Published in final edited form as:

Psychooncology. 2018 December ; 27(12): 2778–2785. doi:10.1002/pon.4887.

Psychosocial Impact of *BRCA* Testing in Young Black Breast Cancer Survivors

Brian D. Gonzalez, PhD¹, Aasha I. Hoogland, PhD^{1,2}, Monica L. Kasting, PhD¹, Deborah Cragun, PhD², Jongphil Kim, PhD¹, Kimlin Ashing, PhD³, Cheryl L. Holt, PhD⁴, Chanita Halbert Hughes, PhD⁵, Tuya Pal, MD⁶, and Susan T. Vadaparampil, PhD¹

¹Moffitt Cancer Center, Tampa, FL, USA

²University of South Florida, Tampa, FL, USA

³City of Hope, Duarte, CA, USA

⁴University of Maryland, College Park, MD, USA

⁵Medical University of South Carolina, Charleston, SC, USA

⁶Vanderbilt-Ingram Cancer Center, Nashville, TN, USA

Abstract

Objective: Prior studies demonstrating minimal psychological consequences for women receiving genetic counseling/genetic testing (GC/GT) for hereditary breast and ovarian cancer rely on predominantly Caucasian women. We conducted a prospective follow-up of a subset of participants from a population-based study of Black breast cancer (BC) survivors receiving GC/GT for *BRCA1* and *BRCA2* mutations.

Methods: Black women with invasive BC at age 50 years diagnosed between 2009–2012 were recruited through the Florida Cancer Registry. Participants (n=215, age $M=44.7$, $SD=6.2$) were offered telephone pre- and post-test GC; a subset completed questionnaires assessing sociodemographic, clinical, and psychosocial variables.

Results: There were no baseline differences in cancer related distress, psychological distress, or quality of life between test result groups. Social well-being improved in women receiving negative results ($p=.01$), but no other outcomes demonstrated significant changes over time between groups.

Corresponding Author: Susan Vadaparampil, 12902 Magnolia Drive, MFC-CRISP, Tampa, FL 33612, Telephone: 813-745-1997, Fax: 813-449-8020, susan.vadaparampil@moffitt.org.

Author Contributions

Brian Gonzalez: Conceptualization, formal analysis, writing – original draft, writing – review and editing. Aasha Hoogland: Formal analysis, writing – original draft, writing – review and editing. Monica Kasting: Formal analysis, writing – original draft, writing – review and editing. Deborah Cragun: Data curation, writing – review and editing. Jongphil Kim: Data curation, formal analysis, writing – review and editing. Kimlin Ashing: Writing – original draft, writing – review and editing. Cheryl Holt: Writing – original draft, writing – review and editing. Chanita Hughes Halbert: Formal analysis, writing – original draft, writing – review and editing. Tuya Pal: Conceptualization, data curation, formal analysis, writing – original draft, writing – review and editing. Susan Vadaparampil: Conceptualization, data curation, formal analysis, writing – original draft, writing – review and editing. All authors have given final approval and agree to be accountable for all aspects of the work.

Conflict of Interest

Authors Hoogland, Kasting, Cragun, Kim, Ashing, Holt, Hughes Halbert, Pal, and Vadaparampil declare they have no conflict of interest. Author Gonzalez has a grant from the National Cancer Institute.

Conclusions: Our study is among the first to demonstrate minimal negative psychosocial outcomes following GC/GT among young Black BC survivors, irrespective of test results.

Keywords

anxiety; Black; breast cancer survivor; cancer; distress; genetic counseling; genetic testing; health disparities; oncology; psychosocial outcomes

Background

Mutations in the *BRCA1* and *BRCA2* (*BRCA*) genes have been implicated in hereditary breast and ovarian cancers, with *BRCA* mutations accounting for an estimated 5–10% of all breast cancer patients and ~15% of all early onset breast cancers.¹ Black women have a higher incidence of both early onset (e.g., prior to age 50) and triple negative breast cancer compared to Caucasian women.² Importantly, both of these characteristics are associated with inherited *BRCA* mutations, which may contribute to the disproportionate burden of early onset breast cancer among Black women.² Research by our group³ and others⁴ supports the use of personal and family cancer history to identify Black women at risk for carrying a *BRCA* mutation.

Despite readily available referral criteria that has been available for well over a decade and important cancer risk management implications,⁵ Black women, particularly breast cancer patients, are less likely to access genetic counseling (GC) and genetic testing (GT) services compared to women from other racial/ethnic groups.^{6,7} This may be due to racial disparities in cost as a barrier to GC/GT,⁸ access to GC/GT,⁹ knowledge about genetics of breast cancer,¹⁰ concern over potential genetic discrimination,¹¹ and potential for feelings of guilt over having passed the mutation to one's children.¹² However, studies done by our group demonstrate that culturally-based recruitment and counseling protocols, free/low cost genetics services, telephone-based GC, and community engagement can produce high uptake of GC and GT among Black women.^{3,13–19} Current data support the clinical utility of *BRCA* GT through reduction in cancer morbidity and mortality among carriers who engage in risk reduction strategies.²⁰

However, some concern remains over the potential psychosocial impact of GC/GT. In the context of GC, increased perception of genetic risk has been associated with greater psychological distress. With regards to GT, a meta-analysis conducted in 2004 found no effects of GT on anxiety or cancer-specific worry,²¹ but a later systematic review found that patients receiving positive results (i.e., a deleterious mutation was identified) reported increases in psychological distress within the first six months after GT that resolved by 12 months.²²

The psychological impact of GT among Black women remains unknown. Although prior studies demonstrate minimal adverse psychological consequences among women participating in face-to-face or telephone based GC/GT, findings are based on predominantly Caucasian women and/or those of high socioeconomic status.^{22–25} One recent study found Black patients reported greater psychological distress after GT than non-Hispanic White patients; however, this study included only a small sample of Black patients with a personal

history of cancer.²⁶ Additional information on the impact of GC/GT among Black women may help inform interventions to reduce health disparities in quality of life and psychosocial outcomes. To fill this gap in our understanding of the impact of GC/GT, we report on the short term and intermediate psychosocial impact of *BRCA* GT among a population-based sample of Black breast cancer survivors diagnosed at or below age 50. We hypothesized that quality of life (primary outcome) and psychological distress would not be significantly impacted by GC/GT. We also sought to explore whether Black women would report worse quality of life than a previously-published sample²⁷ of women receiving treatment for breast cancer.

Methods

Sample

Participants were recruited as part of a larger study examining changes in behavioral, psychological, and social health outcomes after GC/GT. This study focused on the psychosocial impact of GC/GT, a secondary outcome in this study. Recruitment methods and participation are detailed elsewhere and are briefly described here.^{3,28} Eligible participants were self-identified Black women who were: 1) living in Florida when diagnosed with early onset invasive BC (i.e., diagnosed at or below age 50) between 2009–2012, 2) alive at the time of recruitment, and 3) English speaking. Recruitment was initiated upon approval from the University of South Florida (MCC14817) and the Florida Department of Health (DOH H11168) Institutional Review Boards. The Florida Cancer Data System (FCDS) released patient contact information and available clinical and sociodemographic information on all eligible participants and de-identified information on deceased Black women diagnosed with BC between 2009–2012. The lag time between diagnosis and availability of contact information from FCDS ranged from 6–18 months.

Patients were approached using state-mandated recruitment methods of 2 mailings, 3 weeks apart, including a telephone response card giving women the option to decline or express interest in participation. If no response was received within 3 weeks of the second mailing, a study team member telephoned the participant. In those willing to participate, written informed consent was obtained via mail. Study participation included completion of a medical records release, pre- and post-test telephone-based GC, and saliva sample collection for DNA extraction, and completion of study questionnaires at baseline as well as 1 month and 12 months post-results disclosure.

Genetic testing included full gene sequencing and comprehensive rearrangement testing (MLPA) of the *BRCA1* and *BRCA2* genes.²⁹ All *BRCA* alterations were evaluated through available clinical and research data, however a variant was classified as pathogenic if there were several lines of evidence confirming its pathogenicity through the multi-factorial model.³⁰ All variants were searched in the literature and through the publicly available Breast Cancer Information Core (BIC) database.³¹

Of the 1,647 Black women with BC in FCDS who qualified for the parent study, we were able to establish contact with 882. Of these, 480 consented to participate (54%). Given our focus on the psychosocial impact of genetic counseling and testing, we limited analyses to

the 215 participants who did not have previous GC and/or GT at the time of study enrollment and received GT results after testing in the current study. Of those 215 participants, 164 (76.3%) completed a questionnaire at 1 month post-results disclosure and 149 (69.3%) completed a questionnaire at 1 year post-results disclosure.

Demographic characteristics.—Participants reported their age, relationship status, education, income, and insurance status.

Cancer-related medical factors.—Factors extracted from FCDS data included: hormone receptor status, age at diagnosis, time since diagnosis, type of surgery, and adjuvant therapy, with information supplemented through review of medical records where necessary.

BRCA Mutation Status.—Results were classified as ‘positive’ if a deleterious mutation was identified, negative if a deleterious mutation was not identified, and as a VUS if a change in the *BRCA1* or *BRCA2* gene was detected, yet the conferred cancer risk resulting from that change is unknown.

Health Related Quality of Life (HRQOL).—HRQOL was assessed with the Functional Assessment of Cancer Treatment-Breast (FACT-B) which is a 37-item measure assessing multidimensional HRQOL in breast cancer patients.³² The FACT-B includes subscales to assess: physical, social/family, emotional, and functional well-being as well as the Breast cancer scale. Respondents indicated how true each statement had been for them in the previous 7 days on a 5-point scale (0=not at all, 4=very much). The total score was calculated by summing all five subscale scores.

Psychosocial Outcomes.—Anxiety and Depression were assessed using the 14-item Hospital Anxiety and Depression Scale (HADS),³³ which evaluated participant anxiety (7-items) and depression (7-items) on an ordinal scale of 0–3, with 3 indicating higher symptom frequencies.

Cancer Related Distress was measured using the Intrusion subscale of the 15-item Impact of Event Scale (IES).³⁴ This scale assessed current, subjective distress related to the breast cancer diagnosis over the last 7 days.

Statistical Analyses

Descriptive statistics were first calculated for demographic and clinical factors. Chi-square tests and analyses of variance were conducted to identify differences between participants who received negative, positive, or VUS results on demographic and clinical factors. We planned to include any covariates that significantly varied between groups in multivariate analyses comparing groups on HRQOL and psychological distress. Main effects and group-by-time interactions were used to examine group differences on quality of life and distress outcomes at baseline and group differences in change over time in these outcomes. These analyses were conducted using linear mixed models with random intercepts using PROC MIXED in SAS (version 9.4; SAS Institute Inc., Cary, North Carolina). One important benefit of linear mixed models is that these analyses allow for the use of all available data at

each assessment without the need for excluding participants with missing data or imputing missing data.^{35,36}

Power Analysis

A post-hoc power analysis was conducted to determine whether the sample sizes obtained in this study were sufficient to detect a clinically significant difference between groups in change over time in overall quality of life. This power analysis was conducted using PASS version 16.0.1 (Kaysville, UT) modeling a mixed model test for the slope difference in a 2-level hierarchical design with fixed slopes. The power analysis determined the power of the sample sizes we obtained to detect differences in change from baseline to 12 months of at least a minimal clinically important difference on the primary outcome (i.e., 8 points on the FACT-G).³⁷ Because this software allows for comparisons between two groups' slopes, but not three groups' slopes, we modeled the ability to compare the slope of the group receiving negative results to the other two groups in separate analyses. With alpha at .05, 3 assessments, a standard deviation in quality of life scores of 21 points,³⁷ and a within-subject correlation of .80 (determined by analyzing obtained data), the sample sizes obtained in this study provided power at .74 and .98 to detect differences in slopes such that groups would differ in quality of life scores by 8 points by the 12-month assessment.

Results

Demographic and Clinical Factors

Sociodemographic and clinical factors are presented in Table 1. Most participants were not partnered, had received some vocational training or college, and earned > \$25,000 per year. On average, participants were 45 years old, had BMI in the obese range, and were diagnosed at age 43, approximately 20 months before participating in this study. Most reported good or better current general health and reported little or no limitations on moderate activity due to their health. Significant variability was not observed between participants with negative, positive, or VUS results on any demographic or clinical factors examined in Table 1 (all $p > .10$). Thus, covariates were not included in analyses comparing groups on quality of life or other psychosocial outcomes.

Quality of Life

Baseline estimated means for the overall sample's quality of life are reported in Table 2. For purposes of comparison, we also present values for a previously-published general sample of women receiving treatment for breast cancer²⁷ as well as published minimal clinically important difference scores³⁷ for each scale. Relative to the comparative sample of women receiving treatment for breast cancer, the worse breast cancer-specific quality of life, physical well-being, functional well-being, and social well-being reported by the Black women in our sample exceeded the minimal clinically important difference scores. Graphic representations illustrating scores by group and changes over time can be seen in Figure 1. Linear mixed model analyses demonstrated that participants with negative, positive, or VUS results did not differ from each other on baseline overall quality of life (Figure 1a), breast cancer-specific quality of life (Figure 1b), emotional well-being (Figure 1c), physical well-being (Figure 1d), functional well-being (Figure 1e), or social well-being (Figure 1f) ($p > .10$).

21). In addition, groups did not differ on change over time in overall quality of life (Figure 1a), breast cancer-specific quality of life (Figure 1b), emotional well-being (Figure 1c), physical well-being (Figure 1d), or functional well-being (Figure 1e) (all $p \geq .12$). However, significant differences in change over time were observed for social well-being (Figure 1f) ($p = .01$). Post-hoc analyses showed that over the 12-month follow-up period, patients who received negative results reported increased ($p = .01$) social well-being, and patients with positive or VUS results reported no change in social well-being.

Psychosocial Outcomes

Graphic representations illustrating scores by group and changes over time can be seen in Figure 2. Baseline estimated means for the overall sample's psychological distress demonstrated subclinical levels of anxiety ($M = 6.86$, $SE = 0.31$) and depression ($M = 6.70$, $SE = 0.21$). Linear mixed model analyses demonstrated no group differences in baseline scores for anxiety (Figure 2a), depression (Figure 2b), or cancer-related distress (Figure 2c) ($p \geq .08$). Similarly, there were also no observed differences between groups for change over time in anxiety (Figure 2a), depression (Figure 2b), or cancer-related distress (Figure 2c) ($p \geq .32$).

Conclusions

Though prior studies suggest that adverse psychological consequences after GT are rare,³⁸ few studies have included representation from Black women. While two prior studies focused on health outcomes of *BRCA* testing in Black women, generalizability is limited. The first study represented 85 members of a single large kindred with a documented *BRCA1* mutation.³⁹ The second study provided important information about the impact of culturally tailored GC; however, only 49 of the 176 Black participants who agreed to be randomized opted to receive GT results and fewer completed a one-month follow-up assessment, making it difficult to evaluate psychosocial outcomes.^{40,41} Thus, the current study is the largest to date reporting on psychosocial outcomes of genetic testing in young, Black breast cancer survivors.

Findings demonstrate that Black women reported significantly lower levels of quality of life before GC/GT than a previously-published general sample of women receiving treatment for breast cancer.²⁷ The difference between quality of life values between the current sample of Black women and the previously published sample of women currently receiving treatment exceeded the cutoff for minimal clinically important differences³⁷ for overall quality of life, breast cancer-specific quality of life, physical well-being, functional well-being, and social well-being. These data are in line with previous research demonstrating that minority cancer patients report lower quality of life than White, non-Hispanic cancer patients.^{42–44}

While GC/GT results were associated with change in social well-being at 12 months, women receiving negative, positive, or VUS results did not differ on change over time in overall quality of life, breast cancer-specific quality of life, or emotional, physical, or functional well-being. These results are in line with previous studies indicating that receipt of GC/GT has limited impact on quality of life.⁴⁵ Given the previous research demonstrating that minority cancer patients report lower quality of life than White, non-Hispanic cancer

patients,^{42–44} the limited impact of GC/GT results on quality of life underscores the urgent need for interventions to improve quality of life among Black cancer survivors.

With respect to psychological distress, participants reported subclinical baseline levels of depressive symptoms, anxiety, and cancer-specific distress. In addition, no group differences were observed for change over time in depressive symptoms, anxiety, and cancer-specific distress. However, the overall sample reported decreased cancer-related distress over the 12 months after receipt of GC/GT results. These data are consistent with studies in the general population showing that while psychological distress remains stable among women receiving positive results, distress *decreases* among women with negative or VUS results. For example, a meta-analysis of GC/GT studies in the general population of women found that after 12 months, distress in women with positive results had returned to baseline levels of distress, but women with negative or VUS results reported markedly decreased distress.⁴⁶ Conversely, a systematic review reported short-term increases in psychological distress after GT among patients receiving positive results.²² It is possible that patients in the current study who received positive results exhibited short-term increases in distress after the 1-month assessment but that their levels of distress had reduced by the time of the 12-month assessment.

Strengths of this study included a relatively high rate of completion of pre- and post-test GT and GC. However, to improve health equity and reduce cancer prevention and control disparities, strategies and policies for increasing accessibility to GC/GT among persons of African Ancestry – especially premenopausal Black women who are at elevated risk for younger age at diagnosis – is urgently needed.

Study Limitations

A limitation of this study is that participants were drawn only from the state of Florida, limiting generalizability. Although the sample represented significant socioeconomic diversity, generalizability to other populations of Black women may be limited. Another limitation is the potential for selection bias in the subset of consented participants who completed psychosocial measures. In addition, the lack of change over time in the psychosocial outcome measures may be partly due to limited sensitivity of the measures used (IES, HADS) to detect changes in distress associated with GC/GT. Researchers in future studies may consider measures designed specifically to assess psychosocial issues related to GC, such as the Psychosocial Aspects of Hereditary Cancer.⁴⁷ Lastly, a post-hoc power analysis determined that the study was sufficiently powered to compare the group receiving negative results to the other two groups in separate analyses; however, the analyses we used in this study compared all three groups to one another in a single analysis. Nonetheless, the very small differences observed between groups on almost all outcomes suggest that even if the groups did differ on change over time, these differences likely do not exceed cutoffs for minimal clinically important differences.

Clinical Implications

Women in this study reported minimal change in quality of life and psychological distress, irrespective of test results. Thus, our study results may indicate the need for interventions to

improve quality of life irrespective of genetic risk among young Black breast cancer survivors. Future studies should also further examine the increases in social well-being reported by women receiving negative results relative to women receiving positive or VUS results. This finding, if replicated, could comprise an important target for intervention to improve overall quality of life and psychological distress after receipt of GT/GC results. For example, interventions could incorporate components of Interpersonal Psychotherapy, an intervention that aims to address problems with interpersonal relationships and could be adapted to address interpersonal issues related to GC/GT.

Acknowledgments

This work was supported by grants from the American Cancer Society: RSG-11-268-01-CPPB (PI: Vadaparampil), the Florida Biomedical Research Program: IBG10-34199 (PI: Pal) and the National Cancer Institute: K01 CA211789 (PI: Gonzalez), P30CA076292 (PI: Sellers) and R25 CA090314 (PI: Brandon).

References

1. Claus EB, Schildkraut JM, Thompson WD, et al.: The genetic attributable risk of breast and ovarian cancer. *Cancer* 77:2318–24, 1996 [PubMed: 8635102]
2. Daly B, Olopade OI: A perfect storm: How tumor biology, genomics, and health care delivery patterns collide to create a racial survival disparity in breast cancer and proposed interventions for change. *CA Cancer J Clin* 65:221–38, 2015 [PubMed: 25960198]
3. Pal T, Bonner D, Cragun D, et al.: A high frequency of BRCA mutations in young black women with breast cancer residing in Florida. *Cancer* 121:4173–80, 2015 [PubMed: 26287763]
4. Kurian AW, McClure LA, John EM, et al.: Second primary breast cancer occurrence according to hormone receptor status. *J Natl Cancer Inst* 101:1058–65, 2009 [PubMed: 19590058]
5. Daly MB, Pilarski R, Berry M, et al.: NCCN Guidelines Insights: Genetic/Familial High-Risk Assessment: Breast and Ovarian, Version 2.2017. *J Natl Compr Canc Netw* 15:9–20, 2017 [PubMed: 28040716]
6. Cragun D, Weidner A, Lewis C, et al.: Racial disparities in BRCA testing and cancer risk management across a population-based sample of young breast cancer survivors. *Cancer*, 2017
7. Levy DE, Byfield SD, Comstock CB, et al.: Underutilization of BRCA1/2 testing to guide breast cancer treatment: Black and Hispanic women particularly at risk. *Genetics in medicine : official journal of the American College of Medical Genetics* 13:349–355, 2011 [PubMed: 21358336]
8. Armstrong K, Micco E, Carney A, et al.: Racial differences in the use of BRCA1/2 testing among women with a family history of breast or ovarian cancer. *Jama* 293:1729–1736, 2005 [PubMed: 15827311]
9. Kolb B, Wallace AM, Hill D, et al.: Disparities in cancer care among racial and ethnic minorities. *Oncology (Williston Park, NY)* 20:1256–61; discussion 1261, 1265, 1268–70, 2006
10. Mai PL, Vadaparampil ST, Breen N, et al.: Awareness of cancer susceptibility genetic testing: the 2000, 2005, and 2010 National Health Interview Surveys. *American journal of preventive medicine* 46:440–448, 2014 [PubMed: 24745633]
11. Zimmerman RK, Tabbarah M, Nowalk MP, et al.: Racial differences in beliefs about genetic screening among patients at inner-city neighborhood health centers. *Journal of the National Medical Association* 98:370, 2006 [PubMed: 16573301]
12. Thompson HS, Valdimarsdottir HB, Duteau-Buck C, et al.: Psychosocial predictors of BRCA counseling and testing decisions among urban African-American women. *Cancer Epidemiology and Prevention Biomarkers* 11:1579–1585, 2002
13. Pal T, Bonner D, Kim J, et al.: Early onset breast cancer in a registry-based sample of African-american women: BRCA mutation prevalence, and other personal and system-level clinical characteristics. *The Breast Journal* 19:189–92, 2013 [PubMed: 23320992]

14. Pal T, Permuth-Wey J, Holtje T, et al.: BRCA1 and BRCA2 mutations in a study of African American breast cancer patients. *Cancer Epidemiol Biomarkers Prev* 13:1794–9, 2004 [PubMed: 15533909]
15. Pal T, Rocchio E, Garcia A, et al.: Recruitment of black women for a study of inherited breast cancer using a cancer registry-based approach. *Genetic testing and molecular biomarkers* 15:69–77, 2011 [PubMed: 21117951]
16. Pal T, Stowe C, Cole A, et al.: Evaluation of phone-based genetic counselling in African American women using culturally tailored visual aids. *Clinical genetics* 78:124–31, 2010 [PubMed: 20662853]
17. Permuth-Wey J, Vadaparampil S, Rumphs A, et al.: Development of a culturally tailored genetic counseling booklet about hereditary breast and ovarian cancer for Black women. *American journal of medical genetics. Part A* 152A:836–45, 2010 [PubMed: 20358592]
18. Vadaparampil ST, Pal T: Updating and refining a study brochure for a cancer registry-based study of BRCA mutations among young African American breast cancer patients: lessons learned. *Journal of Community Genetics* 1:63–71, 2010 [PubMed: 22460206]
19. Vadaparampil ST, Quinn GP, Gjyshi A, et al.: Development of a brochure for increasing awareness of inherited breast cancer in black women. *Genetic testing and molecular biomarkers* 15:59–67, 2011 [PubMed: 21275654]
20. Rebbeck TR, Friebel T, Lynch HT, et al.: Bilateral prophylactic mastectomy reduces breast cancer risk in BRCA1 and BRCA2 mutation carriers: the PROSE Study Group. *J Clin Oncol* 22:1055–62, 2004 [PubMed: 14981104]
21. Braithwaite D, Emery J, Walter F, et al.: Psychological impact of genetic counseling for familial cancer: a systematic review and meta-analysis. *J Natl Cancer Inst* 96:122–33, 2004 [PubMed: 14734702]
22. Ringwald J, Wochnowski C, Bosse K, et al.: Psychological distress, anxiety, and depression of cancer-affected BRCA1/2 mutation carriers: a systematic review. *Journal of genetic counseling* 25:880–891, 2016 [PubMed: 27074860]
23. Hamilton JG, Lobel M, Moyer A: Emotional distress following genetic testing for hereditary breast and ovarian cancer: a meta-analytic review. *Health Psychol* 28:510–8, 2009 [PubMed: 19594276]
24. Schwartz MD, Valdimarsdottir HB, Peshkin BN, et al.: Randomized noninferiority trial of telephone versus in-person genetic counseling for hereditary breast and ovarian cancer. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 32:618–26, 2014 [PubMed: 24449235]
25. Kinney AY, Steffen LE, Brumbach BH, et al.: Randomized Noninferiority Trial of Telephone Delivery of BRCA1/2 Genetic Counseling Compared With In-Person Counseling: 1-Year Follow-Up. *J Clin Oncol* 34:2914–24, 2016 [PubMed: 27325848]
26. Lumish HS, Steinfeld H, Koval C, et al.: Impact of panel gene testing for hereditary breast and ovarian cancer on patients. *Journal of genetic counseling* 26:1116–1129, 2017 [PubMed: 28357778]
27. Fallowfield LJ, Leaity SK, Howell A, et al.: Assessment of quality of life in women undergoing hormonal therapy for breast cancer: Validation of an endocrine symptom subscale for the FACT-B. *Breast cancer research and treatment* 55:187–197, 1999
28. Bonner D, Cragun D, Reynolds M, et al.: Recruitment of a Population-Based Sample of Young Black Women with Breast Cancer through a State Cancer Registry. *Breast J* 22:166–72, 2016 [PubMed: 26661631]
29. Zhang S, Royer R, Li S, et al.: Frequencies of BRCA1 and BRCA2 mutations among 1,342 unselected patients with invasive ovarian cancer. *Gynecol Oncol* 121:353–7, 2011 [PubMed: 21324516]
30. Plon SE, Eccles DM, Easton D, et al.: Sequence variant classification and reporting: recommendations for improving the interpretation of cancer susceptibility genetic test results. *Hum Mutat* 29:1282–91, 2008 [PubMed: 18951446]
31. BIC: Breast Cancer Information Core. Web-site: http://www.nhgri.nih.gov/Intramural_research/Lab_transfer/BIC/, 2015

32. Brady MJ, Cella DF, Mo F, et al.: Reliability and validity of the Functional Assessment of Cancer Therapy-Breast quality-of-life instrument. *J Clin Oncol* 15:974–86, 1997 [PubMed: 9060536]
33. Zigmond AS, Snaith RP: The hospital anxiety and depression scale. *Acta Psychiatr Scand* 67:361–70, 1983 [PubMed: 6880820]
34. Horowitz M, Wilner N, Alvarez W: Impact of Event Scale: a measure of subjective stress. *Psychosom Med* 41:209–18, 1979 [PubMed: 472086]
35. Diggle P: *Analysis of Longitudinal Data* (ed 2nd), Oxford University Press, 2002
36. Singer JD, Willett JB: *Doing data analysis with the multilevel model for change*, Applied longitudinal data analysis: Modeling change and event occurrence, Oxford university press, 2003, pp 75–123
37. Yost KJ, Eton DT: Combining distribution-and anchor-based approaches to determine minimally important differences: the FACIT experience. *Evaluation & the health professions* 28:172–191, 2005 [PubMed: 15851772]
38. Heshka JT, Palleschi C, Howley H, et al.: A systematic review of perceived risks, psychological and behavioral impacts of genetic testing. *Genet Med* 10:19–32, 2008 [PubMed: 18197053]
39. Kinney AY, Bloor LE, Mandal D, et al.: The impact of receiving genetic test results on general and cancer-specific psychologic distress among members of an African-American kindred with a BRCA1 mutation. *Cancer* 104:2508–2516, 2005 [PubMed: 16222692]
40. Halbert CH, Kessler L, Troxel AB, et al.: Effect of Genetic Counseling and Testing for BRCA1 and BRCA2 Mutations in African American Women: A Randomized Trial Public Health Genomics. in press, 2010
41. Halbert CH, Kessler L, Stopfer JE, et al.: Low rates of acceptance of BRCA1 and BRCA2 test results among African American women at increased risk for hereditary breast-ovarian cancer. *Genetics in Medicine* 8:576–582 10.1097/01.gim.0000237719.37908.54, 2006 [PubMed: 16980814]
42. Victorson D, Barocas J, Song J, et al.: Reliability across studies from the functional assessment of cancer therapy-general (FACT-G) and its subscales: a reliability generalization. *Quality of Life Research* 17:1137–1146, 2008 [PubMed: 18841493]
43. Yanez B, Thompson EH, Stanton AL: Quality of life among Latina breast cancer patients: a systematic review of the literature. *Journal of Cancer Survivorship* 5:191–207, 2011 [PubMed: 21274649]
44. Ashing K, George M, Jones V: Health Related Quality of Life and Care Satisfaction Outcomes: Informing Psychosocial Oncology Care among Latina and African-American Young Breast Cancer Survivors. *Psycho-Oncology*, in press
45. Rijnsburger A, Essink-Bot M-L, van Dooren S, et al.: Impact of screening for breast cancer in high-risk women on health-related quality of life. *British journal of cancer* 91:69, 2004 [PubMed: 15199386]
46. Hamilton JG, Lobel M, Moyer A: Emotional distress following genetic testing for hereditary breast and ovarian cancer: a meta-analytic review, American Psychological Association, 2009
47. Eijzenga W, Bleiker EM, Hahn DE, et al.: Psychosocial aspects of hereditary cancer (PAHC) questionnaire: development and testing of a screening questionnaire for use in clinical cancer genetics. *Psycho-Oncology* 23:862–869, 2014 [PubMed: 24443031]

Figure 1a. Total Quality of Life^a **Figure 1b. FACT-B^b** **Figure 1c. Emotional Well-Being^c**

Figure 1a-f.
Quality of Life by *BRCA* Status (N = 215).
Caption for Figure 1a: ^aDid not differ between groups at baseline (p=0.71) or between groups over time (p=0.12).
Caption for Figure 1b: ^bDid not differ between groups at baseline (p=.61) or between groups over time (p=.30).
Caption for Figure 1c: ^cDid not differ between groups at baseline (p=0.99) or between groups over time (p=0.86).

Caption for Figure 1d: ^dDid not differ between groups at baseline ($p=0.79$) or between groups over time ($p=0.85$).

Caption for Figure 1e: ^eDid not differ between groups at baseline ($p=0.21$) or between groups over time ($p=0.66$).

Caption for Figure 1f: ^fDid not differ between groups at baseline ($p=0.88$) but was different between groups over time ($p=0.01$).

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript

Figure 2a-c.

Psychological Distress by *BRCA* Status (N = 215).

Legend for Figure 2a: ^aDid not differ between groups at baseline ($p=0.33$) or between groups over time ($p=0.69$).

Legend for Figure 2b: ^bDid not differ between groups at baseline ($p=0.08$) or between groups over time ($p=0.53$).

Legend for Figure 2c: ^cDid not differ between groups at baseline ($p=0.25$) or between groups over time ($p=0.32$), but decreased over time in the overall sample ($p=.03$).

Table 1

Demographic and clinical characteristics of the sample (N = 215)

	Overall Sample (n=215)	Negative Results (n=128)	Positive Results (n=22)	VUS (n=65)	<i>p</i>
Demographic Characteristics					
Current age (years): <i>M</i> (<i>SD</i>)	44.92 (6.21)	45.06 (5.57)	43.18 (7.12)	45.22 (7.05)	.38
Relationship status (partnered): n (%)	76 (35.35)	44 (34.38)	4 (18.18)	28 (43.08)	.10
Education: n(%)					.76
6th-10th grade	15 (7.04)	7 (5.51)	3 (13.64)	5 (7.81)	
11–12th, GED or equivalent	51 (23.94)	30 (23.62)	4 (18.18)	17 (26.56)	
Vocational or some college	74 (34.74)	43 (33.86)	9 (40.91)	22 (34.38)	
Graduated college or higher	73 (34.27)	47 (37.01)	6 (27.27)	20 (31.25)	
Income: n(%)					.21
<\$15k	53 (26.90)	31 (25.83)	7 (38.89)	15 (25.42)	
\$15k-\$24,999	35 (17.77)	17 (14.17)	2 (11.11)	16 (27.12)	
\$25k-\$49,999	65 (32.99)	42 (35.00)	7 (38.89)	16 (27.12)	
\$50k-\$89,999	33 (16.75)	20 (16.67)	2 (11.11)	11 (18.64)	
\$90k	11 (5.58)	10 (8.33)	0 (0.00)	1 (1.69)	
Insurance status (private): n(%)	90 (46.2)	58 (49.6)	6 (31.6)	2 (44.1)	.32
Cancer-related medical factors					
Age at diagnosis (years): <i>M</i> (<i>SD</i>)	42.72 (6.40)	43.08 (5.53)	40.68 (6.90)	42.71 (7.68)	.27
Time since diagnosis (months): <i>M</i> (<i>SD</i>)	20.20 (10.50)	20.02 (10.14)	19.45 (11.31)	20.78 (11.03)	.84
Type of surgery: n(%)					.49
Lumpectomy	96 (46.15)	54 (43.20)	13 (61.90)	29 (46.77)	
Mastectomy	54 (25.96)	36 (28.80)	3 (14.29)	15 (24.19)	
Bilateral mastectomy	57 (27.40)	35 (28.00)	5 (23.81)	17 (27.42)	
Adjuvant Therapy - radiation: n(%)	137 (63.72)	87 (67.97)	14 (63.64)	36 (55.38)	.23
Adjuvant Therapy - chemotherapy: n(%)	161 (75.59)	100 (78.74)	17 (77.27)	44 (68.75)	.31
Prior hormonal therapy: n(%)	15 (6.98)	9 (7.03)	2 (9.09)	4 (6.15)	.90
Health Status					
Current General Health: n(%)					.70
Poor	8 (3.72)	4 (3.13)	2 (9.09)	2 (3.08)	
Fair	41 (19.07)	21 (16.41)	5 (22.73)	15 (23.08)	
Good	86 (40.00)	54 (42.19)	6 (27.27)	26 (40.00)	
Very Good	52 (24.19)	34 (26.56)	5 (22.73)	13 (20.00)	
Excellent	28 (13.02)	15 (11.72)	4 (18.18)	9 (13.85)	
Health limits moderate activities: n(%)					.59
Yes, limited a lot	96 (44.86)	63 (49.22)	9 (40.91)	24 (37.50)	
Yes, limited a little	65 (30.37)	35 (27.34)	8 (36.36)	22 (34.38)	
No, not limited at all	53 (24.77)	30 (23.44)	5 (22.73)	18 (28.13)	
Current BMI: <i>M</i> (<i>SD</i>)	30.74 (6.63)	30.23 (6.66)	31.52 (5.26)	31.48 (6.99)	.39
Current tobacco use (yes): n(%)	25 (11.63)	13 (10.16)	3 (13.64)	9 (13.85)	.35
Other					

	Overall Sample (n=215)	Negative Results (n=128)	Positive Results (n=22)	VUS (n=65)	<i>p</i>
Perceived risk of cancer recurrence (%)	23.50 (31.36)	25.95 (34.26)	22.75 (32.14)	18.89 (24.20)	.36
Perceived risk of recurrence relative to other women over age 50: n(%)					.60
Lower risk	107 (49.77)	68 (53.13)	12 (54.55)	27 (41.54)	
Same risk	60 (27.91)	33 (25.78)	5 (22.73)	22 (33.85)	
Higher risk	48 (22.33)	27 (21.09)	5 (22.73)	16 (24.62)	

Note. p-values indicate statistical significance of analyses examining whether significant variability between groups was observed for each demographic or clinical factor

Table 2

Estimated means of baseline quality of life outcomes (N = 215)

	Study Participants	Previously Published Sample ²⁷	Minimal Clinically Important Difference ³⁷
	<i>M (SE)</i>	<i>M (SD)</i>	MCID
Overall Quality of Life	93.79 (1.81)	105.8 (20.9)	8
Breast-Specific Quality of Life	19.55 (0.42)	24.1 (6.5)	3
Emotional Well-Being	18.57 (0.33)	16.3 (3.5)	3
Physical Well-Being	19.10 (0.46)	22.1 (5.3)	3
Functional Well-Being	17.49 (0.50)	20.6 (6.4)	3
Social Well-Being	19.04 (0.46)	22.7 (5.2)	3

Note. Means for the (general sample of women) were derived from a previously published sample of women receiving treatment for breast cancer.

²⁷ Minimal clinically important difference (MCID) scores are the *highest* available MCID scores reported in a previously published study.³⁷