Published in final edited form as:

Psychol Health. 2010 April ; 25(4): 401–415. doi:10.1080/08870440802660884.

Enhanced Counseling for Women Undergoing *BRCA*1/2 Testing: Impact on Knowledge and Psychological Distress – Results From a Randomized Clinical Trial

Pagona Roussi,

Aristotle University of Thessaloniki, Psychology Department, Thessaloniki, 54124 United States

Kerry Anne Sherman, PhD,

Macquarie University, Psychology, Sydney, 2109 Australia

Suzanne Miller, Ph.D.,

Fox Chase Cancer Center, Psychosocial and Behavioral Medicine Program, 510 Township Line Road, 3rd Floor, Cheltenham, 19102 United States

Joanne Buzaglo,

Fox Chase Cancer Center, Psychosocial and Behavioral Medicine Program, Philadelphia, 19111 United States

Mary Daly,

Fox Chase Cancer Center, Philadelphia, 19111 United States

Alan Taylor,

Macquarie University, Department of Psychology, Department of Psychology, Sydney, Australia

Eric Ross, and

Fox Chase Cancer Center, Philadelphia, 19111 United States

Andrew Godwin

Fox Chase Cancer Center, Philadelphia, United States

Suzanne Miller: suzanne.miller@fccc.edu

Abstract

This randomized controlled trial evaluated the impact of an enhanced counseling intervention on knowledge about the heritability of breast and ovarian cancer and distress, as a function of *BRCA* test result, among high-risk women. Before deciding about whether or not to undergo genetic testing, participants were randomly assigned to the enhanced counseling intervention ($N = 69$), designed to promote cognitive and affective processing of cancer risk information (following the standard individualized counseling session), or to the control condition ($N = 65$), which involved standard individualized counseling followed by a general health information session to control for time and attention. Women in the enhanced counseling group exhibited greater knowledge than women in the control group one week after the intervention. Further, at the affective level, the intervention was found to be most beneficial for women testing positive: specifically one week after test result disclosure, women in the intervention group who tested positive experienced lower levels of distress than women in the control group who tested positive. The findings suggest that the design of counseling aids should include a component that explicitly activates the individual's cognitive-affective processing system.

Keywords

Genetic testing; enhanced counseling; intrusive ideation; breast cancer; ovarian cancer

The availability of genetic tests for *BRCA1/2* mutations has not only made it possible to identify individuals at high risk for breast and ovarian cancer, but also now offers the promise of providing medical prevention and risk reduction options for eligible individuals (Daly, 1999). At the same time, the challenge for the individual is to make informed decisions about available risk reduction strategies while processing uncertain and unfamiliar outcomes. Being faced with a high level of new and complex information can potentially increase the likelihood of adverse psychological reactions following testing feedback (Hopwood, 2005; Meiser, 2005). This is particularly the case for women who receive either true positive test results, where a known deleterious mutation is detected; or uninformative test results, where a deleterious mutation is not detected and a mutation in the family has not been identified as yet (indeterminate test results), or when a mutation is detected but the clinical significance is not yet known (inconclusive test results). Indeed, studies that use instruments designed specifically to assess cancer- and genetic-testing related distress generally show that women who test positive experience higher distress following test result disclosure than women who test negative (Hamann, Somers, Smith, Inslicht, & Baum, 2005; Meiser et al., 2002; Schwartz et al., 2002; van Dijk et al., 2006; van Roosmalen et al., 2004c; Watson et al., 2004; Wood, Mullineaux, Rahm, Fairclough, & Wenzel, 2000).

Women receiving an uninformative test result are an under-researched group and the few studies that have been conducted show inconsistent findings (Bish et al., 2002; Claes et al., 2004; Hallowell et al., 2002; Schwartz et al., 2002; van Dijk et al., 2006). For example, although two studies found no differences in levels of distress between those receiving a positive test result and those receiving an uninformative test result among women diagnosed with breast and/or ovarian cancer (affected women) (Claes et al., 2004; Schwartz et al., 2002), other studies have indicated that some women misinterpret an uninformative test result as negative (i.e., they believe that the incidences of cancer in their family do not have a genetic basis) and thus experience relief after genetic testing feedback (Hallowell et al., 2002). The present study used a randomized controlled trial to explore the impact of an enhanced counseling intervention on the psychological sequelae following feedback of a positive or an uninformative genetic test result.

Standard pre-testing genetic counseling generally involves assessment of the individual's genetic risk and the provision of personalized information regarding risk; presentation of the benefits, limitations, and risks of genetic testing; and information regarding the meaning of the test result and the options available for surveillance and risk reduction (Wang, Gonzalez, & Merajver, 2004). In addition, the genetic counselor continues to provide clarification and support with further decision making throughout the pre and post testing process. Although the evidence is limited, standard genetic counseling has been shown successful in increasing knowledge about cancer genetics (Braithwaite, Emery, Walter, Prevast, & Sutton, 2004; Meiser & Halliday, 2002; Miller, McDaniel, Rolland, & Feetham, 2006). Further, the results regarding the effects of standard counseling on cancer-specific distress are mixed, in that several studies have shown short-term reductions in affective outcomes (Braithwaite et al., 2004).

Recent work has attempted to augment the impact of standard genetic counseling through the use of decision aids, which are designed to help patients make informed choices that are consistent with their personal values (O'Connor, Legare, & Stacey, 2003). The main focus of existing decisional aid interventions in the *BRCA1/2* context has been on providing education about cancer and heredity, as well as the consequences of genetic testing, and facilitating

decision making around risk management options (Green et al., 2004; Skinner et al., 2002; van Roosmalen et al., 2004a, 2004b; Wang, Gonzalez, Milliron, Strecher, & Merajver, 2005). Most of the available studies have explored the *pre-disclosure* impact of these interventions on cognitive and affective outcomes (Green et al., 2004; Skinner et al., 2002; van Roosmalen et al., 2004a; Wang et al., 2005). The findings show that decision aids, combined with standard genetic counseling for *BRCA1/2* testing, have a positive impact on knowledge and risk accuracy, assessed prior to the receipt of a test result (Green et al., 2004; Skinner et al., 2002; van Roosmalen et al., 2004a; Wang et al., 2005). In addition, one study showed that an educational aid (a CDROM computer program on cancer and genetics, including information on managing risk) had a positive impact on pre-disclosure worry (Wang et al., 2005).

Missing from these studies are interventions that focus on improving affective, as well as cognitive outcomes, immediately after receipt of the genetic test result, when the women are most vulnerable. In the present study, we examined the cognitive *and* affective *post-result* impact of an enhanced counseling intervention, implemented after standard genetic counseling but before undergoing genetic testing. The intervention was specifically designed to help women *psychologically* prepare for genetic testing feedback. The impact of the enhanced counseling intervention was compared to standard counseling followed by a general health information session, designed to provide generic health information to equate for time and attention.

This study was guided by the Cognitive-Social Health Information Processing (C-SHIP) model, which posits that individuals are characterized by a relatively stable structure of cognitions and affects that are activated in the processing of health-threatening information although the individual is not necessarily aware of their own processing biases (Miller, Shoda, & Hurley, 1996). These structures guide how individuals attend to health relevant information and how they ultimately experience specific affects, such as distress (Diefenbach et al., 2007; Miller et al., 1996; Shoda et al., 1998). From this perspective, individuals who have the opportunity to process health threatening information in depth, both cognitively and affectively, ultimately experience less interfering negative affect and thus should be better prepared to act on and cope with the health challenge (Shoda et al., 1998). Further, we have identified two characteristic cognitive-affective signature styles for processing health threats: high monitoring, which involves attention to and scanning for threatening cues; and low monitoring, which involves distraction from and minimization of threat-relevant cues (Miller, 1995). Because monitoring has been found to predict cognitive and affective responses to medically-related stressors it was included in our study as a covariate (Loader, Shields, & Rowley, 2004; Miller, Fleisher et al., 2005; Williams-Piehot, Pizarro, Schneider, Mowad, & Salovey, 2005).

To explore these issues, we designed and evaluated an enhanced counseling “cognitive-affective processing” procedure for women at putative hereditary risk for breast and/or ovarian cancer (Shoda et al., 1998). The goal was to help women anticipate, and take stock of, their potential thoughts and feelings about the possible outcomes following testing, so that they would be psychologically better prepared to deal strategically with the test result they ultimately received. We hypothesized that: 1) women who received the enhanced counseling intervention would be more knowledgeable about genetic testing compared to women in the control group, both one week after the intervention, as well as one-week after receipt of the genetic test result, since they had had the opportunity to process the information provided to them in greater depth; 2) women who received the enhanced counseling intervention would experience less risk-related intrusive ideation and less cancer-related worry, one-week after receipt of the genetic test result, compared to women in the control group. Further, this effect should be more pronounced for women who tested positive, since they would be better psychologically prepared to make needed decisions. A secondary aim of the study was to

explore differences in levels of intrusive ideation and cancer-related worry among women who tested positive, compared to those who receive an uninformative test result.

Method

Procedure

Women were recruited from the Family Risk Assessment Program (FRAP), organized by Fox Chase Cancer Center (FCCC), during their first self-initiated telephone contact. Recruitment occurred between May 1998 and October 2000. In order to be eligible for the study, women had to be at least 21 years of age and have a family history consistent with a putative hereditary pattern of breast and/or ovarian cancer. Women who agreed to participate were randomly assigned to the enhanced counseling group or the general health information control group according to a computer generated randomization list. The code identifying whether a participant received the enhanced counseling or the general health intervention was revealed to the researchers who had contact with the participants only after recruitment, data collection, and analyses were complete. Group assignment was completed by the data management team, distinct from the research team that enrolled the women and collected the data. Following the initial contact call, women who consented to participate were mailed a packet of questionnaires and were asked to return the completed packet during their first visit to FRAP (one week later). FRAP services involve an initial Standard Cancer Education group session (education on risk for breast and ovarian cancer, factors contributing to elevated risk, hereditary patterns, general screening recommendations, and available preventive options), followed two weeks later by an individual counseling session. The purpose of the genetic counseling session was to review and expand on the family pedigree; identify potential hereditary patterns of cancer; and discuss the potential limitations, benefits and risks of genetic testing. Immediately following the individual counseling session, women participated either in the cognitive affective preparation protocol (Enhanced Counseling; EC), or in a General Health Information (GHI) control session.

Participants were then given the option of whether or not they wished to donate blood for genetic testing. They could also choose to donate blood for a national registry, without being notified of the results. The test results were received on average 34 weeks later ($M = 34.43$, $SD = 16.41$). The waiting period for the receipt of test results was long because of the technical time required (three to six months) to complete the testing process at the time. Further, upon the availability of test results, it often took several weeks before the participant could arrange to meet with the counselor to receive the results.

Prior to receiving the test result, participants received a 30 minute pre-disclosure session, at which time the genetic counselor reviewed the issues previously discussed in the pretesting individual counseling session. A disclosure session was conducted subsequently, where the decision to receive the test result was reconfirmed, the test result was communicated, and its implications regarding risk-reduction and surveillance behaviors were discussed. Participants received a positive, a negative, or an uninformative test result. In this study, in the uninformative category were also included four women who received an incomplete test result, three of which were in the control group and one in the enhanced counseling group. This test result was given when only one of the two *BRCA* genes was sequenced and the result was negative; these cases could be regarded as receiving partially uninformative results. Therefore, of the 118 women in the study classified as receiving uninformative results, the overwhelming majority received truly uninformative results.

Participants were assessed at baseline (i.e., one week after their first self-initiated telephone contact), one week after enhanced or standard counseling, and one week after disclosure of the test result. The present study is part of a larger research effort that was conducted with women at risk for breast and/or ovarian cancer (e.g., Miller, Roussi et al., 2005). The background

variables (sociodemographics, cancer history, trait anxiety, and attentional style) and the outcome variables (knowledge, intrusive ideation, and cancer-related worry) were all assessed at baseline. Among the outcome variables, knowledge was re-assessed one week after the intervention and one-week following disclosure of the test result; intrusive ideation and cancer-related worry levels were re-assessed one-week following disclosure of the test results (see Figure 1 for the measures used at each timepoint). The study was approved by the Institutional Review Board at FCCC.

It was determined that a sample size of $N = 135$ was necessary in order to detect an effect size of .25 with at least 80% power and a 5% type I error rate for the outcome measures. One hundred and fifty seven women consented to participate in the study and were randomized to one of the two intervention groups. Of those, one hundred and forty two (90%) opted to donate blood and receive a test result. Only three women received a negative test result. In order to receive this result, another family member must have already been tested and found to be positive; thus, the person testing true negative needs to be at least the second person in the family to be tested. Since this study was conducted when genetic testing was relatively new, there were very few families who had already been systematically tested and for whom genetic test results were known. Due to the small number of women who tested negative, the present study focused on the impact of the intervention on women who opted to be tested and received a positive or an uninformative test result. For five women, information regarding breast and ovarian cancer history was not available and thus these women were excluded from the study, leaving a sample of $N = 134$ women (see Figure 2 for participant flow).

Intervention and control groups—Immediately following the initial standard genetic counseling session, women in the enhanced counseling intervention met for 45 minutes with a Health Educator. The goal of the enhanced intervention was to encourage participants to systematically “pre-live” the possible testing scenarios and to anticipate their personal reactions to each potential outcome (Shoda et al., 1996). Using a role play format, relevant cognitive-affective reactions were activated by asking the participant to vividly imagine that she had decided to proceed with genetic testing. This role play was performed for three main possible testing outcomes (positive, negative, and uninformative). For each outcome, the woman was asked to anticipate her thoughts and feelings about the specific test result and to imagine the possible consequences of the test result in various aspects of her life (e.g., family, professional). Then, she was guided to engage in preparatory planning, that is to evaluate her possible responses to genetic testing feedback and to review ways of coping, including ways of modulating her distress to the test result.

Women assigned to the control condition received standard genetic counseling followed by a 45- minute general health information session. The session was led by a Health Educator and was designed to control for the extra time and attention provided to EC participants.

Measures

Background variables—Participants were assessed on relevant sociodemographic variables, specifically age, education, marital status, number of children, and ethnic status. Categorical variables (i.e., education, marital status, and ethnic status) were dichotomized for the analyses, based on the distribution of responses. In addition, information regarding personal cancer and family cancer history was collected.

In order to take into account background levels of anxiety on the impact of the intervention, we assessed trait anxiety using the trait version of the State-Trait Anxiety Inventory, a self-report instrument which consists of 20 questions (STAI; Spielberger, Gorsuch, & Lushene, 1983). The STAI is a well validated instrument with excellent internal reliability (Cronbach's alpha for the current sample was 0.92).

Monitoring attentional style was assessed using the Miller Behavioral Style Scale (MBSS; Miller, 1987), which measures coping responses to four structured stress-evoking scenarios (e.g., going to the dentist). The monitoring subscale has been found to have acceptable psychometric properties (Miller, Fleisher et al., 2005; Williams-Piehot et al., 2005). Internal reliability for the sample used in the present study was adequate (Kuder-Richardson = 0.64).

Outcome measures

Knowledge: This scale was designed to measure knowledge regarding the heritability of breast and ovarian cancer and was based on a scale developed by Lerman et al. (1996). It consisted of eight true/false/don't know items. Correct responses received a value of one, whereas false and "don't know" responses received a zero. Reliability for the scale in the present sample was 0.90 (Kuder-Richardson). Improvements were made to the initial version of the knowledge scale after the study began, hence, only a subset of the total sample ($N=82$) completed the updated version at baseline. Only data from the updated version of the knowledge scale were used in the analyses.

Intrusive ideation: Intrusive and avoidant ideation about genetic risk for breast and/or ovarian cancer was assessed using the Impact of Events Scale (IES, Horowitz, Wilner, & Alvarez, 1979). Participants were asked to respond to the items in the context of their increased risk for breast/ovarian cancer. This instrument has been used extensively in the genetic testing literature (Schwartz et al., 2002). Cronbach's alpha for the intrusion subscale in the present study was 0.86. The impact of the intervention on avoidant ideation has been presented in an earlier report (Miller, Roussi et al., 2005).

Cancer-related worry: The cancer-related worry measure was based on a scale developed by Lerman et al. (1991). Using a five-point scale, participants were asked: 1) how worried they were about their own chances of developing breast/ovarian cancer; 2) how often thoughts about their own chances of developing breast/ovarian cancer affected their mood; and 3) how often thoughts about their own chances of developing breast/ovarian cancer affected their daily activities, during the past month. Reliability for the scale was adequate (Cronbach's alpha = 0.68).

Results

The results are discussed as follows: First, we present the participant flow and description. Then, we examine whether the intervention and control groups differed at baseline on any of the background (i.e., cancer history, age, marital status, education, number of children, trait anxiety, monitoring style), or outcome (i.e., intrusive ideation, cancer-related worry, and knowledge) variables. In addition, we examine whether type of result was related to the background variables, as well as to baseline measures of knowledge, intrusive ideation, and cancer-related worry. Where differences were found, the variables were treated as covariates in all subsequent analyses. Second, we explore whether the two groups (intervention vs. control) differed on levels of knowledge one week after the intervention and one week after test result disclosure. Third, we test whether the two groups differed on intrusive ideation and cancer-related worry one week after test result disclosure. Because we wanted to take into account each woman's history of breast and/or ovarian cancer and the time elapsed since her diagnosis, we created a variable (disease status) with three levels: level one for women not affected by breast and/or ovarian cancer (unaffected women), levels two and three for women affected within the past four years and for a minimum of five years, respectively. In order to explore the impact of the intervention on the dependent variables, intent to treat analyses were carried out using the multiple imputation technique, five iterations (Sinharay, Stern, & Russell, 2001; van Buren, Boshuizen, & Knook, 1999), to account for participant dropout. Linear

regression analyses were conducted with type of group (EC/GHI) and test result as the independent variables, statistically accounting for the dependent variable at baseline, as well as for attentional style, education, trait anxiety, and disease status. Two-way interactions were included for type of group, test result, and attentional style. In addition, two-way interactions for type of group by disease status were included. The models were reduced by eliminating non-significant interactions. Each regression was run five times, once for each of the five imputed data sets. The parameter estimates from each of the five sets of results were combined to yield a final result.

Participant Flow and Description

Of the 134 women, 99 (74%) attended the one week post-result follow-up session (see Figure 2). Women who did not show up for the follow-up session either refused to continue to participate in the study or were not reachable. Compared to the women who showed up for the follow-up session, women who dropped out after the intervention session were less knowledgeable about genetic testing at baseline, $t(80) = 2.69, p < .01$. Drop out rates did not differ by intervention group, by disease status or by time elapsed since diagnosis. Because the first version of the knowledge questionnaire used in the study was improved after the study began, only sixty-one percent of the women completed the final version at baseline. Women who completed the final version at baseline did not drop out at a higher rate than those who did not. However, women who did not complete the final version of the knowledge questionnaire at baseline scored lower on trait anxiety, $t(132) = 1.95, p = .05$, and were more likely to be affected, $\chi^2 = 3.86, p = .05$. Background and medical information by intervention group are presented in Table 1 and Table 2, respectively. One woman was diagnosed with cancer during the study. Four women, two in each intervention group, had preventive surgery during the course of the study.

Differences in Background Variables

A series of two-tailed t -tests and χ^2 analyses were performed for continuous and categorical variables, respectively, to identify whether the groups differed on any of the background variables. Group differences were detected for trait anxiety, $t(111) = 2.64, p < .05$, and for educational level, $\chi^2 = 7.04, p < .01$. Women in the EC group were more anxious, $EC: M = 36.43, SD = 10.45$; $GHI: M = 31.27, SD = 10.35$, and less likely to be college educated. Both variables were included in subsequent analyses. The dependent variables did not differ by type of intervention at baseline. None of the background or outcome variables differed by type of test result at baseline. In addition, we tested whether the time elapsed between the intervention and the receipt of the test result was related to the dependent variables. No significant correlations were found.

Intervention Effect on Knowledge Regarding Genetic Testing

Multiple imputation estimates were calculated at both one-week after the intervention and one-week after test result disclosure. At post-intervention, the model was significant (adjusted $R^2 = .22$). A main effect was found for type of group ($t(22) = 2.08, p = .05$); see Table 3 for full regression model. Adjusted means show that women who received the enhanced intervention were more knowledgeable about the heritability of breast and ovarian cancer ($M = 7.68$; 95% $CI: 7.14, 8.22$) than women in the general health information group ($M = 7.00$; 95% $CI: 6.53, 7.47$). No significant effects were found one week after test result disclosure.

Post-Test Result Intervention Effect on Intrusive Ideation and Cancer-related Worry

Multiple imputation estimates were calculated one-week after test result disclosure for both intrusive ideation and cancer-related worry. Regarding intrusive ideation, the model was significant (adjusted $R^2 = .35$). Two main effects were found one for type of group ($t(18) =$

$-2.27, p < .05$) and one for test result ($t(80) = -2.84, p < .01$). In addition, there was a significant interaction effect ($t(35) = 2.15, p < .05$); see Table 4 for full regression model. Specifically, among the women who tested positive, those who received the enhanced counseling experienced lower levels of intrusive ideation one week post-test result than women in the general health information group (see Figure 3). No significant effects were found one week after test result disclosure for cancer-related worry.

Discussion

Based on the C-SHIP model (Miller, Shoda et al., 1996), we predicted that women who received the enhanced counseling intervention, and thus had the opportunity to cognitively and affectively anticipate and plan for genetic testing feedback, would be more knowledgeable about the heritability of breast and ovarian cancer. Consistent with this hypothesis, women who received the enhanced counseling intervention demonstrated greater knowledge of breast and ovarian cancer heritability one week after the intervention. This finding is consistent with prior literature showing that educational decision-aids, combined with standard genetic counseling, improve cognitive outcomes (Green et al., 2004; Skinner et al., 2002; van Roosmalen et al., 2004a; Wang et al., 2005). This effect was not observed after the disclosure of test result, probably because the participants in our study were a highly motivated, educated, self-referred group of women, who could readily access additional information regarding hereditary breast and ovarian cancer during the period between the intervention and the disclosure of test result (Randall, Butow, Kirk, & Tucker, 2001).

We also predicted that women receiving enhanced counseling would experience less risk related distress, particularly in the face of a positive test result. We found that one week after disclosure of the test results, women with a positive mutation status -- who are more likely to show distress upon receipt of the test result -- experienced lower levels of intrusive ideation when they had additionally received the enhanced counseling, as opposed to the standard pre-testing genetic counseling protocol alone (Hamann et al., 2005; Meiser et al., 2002; Schwartz et al., 2002; van Dijk et al., 2006; van Roosmalen et al., 2004c; Watson et al., 2004). The present findings complement those from an earlier report using the same intervention, which showed that facilitating women's processing of genetic testing information led to lower avoidant ideation and more action-oriented decisions following the feedback of results, in terms of increased information seeking and greater probability to undergo preventive surgery (Miller, Roussi et al., 2005).

Contrary to our hypotheses, we observed no significant results regarding the impact of the intervention on cancer-related worry. First, it may be that the three-item measure was not sensitive enough to capture differences between the two groups. This, in part, may reflect the fact that 44% of the sample had already been diagnosed with either breast or ovarian cancer. Although the possibility of cancer recurrence or occurrence in the other site exists for diagnosed women, and thus these issues are likely to have retained some level of meaning for the subsample of affected women, the exact items in the cancer worry scale may have been of low salience to these women. Second, worry may be primarily a cognitive process, rather than the commonly-held view that it is an affective process, and thus it may not be an appropriate or pure affective outcome measure in this context (Borkovec & Stoeber, 1998), especially given that our intervention was aimed primarily at helping women deal with the emotions evoked by the genetic testing process.

Finally, one of the aims of the study was to explore whether there were any differences, in terms of affective outcomes, between women who tested positive and women who received an uninformative test result. Our results yielded a disordinal interaction effect between the intervention and the test result on intrusive ideation, that is an interaction effect that is not in

the same direction as the main effects. Although in some cases, main effects can be interpreted even in the presence of an interaction effect, the nature of the interaction in our study does not allow us to draw any definitive conclusions regarding differences between women who tested positive and women who received an uninformative test result (Howell, 1997). We can only speculate that the differences between the two groups of women may not be pronounced enough to be clearly observable over and above the impact of the intervention.

There are certain limitations to this study. First, the generalizability of the results is constrained by such factors as the small sample size, the lack of ethnic variability, the fact that the women were a self-referred group, the low number of negatives, and the inclusion of incomplete test results in the uninformative group. However, the knowledge and affective results are consistent with theory and findings from numerous other studies (Miller et al., 1996). Second, there was an extended time period between the delivery of the intervention and the receipt of the test result receipt. Even so, our results did not vary as a function of the time passed; this aspect of the methodology is therefore unlikely to play a primary role in the main study findings. Third, there was a fairly high dropout rate in this study. We addressed this issue by using intent-to-treat analyses and by relying on the most rigorous multiple imputation technique (Sinharay et al., 2001). Finally, women who were lost to follow-up were less knowledgeable about genetic testing issues. This is an interesting finding and one which suggests that in the future, it may be important to develop strategies to reduce attrition among different -- perhaps more vulnerable -- groups.

This is the first study to examine the impact of an enhanced pre-disclosure intervention on the immediate psychological sequelae (cognitive and affective) of a positive or an uninformative genetic test result. Although preliminary, the findings indicate that the use of an enhanced intervention may be particularly effective for women who test positive in the *BRCA1/2* context. The present results also add to the literature on decision aids and supplemental counseling strategies for high risk women and should have wide applicability to a range of genetic testing and biomarkers feedback (Miller et al., 2006).

References

- Bish A, Sutton S, Jacobs C, Levene S, Ramirez A. No news is (not necessarily) good news: Impact of preliminary results for *BRCA1* mutation searches. *Genetics in Medicine* 2002;4:353–358. [PubMed: 12394348]
- Borkovec TD, Stoeber J. Worry: a cognitive phenomenon intimately linked to affective, physiological and interpersonal behavioral processes. *Cognitive Therapy and Research* 1998;8:561–576.
- Braithwaite D, Emery J, Walter F, Prevast AT, Sutton S. Psychological impact of genetic counseling for familial cancer: A systematic review and meta-analysis. *Journal of the National Cancer Institute* 2004;96(2):122–133. [PubMed: 14734702]
- Claes E, Evers-Kiebooms G, Boogaerts A, Decruyenaere M, Denayer L, Legius E. Diagnostic genetic testing for hereditary breast and ovarian cancer in cancer patients: women's looking back on the pre-test period and a psychological evaluation. *Genetic Testing* 2004;8:13–21. [PubMed: 15140370]
- Daly M. NCCN practice guidelines: Genetics/familial high-risk cancer screening. *Oncology* 1999;13:161–183.
- Diefenbach, MA.; Miller, SM.; Porter, M.; Peters, E.; Stefanek, M.; Leventhal, H. Affect and screening for cancer: A self-regulation perspective. In: Lewis, M.; Haviland, JM., editors. *Handbook of Emotions*. New York, NY: Guilford Press; 2007. p. 645-660.
- Green MJ, Peterson SK, Wagner Baker M, Harper GR, Friedman LC, Rubinstein WS, Mauger DT. Effect of a computer-based decision aid on knowledge, perceptions, and intentions about genetic testing for breast cancer susceptibility. *Journal of the American Medical Association* 2004;292:442–452. [PubMed: 15280342]

- Hallowell N, Foster C, Ardern-Jones A, Eeles R, Murday V, Watson M. Genetic testing for women previously diagnosed with breast/ovarian cancer: examining the impact of BRCA1 and BRCA2 mutation searching. *Genetic Testing* 2002;6:79–87. [PubMed: 12215246]
- Hamann HA, Somers TJ, Smith AW, Inslicht SS, Baum A. Posttraumatic stress associated with cancer history and *BRCA1/2* genetic testing. *Psychosomatic Medicine* 2005;67:766–772. [PubMed: 16204436]
- Hopwood P. Psychosocial aspects of risk communication and mutation testing in familial breast-ovarian cancer. *Current Opinion in Oncology* 2005;17:340–344. [PubMed: 15933464]
- Horowitz M, Wilner N, Alvarez W. Impact of events scale: A measure of subjective stress. *Psychosomatic Medicine* 1979;41:209–218. [PubMed: 472086]
- Howell, DC. *Statistical Methods of Psychology*. 4th edition. Belmont, CA: Wadsworth; 1997.
- Lerman C, Narod S, Schulman K, Hughes C, Gomez-Caminero A, Bonney G, Gold K, Trok B, Main D, Lynch J, Fulmore C, Snyder C, Lemon SJ, Conway T, Tonin P, Lenoir G, Lynch H. BRCA1 testing in families with hereditary breast-ovarian cancer: A prospective study of patient-decision making and outcomes. *Journal of the American Medical Association* 1996;275:1885–1892. [PubMed: 8648868]
- Lerman C, Trok B, Rimer BK, Jepson C, Brody D, Boyce A. Psychological side effects of breast cancer screening. *Health Psychology* 1991;10:259–267. [PubMed: 1915212]
- Loader S, Shields CG, Rowley PT. Impact of genetic testing for breast-ovarian cancer susceptibility. *Genetic Testing* 2004;8:1–12. [PubMed: 15140369]
- Meiser B. Psychological impact of genetic testing for cancer susceptibility: An update of the literature. *Psycho-oncology* 2005;14:1060–1074. [PubMed: 15937976]
- Meiser B, Butow P, Friedlander M, Barratt A, Schnieden V, Watson M, Brown J, Tucker K. Psychological impact of genetic testing in women from high-risk breast cancer families. *European Journal of Cancer* 2002;38:2025–2031. [PubMed: 12376208]
- Meiser B, Halliday JL. What is the impact of genetic counselling in women at increased risk of developing hereditary breast cancer? A meta-analytic review. *Social Science & Medicine* 2002;54:1463–1470. [PubMed: 12061481]
- Miller SM. Monitoring and blunting: Validation of a questionnaire to assess styles of information seeking under threat. *Journal of Personality and Social Psychology* 1987;52:345–353. [PubMed: 3559895]
- Miller SM. Monitoring versus blunting styles of coping with cancer influence the information patients want and need about their disease: Implications for cancer screening and management. *Cancer* 1995;76:167–177. [PubMed: 8625088]
- Miller SM, Fleisher L, Roussi P, Buzaglo JS, Schnoll R, Slater E, Raysor S, Popa-Mabe M. Facilitating informed decision making about breast cancer risk and genetic counseling among women calling the NCI's cancer information service. *Journal of Health Communication* 2005;10:119–136. [PubMed: 16377604]
- Miller, SM.; McDaniel, S.; Rolland, J.; Feetham, S., editors. *Individuals, families and the new era of genetics: Biopsychosocial perspectives*. New York: Norton Publications; 2006.
- Miller SM, Roussi P, Daly MB, Buzaglo JS, Sherman K, Godwin AK, Balshem A, Atchison ME. Enhanced counseling for women undergoing *BRCA1/2* testing: Impact on subsequent decision making about risk reduction behaviors. *Health Education and Behavior* 2005;32:654–667. [PubMed: 16148211]
- Miller SM, Shoda Y, Hurley K. Applying cognitive-social theory to health protective behavior: Breast self-examination in cancer screening. *Psychological Bulletin* 1996;119:70–94. [PubMed: 8559860]
- O'Connor AM, Legare F, Stacey D. Risk communication in practice: the contribution of decision aids. *British Medical Journal* 2003;327:736–740. [PubMed: 14512487]
- Randall J, Butow P, Kirk J, Tucker K. Psychological impact of genetic counselling and testing in women previously diagnosed with breast cancer. *Internal Medicine Journal* 2001;31:397–405. [PubMed: 11584901]
- Schwartz MD, Peshkin BN, Hughes C, Main D, Isaacs C, Lerman C. Impact of BRCA1/BRCA2 mutation testing on psychologic distress in a clinic-based sample. *Journal of Clinical Oncology* 2002;20:514–520. [PubMed: 11786581]

- Shoda Y, Mischel W, Miller S, Diefenbach M, Daly MB, Engstrom PF. Psychological interventions and genetic testing: Facilitating informed decisions about *BRCA1/2* cancer susceptibility. *Journal of Clinical Psychology in Medical Settings* 1998;5:3–17.
- Sinharay S, Stern HS, Russell D. The use of multiple imputation for the analysis of missing data. *Psychological Methods* 2001;6:317–329. [PubMed: 11778675]
- Skinner CS, Schildkraut JM, Berry D, Calingaert B, Marcom PK, Sugarman J, Winer EP, Iglehart JD, Futreal PA, Rimer BK. Pre-counseling education materials for BRCA testing: does tailoring make a difference? *Genetic Testing* 2002;6:93–105. [PubMed: 12215248]
- Spielberger, CD.; Gorsuch, RL.; Lushene, R. State-Trait Anxiety Inventory for Adults: Sampler Set – Manual, Test, Scoring Key. Palo Alto, CA: Mind Garden; 1983.
- van Buren S, Boshuizen HC, Knook DL. Multiple imputation of missing blood pressure covariates in survival analysis. *Statistics in Medicine* 1999;18:681–694. [PubMed: 10204197]
- van Dijk S, Timmermans DRM, Meijers-Heijboer H, Tibben A, van Asperen CJ, Otten W. Clinical characteristics affect the impact of an uninformative DNA test result: The course of worry and distress experienced by women who apply for genetic testing for breast cancer. *Journal of Clinical Oncology* 2006;24:3672–3677. [PubMed: 16877736]
- van Roosmalen MS, Stalmeier PFM, Verhoef LCG, Hoekstra-Weebers JEHM, Oosterwijk JC, Hoogerbrugge N, Moog U, van Daal WAJ. Randomised trial of decision aid and its timing for women being tested for a *BRCA1/2* mutation. *British Journal of Cancer* 2004a;90:333–342. [PubMed: 14735173]
- van Roosmalen MS, Stalmeier PFM, Verhoef LCG, Hoekstra-Weebers JEHM, Oosterwijk JC, Hoogerbrugge N, Moog U, van Daal WAJ. Randomised trial of a shared decision-making intervention consisting of trade-offs and individualized treatment information for *BRCA1/2* mutation carriers. *Journal of Clinical Oncology* 2004b;22:3293–3301. [PubMed: 15310772]
- van Roosmalen MS, Stalmeier PFM, Verhoef LCG, Hoekstra-Weebers JEHM, Oosterwijk JC, Hoogerbrugge N, Moog U, van Daal WAJ. Impact of *BRCA1/2* testing and disclosure of a positive test result on women affected and unaffected with breast or ovarian cancer. *American Journal of Medical Genetics* 2004c;124A:346–355. [PubMed: 14735581]
- Wang CW, Gonzalez R, Merajver SD. Assessment of genetic testing and related counseling services: Current research and future directions. *Social Science & Medicine* 2004;58:1427–1442. [PubMed: 14759687]
- Wang CW, Gonzalez R, Milliron KJ, Strecher VJ, Merajver SD. Genetic counselling for *BRCA1/2*: A randomized controlled trial of two strategies to facilitate the education and counseling process. *American Journal of Medical Genetics* 2005;134A:66–73. [PubMed: 15690408]
- Watson M, Foster C, Eeles R, Eccles D, Ashley S, Davidson R, Mackay J, Morrison PJ, Hopwood P, Evans DGR. Psychosocial impact of breast/ovarian (*BRCA1/2*) cancer-predictive genetic testing in a UK multi-centre clinical cohort. *British Journal of Cancer* 2004;91:1787–1794. [PubMed: 15505627]
- Williams-Piehota P, Pizarro J, Schneider TR, Mowad L, Salovey P. Matching health messages to monitor-blunter coping styles to motivate screening mammography. *Health Psychology* 2005;24:58–67. [PubMed: 15631563]
- Wood ME, Mullineaux L, Rahm AK, Fairclough D, Wenzel L. Impact of BRCA1 testing on women with cancer: A pilot study. *Genetic Testing* 2000;4:265–272. [PubMed: 11142757]

Figure 1.
Study Assessment Flowchart

Figure 2.
Participant Flowchart

^a GHI: General Health Information group; EC: Enhanced Counseling Group.

Figure 3.
One-week Post-result Intrusive Ideation as a Function of Intervention Group and Test Result
($N = 134$)

Table 1 Background Information by Intervention Group ($N = 134$)

	Control	Enhanced Counseling	Total
	<i>N</i> (%)	<i>N</i> (%)	<i>N</i> (%)
Age, years			
≥ 50	29 (45)	34 (49)	63 (47)
< 50	36 (55)	35 (51)	71 (53)
Education ^a			
$\geq$ College	43 (66)	35 (51)	78 (58)
$<$ College	22 (34)	34 (49)	56 (42)
Marital status			
Married	51 (78)	44 (64)	95 (71)
Single	14 (22)	25 (36)	39 (29)
Ethnicity			
White	62 (95)	68 (99)	130 (97)
Other	3 (5)	1 (1)	4 (3)
Children			
Yes	50 (81)	49 (77)	99 (79)
No	12 (19)	15 (23)	27 (21)

^a $p < .05$.

Table 2 Medical Information by Intervention Group ($N = 134$)

	Control	Enhanced Counseling	Total
	<i>N (%)</i>	<i>N (%)</i>	<i>N (%)</i>
Affected with breast and/or ovarian cancer			
No	38 (58)	37 (54)	75 (56)
Yes	27 (42)	32 (46)	59 (44)
Genetic test result			
Positive	7 (11)	9 (13)	16 (12)
Unaffected	2	3	5
Affected	5	6	11
Uninformative	58 (89)	60 (87)	118 (88)
Unaffected	36	34	70
Affected	22	26	48

Table 3 Final Regression Model for Knowledge ($N = 134$)

Variable	<i>B</i>	<i>SE B</i>	β
Baseline variables			
Knowledge	0.27	0.08	0.40**
Trait anxiety	0.01	0.02	0.05
Attentional style	0.04	0.06	0.08
Education ^a	0.13	0.32	-
Time since diagnosis ^b			
Less than five years	-0.01	0.39	-
Five years or more	-0.54	0.46	-
Post-intervention variables			
Intervention group ^c	0.68	0.33	-.†

Note. Mean R^2 for imputed datasets = .52. Standardized coefficients are not given for indicator variables.

^a College educated women compared to women who have completed high school.

^b Affected women compared to non-affected women.

^c Enhanced counseling intervention compared to the general health education intervention.

† $p = .05$

** $p < .01$.

Table 4 Final Regression Model for Intrusive Ideation ($N = 134$)

Variable	<i>B</i>	<i>SE B</i>	β
Baseline variables			
Intrusive ideation	0.44	0.09	0.49**
Trait anxiety	0.10	0.69	0.15
Attentional style	0.06	0.26	0.02
Education ^a	1.23	1.37	-
Time since diagnosis ^b			
Less than five years	-0.97	1.67	-
Five years or more	0.63	1.97	-
Post-result variables			
Test result ^c	-8.80	3.10	- **
Intervention group ^d	-8.82	3.92	- **
Intervention by test result interaction	8.81	4.11	- *

Note. Mean R^2 for imputed datasets = .63. Standardized coefficients are not given for indicator variables.

^a College educated women compared to women who have completed high school.

^b Affected women compared to non-affected women.

^c Women who tested uninformative compared to women who tested positive.

^d Enhanced counseling intervention compared to the general health education intervention.

* $p < .05$.

** $p < .01$.