

Effect of Genetic Counseling and Testing for *BRCA1* and *BRCA2* Mutations in African American Women: A Randomized Trial

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Key Words

African American · *BRCA1* · *BRCA2* · Cultural factors · Genetic counseling

Abstract

Background: Limited empirical data are available on the effects of genetic counseling and testing among African American women. **Objective:** To evaluate the effects of genetic counseling and testing in African American women based on different levels of exposure: (a) women who were randomized to culturally tailored (CTGC) and standard genetic counseling (SGC) to women who declined randomization (non-randomized group), (b) participants and non-participants in genetic counseling, and (c) *BRCA1* and *BRCA2* (*BRCA1/2*) test result acceptors and decliners. **Design:** Randomized trial of genetic counseling conducted from February 2003 to November 2006. **Measures:** We evaluated changes in perceived risk of developing breast cancer and cancer worry. **Results:** Women randomized to CTGC and SGC did not differ in terms of changes in risk perception and cancer worry compared to decliners. However, counseling participants had a significantly greater likelihood of reporting reductions in perceived risk compared to non-participants ($p = 0.03$). Test result acceptors also had a significantly greater likelihood of reporting decreases in cancer worry ($p =$

0.03). However, having a cancer history ($p = 0.03$) and a *BRCA1/2* prior probability ($p = 0.04$) were associated with increases in cancer worry. **Conclusions:** Although CTGC did not lead to significant improvements in perceived risk or psychological functioning, African American women may benefit from genetic counseling and testing. Continued efforts should be made to increase access to genetic counseling and testing among African American women at increased risk for hereditary disease. But, follow-up support may be needed for women who have a personal history of cancer and those with a greater prior probability of having a *BRCA1/2* mutation.

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It is estimated that about 16–28% of African American women who have a personal or family history of breast and/or ovarian cancer that is suggestive of hereditary disease carry a *BRCA1* or *BRCA2* (*BRCA1/2*) mutation [1–3]. Because of the excess rates of breast cancer morbidity and mortality among African American women [4] and the similarities between hereditary disease and breast cancer in this population [5], efforts are now focused on increas-

Trial registration: www.clinicaltrials.gov (registration #NCT00419510).

ing access to genetic counseling and testing in this population [6]. Recent research has shown that uptake of genetic counseling and testing is variable among African Americans [6–8]. However, regardless of whether women choose to receive *BRCA1/2* test results, participation in genetic counseling may be beneficial to African American women because of the attention given to psychological issues and provision of personalized risk information.

To our knowledge, only a single observational study has evaluated the impact of genetic counseling and testing among African Americans who were members of one *BRCA1* kindred [9]. This study, which provided participants with culturally targeted education materials, found that receiving *BRCA1* test results did not lead to adverse psychological functioning. Specifically, intrusive thoughts about cancer and attempts to avoid cancer-related thoughts and feelings did not change significantly among African American women following disclosure of positive *BRCA1* test results and non-carriers reported significant declines in distress [9].

Increasingly, cultural factors are being recognized as being important to decisions about cancer prevention and control. Prior studies have shown that cultural beliefs and values such as temporal orientation, or the extent to which individuals are more focused on past, present, or future concerns and outcomes [10], are important to attitudes about and participation in genetic counseling and testing for *BRCA1/2* mutations [11, 12]. For this reason, culturally tailored interventions, or protocols in which beliefs and values related to temporal orientation and other cultural factors are targeted through written or verbal strategies, are being developed and evaluated [13, 14]. In our previous work, culturally tailored genetic counseling (CTGC) was not associated with increased uptake of *BRCA1/2* test results among African American women [7]; however, women who received CTGC were more likely than those who received standard counseling to report that the counselor lessened their worries [15]. This finding suggests that CTGC may have greater psychological benefits relative to standard protocols. Therefore, we evaluated the effects of CTGC and standard genetic counseling (SGC) on psychological outcomes among African American women in a randomized trial. While informed decision-making is the primary outcome of genetic counseling, perceived risk and cancer-related distress are also important outcomes of genetic counseling and testing, because they influence cancer screening behaviors [16, 17]. Since limited empirical data are not available on whether or not African American women derive any benefit from genetic counseling, we also compared

changes in psychological outcomes between women who completed genetic counseling and those who declined, regardless of randomization. To expand our knowledge on the impact of *BRCA1/2* testing among African American women, we also determined whether decisions to have genetic testing and receive results had a significant independent association with changes in psychological functioning.

Methods

Study Participants

The study was approved by the Institutional Review Board at the University of Pennsylvania. Participants were adult women who self-identified as being African American and/or Black and who had a minimum 5% prior probability of having a *BRCA1/2* mutation. Participants were recruited into the study between February 2003 and November 2006. It should be noted that some women ($n = 28$) had previously participated in an epidemiological study designed to identify genetic risk factors for breast cancer; however, genetic counseling, clinical testing, and test results were not provided to women as part of the epidemiological study.

Procedures

Detailed information about the study procedures has been provided previously [6] and is summarized here. Eligible women were invited to participate in the study following referral from clinical and community oncology resources. Verbal consent for enrollment was obtained using a structured consent script. In a small number of cases, more than one person from a family was enrolled in the study; however, this occurred in less than 10% of families and the average number of individuals per family was one. After enrollment, the baseline interview was completed. At the end of the interview, women were invited to participate in genetic counseling. Those who accepted the invitation were randomized to CTGC or SGC. We used a computer-based randomization program to assign women to counseling interventions. Women from the same family were assigned to the same counseling group.

Following randomization, women were scheduled for an individual genetic counseling session. Genetic counseling was provided at no cost to all participants. All sessions were completed at the University of Pennsylvania using semi-structured counseling protocols (see Interventions) after obtaining written informed consent. SGC lasted about 90 min and CTGC lasted about 90–120 min. At the end of counseling, women were given an opportunity to provide a blood sample for genetic testing. Those who were interested in testing met with a medical oncologist to discuss new medical issues and were offered a clinical breast examination. Possible test result outcomes and the risks and benefits of genetic testing were reviewed by the medical oncologist. At the end of this appointment, women who were interested in testing provided written informed consent and gave a blood sample. Genetic testing was provided at no cost to women with a $\geq 10\%$ prior probability of having a *BRCA1/2* mutation; for women with a 5–9% prior probability, these costs were submitted

for payment by the participant's insurance company. When test results became available, a test results disclosure session was scheduled.

During this session, *BRCA1/2* test results were provided by the genetic counselor and medical oncologist after obtaining written informed consent. Women were also given information about their risk of developing cancer, individualized guidelines for surveillance and prevention, and risk of having a *BRCA1/2* mutation among family members. Regardless of test result and randomization to CTGC or SGC, all women received a written report that included an interpretation of their *BRCA1/2* test result and guidelines for medical management. Women were also contacted by the study genetic counselor approximately 2 weeks following the disclosure session to answer any additional questions and to provide referrals for surveillance and prevention options, if needed. All participants were contacted 1 month after disclosure or the date that counseling, testing, and/or results were declined for a follow-up telephone interview to re-assess psychological functioning.

Interventions

The CTGC and SGC protocols have been described in detail elsewhere [7, 15]. Both protocols were semi-structured and included visual aids. All genetic counseling sessions were conducted by a board-certified genetic counselor, who was white. Adherence to the protocols was monitored by reviewing audio tapes of selected sessions and documenting the issues that were addressed during SGC and CTGC. SGC consisted of education about hereditary breast and ovarian cancer, the process of genetic testing for *BRCA1/2* mutations, and interpretation of genetic test results. Information about cancer risks associated with *BRCA1/2* mutations and the probability of having a *BRCA1/2* mutation was provided to women as part of the SGC protocol. Women also received information about the benefits, limitations, and risks of genetic testing. Information about the unique aspects of breast cancer in African American women was also provided to women as part of the SGC protocol.

The educational information provided as part of SGC was also given to women randomized to CTGC. CTGC differed from SGC in that cultural beliefs and values related to health care decision-making were addressed. Consistent with guidelines for culturally competent genetic counseling [18, 19], the CTGC protocol incorporated discussion of beliefs and values related to spirituality and religion, temporal orientation, and communalism, which have been associated with decisions about genetic testing, medical care, and risk perceptions among African American women [20–22]. Specifically, a genogram and structured probes were used in the CTGC protocol to encourage women to discuss how these beliefs and values would be used to make decisions about genetic testing and cope with testing outcomes.

Measures

Sociodemographics. Age, income, marital status, education and employment status were obtained during the baseline telephone interview.

Clinical Factors. Clinical factors included personal history of breast and/or ovarian cancer, prior probability of having a *BRCA1/2* mutation and family history of disease. Personal and family history of cancer was obtained by self-report. We used risk estimation models (e.g. BRCAPro) and mutation prevalence tables to estimate each woman's probability of having a *BRCA1/2* muta-

tion (5–9% or $\geq 10\%$) [23]. Women were also categorized as having 2 or more or fewer than 2 affected relatives based on the total number of family members diagnosed with breast and/or ovarian cancer.

Genetic Counseling and Testing Variables. Genetic counseling and testing variables included: (a) randomization to genetic counseling protocols, (b) participation in genetic counseling, and (c) *BRCA1/2* testing decisions. For randomization to genetic counseling interventions, we compared women who were randomized to CTGC or SGC. Since many African American women may decline participation in genetic counseling following randomization [6, 7], or may decline to be randomized, those who declined randomization were included in the comparison of CTGC and SGC as a non-randomized control group. For participation in genetic counseling, women who completed pre-test counseling (regardless of randomization) were categorized as participants. Women who declined the invitation for genetic counseling and those who did not complete counseling after randomization were categorized as non-participants in the analysis of participation in genetic counseling. For *BRCA1/2* testing decisions, women who participated in pre-test genetic counseling, provided a blood sample for testing and received genetic test results were categorized as test result acceptors. Test result decliners included women who declined to participate in pre-test counseling, those who participated in pre-test counseling but declined to provide a blood sample for testing, and women who declined to receive test results after participating in pre-test counseling and providing a blood sample for testing.

Perceived Risk. We used a validated Likert style item to evaluate breast cancer risk perceptions [22, 24]. Specifically, women were asked what their chances of getting breast cancer were compared to other women their age (1 = much lower to 5 = much higher). As in previous reports [25], women who reported that both breasts were removed at baseline were excluded from the analysis of risk perceptions. Thus, the sample size for the perceived risk analysis is slightly lower than for other analyses.

Cancer Worry. We used the Breast Cancer Worry Scale to evaluate psychological functioning [26]. This is a 3-item Likert style scale that evaluates the extent to which women thought about their chances of developing breast cancer and how much these thoughts affected their mood and ability to perform their daily activities. This scale had acceptable internal consistency in this sample (Cronbach's alpha = 0.72).

Statistical Analysis

The trial initially called for enrollment of 360 women; for reasons of feasibility, this was reduced to 180 women. The initial design provided 80% power to detect differences between the randomized groups of about 20% in test acceptance, and about one standard deviation in cancer worry; the revised design provided 80% power to detect differences of about 30% in test acceptance and 1.5 standard deviations in cancer worry. Our power to detect changes in risk perception and psychological functioning for our comparisons between women who were randomized to CTGC and SGC and those in the non-randomized control group was necessarily reduced due to the relatively small size of the non-randomized group; here we had about 80% power to detect differences of approximately 2 standard deviations.

First, we generated descriptive statistics to characterize the study sample in terms of sociodemographic factors and clinical characteristics. We then conducted χ^2 tests of association to deter-

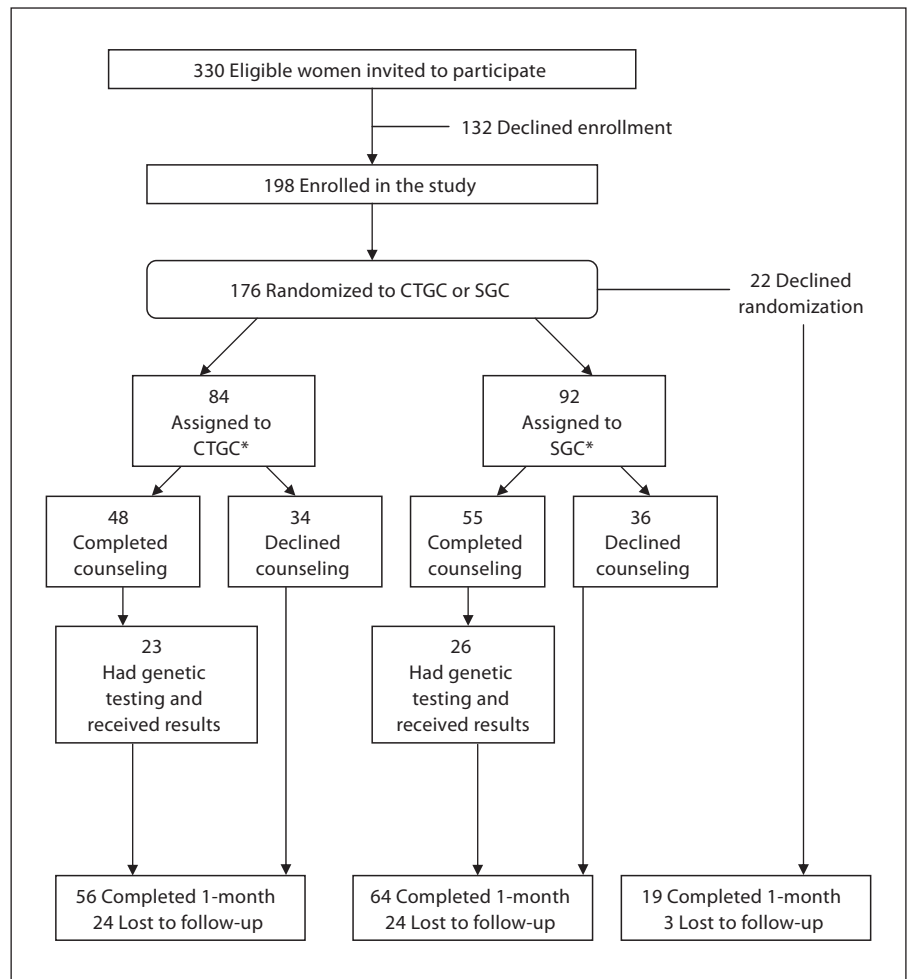


Fig. 1. Study participation. *Women who were pending completion of counseling (n = 3) or the 1-month follow-up (n = 4), and those who became ineligible for the follow-up (n = 1) were excluded from the analysis. The final sample included 56 women assigned to CTGC, 64 assigned to SGC, and 19 non-randomized decliners who were retained in the study.

mine if counseling groups were unbalanced with respect to these characteristics and to identify factors that were associated with participation in genetic counseling and retention in the follow-up telephone interview. Bivariate analyses were also conducted to evaluate the relationship between sociodemographic and clinical factors and baseline levels of study outcomes. Next, we used ordered logistic regression analysis to evaluate the effects of randomization to CTGC and SGC on perceived risk and psychological functioning. For these analyses, change scores between baseline and 1 month follow-up were calculated and were grouped into categories that roughly balanced the distributions for both measures. This resulted in 6 categories for changes in cancer worry (decrease of 3 or more units, decrease of 2 units, decrease of one unit, no change, increase of one unit, increase of 2 or more units) and 4 categories for change in perceived risk (decrease of 2 or more units, decrease of one unit, no change, increase of one or more units). For both measures, positive values indicated an increase in the outcome while negative values indicated a decrease. Variables that were associated significantly ($p < 0.05$) with randomization, participation in genetic counseling and study retention were included in each of the regression models as controlling factors. Sociodemo-

graphic and clinical factors associated with baseline levels of study outcomes were included in the regression models if they were significant predictive factors or if they caused confounding, assessed as $>10\%$ change in other estimated odds ratios in the models.

Results

Enrollment Rates and Sample Characteristics

A total of 330 eligible women were invited to participate and 198 (60%) enrolled in the study (fig. 1). Of the women who enrolled in the study, 176 accepted the invitation to participate in genetic counseling and were randomized to CTGC and SGC. With the exception of education and income, women who accepted the invitation for genetic counseling did not differ from those who declined in terms of sociodemographic or clinical characteristics. Women with household incomes greater than

USD 35,000 were most likely to agree to randomization ($\chi^2 = 4.14$, $p = 0.04$) as were those with greater education ($\chi^2 = 21.8$, $p = 0.001$). There were no differences in sociodemographic or clinical characteristics between women who were randomized to CTGC or SGC; however, women who had previously participated in the epidemiological study were most likely to have been assigned to SGC ($\chi^2 = 7.43$, $p = 0.01$). With respect to participation in genetic counseling among women who were randomized to CTGC or SGC, those with a $\geq 10\%$ prior probability of having a *BRCA1/2* mutation were most likely to complete counseling ($\chi^2 = 10.44$, $p = 0.001$) as were women who had a personal history of cancer ($\chi^2 = 4.59$, $p = 0.03$). No other sociodemographic or clinical factors were associated significantly with participating in genetic counseling.

Among women who were eligible for the 1-month follow-up telephone interview ($n = 190$), 73% were retained. Only being unemployed was associated significantly with being lost to follow-up ($\chi^2 = 10.02$, $p = 0.002$). There were no differences in retention between women who were randomized to CTGC or SGC ($\chi^2 = 0.15$, $p = 0.70$) and those who agreed to randomization and women who declined ($\chi^2 = 2.21$, $p = 0.14$). The sample included in this analysis included 139 women (56 women randomized to CTGC, 64 randomized to SGC, and 19 non-randomized decliners) who were retained in the study.

Table 1 shows the characteristics of the study sample and figure 1 shows the number of women who were randomized to CTGC and SGC and participated in genetic counseling and testing. Among women who had genetic testing, 7 were mutation carriers (17%), 28 were *BRCA1/2*-negative (67%), and 7 (17%) had variants of uncertain significance. Marital status (Kruskal-Wallis $\chi^2 = 3.88$, $p = 0.05$), education (Kruskal-Wallis $\chi^2 = 6.75$, $p = 0.01$), and income (Kruskal-Wallis $\chi^2 = 5.15$, $p = 0.02$) were associated significantly with risk perception at baseline. Marital status (Kruskal-Wallis $\chi^2 = 5.93$, $p = 0.01$), age (Kruskal-Wallis $\chi^2 = 13.48$, $p = 0.0002$), *BRCA1/2* prior probability (Kruskal-Wallis $\chi^2 = 6.86$, $p = 0.01$), family history of cancer (Kruskal-Wallis $\chi^2 = 4.03$, $p = 0.05$), and randomization to CTGC or SGC (Kruskal-Wallis $\chi^2 = 6.0$, $p = 0.05$) were also associated significantly with cancer worry at baseline.

Effect of Genetic Counseling and Testing Decisions on Risk Perception

The results of the regression analyses for changes in risk perception are shown in table 2. There were no differences in changes in risk perception between women who were randomized to CTGC and SGC and those

Table 1. Sample characteristics ($n = 139$)

Variable	Level	n (%)
Age	≤ 50	82 (59%)
	> 50	57 (41%)
Marital status	unmarried	97 (70%)
	married	42 (30%)
Education level	\geq some college	97 (70%)
	\leq high school	42 (30%)
Employment status	employed	95 (68%)
	unemployed	44 (32%)
Income*	$< 35,000$ USD	71 (51%)
	$> 35,000$ USD	67 (49%)
Insurance status	yes	134 (96%)
	no	5 (4%)
Cancer history	affected	96 (69%)
	unaffected	43 (31%)
Family history of cancer	2 or more relatives	88 (63%)
	less than 2 relatives	51 (37%)
<i>BRCA1/2</i> prior probability	$\geq 10\%$	78 (56%)
	5–9%	61 (44%)
Genetic counseling	participants	79 (57%)
	non-participants	60 (43%)
<i>BRCA1/2</i> testing decisions	accept	42 (30%)
	decline	97 (70%)

* One participant was missing data for income.

in the non-randomized group. These results were confirmed in analyses that evaluated changes in risk perception between participants in CTGC and SGC, genetic counseling non-participants, and those in the non-randomized group (likelihood ratio test [LRT] = 5.14, $p = 0.16$). There were also no differences in changes in risk perception between participants in CTGC and SGC (LRT = 0.07, $p = 0.79$) and *BRCA1/2* testing decisions did not have a significant effect on changes in risk perception (table 2). However, regardless of the type of genetic counseling, participation had a significant effect on changes in risk perception. Counseling participants had a significantly greater likelihood of reporting decreases in perceived risk of developing breast cancer compared to non-participants. We repeated these analyses excluding women who had a bilateral mastectomy at follow-up and the results were unchanged (data not shown).

Table 2. Effect of genetic counseling and testing decisions on risk perception

Variable	Level	Comparisons					
		Intention-to-treat: CTGC vs non-randomized control (a) SGC vs non-randomized control (b)		Participation in genetic counseling: participants vs non-participants		Testing decisions: accept vs decline	
		OR	95% CI	OR	95% CI	OR	95% CI
Study group	+	0.47 (a) 0.55 (b)	0.16, 1.41 0.18, 1.73	0.45	0.22, 0.92*	0.46	0.20, 1.05‡
Education level	≥ some college ≤ high school	1.26	0.56, 2.86	1.16	0.54, 2.47	1.16	0.54, 2.48
Employment status	employed unemployed	1.07	0.52, 2.20	1.10	0.53, 2.29	1.01	0.49, 2.08
Cancer history	affected unaffected	0.82	0.38, 1.78	0.91	0.42, 1.97	0.95	0.44, 2.07
<i>BRCA1/2</i> prior probability	≥10% 5–9%	1.34	0.65, 2.72	1.24	0.61, 2.54	1.11	0.52, 2.38
Prior study participation	yes no	1.32	0.50, 3.48	1.30	0.51, 3.35	1.42	0.57, 3.66

+ Comparisons are described above. ** $p < 0.01$, * $p < 0.05$, ‡ $p < 0.10$.

Table 3. Effect of genetic counseling and testing decisions on psychological functioning

Variable	Level	Comparisons					
		Intention-to-treat: CTGC vs non-randomized control (a) SGC vs non-randomized control (b)		Participation in genetic counseling: participants vs non-participants		Testing decision: accept vs decline	
		OR	95% CI	OR	95% CI	OR	95% CI
Study group	+	0.46 (a) 0.39 (b)	0.17, 1.23 0.14, 1.08‡	0.65	0.35, 1.23	0.44	0.21, 0.93*
Education level	≥ some college ≤ high school	0.87	0.42, 1.81	0.71	0.37, 1.40	0.72	0.36, 1.40
Employment status	employed unemployed	1.12	0.58, 2.18	1.11	0.57, 2.15	0.97	0.50, 1.90
Cancer history	affected unaffected	1.86	0.89, 3.88	2.06	0.99, 4.30*	2.27	1.08, 4.77*
<i>BRCA1/2</i> prior probability	≥10% 5–9%	2.45	1.24, 4.85**	2.55	1.29, 5.03**	2.23	1.11, 4.47*
Prior study participation	yes no	1.28	0.51, 3.21	1.45	0.60, 3.53	1.61	0.66, 3.89

+ Comparisons are described above. ** $p < 0.01$, * $p < 0.05$, ‡ $p < 0.10$.

Effect of Genetic Counseling and BRCA1/2 Testing Decisions on Psychological Functioning

Table 3 shows the results of the regression analyses for psychological functioning. There were no changes in cancer worry among women who were randomized to CTGC and SGC compared to those in the non-randomized decliner group. In analyses that compared women in the non-randomized group to participants in CTGC or SGC and non-participants who declined following randomization, the effect of SGC was significant (OR = 0.31, 95% CI = 0.11, 0.90, $p = 0.03$). This result should be interpreted with caution since the overall effect of study groups was not significant (LRT = 5.14, $p = 0.16$) and participation in genetic counseling did not have a significant effect on changes in psychological functioning (table 3). However, test result acceptors had a significantly greater likelihood of reporting decreases in cancer worry compared to test result decliners. Women who had a personal history of cancer and those with a $\geq 10\%$ prior probability also had a significantly greater likelihood of reporting increases in cancer worry compared to unaffected women and those who had a lower prior probability. Cancer history and *BRCA1/2* prior probability had significant effects on changes in functioning when the comparison was counseling participants versus non-participants as well as test result acceptors versus decliners (table 3). We repeated these analyses excluding women who were diagnosed with a cancer recurrence and the results were unchanged (data not shown).

Discussion

Despite significant efforts, breast cancer morbidity and mortality continues to be substantially greater in African American women compared to women from other ethnic and racial groups [4]. Genetic counseling and testing for *BRCA1/2* mutations is a strategy for providing women with information about their risk of developing breast cancer and addressing concerns about disease [27, 28]. To our knowledge, this is the first randomized trial to evaluate the effects of CTGC and SGC on psychological outcomes among African American women at increased risk for having a *BRCA1/2* mutation.

Although culturally competent interventions are hypothesized to improve health outcomes in ethnic and racial minorities [29, 30], CTGC did not lead to significant changes in perceived risk or psychological functioning in the present study. This finding is consistent with a recent study which found that culturally tailored information

about cancer screening and dietary behaviors was not more effective than a combined intervention that addressed both behavioral and cultural factors in improving mammography utilization and fruit and vegetable intake among African American women [13]. A possible explanation for our finding is that the individualized nature of genetic counseling is sufficient to address the needs of African American women. However, our previous work has shown that immediately after pre-test counseling, African American women who received CTGC were significantly more likely to report that the counselor lessened their worries compared to those who received SGC [15]. It could be that women derive greater benefits from CTGC, but these effects are diminished as women move from pre-test counseling to making testing. This may explain why receipt of *BRCA1/2* test results was associated with significant changes in cancer worry. Another possible explanation is that CTGC is more effective for women who hold certain beliefs and values (e.g. greater religiosity, temporal orientation). Future studies should evaluate whether the effects of CTGC are moderated by women's cultural beliefs and values.

We found that counseling participants were most likely to report reductions in perceived risk whereas women who received *BRCA1/2* test results were most likely to report reductions in cancer worries compared to decliners. It is possible that decreases in cancer worry were observed among test result acceptors because the information provided during pre-test counseling was reinforced by the medical oncologist and genetic counselor during subsequent visits. However, an equally plausible explanation is that cancer worries were reduced as a result of receiving *BRCA1/2* test results. A recent study found that depressive symptoms and anxiety decreased significantly following test result disclosure in both mutation carriers and non-carriers who were members of African American *BRCA1* kindred [9]. Because test results were highly correlated with *BRCA1/2* testing decisions, we did not evaluate the effects of receiving positive, negative, or inconclusive *BRCA1/2* test results on cancer worry. However, previous research has shown that uncertainty is reduced following genetic testing among African Americans regardless whether the results are positive or negative [31].

While reduction in cancer worry is clearly a benefit of genetic testing, it is important to consider whether reduction in perceived risk following genetic counseling is beneficial to African American women, especially in light of previous research which has shown that African American women with a personal and/or family history of

breast cancer may not recognize that they have an increased risk of developing disease [22, 32]. Greater perceived risk has been positively associated with utilization of cancer screening and risk reduction options among women in the general population [16] and those from hereditary cancer families [17], respectively. Since African American women may not feel vulnerable to developing breast cancer before genetic counseling and testing [22, 32], further reductions in perceived risk may not be beneficial. On the other hand, African American women are likely to base their risk perceptions on subjective factors such as worries about affected family members [32] and thoughts about past experiences [22]; thus, reductions in perceived risk may be an indication that genetic counseling is an effective strategy for addressing these concerns. Nevertheless, participation in genetic counseling alone may not be sufficient to improve psychological functioning among African American women; there was no difference in changes in cancer worry between counseling participants and non-participants. Further, women who had a personal history of cancer and those who had a greater prior probability of having a *BRCA1/2* mutation were likely to experience increases in cancer worry.

In considering the results of this study, some limitations should be noted. First, our findings are generalizable to African American women who are recruited from clinical and community resources. Other potential limitations may be that we did not evaluate the effects of *BRCA1/2* test results on changes in study outcomes because of the small number of women who received genetic test results. Also, we compared the effects of CTGC

and SGC to a non-randomized control group. This decision was based on ethical concerns surrounding randomizing women to a non-intervention or wait-list control group. By including a non-randomized control group, we were able to compare the effects of CTGC and SGC to no counseling in addition to evaluating the effects of 2 alternate forms of genetic counseling. This approach, along with comparing counseling participants versus non-participants and test result acceptors versus decliners, allowed us to conduct a comprehensive evaluation of all aspects of genetic counseling and testing for *BRCA1/2* mutations in a population that is under-represented in cancer prevention and control research. While the beneficial effect of genetic counseling in the absence of testing is less clear, our findings support continuing efforts to increase access to genetic counseling and testing among African American women. But, additional follow-up may be needed for women who have a personal history of cancer and those who have a 10% or greater prior probability of having a *BRCA1/2* mutation to address worries about developing cancer.

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