphs or written words; there's no pictures bringing it up or graphics like the other one and that's another reason why the bullets might work well on that second paragraph because it will make it a little bit less intimidating if you don't like to read." "…and I think that the family tree is a good thing at the beginning…also 'cause…in the visual, that really says, wow, or like this is me and then yea, that was my Aunt Sally and then this…you kinda see just like that so that's kind of like a good thing at the beginning whereas this sounds more complicated, more like you've already had more knowledge about what's going on…" "I think it's a nice visual…for me, because I'm a visual person, I think it would stimulate me to be thinking about…care and…my history, my mother's history, my family's history and where I wanna go with this." "One thing that stands out to me is that first, I didn't notice the headings on the side when I was reading, I didn't see what the headings were and then I realized I had switched into pelvic, breast to pelvic." "I like the silhouette though; it's kind of an interesting graphic."	Deleted sections that the women thought were confusing and irrelevant to making a decision about genetic counseling (e.g., screening and surveillance measures for *BRCA*-positive women, the section about other types of genetic/genomic tests)
Comprehension	Many of the women felt that the section trying to clarify the difference between genetic genomic tests (e.g., estrogen receptor/progesterone receptor status and Onco*type* DX) and *BRCA* testing was confusing Many of the women had questions related to the insurance process Many of the women thought that the idea of a family tree was very helpful, also to put all cancers in the family in perspective; especially male risk Women felt that they learned the following through the booklet: • Difference between genetic counseling and genetic testing • *BRCA1/2* related to ovarian cancer • The commonness of breast cancer	"…the top part's talking about the doctor referring you for genetic counseling and then the bottom part [states] these tests could be run and you're like what are those?" "…one drew the blood and another office was the one trying to get it pushed through the insurance and then…the blood wasn't drawn here so it was confusing…" "…as far as gathering the family tree information, any cancers, even if you don't think it's applicable, it needs to be included…" "An easy read; it was easy to read and not too overwhelming." "I thought it was informative for me." "I think it's well laid out and the…displays used to sort of explain certain areas were very helpful…" "I learned that *BRCA1, BRCA2* is also connected to ovarian cancer which I did not realize…" "Yes, and what I see here is that you can ask for counseling during treatment or after treatment but what about before treatment so you know what…what avenues to take." "…I mean, everything is spelled out for you so I don't know what I would wanna write down." "I didn't actually didn't even know that there was counseling and testing until I got this book and looked through it and saw the	Deleted section about other genetic tests Increased information about insurance coverage: • Separated costs of genetic counseling and genetic testing, and included information about co-pays • How the genetics clinic obtains insurance authorization • Having genetic counseling does not obligate a woman to have testing

Learner Verification Element	Summary	Sample quotes	Modification (if indicated; based on focus group data)
	What most insurance companies will cover	difference; it's like, oh, ok, it must be counseling and then you go to testing if it's determined that you wanna move forward with the actual testing to see." "Here they're giving you information if you wanna make an appointment but here, they look like they're signing a consent form." "…A glossary would be fun."	
Acceptability	The majority of women learned the following: genetic counseling was a separate process from genetic testing, there were more reasons to have the test done than to inform family, there was a relationship between breast and ovarian cancer All of the women liked the booklet format The majority learned that not all of the women were referred for genetic testing and the specific risk factors determining eligibility; however, these points came across only after reading the booklet	"…as far as any repercussions [genetic testing] may have on your family…or even life…health insurance and different things; it's all covered in that [genetic counseling] session." "…you're only going to remember a little piece of what they [say] …but hand me books …I can flip through it and then…write down notes to ask the next time I see somebody." "It gives you a lot of information, the first section and I think it's needed; I think it is laid out nicely; I mean, it really tells you who was being referred for genetic counseling." "I would see it; I can hold it; I can turn the pages…it prompts me to start thinking." "I think if you provide as many websites as possible, it saves a lot of searching cause sometimes you run across stuff on the Internet you probably shouldn't be looking at."	No changes
Persuasion	The majority of women said that they understood now, in a way they had not before the booklet, that they could have genetic counseling to understand whether genetic testing was right for them Women felt that this booklet needed to emphasize when genetic counseling was needed to help understand how genetic counseling can help your children help explain who would benefit from genetic counseling to decide about testing advise that genetic counseling is available to help make a decision about genetic testing	"…when I was reading it I felt like I had options; I kinda felt a little bit empowered that I had the option to have the counseling and the testing and make decisions from there." "I think, for me, I would read it to help me decide if I wanted to, yeah; I think it would help me to make a decision; that's just how I am; I like to have all the information I need to have to make decisions." "I put [genetic testing] off for a year because I didn't know what to expect…" "… it was letting you know about the genetics counseling, especially for me, what stood out the most when I took the time to read it was about the … the cost of the counseling and the testing." "Call for an appointment." "I see the information…like call to make an appointment but I don't see, most of the time, when I see things like that, I don't see additional information…so it's usually just a number…" "…I think that most women at this point have been through so many doctors; we know about the HIPAA and the confidentiality and you have to sign a release of information for anybody to get your information and short of any breach of…technology, it's pretty safe I guess."	Added information about when in the breast cancer diagnosis and treatment process genetic counseling was useful, and emphasized that this booklet was targeted to patients who already had a breast cancer diagnosis