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Prophylactic, Risk-Reducing Surgery in Unaffected BRCA-Positive Women: Quality Of Life, Sexual Functioning and Psychological Well-Being

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by

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Dedication

I dedicate this dissertation to my husband, Michael, without whom I surely would have withered away at the computer, seeing neither the light of day nor the light at the end of the tunnel. Thank you for your love, support, and the fried egg sandwiches at my desk.

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Abstract

Women with an inherited BRCA mutation are at significantly increased risk for breast and ovarian cancer, often diagnosed at an earlier age than sporadic cancers. Prophylactic surgery, with bilateral mastectomy and/or bilateral prophylactic salpingo-oophorectomy, represents an option for risk reduction. The purpose of this study was to explore quality of life, sexual functioning, menopausal symptoms, psychological well-being and satisfaction with risk management decisions for BRCA-positive women ages 21 to 50 (M = 38.4 years), without a personal history of cancer. A web-based, cross-sectional study design was utilized to compare women opting for any prophylactic surgery (n = 160) with those without a history of prophylactic surgery (n = 71). Quality of life (per the Quality of Life Index, Self-Anchoring Striving Scale and Body Image Quality of Life measures) and Psychological General Well-Being Index scores were essentially the same across the entire study sample. While controlling for age, prophylactic surgery (PS) predicted more severe symptoms of sexual dysfunction as measured by the Female Sexual Functioning Index (total score, Desire, Arousal, Lubrication and Satisfaction domains). Similarly, PS predicted menopausal symptoms and sleep difficulties. Women who had not undergone any prophylactic surgery had higher levels of Stigma and lower levels of Mastery, as measured by the BRCA Self-Concept scale. Prophylactic surgery also predicted higher levels of Satisfaction with Decision for hereditary cancer risk management. Findings from this exploratory study provide insight into the quality of life, sexual functioning and psychological well-being

for unaffected, BRCA-positive women. Additional research is needed to examine sexual functioning prospectively, to further investigate the potential sequelae of risk-reducing surgery.

Chapter 1

Introduction

During 2011 it is estimated over 230,000 women will be diagnosed with invasive breast cancer and over 21,000 women with ovarian cancer in the United States alone (American Cancer Society, 2011). About 10% of all breast and ovarian cancers are due to hereditary factors (Ferla et al., 2007; Lynch, Silva, Snyder, & Lynch, 2007). Hereditary breast and ovarian cancer (HBOC) is most often attributed to a genetic mutation in either the BRCA1 or BRCA2 gene. Estimates are that deleterious mutations in BRCA account for 30% to 50% of all hereditary breast cancers (Ferla et al., 2007; Lynch, Silva, Snyder & Lynch, 2007) and 80% of all hereditary ovarian cancer cases (Majdak, 2005).

Other inherited mutations inferring an increased risk of breast cancer include PTEN (Cowden disease), ATM (ataxia-telangiectasia mutation), CHEK2, p53 (Li-Fraumeni syndrome) (Smith & Isaacs, 2007) and hereditary diffuse gastric cancer (HDGC) (Pharoah, Guilford, & Caldas, 2001). Hereditary ovarian cancer can be associated with inherited mutations in Hereditary Non-Polyposis Colon Cancer (HNPCC) or Lynch Syndrome (Petrucelli, Daly, & Feldman, 2011).

Genetics

The fundamental unit of heredity is the gene (Clark & Russell, 2000). Genes are found in the nucleus of the cell, and composed of deoxyribonucleic acid (DNA). The DNA is organized in chromosomes of varying size. A chromosome is a very long single

double-stranded DNA molecule made up of many genes and tightly folded until it is about 5 microns in diameter. The chromosomes contain the genes, which have a particular sequence of the A, T, G, or C bases. The sequence of the base pairs provides instructions to the cell for making proteins (Stansfield, Colome & Cano, 2003).

Genetic mutations. An allele is a minor variation in a gene. Human cells have two duplicate sets of 23 different chromosomes, for a total of 46. However, the germ-line cells (egg and sperm cells) contain a single copy of each gene. We receive one allele of each gene from each parent. The wild-type allele is the one most often seen. A mutant allele is the result of a genetic alteration in the sequencing of the A, T, G or C bases of DNA. During gene replication, any error within a DNA molecule leading to the insertion, deletion or substitution of one or more bases will result in a mutation. A somatic or acquired mutation refers to an alteration which is not inherited (Kumar, Abbas & Fausto, 2003).

Hereditary Breast and Ovarian Cancer

Historical accounts of the 18th century document descriptions of breast cancer cases clustered among young, related family members (Cady, 1970; Handley, 1938). Other family pedigrees recorded male breast cancers and descriptions suggestive of ovarian or peritoneal cancers (Everson et al., 1976; Marger, Urdaneta, & Fischer, 1975). Lynch et al. (1984) among others questioned whether a hereditary form of breast cancer existed, one distinctly different from sporadic breast cancers. Epidemiologic studies supported the hypothesis of a familial risk; however, options for further evaluation were limited by technical expertise. Biomarker research was deemed a priority to enhance the identification of those individuals at increased risk (Lynch & Kullander, 1987).

In 1990, Hall et al. conducted a genetic analysis of individuals in 23 Caucasian families with 146 cases of early-onset breast cancer. That research led to the discovery of a specific gene at the q21 position on chromosome 17 associated with an increased susceptibility to inherited breast cancer. The mutation would come to be known as the BRCA1 gene, after further identification of the mutation in families with multiple cases of breast cancer (Miki et al., 1994). Identification of the BRCA2 breast cancer susceptibility gene on chromosome 13 (13q12-q13) followed shortly thereafter (Wooster et al., 1994) and was cloned one year later (Wooster et al., 1995). The BRCA acronym is derived from the words "breast cancer", although the mutation also infers an increased risk of ovarian cancer. In the United States testing is currently performed by only one facility, the Myriad Genetics Laboratories.

The BRCA genes are inherited in an autosomal dominant pattern, and mutations can be inherited from either biological parent. One normal or wild-type allele would be inherited from the parent without a mutation. BRCA1 and 2 are tumor suppressor genes, involved in repair of DNA damage by coding for particular proteins involved in cell-cycle progression, chromatin remodeling, apoptosis and ubiquitylation (Friedenson, 2005; Narod & Foulkes, 2004).

Risk

An inherited, or germline mutation in one allele of either BRCA1 or BRCA2 confers a lifetime breast cancer risk of 70-85% (Lynch, Shaw & Lynch, 2004; Ray, Loescher & Brewer, 2005). A 40-50% lifetime risk of ovarian cancer is associated with the BRCA1 mutation, and a 20-30% risk with the BRCA2 mutation (Russo et al., 2008; King, Marks & Mandell, 2003). This is a significant difference relative to the general

population, with a 12% lifetime risk for breast cancer and 1.4% for ovarian cancer (American Cancer Society, 2011). In addition, BRCA mutations are also associated with an increased risk for melanoma, pancreatic, uterine, gallbladder, bile duct and stomach cancers (Thompson & Easton, 2002; Van Asperen et al., 2005), as well as fallopian tube and primary papillary serous carcinoma of the peritoneum (Aziz et al., 2001; Casey et al., 2005).

Breast and ovarian malignancies typically occur at a younger age in women with a BRCA mutation in comparison to those without a mutation. Indications for a referral to genetic counseling include a personal or family history of early-onset breast cancer (premenopausal or less than age 50), bilateral breast cancer, male breast cancer, Ashkenazi Jewish heritage, and/or ovarian cancer at any age (Allain, 2008; Godfrey & Chlebowski, 2008; USPSTF, 2005).

Risk management. Increased surveillance and risk-reducing strategies are available for individuals at increased risk for hereditary breast and ovarian cancer. Management options include surveillance with regular breast imaging with mammography, breast-dedicated magnetic resonance imaging (MRI) and focused breast ultrasound (Smith & Isaacs, 2007). The goal of these strategies is early detection, rather than primary prevention. Risk reduction with chemoprevention includes oral contraceptive pills, tamoxifen or raloxifene. Prophylactic surgeries, including removal of the breast tissue (mastectomy) and/or removal of the fallopian tubes and ovaries (bilateral salpingo-oophorectomy) are also options recommended to minimize risk of developing a malignancy (Hartmann, et al., 2001; Meijers-Heijbor, et al., 2001; Rebbeck, Kauff & Domcheck, 2009). Current National Comprehensive Cancer Network (NCCN, 2011)

clinical guidelines recommend risk-reducing, bilateral prophylactic mastectomy (BPM) be considered only for women with a BRCA mutation, or other evidence of significant familial cancer risk.

Ovarian cancer is notoriously difficult to detect in the early stages. Ovarian cancer symptoms are typically absent early in the disease process, as are accurate screening tests (Coates, Kolor, Stewart & Richardson, 2008). Consequently, the majority of ovarian malignancies are diagnosed at later stages resulting in a decreased survival rate. For women at increased risk of hereditary breast ovarian cancer, the NCCN clinical guidelines (2011) recommend bilateral prophylactic salpingo-oophorectomy (BPSO) between the ages of 35 and 40, after child bearing, or based on family history considering the earliest age of an ovarian cancer diagnosis.

Uptake of contralateral prophylactic mastectomy in women diagnosed with breast cancer has been estimated at 50% (Schwartz et al., 2008). The rate of BPSO in women with a BRCA mutation (BRCA+) has been similar at 49% (Meijers-Heijboer et al., 2003). A more recent retrospective study at one United States medical center examined medical records for 90 BRCA+ women (Stuckey et al., 2010). Of those, 42% were unaffected. Fifty-three percent of unaffected women, those without a personal history of cancer, chose to have prophylactic surgery (BPM and/or BPSO).

The NCCN guidelines for surveillance in the absence of BPSO recommend regular pelvic ultrasound imaging and CA-125 blood levels, with the understanding of the limitations and low sensitivity of these screening modalities. Decisions regarding the timing of risk-reducing, prophylactic surgeries can play a critical role in disease prevention, morbidity and mortality. Occult malignancies have been detected in women

at the time of elective, risk-reducing surgeries (Khurana, Loosmann, Numann & Khan, 2000; Lamb, Garcia, Goff, Paley & Swisher, 2006; Stuckey et al., 2010).

Significance of Study

Inherited mutations in the BRCA gene dramatically increase the risk of breast and ovarian cancer. Unaffected women, those with a BRCA mutation and no personal history of cancer, face complex and challenging decisions which require accurate, evidence-based information and appropriate psychosocial support. Prophylactic surgical interventions are irreversible. To contribute to our limited knowledge of these psychosocial sequelae of prophylactic, risk-reducing surgeries an exploratory study was conducted.

Purpose and Specific Aims

The purpose of this cross-sectional study was to compare BRCA+ women who have had any prophylactic, risk-reducing surgery with those who have not had any prophylactic surgery. Variables included quality of life, body image quality of life, sexual functioning, menopausal symptoms, psychological well-being, BRCA self-concept and satisfaction with the decision for risk management.

Aim (1). To compare self-reported socio-demographics, quality of life, body image quality of life, sexual functioning, menopausal symptoms, psychological well-being and BRCA self-concept differences between BRCA-positive women electing any prophylactic, risk-reducing surgery and those who have not had prophylactic surgery.

Aim (2). To determine the level of satisfaction with the decision for risk management based on the research participants' choice for prophylactic surgery, chemoprevention, and/or clinical surveillance.

Aim (3). To examine the potential moderating role of prophylactic surgery on the relationships between sexual functioning, psychological well-being, BRCA self-concept, body image quality of life and quality of life.

Theoretical Framework

The schema model of self-concept provided the theoretical framework for this research. Self-schemata are "cognitive generalizations about the self, derived from past experience", providing an organizing framework to process information about the self (Markus, 1977). Some self-conceptions are positive, while others are negative. Some represent the present time, and others characterize past or future experiences. Additionally some self-representations reflect what we could be, the possible future self (Markus & Wurf, 1987). This middle-range theory is based on the cognitive approach to social psychology, encompassing structural and functional components of the self-concept (Stein, 1995). The dynamic self-concept mediates both intrapersonal processes (affect and motivation) and interpersonal processes (social perception and interaction strategy) and the perception/response to one's situation (Markus & Wurf, 1987).

Definitions

Body image. Body image is a complex, multidimensional component of the self image encompassing perceptions and attitudes about one's own body, although not exclusively related to physical appearance (Cash, 2004). The body image schema is conceptualized as a component of the self-concept schemata.

Body image quality of life. Body image quality of life refers to the impact of one's perceptions of self on an individual's psychosocial quality of life. Body image

quality of life is measured by the Body Image Quality of Life Inventory (Cash & Fleming, 2002).

Prophylactic surgery. Prophylactic surgery refers to elective surgical procedures to prevent the occurrence of disease, measured by self-report. Examples of prophylactic surgery include a bilateral prophylactic mastectomy (surgical removal of the breast tissue) with or without breast reconstruction and/or salpingo-oophorectomy (removal of the fallopian tubes and ovaries) with or without a hysterectomy (removal of the uterus) (http://www.merriam-webster.com/medlineplus/prophylactic).

Psychological well-being. Psychological well-being refers to a "sense of subjective well-being or distress" (Revicki, Leidy & Howland, 1996). Six affective states are included: anxiety, depressed mood, positive well-being, self-control, general health and vitality. The Psychological General Well-Being Index was the instrument used to measure well-being in the current study.

Quality of life. Quality of life as defined by Ferrans and Powers (1992) is a "person's sense of well-being that stems from satisfaction or dissatisfaction with the areas of life that are important to him/her" (p. 29). The Quality of Life Index was based on a conceptual model developed from qualitative research.

Satisfaction with decision. Satisfaction refers to the individual participant's level of satisfaction with their health care decision (Holmes-Rovner, et al., 1996), relative to the choice for either prophylactic surgery or surveillance due to an inherited risk of breast and ovarian cancer.

Self-concept. The definition of self-concept is based on the self-schemata conceptualization (Markus, 1977; Markus & Wurf, 1987; Stein, 1995). The self-concept

is a dynamic structure and process, representing a frame of reference about one's self based on past experiences, present views of the self and the possible self-- a sense of what we may become in the future.

Sexual functioning. Sexual functioning was evaluated by the Female Sexual Function Index (FSFI), a self-report measure of desire, subjective arousal, lubrication, orgasm, satisfaction, and pain (Rosen et al., 2000). These domains reflect those currently used for the diagnosis of female sexual dysfunction disorders (Sobczak, 2009).

Unaffected. The term unaffected refers to an "individual who does not manifest any symptoms of a particular condition" (Gene Reviews, n.d.). Individuals with an inherited genetic predisposition to a particular disease state who have not been diagnosed with that disease, are considered unaffected. For example, those individuals at increased risk for hereditary breast and ovarian cancer due to an inherited BRCA mutation without any personal history of cancer are unaffected. This was measured by self-report.

Summary

Inherited mutations in BRCA genes have been characterized as significantly increasing the lifetime risk for breast and ovarian cancer, malignancies which often occur earlier than sporadic cancers. Women with a BRCA mutation who develop cancer are typically diagnosed prior to the age of natural menopause. Prophylactic surgeries and chemoprevention are options for risk reduction, but not without consequences. The challenging decisions related to risk management merit the opportunity for informed consent. Accurate and timely information, counseling related to cancer risk and risk-management options, and psychosocial support are important for the decision-making process. This exploratory study was conducted to contribute to our knowledge of the

quality of life, body image quality of life, sexual functioning, menopausal symptoms, psychological well-being, and satisfaction with risk-management decisions in this high-risk population.

Chapter 2

Literature Review

This chapter of the dissertation provides a review of the literature focused on choices for and outcomes of prophylactic, risk-reducing surgery in women at increased risk for hereditary breast and ovarian cancer (HBOC), most often attributed to a hereditary mutation in the BRCA gene. Research studies were identified by multiple computerized literature searches of the following databases: CINAHL, PsycINFO, PubMed and Cochrane. Keyword combinations included: BRCA, genetic testing, hereditary breast ovarian cancer syndrome, prophylactic mastectomy, oophorectomy, cancer screening, surveillance, risk reduction, body image, sexuality, sexual functioning, intimacy, anxiety, and quality of life. Additional articles were found after review of the studies found in the original database searches.

Risk Reduction

Chemoprevention, or cancer risk reduction using medication, is one option for decreasing the risk of breast and ovarian cancer due to a BRCA mutation. Oral contraceptives, tamoxifen and raloxifene are examples of chemoprevention. Oral contraceptives reduce the risk of gynecologic cancer (fallopian tube and/or ovarian) by 5% for each year of use (Whittemore et al., 2004). Use of oral contraceptives for 6 years or more is associated with an odds-ratio of 0.62. Furthermore, there does not appear to be any increased risk for breast cancer associated with oral contraceptive use. The oral contraceptives may actually reduce breast cancer risk slightly in those with a BRCA-1

mutation (Milne et al., 2005). Tamoxifen and raloxifene are selective estrogen receptor modulators (SERMs), which block estrogen from breast tissue cells. Only limited data are available on the use of these medications for primary prevention of breast cancer in BRCA+ women.

The most profound risk reduction in this population is accomplished by prophylactic surgery, or removal of the tissues at risk for cancer prior to the diagnosis of a malignancy. A meta-analysis of bilateral prophylactic salpingo-oophorectomy (BPSO) in BRCA mutation carriers found a strong association in risk reduction for breast, ovarian and fallopian tube cancers (Rebbeck, Kauff & Domchek, 2009). The meta-analysis of 10 studies found an 80% reduction for gynecologic cancer and a 50% risk reduction for breast cancer.

Bilateral prophylactic mastectomy has demonstrated a significant reduction in risk for breast cancer by other researchers as well (Hartmann et al., 2001; Meijers-Heijboer et al., 2001; Rebbeck, Kauff & Domcheck, 2009). Rebbeck et al. (2004) reported BPM decreased breast cancer risk by 90% in those with intact ovaries, and 95% in women with a previous history of BPSO. Kramer et al. (2005) found BPSO was associated with a 62% reduction in breast cancer risk in BRCA1 carriers ($n = 673$). The most profound benefit was seen in women electing BPSO at premenopause ($HR = 0.38$). Risk reduction was also seen in BRCA1 carriers with BPSO prior to the age of 40 ($OR = 0.36$) by Eisen et al. (2005). When examined together, BRCA1/2 carriers had a significant reduction in risk within 15 years of BPSO ($OR = 0.39$). Kauff et al. (2008) published data from a prospective, multicenter trial enrolling 1,079 unaffected BRCA+ women choosing either observation or BPSO. BPSO in that study was associated with a 72% reduction in

BRCA2-associated breast cancer risk and an 85% reduction in BRCA1-associated gynecologic cancer risk at three years of follow up.

Domchek et al. (2010) reported their findings for a prospective, multi-center cohort study with 2,482 women evaluating risk and mortality reduction in BRCA carriers. Women in 22 centers across North America and Europe were followed from 1974-2009. No breast cancer was seen in unaffected women who opted for BPM, in comparison to a 7% breast cancer incidence in those women without BPM (mean follow up of 3 years). A reduction in risk for ovarian cancer was seen with BPSO. During 6 years of prospective follow up, no ovarian cancer was seen in unaffected BRCA2 carriers. The hazard ratio for ovarian cancer in BRCA1 mutation carriers was 0.31 (95% CI: 0.12, 0.82). Six women (2%) developed a primary peritoneal cancer after risk-reducing BPSO. Seven percent of the BRCA1 positive women and 3% of the BRCA2 positive controls, without BPSO, were diagnosed with ovarian cancer. A risk reduction for breast cancer was also associated with BPSO in BRCA1 (*HR* = 0.63; 95% CI: 0.41-0.96) and BRCA2 positive women (*HR* = 0.36, 95% CI: 0.16-0.82). In addition, a reduction in all-cause mortality was observed in unaffected BRCA mutation carriers with BPSO (*HR* = 0.45, 95% CI: 0.21-0.95).

Predictors for risk-reducing surgery. Why do some women choose prophylactic surgery? Two studies in the Netherlands examined factors predictive for prophylactic surgery in high-risk women (Madalinska et al., 2007; Meijers-Heijboer et al., 2000). Meijers-Heijboer et al. (2000) found parenthood to be a significant predictor for BPM, and age was the only significant predictor for BPSO. Women opting for prophylactic surgery were older than those who did not. In a longitudinal, observational

study of 160 BRCA+ women, predictors for BPSO versus surveillance were age, marriage, and postmenopausal status (Madalinska et al., 2007). Tiller et al. (2002) also found age to be a significant predictor for the 23% of women who opted for BPSO in an Australian study (n =95). In that same study, parity (children versus no children), the number of first and second-degree relatives with ovarian cancer, and breast/ovarian cancer anxiety as measured by the Impact of Event Scale were not significantly predictive.

A retrospective study of 90 women followed in a high-risk clinic in the United States found 51% opted for prophylactic surgery (Stuckey et al., 2010). Those who chose any risk-reducing surgery were more likely to carry a BRCA 2 mutation, had children, were married, employed, and had a personal history of breast cancer. Occult disease was found at the time of prophylactic surgery in that study, including ductal carcinoma in situ of the breast (15%), invasive ductal carcinoma of the breast (8%), adenocarcinoma of the fallopian tube (3%) and ovarian adenocarcinoma (3%).

In an exploratory, retrospective review at a cancer center in the United States, 132 women were found to be BRCA+ (Uyei et al., 2006). Sixty-two percent of a subset of 37 unaffected BRCA+ women chose surveillance over prophylactic surgery. Overall, women who were BRCA+, had a personal history of cancer and diagnosed at an earlier stage of disease were more likely to choose surgery. In a post-test only study design, Metcalfe et al. (2005) examined predictors in unaffected women after BPM (n = 60). Vulnerability and psychological distress, as measured on a study-specific quality of life (QOL) instrument, were determined to be predictors for prophylactic surgery in that group.

A Danish study followed 306 unaffected BRCA+ women prospectively (Skytte et al., 2010). The 10-year uptake for BPSO was 75% and 50% for BPM. No difference was observed between BRCA1 and BRCA2 mutation carriers. Again, age and parity were associated with a decision to undergo prophylactic surgery. Younger women between 30 to 40 years old were more likely to choose BPM, while 90% of those opting for BPSO had children.

A study in the Netherlands offered 163 unaffected BRCA mutation carriers participation in an educational-support group (Landsbergen et al., 2010). Women were then followed prospectively after disclosure of their genetic test results. Forty-eight percent of the women chose to participate in the group. The group participants were more likely to be interested in prophylactic mastectomy (34%) than non-participants (19%; $p = 0.05$) at baseline. Of those with a preference for BPM, the educational-support group participants were more likely to undergo BPM within 2 years (89%), in contrast to the non-participants (63%).

More recently, Schwartz et al. (2011) reported uptake for BPM after BRCA genetic testing was associated with greater cancer distress prior to genetic counseling, higher anxiety levels, a personal diagnosis of breast or ovarian cancer, and intact ovaries prior to genetic counseling ($n = 465$). Predictors for BPSO were a history of breast cancer and age ≥ 40 years.

Quality of Life and Psychological Distress

Genetic testing. A high level of psychological distress was found in French Canadian women ($n = 640$) who underwent BRCA genetic testing in comparison with the general population, regardless of any personal cancer history (Dorval et al., 2008). The

levels of distress were similar to those of women with a newly-diagnosed breast cancer. A longitudinal study of 126 women undergoing genetic testing found no difference in psychological distress between women with or without a cancer diagnosis (Smith et al., 2008). Levels of psychological distress in mutation carriers were diminished by 6 months post-testing. However, 39% of the women in the study had high distress levels at baseline, including depressive and anxious mood.

A Canadian study examined cancer-related distress and risk perception in 2,080 Ashkenazi Jewish women undergoing genetic testing (Metcalfe et al., 2010). At one-year follow up, 1,516 women completed study questionnaires. Cancer-related distress was increased for BRCA+ women as measured by the Impact of Event Scale. The perceived risk of breast cancer increased significantly for those with a BRCA mutation, with a mean of 41.1% (pre-test) and 59.6% (post-test) ($p = 0.002$).

Prophylactic surgery. The Toronto BRCA Self-Concept Scale (Esplen et al., 2009) includes three factors relevant to coping: stigma, vulnerability and mastery. A study of 241 BRCA+ women found cancer-specific anxiety to be low among affected and unaffected women, regardless of a choice for prophylactic mastectomy, oophorectomy or both (Vodermaier, Esplen & Maheu, 2010). Cancer-specific anxiety, assessed by the Impact of Event Scale, was associated with younger age. Lower levels of anxiety were associated with higher levels of self-esteem and mastery.

Overall the limited studies examining QOL in women at risk for HBOC undergoing prophylactic surgery have had inconsistent findings. Research has typically included a heterogeneous population, including affected (diagnosed with cancer) and

unaffected women (without cancer) (Brandberg et al., 2004, 2008; Isern, Tengrup, Loman, Olsson & Ringberg, 2008; Madalinska et al., 2005; Robson et al., 2003).

Bilateral prophylactic mastectomy. A Swedish research study investigated health-related QOL and patient satisfaction in 61 women after BPM with immediate reconstruction; one-half with a prior breast cancer diagnosis (Isern et al., 2008). Genetic testing had been completed for 48 of the 61 study participants, 27 of whom were BRCA+. Instruments included the SF-36, the Hospital Anxiety and Depression scale, and a study-specific questionnaire. Those women without cancer scored higher in the physical function, vitality and social function dimensions.

In a preoperative study examining QOL and BPM in 56 women with a familial risk for breast cancer, 16 had a cancer history (Brandberg et al., 2004). Those without a history of breast cancer were similar in comparison to a normative sample of Swedish women with regard to QOL, anxiety and depressive symptoms. Metcalfe et al. (2005) examined QOL in 59 Canadian women without a history of breast cancer (21.7% BRCA+). The QOL levels were slightly higher than those for the general population and for women with newly diagnosed breast or gynecologic cancers. Metcalfe et al. (2005) also found a positive correlation between QOL and social support in a study of 59 unaffected women; thirteen (21.7%) were BRCA+. Difficulty with emotional adjustment was observed in structured clinical interviews with unaffected women (n = 19) expressing regret after BPM (Payne, Biggs, Tran, Borgen & Massie, 2000).

Prophylactic bilateral salpingo-oophorectomy. A number of studies have evaluated QOL after BPSO. No difference in QOL was seen in high-risk women after BPSO compared with those undergoing gynecologic screening surveillance by

Madalinska et al., 2005. In contrast, Elit et al. (2001) observed menopause-specific QOL was diminished after BPSO in a sample of 40 women. Robson et al. (2003) found women with BPSO between ages 35 and 44 had lower scores than the age-matched general population on physical functioning, bodily pain, general health and the emotional role subscales. Age at the time of BPSO did not affect QOL in a Norwegian study; however, a personal cancer history did (Michelson et al., 2009).

A significant decrease in anxiety regarding ovarian cancer after BPSO was noted in unaffected, high-risk women (n = 120) at three years follow up (Tiller et al., 2002). Forty women with a family history of ovarian cancer opted for risk-reducing BPSO; 40% were BRCA+. Higher levels of psychological distress were reported by those who were premenopausal at the time of surgery.

Sexual Functioning

Human sexual functioning is a complex process under psychoneuroendocrine influence. The classification of sexual dysfunction is based on desire, arousal, orgasm and sexual pain disorders (Basson et al., 2000). The National Health and Social Life survey of American adults (ages 18-59) found sexual dysfunction more prevalent in women (43%), in contrast to men (31%) (Laumann, Paik & Rosen, 1999). A positive association was observed between sexual dysfunction and low physical/emotional satisfaction and low feelings of general happiness. However, the causal order of that relationship was unclear. Similar findings were seen by Davison et al. (2009) in a community-based study of 349 women (55% premenopausal). Those reporting sexual satisfaction also had a higher overall sense of well-being.

Outcomes after surgery. Sexual functioning is a major concern for many women after gynecologic surgery. Findings in research involving otherwise healthy women without a BRCA mutation treated for benign disease have had inconsistent results. One randomized trial found no difference in sexual or psychosocial adjustment among three groups (n =204) treated for dysfunctional uterine bleeding with hysterectomy, hysteroscopy or laser ablation (Alexander et al., 1996). Another prospective study examined sexual functioning before and after hysterectomy for benign disease (n = 1101) (Rhodes et al., 1999). Details regarding the preoperative diagnoses were not provided. The frequency of sexual relations during the month prior to surgery was lower than at the 12 and 24 months postoperative time points. After hysterectomy, vaginal dryness was reported as a persistent problem for 35.2% of the women and a new problem for 8.7%.

The type of gynecologic surgery is another variable for consideration. There was no difference in sexual functioning or quality of life in two groups of women (n = 135) treated for benign disease, randomized to either total hysterectomy or supracervical hysterectomy (Kupperman, 2005). The outcome variable of sexual activity was similar in two groups in another randomized study (n = 177) (Thakar et al., 2002). Satisfaction with sexual life was similar in yet another randomized trial (n = 246) (Gimbel et al., 2003).

Kupperman et al. (2007) found both impaired sexual functioning and diminished quality of life in women with pelvic pain and/or abnormal menstrual bleeding (n = 1,493). Five years after surgery women treated by hysterectomy with BSO (n = 3,397) had more interference in sexual function than those with ovarian conservation

(n = 2,305), while controlling for age and hormone replacement therapy (McPherson et al., 2005).

Women at increased risk for hereditary breast and ovarian cancer. Research evaluating sexual functioning in the high-risk, unaffected BRCA+ population is limited, particularly in the United States. In a single-institution study examining sexual functioning after BPSO in 54 American women, the majority had a personal history of breast cancer (83 %) (Robson et al., 2003). Sexual problems reported included vaginal dryness (58%), difficulty achieving orgasm (48.6%) and lack of arousal (43.2%). In addition, these symptoms were significant predictors for dissatisfaction with the decision to undergo the risk-reducing surgical procedure. Satisfaction with sexual functioning was diminished moderately (42.1%) to extremely (53.7%) after BPSO in a sample of 40 women (Elit et al., 2001).

A breast cancer diagnosis was not an exclusion criterion in a European study that evaluated QOL and sexual functioning after BPSO (Madalinska et al., 2005). Increased discomfort, decreased pleasure, and more endocrine symptoms were seen in the BPSO group (Madalinska, 2005). Both sexual discomfort and diminished libido were more significant in women after BPSO, irrespective of hormone replacement use (Madalinska et al., 2006). Sexual dysfunction, dyspareunia, and diminished pleasure/sexual satisfaction were seen after BPSO (Madalinska et al., 2005; Robson et al., 2003) and after BPM (Brandberg et al., 2008; Metcalfe, Esplen, Goel & Narod, 2004). Vaginal dryness (35.2%) and pain with sex (27.7%) were a problem on average of 23.8 months after BPSO (Robson et al., 2003). Negative effects related to the sexual relationship and feelings of femininity after BPM have also been documented (n = 114) (Bresser et al.,

2006). Moderate-to-extreme sexual functioning symptoms affected 42-53% of women after BPSO (n = 23) including diminished sexual desire, vaginal dryness and intimacy avoidance in a mixed-methods study (Elit, Esplen, Butler & Narod, 2001). Fifteen percent of the women had been treated for breast cancer. Sexual satisfaction was diminished, despite the use of hormone replacement. Participants suggested information related to the potential side effects of surgery was important in the decision-making process prior to surgery. Premenopausal women reported greater psychological distress than those who were postmenopausal at the time of BPSO. Sexual functioning was a significant predictor of satisfaction with the decision to have BPSO, while 34% of women indicated a decline in sexual function after surgery (Robson et al., 2003).

A prospective study examined sexual functioning in two groups: women choosing BPSO (n= 38) and those opting for surveillance (n = 37) (Fang et al., 2009). Women with a personal history of breast cancer were included in both study groups. Individuals in the surgical group reported greater discomfort during sexual intercourse and lower levels of sexual satisfaction; findings were more profound in younger, premenopausal women. Overall QOL was similar for both the surgery and surveillance groups.

High-risk women without any personal history of cancer (n = 168) were followed in a multicenter study (Geiger et al., 2007). Due to an increased risk for breast cancer, 106 underwent BPM and of those 84% chose breast reconstruction. Interestingly, QOL was not associated with prophylactic surgery. However, diminished QOL was correlated with dissatisfaction with sex life for women with or without BPM.

A retrospective study of 98 BRCA+ women post-BPSO found the most common postoperative symptoms were: vaginal dryness (52.1%), changes in libido (50%), sleep disturbances (46.7%), changes in sex life (43.9%), and hot flashes (42.9%) (Campfield, Moyer, & Matloff, 2011). Women with BRCA mutations have concerns about the potential impact of prophylactic surgery on their sexuality and report little preoperative discussion on the topic (Matloff, 2009). Some report feeling guilty about initiating the conversation, considering they should just be grateful they can avoid cancer. The experience "represents an enormous amount of loss---not just future childbearing, but femininity, sexuality. It's like you've got a gun to your head and there is no other option" (Matloff, 2009, p.16).

Body Image

Research evaluating sexual function inevitably must also address the concept of body image. Body image was found to predict sexual satisfaction in an internet-based study of 154 women (Pujols, Meston & Seal, 2010). The instruments used in that research included the Female Sexual Functioning Index (FSFI) and Sexual Satisfaction Scale for Women. Sexual satisfaction was strongly correlated with sexual functioning ($r = 0.59$); the FSFI arousal domain had the strongest association ($r = 0.59$).

Hopwood et al. (2000) evaluated body image in 45 women after BPM, utilizing a combination of psychiatric interviews and written questionnaires. Almost 47% of the women were dissatisfied with their bodies at one year after BPM. Over half of the women felt less sexually attractive and were self-conscious about their appearance.

Lodder et al. (2002) developed a study-specific questionnaire to address these questions. Sixty-three women without a personal history of cancer underwent genetic

testing; 26 were found to be BRCA+. Of the BRCA+ women, 2 had BPM, 12 opted for BPM and BPSO, and the other 12 chose breast surveillance. All 63 women were evaluated prior to testing and at one-year follow up. At the one-year follow up, the BPM group had the highest levels of anxiety (29%) and cancer-related distress. Differences in satisfaction with body image and intimate relationships were seen between the groups, with the lowest levels of satisfaction in the BRCA+ women undergoing BPM. Despite this, the majority were satisfied with their decision to have prophylactic surgery.

Summary

The risk-reducing benefits of prophylactic surgery with BPM and/or BPSO have been documented. However, a review of studies addressing psychosocial factors relative to risk-reducing surgery finds a paucity of research evaluating the long-term implications of prophylactic surgery (Fang, McKenzie, Miller & Daly, 2005). In a systematic review of studies on prophylactic mastectomies, the need for more information on the emotional impact and psychosocial support for women and their partners has been highlighted (Lostumbo, Carbine, Wallace & Ezzo, 2008).

The majority of research to date has not focused on unaffected women at increased risk for hereditary breast and ovarian cancer. Sexual functioning in this high-risk population is relatively unexplored. Women need support and information about the potential risks and benefits of management and risk-reducing options (Babb et al., 2002). Unaffected BRCA+ women, without any personal history of cancer, face complex decisions regarding elective surgical procedures which are irreversible, and not without risk. Research on the psychosocial implications relative to prophylactic surgery has been limited, particularly in the unaffected BRCA+ population in the United States.

Chapter 3

Method

Chapter Three presents a discussion of the method used in this study. Included are a description of the study design, study sample, recruitment strategy and the research instruments.

Study Design

To contribute to our limited knowledge of the psychosocial sequelae of prophylactic surgery in women at increased risk for hereditary breast and ovarian cancer, an exploratory study was conducted. This research used a two-group cross-sectional, web-based survey design. The goal was to recruit women without a personal history of cancer, who had completed genetic testing for HBOC with BRAC*Analysis*® testing, and found to have a deleterious mutation or a variant of undetermined significance in either BRCA1 or BRCA2. Women who had completed any prophylactic surgery (BPM and/or BPSO) were compared with those who had not undergone any prophylactic surgery. As a web-based study, the participants were able to complete all research instruments online, affording a unique level of privacy and anonymity.

Sample

The study sample consisted of a homogenous group: BRCA+ females who were unaffected mutation carriers, without any personal history of cancer (other than non-melanoma skin cancer). Other inclusion criteria for study participants were: ages 21 to 50 years old (inclusive), literate and fluent in the English language, and access to a

computer or other internet-accessible device. The age limitations for participation were chosen to contribute to homogeneity of the sample, essentially representing what would be a premenopausal age group.

Two groups of women were included in the study: women choosing surveillance (with or without chemoprevention) and women who had any prophylactic, risk-reducing surgery. As the purpose of this study was to explore issues relevant to high-risk females who are candidates for prophylactic surgery, no males or women under the age of 21 were included in the research.

Procedures

Institutional Review Board. This study was approved by the University of South Florida (USF) Institutional Review Board (IRB) and qualified for a waiver of the requirements for documentation of informed consent (IRB#: Pro00000842). The document of informed consent included contact information for any participant questions, concerns or complaints.

Web-based survey development. All study instruments were incorporated into a single online survey using Checkbox ® 4.6 Web Survey Software. The USF Information Technology department was consulted for training in the software program required to create the survey. After development, the web-based survey was initially tested for functionality, clarity, and average time for completion by both lay individuals and health care personnel (20 minutes on average). Appropriate revisions were completed prior to the initiation of study recruitment. The Checkbox Survey program offers password-protected data security and has reporting capabilities for data collection into Excel or

SPSS-compatible formats. (Please refer to the Web-Based Survey Development Task-List, Appendix A.)

Recruitment. Participants were initially recruited from a convenience sample of individuals attending a conference for education and support regarding hereditary breast and ovarian cancer. The annual Joining FORCEs Against Hereditary Cancer Conference is a collaboration between H. Lee Moffitt Cancer Center and Research Institute in Tampa, Florida and the national non-profit organization Facing Our Risk of Cancer Empowered (FORCE). Moffitt Cancer Center is the only National Cancer Institute designated cancer center in the state of Florida. Also based in Tampa, the mission of FORCE is to improve the lives of individuals and families affected by hereditary breast and ovarian cancer. FORCE has a national e-mail and print mail distribution list of 13,000 people. The FORCE website and message boards contain the largest collection of personal experiences from this high-risk community. The annual conference is the only national conference by and for this high-risk community and was held in Orlando, Florida from June 23 to June 25, 2011. A letter of support was obtained from the FORCE organization.

At the 2011 FORCE conference, an announcement regarding the research study was made from the podium during the opening session by Dr. Sue Friedman, the founder and President of the Board of Directors for FORCE. All recruiting materials were IRB-approved, including a slide shown on the large screen during the opening session. The slide, essentially a duplication of the study flyer, was also shown in a rotating sequence on the same screen at intervals throughout the conference. Tote bags for all conference attendees included book marks and paper flyers regarding the study. The research study

flyer included photographs of racially-diverse women, in an effort to recruit minorities into the study. Study flyers were intended for attendees who might be interested in the study, or to share with other friends or family members who might qualify for the research. The recruiting materials included information regarding the purpose of the study, eligibility criteria, contact information for any questions and a link to access the web-based study (www.previvorstudy.info). The intention was to make study access simpler than typing in the original, lengthy URL required to access the research study on the USF web site at http://hsccm2.hsc.usf.edu/checkbox/Survey.aspx?surveyid=5721. Other recruiting materials used at the conference included tent cards placed throughout the hotel meeting rooms used during various conference sessions.

Another effort to include a racially and ethnically diverse study sample involved making computers available at the conference. Some conference attendees received scholarships for assistance with travel and conference registration expenses. Space was secured at the conference hotel for individuals who were interested in completing the study while attending the conference. Three high-top tables with chairs, lap-top computers and internet access were provided for interested individuals. A water cooler and drinking cups were available in the same location. The web-based survey included the informed consent document. Printed copies of the informed consent were made available for women attending the conference. After the conference, study participants were encouraged to print out the consent for their own records.

During recruitment at the conference, a member of the research team was available to answer questions, provide technical assistance with the lap top computers and assist participants with accessing the research study online if necessary. Potential

study participants were advised of the highly confidential (anonymous) nature of the information shared. Interested parties were able to access the study link, review the informed consent and if they chose to, were able to proceed with the survey. Participants were afforded privacy and left undisturbed if they did not have any questions. Study participants were not required to complete the study once they had started and could skip items in the survey if they chose to. The only questions requiring a response were the following:

> It is up to you to decide whether you want to take part in this study. If you want to take part, please sign the electronic form, if the following statements are true.
> I freely give my consent to take part in this study. I understand that I am agreeing to take part in research. All of my responses will be completely anonymous. I have printed a copy of this form for my own records. Would you like to participate in this study?

The requisite response to this item was "yes", in order to proceed with the survey. Clicking yes was considered an electronic signature. No names or identifying information were collected.

The other question requiring a response was: "Have you had any type of cancer, other than a non-melanoma skin cancer?" That item required a response of "no" in order to continue participation in the research study. Any participants who indicated a personal history of cancer, other than non-melanoma skin cancer, then saw the final page of the study. The information on that screen included a thank you for participating message and reinforced the message of anonymity for all study participants.

Subsequent to the conference, additional study recruitment was primarily through web-based announcements, approved and posted by FORCE on the organization's website (http://www.facingourrisk.org). In an effort to enhance recruitment, in September of 2011, announcements regarding the study were also posted on the website for another organization for women affected by hereditary breast and ovarian cancer, Bright Pink (http://www.bebrightpink.org).

Compensation. All study participants had the option of submitting their e-mail address for participation in a random drawing for a $100 electronic gift card. Completion of the entire study survey was not requisite for participation in the drawings. In an effort to maintain anonymity for the participants, any interested individuals were encouraged to submit their e-mail address to a separate e-mail account created specifically for the research study (BRCAecard@gmail.com). If the participants chose to participate in the drawing, they received an automated e-mail response thanking them for their participation in the study. A total of 5 random drawings for $100 gift cards were scheduled at regular intervals, based on study accrual. Winners of the random drawings were notified by e-mail. They were able to access and redeem the electronic gift cards directly at http://amazon.com.

Although all data collected through the web-based research survey was anonymous, the electronic data files have been maintained in a secure, password-protected location. The list of e-mail addresses submitted for the random drawings are kept in a separate password-protected electronic file.

Additional resources. Research questions regarding sexual functioning could have been perceived as sensitive and private in nature. As the research was web-based,

participants had the opportunity to select a private setting to complete survey. To address the potential for survey items which could elicit uncomfortable feelings or health-related questions, participants were encouraged to seek appropriate resources.

The names of resources and electronic links for mental health services and domestic violence were included in the online survey. Participants were advised of the option to call "911", a national service. Contact information regarding Mental Health America, a national non-profit organization was provided. Local community resources, treatment information, and support groups are available on the Mental Health America website (www.mentalhealthamerica.net). A link for community resources for any domestic violence concerns was provided for the National Domestic Violence Hotline, available 24/7 by telephone or on the web (www.ndvh.org). The National Domestic Violence organization offers services for crisis intervention, safety planning, referrals, and information. Additional links for the FORCE website included a confidential, peer support toll-free helpline for individuals concerned about hereditary cancer, available at 1-866-288-RISK (7475); (www.facingourrisk.org). For other questions about any health issues, information was provided with a link for www.healthfinder.gov.

Diversity. The targeted enrollment of ethnically and racially diverse study participants (Table 1) was based on the Myriad Genetics' clinical database (Hall et al., 2009). Myriad Genetics is currently the only laboratory offering the BRAC*Analysis*® genetic testing for BRCA mutations. Between November 1996 and March 2006, the majority of individuals tested were of Western or Central European ancestry (87.4%). Middle Eastern women were tested the least often (1.1%). Those of Latin American ethnicity were 4.2% and African Americans were only 3.8% of the women tested during

that time frame (Hall et al., 2009). Numerous socioeconomic and psychosocial barriers to genetic services for underserved populations have been identified (Forman & Hall, 2009).

Table 1

Targeted Enrollment

Ethnic/Racial Categories	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	17	0	17
Not Hispanic or Latino	383	0	383
Ethnic Category: Total of All Subjects	400	0	400
American Indian/Alaska Native	6	0	6
Asian	11	0	11
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	17	0	17
White	366	0	366
Racial Category: Total of All Subjects	400	0	400

Measures

Demographics and health history. Self-reported socio-demographics, personal medical history and a family cancer history were obtained through a study-specific questionnaire developed by the researcher (Appendix B). The readability for this measure was at the 6.8 grade level (Flesch-Kincaid).

Quality of Life Index. This scale measures QOL as defined by Ferrans and Powers (1992) and refers to a "person's sense of well-being that stems from satisfaction or dissatisfaction with the areas of life that are important to him/her" (p. 29). The Quality of Life Index (QLI) is based on a conceptual model developed from qualitative research. Exploratory factor analysis was utilized to determine the domains of health and functioning, social and economic, family, and psychological/spiritual (Ferrans, 1996). The QLI consists of two sections of 33 items each. The first section addresses

satisfaction with items in each of the domains, while the second focuses on the importance of those items to the individual. Satisfaction responses are weighted with the paired importance score. The total score reflects overall quality of life. Respondents answer on a 6 point Likert-type scale and the answers are scored based on a computational formula which provides an overall quality of life score, and 4 subscores for the domains. Internal consistency reliability for the total score has ranged from 0.73 to 0.99 among 48 studies. The authors report alphas for the subscales of health and functioning (0.87), social and economic (0.82), family (0.77), and psychological/spiritual (0.90) (Ferrans & Powers, 1992). In the current study, the Cronbach alpha coefficient for the QLI total score was 0.95. The alphas for the subscales in the current study were: health and functioning (0.87), social and economic (0.85), family (0.78), and psychological/spiritual (0.80). The computation commands for SPSS are available (Ferrans & Powers, 2010). Readability is at the 6.6 grade level (Flesch-Kincaid). Numerous disease-specific versions of the QLI have been developed, and translated into multiple languages. This study used the Quality of Life Index, Generic Version III, with the author's permission (Appendix C).

Self-Anchoring Striving Scale. Developed by Cantrill (1965), the Self-Anchoring Striving Scale (SASS) is a subjective, single-item measure utilizing a visual scale in the form of a ladder, with response options from 10 to 1. The following description accompanies the ladder scale. "We all desire certain things out of life. When you think about what really matters in your own life, where on the ladder would you place your life at the present time?" Ten represents the best one could imagine, and 1 is the worst one could imagine (Appendix D). The measure yields one score, with a range

of 1 to10. The SASS has also been used in other studies to measure quality of life (Beckie & Hayduk, 1997). However, the focus of that analysis was the use of structural equation modeling to investigate the dimensionality of QOL. The Flesch-Kincaid readability for the SASS is at the 3.9 grade level.

Dyadic Adjustment Scale. The original Dyadic Adjustment Scale (DAS) (Spanier, 1976) was a 32-item scale with subcales for dyadic satisfaction, consensus, cohesion and affectional expression. A Revised Dyadic Adjustment Scale (RDAS) with 14 items was developed with a total score Cronbach's alpha of 0.90 (Busby, Christensen, Crane & Lason, 1995). The 3 subscales for the RDAS are dyadic satisfaction, consensus and cohesion. Other researchers have developed even more concise versions of the DAS. One abbreviated version of the DAS was developed for use as a brief screening tool (Sabourin, Valois, & Lusier, 2005). All 4 items of the abbreviated scale (DAS-4) came from the Satisfaction subscale of the original DAS. The authors evaluated the measure with both clinical and community samples in 5 different studies. A total of 8,256 married or cohabitating individuals were in those studies, which included comparisons with the original DAS and other revised versions. The alphas for the DAS-4 ranged from 0.84 to 0.91.

The current study included only one item from the DAS-4, rating the level of happiness in the relationship. The responses range from extremely unhappy (0) to perfect (6). This single item was seen in the present research survey by any participants indicating their relationship status as married or in a committed relationship with a partner (Appendix E). The Flesch-Kincaid readability for this single item is at the 10.1 grade level.

Body Image Quality of Life Inventory. The specific dimension of body image to be investigated is an important consideration in selecting the appropriate measure (Thompson, 2004). The focus of this research was quality of life and psychosocial well-being. Therefore, the Body Image Quality of Life Inventory (BIQLI) (Cash & Fleming, 2002) was utilized with the author's permission (Appendix F). The instrument does not actually assess body image, but rather the effects of body image in various life domains, including social functioning, sense of self, and sexuality. A 7-point bipolar scale is used to rate the impact of body image on 19 aspects of individuals' lives, yielding one composite score. There is a 7-point response format, ranging from -3 (very negative) to +3 (very positive). Higher scores indicate a more positive influence of body image on quality of life. The initial Cronbach's alpha was 0.95, and test-retest reliability was 0.79 over a 2-3 week time frame. The instrument was further validated with college students of both genders (n= 603) (Cash, Jakatdar & Williams, 2004). The measure was found to be internally consistent for both sexes. Principal components analysis confirmed the unidimensional structure of the scale. The Cronbach's alpha for the BIQLI across 7 studies has ranged from 0.94 to 0.96 (Cash & Grasso, 2005). The alpha for the current study is 0.97. The authors have reported the test-retest reliability with 107 college students at 0.82, confirming temporal stability for a 2-week time frame. Measurement invariance of the BIQLI was confirmed in a sample of over 1,200 adults (Rusticus, Hubley, & Zumbo, 2008). The researchers conducted multigroup confirmatory factor analyses for data collected from 422 men and 840 women ages 18-98. Three age categories were analyzed. Configural, metric and scalar invariance were evaluated and

the all three levels of invariance were met. The BIQLI is appropriate to use across all age and gender groups and is at the 7.7 grade level for readability (Flesch-Kincaid).

Female Sexual Functioning Index. Sexual functioning was evaluated by the Female Sexual Function Index (FSFI), a 19-item, self-report measure of 6 domains over the previous 4 weeks: desire, subjective arousal, lubrication, orgasm, satisfaction, and pain (Rosen et al., 2000). The total FSFI score has a possible range of 2.0 to 36.0. Higher scores reflect less severe symptoms, or less dysfunction. A score of zero in a domain indicates a lack of sexual activity during the previous 4 weeks (Appendix G).

This was the first empirically validated instrument to assess female arousal and has a high degree of internal consistency, with Cronbach's alpha values of 0.82 to 0.97 reported. The Cronbach's alpha coefficient for the current study was 0.97. The alphas for the FSFI subscales were: desire (0.93), subjective arousal (0.97), lubrication (0.97), orgasm (0.95), satisfaction (0.89), and pain (0.98).

Test-retest reliability is high for each domain at 0.79 to 0.86. Scores are calculated for each domain and then multiplied by a specified domain factor. The total score is obtained by adding all of the domain scores. The instrument was developed on a sample of normal controls and women meeting the diagnostic criteria for female sexual arousal disorder (Meston & Derogatis, 2002). This instrument is at the 10^{th} grade level (Flesch-Kincaid).

To elicit additional information relative to those participants who indicated a lack of sexual activity during the previous 4 weeks on the FSF, an additional item was added to the research survey. Response options included the lack of a partner, lack of interest or

physical problems related to sex (for the study participant or partner) and other- with an opportunity to free text a response.

Menopausal Symptom Scale. The Menopausal Symptom Scale (MSS) was adapted from the Breast Cancer Prevention Trial Symptom Checklist (Ganz et al., 2000). The original 43-item measure was used to assess symptoms associated with menopause and/or tamoxifen use in the National Surgical Adjuvant Breast and Bowel Project (NSABP) P-1 clinical trial conducted to investigate the effect of tamoxifen on breast cancer incidence. When used in a study of breast cancer survivors, the Cronbach alphas were 0.76 (hot flash subscale), 0.73 (vaginal subscale) and 0.76 (urinary subscale). The MSS assesses menopausal symptoms experienced during the prior week, including: hot flashes, night sweats, vaginal dryness, genital itching/irritation, pelvic pain, and difficulty with bladder control when laughing/crying or difficulty with bladder control at other times. Participants respond how bothered they are by each symptom from not at all (1) to extremely bothered (5). Neither a total score, nor any subscale scores were used for the MSS measure. Each of the 7 symptoms was analyzed individually.

One additional question was included in this research study to explore any problems related to sleep (difficulty falling asleep, sleeping through the night, waking up early). The same MSS response scale was used for this one item (Appendix H). Readability for this measure is at a grade level of 6.5 (Flesch-Kincaid).

Psychological General Well-Being Index (Revised). Subjective well-being was measured by the Psychological General Well-Being Index (PGWBI), a 22 item self-administered questionnaire including 6 subscales: vitality, general health, self-control, positive well-being, depressed mood and anxiety (Revicki, Leidy, & Howland, 1996).

The PGWBI-revised version was used in this study (Appendix I). Changes from the original measure by Revicki et al. (1996) include the wording format for the stem items (including frequency of experience), but not the response format. The measure was originally developed by Dupuy (1984) for use in face-to-face interviews and then modified for self-administration. The instrument has been used in numerous community-based studies, including the National Health Examination study (n = 6,913). The revised instrument still uses a 6-point Likert-type scale, with 0 the most negative response and 5 the most positive well being. Respondents were asked to rate their experiences over the prior one month. Higher scores reflect greater levels of well-being and less distress for each scale. A higher score on the depressed mood scale reflects a lower level of depressed mood, or greater well-being.

Internal consistency has been documented with alpha coefficients of 0.90 to 0.96. The current study had a Cronbach alpha coefficient of 0.95 for the total PGWBI score. The alphas for the subscales in the current study were: vitality (0.85), general health (0.66), self-control (0.64), positive well-being (0.86), depressed mood (0.84) and anxiety (0.89). Levels of test-retest reliability at one week have ranged from 0.71 to 0.86. Correlation between the PGWBI and other measures has been documented, including the Zung Self-Rating Depression Scale (ZSRS) (-0.75) (Revicki, Leidy, & Howland, 1996). Readability for this measure is at the 4.9 grade level (Flesch-Kincaid).

BRCA Self-Concept Scale. The development of this instrument was based on individual interviews and focus groups with BRCA+ women (Esplen et al., 2009). Both affected and unaffected individuals with a BRCA mutation were included in the two-phase process of instrument development, refinement and validation. The schema model

of self-concept provided the theoretical framework for the measure. An individual's self-concept and definition of herself, or self-schema, mediates the response to BRCA genetic testing results and health behaviors. The final version of the BRCA Self-Concept Scale (BRCA-SCC) uses a Likert-type scale, with 17 items (Appendix J). Higher scores indicate a more negative self-concept. Principal components analysis of the final BRCA-SCC instrument revealed three factors. The reported Cronbach's alpha for the total scale was 0.90. The resulting Cronbach's alphas for the 3 subscales were: stigma (0.87), mastery (0.68) and vulnerability (0.76). No difference was found between women with or without a personal history of cancer on the mean self-concept scores. Validating measures included the Impact of Event Scale and the Rosenberg Self-Esteem Scale to assess for convergent validity. In the current study, the Cronbach's alpha for the BRCA-SCC total score was 0.86. The alphas for the subscales were: stigma (0.82), mastery (0.74) and vulnerability (0.67). The Flesch-Kincaid readability for this measure is at the 9th grade level.

Satisfaction with Decision. Individual satisfaction with the choice for risk management with prophylactic surgery, chemoprevention, and/or clinical surveillance due to elevated risk of breast and ovarian cancer was evaluated with the Satisfaction with Decision Scale (SWD) (Holmes-Rovner et al., 1996). The SWD was originally developed using a sample of women regarding decisions related to hormone replacement therapy. The 6-item scale provides one global satisfaction with decision score (Appendix K). A Cronbach's alpha of 0.86 was reported at the time of the initial instrument development. The alpha for the current study was 0.97. The Flesch-Kincaid readability is at the 8.6 grade level.

Analysis

All statistical analyses were performed with SPSS (version 17.0). Variables were screened for normality and appropriately transformed based on published recommendations (Tabachnick & Fidell, 2007). Analyses were performed both prior to and after transformation. No differences relative to statistical significance were seen in comparison of the two analyses. Participants were not required to answer all of the study questions and could skip items without a prompt or reminder message. Consequently, any missing data were not included in the analyses. Those p values $< .05$ were considered statistically significant. Statistical analyses included descriptive statistics, independent samples t-tests (two-tailed), hierarchical multiple regression, and bivariate analysis with Pearson product-moment correlation (Aim 1); independent samples t-tests (two-tailed) and hierarchical multiple regression (Aim 2); independent samples t-tests (two-tailed), hierarchical multiple regression and analysis of variance (ANOVA) (Aim 3).

Conclusion

Study participants were able to complete all research instruments online and at their own pace. After the informed consent, the instruments were presented in the following sequence: the study-specific socio-demographics questionnaire, one-item from the Dyadic Adjustment Scale, family cancer history, personal medical history and relevant surgical history, Satisfaction with Decision, Self-Anchoring Striving Scale, Menopausal Symptom Scale, BRCA Self-Concept Scale, Psychological General Well-Being Index, Body Image Quality of Life Inventory, Quality of Life Index, and the Female Sexual Functioning Index (FSFI). On the final web page of the study, an opportunity was given to provide comments by free text. There were no space limitations

for the comment section. An average of 20 minutes was required to complete all study materials. The responses for some of the questions or study items were conditional. Consequently, for individuals without a history of surgery, the time to complete the survey was expedited.

Chapter 4

Results

This chapter addresses the results of the web-based research survey. The original goal for study recruitment was 400 BRCA+ women, ages 21 to 50 (inclusive), unaffected (without a personal history of cancer), fluent and literate in English, and with computer access. A total of 267 women enrolled in the study. Of those, one woman had just recently tested negative for BRCA, another was 63 years of age and 32 others had a personal history of cancer (affected). Therefore, $n = 233$ met the study inclusion criteria and completed the majority of the survey questions. Two women completed a portion of the survey, but did not indicate their status with regard to prophylactic surgery. Consequently, those were deleted from any relevant analyses requiring prophylactic surgery status.

Aim (1)

To compare self-reported socio-demographics, quality of life, body image quality of life, sexual functioning, menopausal symptoms, psychological well-being and BRCA self-concept differences between BRCA+ women electing any prophylactic, risk-reducing surgery and those who have not had prophylactic surgery.

Participants. Study participants were predominantly residents of the United States ($n = 208$); however, residents of Canada, Australia, Netherlands, Israel, Belgium, and Germany were also represented in the sample. The initiation of study recruitment was at the FORCE Conference, and 56 women (24%) reported becoming aware of the

study there. The remainder learned about it on a website (*n* = 94; 40.3%), by brochure/flyer (*n* =3; 1.3%), by word-of-mouth (*n* =3; 1.3%) or other (*n* = 71; 30.5%).

Reflective of the Myriad Genetics clinical database (Hall et al., 2009), the study sample was predominantly Caucasian (98.7 %) (Table 2). Other participants included African American (0.4%), Asian (0.4%), and American Indian/Alaskan Native (0.4%). Hispanic/Latinas made up 4.3% of the sample, and 14.6% of the women were of Ashkenazi Jewish heritage. Most of the women (84.5%) were either married or in a committed relationship with a partner/significant other.

Table 2
Demographics: All Participants

Total sample: *n* = 233		
Age	*M* = 38.4	Range = 21-50
Race		
Caucasian	222 (98.7%)	
African American	1 (0.4%)	
Asian	1 (0.4%)	
American Indian/Alaskan Native	1 (0.4%)	
Ethnicity		
Hispanic or Latino	10 (4.3%)	
Ashkenazi Jewish heritage	34 (14.6%)	

Study participants reported their BRCA mutation, with the breakdown as follows: BRCA 1- deleterious mutations were 121 (51.9%), BRCA 2-deleterious were 101 (43.3%), and a BRCA-variant of undetermined significance (VUS) was reported by 5 (2.1%). Women with a BRCA-VUS are often still considered high risk, and all 5 of the women in this study had elected to have prophylactic surgery. One hundred percent of the sample had some family history of cancer. Having a relative with cancer who undergoes genetic testing (the proband) is often the first step in the process leading to determination of a particular familial BRCA mutation.

The mean age for study participants was 38.4 years (range 21 – 50). The sample was well educated; 16.7% attended some college, 38.6% had a Bachelor's Degree, and 36.5% had completed a Graduate Degree or Professional School. The remaining 5.6% were high school or technical school graduates, and one individual had completed middle school. The majority of women worked outside of the home (78.5%). Five women were actively seeking employment, and the others described themselves as homemakers, students, or retired. Of the women who responded to the query (n =204), 98.5% had health insurance at the time of the study. The majority lived within 25 miles of their primary health care provider (90.6%). Around half (52.9%) participate in a support group or community forum. Of those, 17.6% met in person and the other group participation was web-based (35.3%).

Only 9 of the women in the study were current smokers; 76.8% drank alcohol, and the majority exercised on a regular basis (64.4%). Fifty-one percent (n = 119) reported being followed in a high-risk clinic setting. With regard to chemopreventive measures, 39 (16.7%) were on oral contraceptives, and only 4 women (1.7%) were taking tamoxifen.

More than half of the study sample (68.7%) had a history of prophylactic, risk-reducing surgery, n = 160. The distribution of surgical procedures was: BPM (n = 117; 50.2%), BPSO (n= 108; 46.4%), and hysterectomy (n=62; 26.6%). Forty women (17%) had BPM, BPSO, and hysterectomy (Table 3).

An independent samples t-test (n = 227) comparing the mean age for women with a history of prophylactic surgery (PS) and those without surgery (NO PS) was conducted. There was a significant difference in age for the PS group (M = 40.7, SD = 6.5, n = 158)

and the NO PS group (M = 32.4, SD = 7.1, n = 69); t (225) = 8.54, $p < .001$. Of the women who had not had any prophylactic surgery, 83% were planning on some type of risk-reducing surgical procedure in the future. Twenty-four percent of the study participants expressed a desire to have children in the future. Five women were pregnant at the time of completing the research survey.

For those women opting for BPM, the average age at the time of surgery was 38.3 years of age (range 23 to 49 years). The average time since surgery after BPM was M=1.9 years (SD= 2.0; n = 107). The average age for BPSO was 40.7 years (range 27 to 50 years). For participants missing data relative to the age at BPSO, the figures were derived from surrogate data, utilizing the last menstrual period (recorded in the gynecologic history). The time since BPSO (with or without hysterectomy) was M =2.8 years (SD= 2.6; n = 106). The majority of BPSO procedures were completed laparoscopically (92%), with robotic-assistance for 15% of those. The remainder of the BPSO surgical procedures were open laparotomies (7%). Just over half (53%) of the women who had BPSO also had hysterectomies.

Table 3
Demographics: Any Prophylactic Surgery/ No Surgery

	Prophylactic Surgery (n = 160)	No Prophylactic Surgery (n = 71)
Age	M = 40.7 (SD = 6.5) Range = 24-50	M = 32.4 (SD = 7.1) Range = 21-49
Marital Status		
Single	27 (16.9%)	24 (33.8%)
Married	119 (74.4%)	41 (57.7%)
Separated	2 (1.3%)	----
Divorced	12 (7.5%)	5 (7.0%)
Widowed	----	----
Unmarried/ Partnered	18 (11.3%)	18 (25.4%)
Nulliparous	35 (21.9%)	32 (45.1%)
Desire children in future	21 (13.1%)	31 (43.7%)
Health insurance @ present time	138 (86.3%)	62 (87.3%)
BRCA		
1	81 (50.6%)	40 (56.3%)
2	71 (44.4%)	30 (42.3%)
VUS	5 (3.1%)	----
Unspecified	3	1
Time since results Genetic testing		
0-6 months	6 (3.8%)	15 (21.1%)
6-12 months	21 (13.1%)	20 (28.2%)
1-2 years	32 (20.0%)	11 (15.5%)
2-3 years	27 (16.9%)	8 (11.3%)
3-4 years	24 (15.0%)	9 (12.7%)
4-5 years	11 (6.9%)	4 (5.6%)
> 5 years	38 (23.8%)	4 (5.6%)
PS	160 (68.7%)	
BPM	117 (50.2%)	
BPSO	108 (46.4%)	
Hysterectomy	62 (26.6%)	
BPM & BPSO	70 (30.0%)	
BSO & Hysterectomy	56 (24.0%)	
BPM, BPSO & Hysterectomy	40 (17.0%)	

Note: VUS= variant of undetermined significance; PS= prophylactic surgery; BPM= bilateral prophylactic mastectomy; BPSO= bilateral prophylactic salpingo-oophorectomy.

Quality of Life Index. The possible range of scores for the QLI measure is 0-30. The range in this study sample was 8.7-29.2; $M = 21.8$, $Mdn = 22.8$ ($n = 233$). The subscales for this instrument are Health and Functioning, Social & Economic, Psychological/Spiritual, and Family. Independent samples t-tests were used to examine the difference between the groups. No statistically significant difference was seen between women in the PS group and the NO PS group on the total QLI or any subscale; with the exception of the Family subscale. Per an independent samples t-test the PS group ($M = 23.3$, $SD = 5.1$, $n = 156$) and the NO PS group ($M = 21.5$, $SD = 4.7$, $n = 70$) were significantly different; $t\ (224) = 2.49$, $p = .013$. The QLI Family subscale includes items of satisfaction/importance relating to: children, family health and happiness, and one's spouse, lover or partner.

Hierarchical multiple regression examining the dependent variable of the total QLI score, while controlling for age, was not significantly predicted by prophylactic surgery. However, the QLI Family subscale was predicted by prophylactic surgery in a similar analysis. The total variance explained by the model as a whole was 4% (R^2), $F\ (2, 221) = 4.5$, $p = .012$ (Table 4).

Table 4

Hierarchical Multiple Regression Analyses with Significant Results; Outcome Variable: QLI Family Subscale

Variable	R^2	Adjusted R^2	ΔR^2	*df*	*F*	*p*
QLI -Family						
Step 1 (Control)						
Age	.03	.03	.03			
Step 2						
PS	.04	.03	.01	2,221	4.5	.012*

Note: QLI = Quality of Life Index

Self-Anchoring Striving Scale. Descriptive statistics for the entire sample (n = 228) found M = 3.7, SD = 1.5, Mdn = 4.00 (range 1– 8). An independent samples t-test found no significant difference between the PS and NO PS groups on this QOL measure. Hierarchical multiple regression analysis for the SASS, while controlling for age, was not statistically significant when PS was used as a predictor variable.

Body Image Quality of Life Inventory. The scores for this sample on the Body Image Quality of Life Inventory (BIQLI) ranged from – 40.2 to +54.2. No statistically significant difference was seen between the PS group (M = 12.1, SD = 22.0, n =146) and the NO PS group (M = 16.6, SD = 22.2, n = 66) on independent samples t-test. The hierarchical multiple regression analysis was not significant when BIQLI was examined with PS as a predictor, again controlling for age. In addition, BIQLI was not significantly correlated with the variables for any prophylactic surgery, BPM, or BPSO when examined with a bivariate Pearson product-moment correlation.

Dyadic Adjustment Scale. No statistically significant difference was seen between the PS group (M = 4.8, SD = 1.6, n =140) and the NO PS group (M = 4.9, SD = 1.6, n =60) on independent samples t-test for the one-item DAS question related to the degree of happiness in the relationship (with spouse, partner or significant other). Nor were the results significant when the one-item DAS was examined with hierarchical multiple regression, controlling for age, with PS as the predictor variable.

Female Sexual Functioning Index. The possible range of 2.0 to 36.0 for the total FSFI score was reflected in this study. Other FSFI descriptive statistics are reported in Table 5. An independent samples t-test comparing the total FSFI score for the PS group (M = 21.5, SD = 9.3) and the NO PS group (M =25.0, SD = 9.0) found a significant

difference; t (189) = 2.46, p =.015. Higher scores reflect less severe symptoms, or less dysfunction.

Table 5

Descriptive Statistics: Female Sexual Functioning Index

	N	Min	Max	Mean	SD
Desire	229	1.2	6.0	3.1	1.3
Arousal	224	0	6.0	3.6	1.9
Lubrication	219	0	6.0	3.8	2.1
Orgasm	221	0	6.0	3.5	2.1
Satisfaction	209	0.8	6.0	3.9	1.7
Pain	222	0	6.0	4.0	2.3
FSFI-Total	192	2.0	36.0	22.5	9.3

Note: FSFI= Female Sexual Functioning Index; higher scores reflect less sexual dysfunction.

The findings were similar when the domains of Desire, Arousal, Lubrication and Satisfaction were examined with independent samples t-tests. The women in the PS group had more severe symptoms (greater dysfunction) than the women in the NO PS group. Significant differences were seen in the individual domain of Desire for the PS group (M =2.9, SD=1.3) and the NO PS group (M = 3.7, SD= 1.3), t (225) = 4.37, p < .001. The Arousal domain was significantly different for the PS sample (M = 3.4, SD= 1.9) and the NO PS sample (M = 4.1, SD= 2.0), t (221) = 2.58, p =.01. The Lubrication domain scores for the PS group (M =3.7, SD= 2.0) and the NO PS group (M =4.3, SD= 2.2) were significantly different, t (216) = 2.04, p =.043. Similarly, the independent t-test for the Satisfaction scores in the PS group (M = 3.7, SD =1.7) and the NO PS group (M = 4.4, SD = 1.5) were significantly different, t (206) = 2.58, p =.011. On the whole, women who had any prophylactic surgery had more severe symptoms on the FSFI than the NO PS group. No significant differences were found in the Orgasm or

Pain domains of the FSFI on independent samples t-test. The PS and NO PS group statistics are shown in Table 6.

Table 6

Group Statistics: Female Sexual Function Index

Variable	N	Mean	SD
Desire			
NO PS	69	3.7	1.3
PS	158	2.9	1.3
Arousal			
NO PS	68	4.1	2.0
PS	155	3.4	1.9
Lubrication			
NO PS	67	4.3	2.2
PS	151	3.7	2.0
Orgasm			
NO PS	67	3.7	2.0
PS	153	3.4	2.0
Satisfaction			
NO PS	63	4.4	1.5
PS	145	3.7	1.7
Pain			
NO PS	66	4.0	2.5
PS	155	4.0	2.3
FSFI- Total			
NO PS	58	25.0	9.0
PS	133	21.5	9.3

Note: NO PS = no prophylactic surgery; PS = prophylactic surgery. Higher scores reflect less sexual dysfunction.

Hierarchical multiple regression was used again in separate analyses, to examine the ability of any prophylactic surgery to predict the total FSFI score and each of the FSFI domains, while controlling for age (Table 7). In the analysis for the total FSFI score, the total variance explained by the model as a whole was 4.7% (R^2), F (2, 187) = 4.6, p = .012. For the Desire subscale, the total variance explained by that model as a

whole was 8.7% (R^2), F (2, 222) = 10.62, p = .003. The Arousal domain of the FSFI was analyzed with hierarchical multiple regression, controlling for age. The total variance explained by that model was 4.3% (R^2), F (2, 217) = 4.84, p =.009. For the Lubrication domain of the FSFI, the total variance explained by that model was 4.7% (R^2), F (2, 212) = 5.26, p =.006. The Satisfaction domain of the FSFI was also analyzed with hierarchical multiple regression, controlling for age. The total variance explained by that model was 4.3% (R^2), F (2, 203) = 4.57, p =.011. Similar multiple regression analyses with the Orgasm and Pain domains did not reach statistical significance.

Although the one-item DAS question was not significantly different in the independent samples t-test for the PS and NO PS groups, it was significant when examining the total FSFI as a dependent variable. Again controlling for age, the one-item DAS question was able to predict the total FSFI score in a hierarchical multiple regression analysis, with the total variance explained by that model at 13% (R^2), F (2, 170) = 12.6, $p < .001$ (included in Table 7).

Table 7

Hierarchical Multiple Regression Analyses with Significant Results: Outcome Variable FSFI and Subscales

Variable	R^2	Adjusted R^2	ΔR^2	*df*	*F*	*p*
FSFI						
Step 1 (Control)						
Age	.04	.03	.04			
Step 2						
PS	.05	.04	.01	2,187	4.6	.012*
Desire						
Step 1 (Control)						
Age	.05	.05	.05			
Step 2						
PS	.09	.08	.04	2,222	10.6	.003*
Arousal						
Step 1 (Control)						
Age	.03	.03	.03			
Step 2						
PS	.04	.03	.01	2,217	4.8	.009*
Lubrication						
Step 1 (Control)						
Age	.05	.04	.05			
Step 2						
PS	.05	.04	.001	2,212	5.3	.006*
Satisfaction						
Step 1 (Control)						
Age	.03	.03	.03			
Step 2						
PS	.04	.03	.01	2,203	4.6	.011*
FSFI						
Step 1 (Control)						
Age	.04	.03	.04			
Step 2						
DAS	.13	.12	.09	2,170	12.6	<.001*

Note: PS= any prophylactic surgery; dichotomous variable. FSFI= Total Female Sexual Functioning Index score. DAS= one item Dyadic Adjustment Scale.

The FSFI total score was further investigated using Pearson product-moment correlation coefficient (Table 8). No significant correlations were found between the FSFI total score and the prophylactic mastectomy or hysterectomy variables.

Table 8

Pearson Product-Moment Correlations Among Female Sexual Functioning Index and Other Study Variables

Variable	1	2	3	4	5	6	7	8
1. FSFI								
2. Any PS	-.18*							
3. BPSO	-.22*	≈						
4. DAS	. 32*	-.04	-.11					
5. SASS	-.42*	-.07	.01	-.30*				
6. BIQLI	.40*	-.09	.02	.25*	-.45*			
7. QLI	.46*	.09	.03	.36*	-.62*	.63*		
8. BRCASCC	-.24*	-.26*	-.18*	-.11	.44*	-.34*	-.55*	
9. PGWBI	.48*	.09	.01	.33*	-.64*	.52*	.76*	-.55*

Note: *$p < .05$; (≈not computed, one of variables is constant); FSFI= Female Sexual Functioning Index; PS= prophylactic surgery; BPSO= bilateral prophylactic salpingo-oophorectomy; DAS= one-item Dyadic Adjustment Scale; SASS= Self-Anchoring Striving Scale; BIQLI= Body Image Quality of Life Index; QLI= Quality of Life Index (total score); BRCASCC= BRCA-Self Concept Scale (total score); PGWBI= Psychological General Well-Being Index (total score).

Menopausal Symptom Scale. Independent t-tests were used to examine each of the menopausal symptoms. The hot flashes symptom was significantly different between the PS group (n =156), M=2.0 (SD = 1.2) and the NO PS group (n = 70), M=1.2 (SD = 0.7); t (224) = - 6.2, $p < .001$. In addition, the night sweats symptom was significantly different in the PS group (n =157), M=1.8 (SD = 1.1) and the NO PS group (n = 70), M=1.3 (SD = 0.8); t (225) = -3.6, $p <.001$. The vaginal dryness symptom was

also significantly different for the PS group (n =154), M= 2.1 (SD = 1.3) and the NO PS group (n = 70), M=1.4 (SD = 0.8); t (198.8) = 4.917, $p < .001$. No significant difference was seen between the groups for the other menopausal symptoms on the MSS using the independent samples t-tests. The additional question regarding any problems related to sleep difficulty was analyzed with an independent t-test. Difficulty sleeping was significantly different between the PS group (n =157), M= 2.8 (SD = 1.4) and the NO PS group (n = 70), M = 2.3 (SD = 1.3); t (225) = 2.96, p =.003.

When PS was examined as a predictor in a hierarchical multiple regression, controlling for the variable of age, the menopausal symptom of hot flashes was again statistically significant. The total variance explained by the model as a whole was 15.4% (R^2), F (2, 221) = 20.09, $p < .001$. The menopausal symptom of night sweats was similarly examined in a hierarchical multiple regression, controlling for the variable of age. Prophylactic surgery was able to predict 8.1% (R^2) in the model as a whole, F (2, 222) = 9.81, $p < .001$. A similar analysis for the vaginal dryness symptom found 13.1% (R^2) of the total variance explained, F (2, 219) = 16.5, $p < .001$.

Although not significantly different in the independent samples t-test, the symptom of difficulty with bladder control (while laughing or crying) was significant in the hierarchical multiple regression analysis controlling for age, as predicted by PS. The total variance explained by the model as a whole was 5% (R^2), F (2, 219) = 5.61, p = .004. Findings were similar in the same analysis for the symptom of difficulty with bladder control (at other times): 5% (R^2), F (2, 218) = 5.95, p = .003. Another hierarchical multiple regression analysis to examine the symptom of sleep difficulties

was conducted. The total variance explained by the model as a whole was 7.1% (R^2), F (2, 222) = 8.48, p < .001.

Table 9

Hierarchical Multiple Regression Analyses with Significant Results: Outcome Variable: Menopausal Symptoms

Variable	R^2	Adjusted R^2	ΔR^2	*df*	*F*	*p*
Hot Flashes						
Step 1 (Control)						
Age	.13	.12	.13			
Step 2						
PS	.15	.15	.03	2,221	20.09	<.001*
Night Sweats						
Step 1 (Control)						
Age	.07	.07	.07			
Step 2						
PS	.08	.07	.009	2,222	9.8	<.001*
Vaginal Dryness						
Step 1 (Control)						
Age	.12	.11	.12			
Step 2						
PS	.13	.12	.01	2,219	16.5	<.001*
Bladder Control (laughing/crying)						
Step 1 (Control)						
Age	.04	.04	.04			
Step 2						
PS	.05	.04	.005	2,219	5.6	.004*
Bladder Control (other times)						
Step 1 (Control)						
Age	.05	.05	.05			
Step 2						
PS	.05	.04	.00	2,218	5.9	.003*
Sleep Difficulties						
Step 1 (Control)						
Age	.07	.06	.07			
Step 2						
PS	.07	.06	.006	2,222	8.5	<.001*

Note: PS= any prophylactic surgery; dichotomous variable.

Psychological General Well-Being Index (Revised). Analysis with independent samples t-test for the PGWBI total score found no statistically significant difference between the PS group (M = 74.83, SD = 18.03, n =143) and the NO PS group (M =71.13, SD = 17.95, n =59). No significant difference was seen in comparison of the 2 groups on any of the PGWBI subscales. There were no significant findings when the PGWBI was examined in a hierarchical multiple regression analysis with prophylactic surgery as a predictor variable, while controlling for age. Results for 2 subscales are not reported, due to the low Cronbach's alphas for self-control (0.64) and general health (0.66). The PGWBI descriptive statistics for the entire sample are presented in Table 10.

Table 10

Descriptive Statistics: Psychological General Well-Being Index Subscales and Total Score

Scale	*n*	Min	Max	Mean	SD
Anxiety	225	0	25	16.2	5.1
Depressed Mood	225	0	15	12.0	2.7
Positive Well-Being	229	4	20	12.8	3.8
Vitality	230	1	19	11.4	4.2
PGWBI- Total	204	17	108	73.8	18.0

Note: PGWBI = Psychological General Well-Being Index

BRCA Self-Concept Scale. Independent samples t-test (n = 221) examining the total BRCA-SCC score were significantly different for the PS and NO PS groups. There were also significant differences for each of the Mastery and Stigma subscales (Table 11). Vulnerability scores are not reported here, due to the low Cronbach's alpha for the current study (0.67). Higher scores on the BRCA-SCC reflect a more negative self-

concept. The PS group had lower scores, reflecting a greater mastery and lower sense of stigma, in comparison with the NO PS group.

Table 11

BRCA Self-Concept Scale: Subscales and Total Score

	PS			NO PS					
Score	*n*	M	SD	*n*	M	SD	t	df	*p*-value
Mastery	157	7.7	4.0	69	9.5	4.2	2.95	224	.003*
Stigma	158	24.6	9.7	69	29.5	9.8	3.50	225	.001*
Total Score	153	50.3	16.9	68	60.2	16.4	4.16	219	<.001*

Note: *p< .05; PS = prophylactic surgery; NO PS = no prophylactic surgery

In addition, separate hierarchical multiple regression analyses controlling for age, were used to examine the prediction of the BRCA-SCC total score and the Mastery and Stigma subscales by any prophylactic surgery (Table 12). Each of these was statistically significant. For the BRCA-SCC total score, the total variance explained by the model as a whole was 8.5% (R^2), F (2, 217) = 10.05, $p < .001$. For the Mastery subscale, the total variance explained by the model as a whole was 4% (R^2), F (2, 222) = 4.57, $p = .011$. With the Stigma subscale, the total variance explained by the model as a whole was 5.5 % (R^2), F (2, 223) = 6.52, $p = .002$.

Table 12

Hierarchical Multiple Regression Analyses with Significant Results: Outcome Variable: BRCA-Self Concept Scale and Subscales

Variable	R^2	Adjusted R^2	ΔR^2	*df*	*F*	*p*
BRCA-SCC						
Step 1 (Control)						
Age	.06	.05	.06			
Step 2						
PS	.09	.08	.03	2,217	10.05	<.001*
Mastery						
Step 1 (Control)						
Age	.003	-.001	.003			
Step 2						
PS	.04	.03	.04	2,222	4.6	.011*
Stigma						
Step 1 (Control)						
Age	.03	.03	.03			
Step 2						
PS	.06	.05	.03	2,223	6.5	.002*

Note: PS= any prophylactic surgery; dichotomous variable. BRCA-SCC= BRCA-Self concept Scale total score.

Aim (2)

To determine the level of satisfaction with the decision for risk management based on the research participants' choice for prophylactic surgery, chemoprevention, and/or clinical surveillance.

Satisfaction with Decision. The independent samples t-test (n = 225) compared the participants' satisfaction regarding the decision on hereditary cancer risk management. For women with a history of any prophylactic surgery (PS) (M = 26.9, SD = 5.9, n =154) and those without surgery (NO PS) (M = 24.2, SD = 6.1, n =71) there was a significant difference; t (223) = 3.06, p =.002. Higher scores indicate a higher level of satisfaction with the decision. No statistically significant difference was seen

when the prophylactic surgery subgroups were compared with independent samples t-tests.

Prophylactic surgery was predictive of the SWD outcome variable using hierarchical multiple regression, controlling for age (Table 12). Total variance explained by the model as a whole was 4% (R^2), F (2, 220) = 4.63, p = .011. Multiple regression using time since surgery (BPM or BPSO) to predict the SWD score was not statistically significant.

Table 13

Hierarchical Multiple Regression Analysis; Outcome Variable: Satisfaction with Decision

Variable	R^2	Adjusted R^2	ΔR^2	*df*	*F*	*p*
SWD						
Step 1 (Control)						
Age	.008	.004	.008			
Step 2						
PS	.04	.03	.03	2,220	4.6	.011*

Note: PS= any prophylactic surgery; dichotomous variable. SWD= Satisfaction with Decision.

Study participants provided information regarding medications for chemo-prevention, or risk reduction with prescription medications. With regard to women taking oral contraceptives (n = 39; 16.7%), there was no significant difference in SWD seen for women in this subgroup when examined with independent t-test or with hierarchical multiple regression (controlling for age). Only 4 (1.6%) of the study sample was taking tamoxifen for chemoprevention, so analysis for that subgroup was deferred. With regard to surveillance, no difference was seen in SWD for women followed in a high-risk clinic setting compared with those who were not with independent samples t-test.

Aim (3)

To examine the potential moderating role of prophylactic surgery on the relationships between the independent variables of the Total Female Sexual Functioning score, Global Psychological General Well-Being Index, Total BRCA Self-Concept score, Body Image Quality of Life, and the dependent variable of the Total Quality of Life Index score.

Moderation, or a potential interaction of the variables, was evaluated in this study sample by first creating a centered product term for each relevant indicator. This was achieved by subtracting the mean score from each variable and multiplying that value by the variable for any prophylactic surgery (yes/no). This step was performed to minimize concerns regarding multicollinearity, or high intercorrelations between the independent variables. Each centered product term was then used in multiple regression analyses, with the total QLI score as the dependent variable for the pairs (see Table 13 for the relevant descriptive statistics).

Statistically significant main effects were found for the: BRCA-SCC, the Body Image Quality of Life Inventory/any prophylactic surgery, the Female Sexual Functioning Index/any prophylactic surgery, and the Psychological General Well-Being Index total score. No statistically significant interaction effects were found for any of the interaction terms (Table 14).

Table 14

Aim 3: Descriptive Statistics

Variable	*n*	Mean	SD
Total QLI	233	21.8	4.5
PS	231	.69	.46
BRCA-SCC	223	53.4	17.3
BRCA-SCC * PS	224	- 2.1	14.0
BIQLI	214	13.8	22.6
BIQLI * PS	217	-1.1	18.5
FSFI	192	22.5	9.3
FSFI * PS	204	-.67	7.5
PGWBI	204	73.8	18.0
PGWBI * PS	214	.71	14.7

Note: PS= any prophylactic surgery; dichotomous variable. BRCA-SCC = total BRCA Self-Concept Score. BIQLI= Body Image Quality of Life score. FSFI= total Female Sexual Functioning Index score. PGWBI= total Psychological General Well-Being Index score.

Table 15

Aim 3: Multiple Regression Analyses to Examine for Main Effects and Interaction Effects; Dependent Variable: Total Quality of Life Index Score

Variable	R^2	Adjusted R^2	β	t	*df*	*F*	*p*
BRCA-SCC			-.53	-4.9			<.001*
PS			-.06	-.97			.333
BRCA-SCC * PS			-.04	-.42			.676
Model	.31	.30			3,217	32.0	<.001*
BIQLI			.56	5.8			<.001*
PS			.14	2.7			.008*
BIQLI * PS			.09	.99			.322
Model	.42	.41			3,208	49.6	<.001*
FSFI			.38	3.2			.002*
PS			.16	2.5			.015*
FSFI * PS			.13	1.0			.296
Model	.24	.23			3,187	20.0	<.001*
PGWBI			.74	8.6			<.001*
PS			.02	.34			.732
PGWBI * PS			.03	.29			.773
Model	.58	.58			3,198	92.1	<.001*

Note: PS= any prophylactic surgery; dichotomous variable. BRCA-SCC = Total BRCA Self-Concept Score. BIQLI= Body Image Quality of Life score. FSFI= Total Female Sexual Functioning Index score. PGWBI= Global Psychological General Well-Being Index score. β = standardized coefficient.

Twenty-seven percent of the participants had received their BRCA genetic testing results within the previous 1 year, while 18.5% were between 1 to 2 years, 15% from 2 to 3 years, 14.2% from 3 to 4 years, 6.4% between 4 to 5 years and 18% had received their results more than 5 years prior. Seventy-eight percent of the women had consulted with a Genetic Counselor prior to BRCA testing.

Analysis of variance (ANOVA) was used to investigate for the presence of an interaction effect between the time since receiving genetic test results (ranging from intervals of 0 to 6 months to greater than 5 years) and prophylactic surgery (yes/no) relative to the total QLI score. The analysis did not reveal statistical significance for an interaction, or any significant main effects for the two independent variables.

Summary.

These data analyses address the findings for the 3 research aims of this exploratory study. Please refer to Table 15 for a summary of the group statistics for all instruments. The next chapter addresses these data in relation to previously published research.

Table 16

Summary Table: Group Statistics for All Study Instruments

Instrument/ Subscales	# items	Range	*n*	Range-study	Mean (SD)	α
Quality of Life Index (QLI)	66	0-30	233	8.65-29.23	21.79 (4.46)	0.95
Health & Functioning	13	0-30	231	5.62-29.88	21.49 (4.70)	0.87
Social & Economic	8	0-30	228	5.00-30.00	22.22 (4.82)	0.85
Psychological/Spiritual	7	0-30	230	6.86-29.17	21.24 (5.05)	0.80
Family	5	0-30	228	3.40-30.00	22.76 (5.03)	0.78
Self-Anchoring Striving Scale (SASS)	1	1-10	228	1-8	3.71 (1.46)	-
Dyadic Adjustment Scale- 4 (DAS-1)	1	0-6	201	0-6	3.80(1.55)	-
Body Image Quality of Life Inventory (BIQLI)	19	-57- +57	214	-40.16- +54.16	13.78 (22.60)	0.97
Female Sexual Functioning Index (FSFI)	19	2.0-36.0	192	2.0-36.0	22.50 (9.33)	0.97
Desire	2	1-5	229	1.2-6.0	3.10(1.33)	0.93
Arousal	4	0-5	224	0-6.0	3.63(1.94)	0.97
Lubrication	4	0-5	219	0-6.0	3.85 (2.09)	0.97
Orgasm	3	0-5	221	0-6.0	3.50 (2.06)	0.95
Satisfaction	3	0 (or1)-5	209	0.8-6.0	3.93 (1.69)	0.89
Pain	3	0-5	222	0-6.0	3.97 (2.34)	0.98
Menopausal Symptom Scale (MSS)		1-5				
Hot flashes	1		228	1-5	1.75 (1.10)	-
Night sweats	1		229	1-5	1.62 (1.02)	-
Vaginal dryness	1		226	1-5	.84 (1.20)	-
Genital itching/irritation	1		227	1-5	1.44 (.82)	-
Pain in pelvic area	1		227	1-4	1.28 (.65)	-
Difficulty- bladder control (while laughing or crying)	1		226	1-5	1.33 (.77)	-
Difficulty-bladder control (at other times)	1		225	1-4	1.35 (.73)	-
Sleep problems	1		229	1-5	2.67 (1.38)	-

Table 16 (continued)

Summary Table: Group Statistics for All Study Instruments

Instrument/ Subscales	# items	Range	*n*	Range-study	Mean (SD)	α
Psychological General Well-Being Index (PGWBI)	22	0-110	204	17-108	73.77 (17.96)	0.95
Anxiety	5	0-25	225	0-25	16.20 (5.13)	0.89
Depressed Mood	3	0-15	225	0-15	11.97 (2.70)	0.84
Positive Well-Being	4	0-20	229	4-20	12.82 (3.65)	0.86
Self-Control	3	0-15	228	4-15	10.85 (2.66)	0.64
General Health	3	0-15	224	2-15	10.60 (2.87)	0.66
Vitality	4	0-20	230	1-19	11.35 (4.21)	0.85
BRCA Self-Concept Scale (BRCA-SCC)	17	7-119	223	16-100	53.39 (17.26)	0.86
Mastery	4	0-28	228	3-23	8.29 (4.12)	0.74
Vulnerability	5	0-35	224	3-35	19.16 (6.83)	0.67
Stigma	8	0-56	229	8-52	26.16 (9.97)	0.82
Satisfaction with Decision (SWD)	6	6-30	227	6-30	26.03 (6.07)	0.97

Chapter 5

Discussion

Quality of Life

Results from this web-based research study provide new data for a relatively large sample of women at risk for hereditary breast and ovarian cancer, in contrast to previously published studies. Analyses with independent t-tests found a significant difference between the PS and NO PS group on the QLI Family subscale of the QLI, but not on any other QOL measures. Controlling for age, the hierarchical multiple regression found PS was predictive of the QLI Family subscale.

For the total QLI score (M = 21.8, SD 4.5; n = 233), the results are similar to the findings in a Norwegian research study examining QOL pre-operatively in women undergoing hysterectomy for benign disease (n = 111) and a control group (n = 173) (Rannestad, Eikeland, Helland & Qvarnstrom, 2000). The total QLI score for the patients in that study was M = 22.11 (SD = 4.27) and for the healthy controls M = 22.98 (SD = 3.93). Sammarco (2001) used the QLI- Cancer Version in a study of women diagnosed with breast cancer under the age of 50 (years since diagnosis, M = 3.36, SD= 2.76, n =101). The total QLI score for that group was M = 21.96, SD = 4.46.

There were no significant differences for the SASS and BIQLI measures in the current study. The results on the SASS were similar for both groups, with a mean score of 3.7. As an exploratory study, there are no comparisons for this measure. However, this finding does provide a basis for further inquiry.

Finch et al. (2011a) assessed health-related quality of life with the Short Form Health Survey (SF-12) in a study of affected and unaffected BRCA+ women after BPSO *(n* =114). Lower scores on physical functioning were reported for women with a previous history of breast cancer and those not taking any hormone replacement therapy. Mental health functioning was similar before and after BPSO, and at levels reported for the general population.

Psychological Well-Being

The PGWBI total score in the current study (*n* = 204) found the scores M =73.8 (SD 18.0) reflect a high level of positive well-being, in comparison with national reference scores (McDowell & Newell, 1987).

BRCA Self-Concept

In the current study, there were statistically significant differences seen between women completing any prophylactic, risk-reducing surgery and those who had not had surgery in the BRCA Self-Concept scale (total score and all 3 subscales, Mastery, Stigma and Vulnerability). However, the Cronbach's alpha for the Vulnerability subscale in the current study was 0.67. Mastery and vulnerability may be two sides of the same coin, another issue requiring further analysis.

On the BRCA Self-Concept measure, the higher scores reflect a more negative finding. For the total BRCA-Self Concept score, prophylactic surgery explained 8% of the variance. Both Mastery and Stigma scores were higher for those women who had not had any prophylactic surgery when examined as a group. Women in the current study who have had prophylactic surgery appear to have a greater sense of Mastery. Items in the Mastery scale include: "I am able to deal with my test result; I know my body well; I

am hopeful about myself in the future; I am in control of my health" (Esplen et al., 2009, p. 1224). Items on the Stigma subscale include "I feel labeled; I feel different from others my age; I think about my test result a lot". In the perspective of self-concept, there would be a greater sense of Stigma indicated by the higher scores.

Vodermaier et al. (2010) used the BRCA Self-Concept scale in a multisite Canadian study, including 241 women with a BRCA mutation; n =133 with a personal history of cancer. Unaffected women in that study (n = 104) had Mastery scores of M = 23.02 (SD = 4.04), and Stigma scores of M = 23.24 (SD = 10.84). The results for the vulnerability subscale were not reported for that sample. In contrast, the findings in this study sample (n = 223) for the Mastery scale were only M = 8.28 (SD = 4.12) and were more similar for the Stigma score, M =26.16 (SD= 9.97). The average age of the unaffected participants in the Canadian study was 43.88 years; 39.5% of whom had not had any prophylactic surgery.

Menopausal Symptoms

Menopausal symptoms were more predominant in the prophylactic surgery group in this study; specifically hot flashes, night sweats and vaginal dryness on independent t-tests. The same PS group also had more difficulty with sleep, which could potentially impact other aspects of their lives. Hierarchical multiple regression, controlling for age, found PS predictive for all menopausal symptoms and sleep difficulties. Prophylactic surgery accounted for 15% of the variance in the hot flashes symptom, 12% for vaginal dryness, 7% of the variance for the night sweats symptom and 6% for the sleep difficulties. Only 4% of the variance in bladder control was accounted for by PS.

Chapman et al. (2011) reported results of a small study (*n* =51) of both affected and unaffected BRCA+ women after BPSO; 47% were under the age of 50 at the time of the study. Menopausal symptoms were assessed with a modified Menopause Symptoms List, including the symptoms of hot flashes, weight gain, vaginal dryness, low sex drive, uncomfortable sex, memory problems and depression. The study participants reported an average of 3.5 menopausal symptoms, but details regarding the frequency or specific symptoms were not addressed. In a prospective study using a pre/post-surgical study design, Finch et al. (2011b) also examined menopausal symptoms in affected and unaffected BRCA+ women undergoing BPSO (*n* =114). A modified Menopause-Specific Quality of Life measure was used to evaluate symptoms during the previous one week. For those women experiencing surgical menopause after BPSO, vasomotor symptoms were significantly worse after surgery. Vasomotor symptoms included hot flashes, night sweats and sweating. Symptoms were also exacerbated in women with a prior history of breast cancer. Hormone replacement therapy helped to improve the symptoms, but not to baseline levels.

Sexual Functioning

The FSFI total score and domains of Desire, Arousal, Lubrication and Satisfaction were predicted by DAS in hierarchical multiple regression, while controlling for age, and also predicted by PS in a similar analysis. Significant differences in the PS and NO PS groups were also seen on independent samples t-tests for the same FSFI dependent variables. No differences were seen in the Orgasm or Pain domains for the 2 groups, nor were the findings significant in the hierarchical multiple regression.

Prophylactic surgery explained a small portion of variance in the FSFI total score (4%) and the domain scores (3-8%). However, the one-item DAS score explained 13% of the variance in the FSFI. The DAS question specifically addresses the degree of happiness in one's relationship. A moderate positive correlation was seen between the DAS and total FSFI (r = .32), as well as the total QLI score (r =.46) and PGWBI (r =.48). Any PS had a smaller, negative correlation with FSFI (r = -.18). Sexual functioning is a complex process. Prophylactic surgery appears to have less to do with sexual functioning in the current study than one's relationship status and overall well-being, as seen in other community-based research (Davison et al., 2009).

Of note, estrogen replacement was used by 56.7% of the women who had BPSO (resulting in surgical menopause). The effect of chemoprevention on sexual function was not evaluated. Only a small fraction of women in this study sample were utilizing tamoxifen as a chemopreventive measure (1.7%). In contrast, Schwartz et al. (2011) reported 17% use of tamoxifen or raloxifene in unaffected carriers participating in their study (n = 106), which also included BRCA+ women affected by breast or ovarian cancer (total N = 465).

Satisfaction with Decision

In this study sample, women who had undergone any prophylactic surgery were more satisfied with their decision than those who had not any risk-reducing surgery, significant on independent t-test. Prophylactic surgery was also predictive of SWD on the hierarchical multiple regression, controlling for age. This author hypothesizes the women who participated in this research may have had a preference for prophylactic

surgery over surveillance. In the current study, the majority of women who had not any prophylactic surgery were intending to have surgery in the future (83%).

Westin et al. (2011) also used the Satisfaction with Decision scale in research comparing women undergoing periodic screening with those choosing BPSO (n = 182). Levels of satisfaction with decision for the surgical group were also higher in that study. In a retrospective study of BRCA+ women after BPSO (n=98), 59.2% of women reported they would have preferred more information about sexual side effects prior to surgery (Campfield, Moyer, & Matloff, 2011). Most participants in that study also indicated they would pursue the same surgery again (96.9%) and the majority would also recommend BPSO to other BRCA+ women in a similar situation (97.9%). Finch et al. (2011b) found a decrease in sexual desire and an increase in vaginal dryness, as measured by the Sexual Activity Questionnaire in BRCA+ women after BPSO. Overall, those women were also satisfied with the decision to undergo BPSO. Measured with a study-specific satisfaction questionnaire, the participants reported a mean satisfaction score of 4.55 out of 5, with 5 representing extremely satisfied.

Moderating Role of Prophylactic Surgery

No relationship was seen between FSFI, PGWBI, BRCA-SCC or BIQLI in combination with any prophylactic surgery and the total QLI when examined for interaction effects, independent of the effect of each variable alone. There were significant main effects for the BRCA-SCC, the BIQLI/any prophylactic surgery, the FSFI/any prophylactic surgery, and the PGWBI total score. This result parallels the lack of a significant difference between the PS and NO PS groups on all of the QOL measures in this current study, other than the Family subscale of the QLI measure.

Strengths

This research was innovative in the approach to initiate recruitment at a national conference, with subsequent ongoing web-based recruitment after the conference. Study accrual was relatively rapid, and many participants provided commentary regarding their appreciation for research in this arena. The BRCA Self-Concept Scale, a unique instrument only recently developed for use in this specific population, was utilized. This study was also unique relative to the large sample size and inclusion of only unaffected BRCA+ women, without a personal history of cancer. The majority of published studies have had smaller samples and included women with a personal history of breast or ovarian cancer. These data contribute to our knowledge of quality of life, sexual functioning and psychological well-being in this population.

Study Limitations

These research findings are from a self-selected sample of women with a hereditary risk for breast and ovarian cancer. Most participants became aware of this research effort through one organization, which could bias the results. The data collected is entirely self-report. There was no requirement to answer any research survey items, other than those required for informed consent and confirmation of eligibility with respect to the inclusion criteria. Due to the nature of the research design, this cross-sectional study does not allow for speculation relative to cause and effect.

As a web-based research survey, individuals without access to the internet were unable to participate. In addition, intermittent problems with internet access to the study link could have prevented some individuals from either initiating or completing the study. Recruiting materials included the term previvor in an effort to use the lay language with

which this population self-identifies. The term previvor, or presurvivor, describes an individual who does not have cancer, but possesses a genetic predisposition. This expression may have been unfamiliar to some individuals, precluding participation or possibly confusing potential study participants. The term previvor also implies a certain inevitability of a future cancer diagnosis, which is inaccurate in the face of a BRCA mutation. This potential confusion may also account for the number of individuals who accessed the research study online in an attempt to participate, but were ineligible due to a personal history of cancer.

The study participants were mostly Caucasian, well-educated, with health insurance and access to medical care. They may not be representative of the larger population affected by hereditary breast and ovarian cancer. They do, however, represent a large majority of women reported as undergoing genetic testing with BRAC*Analysis*®.

Implications for Nursing

Practice. The results of this research contribute to our understanding of quality of life in BRCA+ women, particularly those opting for risk-reducing prophylactic surgery. Evidence-based information is important for patient counseling, the informed consent process, and decision-making relative to risk management options. After going through genetic testing, women with a BRCA mutation face difficult life choices. Accurate information regarding the potential risks and benefits relative to those choices is crucial. Health care decisions impact their individual well-being, as well as that of their families and significant others.

Counseling related to risk management is important for patients, couples, and families affected by hereditary breast and ovarian cancer. Potential side effects related to

sexual functioning should be requisite in any discussion prior to prophylactic surgery. Symptom management and appropriate interventions relative to psychosocial well-being and sexual functioning can be tailored to meet the needs of individuals and couples. Ongoing assessment is important in order to provide timely, appropriate referrals for psychological counseling, support and/or consultation with a therapist competent in issues related to sexual health.

Education. Implications for nursing education include the importance of incorporating genetics and genomics into the curriculum. A basic understanding is critical as the science advances and genetics/genomics become a tool in a broader spectrum of patient care. Other important considerations include addressing nursing skills in risk assessment, patient counseling, communication, and human sexuality.

Future research. These data provide a foundation for future research. A prospective longitudinal study, including measures both before and after prophylactic surgery, would provide more insight into the research questions. Additional research is needed to focus on specific hormonal and non-hormonal symptom management interventions, to minimize the sequelae of prophylactic surgery related to female sexual functioning, menopausal symptoms and sleep disturbances. Further investigation is needed to explore the discrepancy in the quality of life scores observed in the QLI and the SASS in this study. Perhaps a mixed- methods design, incorporating focus groups could provide additional insight. Little data are available for BRCA+ women older than 50 years of age, often the parents of offspring of reproductive age who potentially carry a mutation themselves. In addition, couples research could contribute to our knowledge and understanding of the dynamics of inherited cancer risk on the dyad. All of these

individuals face unique challenges in the journey of living with a BRCA mutation. As members of multidisciplinary clinical and research teams, nurses have a fundamental role in risk assessment, referral, education, and research to improve quality of life for this high-risk population.

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Appendices

Appendix A: Web-based Survey Development Task List

1. Develop dissertation research proposal.
2. Defend proposal and obtain approval from Dissertation Committee.
3. Secure funding for research.
4. Develop study-specific Socio-Demographics/ Medical History/ Family Cancer History form.
5. Obtain Institutional Review Board (IRB) approval at the University of South Florida.
    a. Continuing review approval after one year.
6. Obtain letter of support from community agency (Facing Our Risk of Cancer Empowered; FORCE).
7. Obtain password and secure training in Checkbox ® 4.6 Web Survey Software.
8. Convert paper-based research instruments into web-based electronic survey format.
    a. Create conditional questions:
        i. Use question skip patterns as appropriate; develop survey algorithm so study participants only see relevant survey items.
    b. Score web-based survey items, using the previously validated research instruments.
9. Test the web-based survey for functionality, clarity of items.
    a. Revise survey as indicated based on feedback from preliminary testing.
10. Delete all test responses in the final data set.
11. Secure physical space, tables, Wi-Fi internet access, computers, combination locks, Information Technology (IT) support and research study staff for recruitment 06/2011 at the Joining FORCEs Against Hereditary Cancer Conference venue (Hyatt Regency Grand Cypress, Orlando, Florida).
12. Create separate e-mail account for study participants to submit e-mail address for random drawings ($100 e-cards).
13. Establish automated response to any e-mails.
14. Purchase domain name, with shortened URL for easy internet access to web-based study.
15. Create study recruitment materials.
    a. Obtain IRB approval for study recruitment materials and additional study personnel.
16. Commence study recruitment.
17. Export data files in SPSS .sav and Excel formats; secure data in password-protected program.

Appendix A: Web-based Survey Development Task List (Continued)

18. Analyze data.
19. Create spreadsheet for e-mail addresses submitted for e-card drawings.
    a. Random drawings for the $100 e-card, at intervals of every 75-80 respondents.
    b. Notify by e-mail when selected; confirm redemption of e-card from Amazon.com
    c. Send second reminder if not redeemed; re-send gift card, as indicated.
20. Periodic updates and announcements regarding ongoing research study recruitment to study via FORCE website and monthly newsletters.
21. Contact other researchers, organizations, interested parties regarding study (as indicated).
22. Respond to any e-mails and/or questions from participants or potential study participants (ongoing).
23. Provide periodic progress reports to funding agencies: American Cancer Society and the National Institute of Nursing Research and to Dissertation Committee.
24. Disseminate research results:
    a. Poster presentation of preliminary findings at the International Society of Nurses in Genetics (ISONG); Montreal, Quebec, Canada (10/10/2011).
    b. Podium presentation of preliminary findings at the H. Lee Moffitt Cancer Center and Research Institute Nursing Research Day; Tampa, Florida, USA (10/28/2011).

Appendix B: Socio-Demographics, Personal Medical History and Family Cancer History Form

Current age

Where do you live?
State/Province; Country

Last 4 digits of Social Security # /SIN

How did you hear about this study?
Website / Brochure/ Word of mouth / FORCE Conference/ Other

Ethnicity: Hispanic or Latina?

Race: American Indian/Alaska Native
Asian
Native Hawaiian or Pacific Islander
Black or African American
White

Education: highest level completed
Grade School
Middle School
High School
Technical School
Some College
Bachelor's Degree
Graduate Degree /Professional School

Are you currently employed outside of the home?
If no: Are you seeking employment?
Yes/ no; Retired? Student? Homemaker? Other:
If yes, then: current occupation

Marital status: Single / Married / Separated/ Divorced / Widowed

Are you in a committed relationship with a partner? (yes/no)

Do you currently have health insurance coverage? (yes/no)

Appendix B: Socio-Demographics, Personal Medical History and Family Cancer History Form (Continued)

Estimated distance to your primary health care provider? [Miles/Km]
Within 25 miles / 50-100 miles / 100-250 miles /more than 250 miles away
Do you participate in a support group or community forum?
Yes, in person / Yes, web-based / No

Have any blood relatives been diagnosed with cancer?
(Parents, Grandparents, aunts, Uncles, Siblings)
Yes/No/ Adopted or Unknown

Ashkenazi Jewish heritage (yes/no)

If you know any information about your biological family, please address the following as applicable.
Maternal= Mom's side of family / Paternal = Dad's side of the family
Type of cancer = primary site if known.
Cancer type/ Age at diagnosis/ Still Living (yes/no)
Mother
Father
Sister (s)
Brother(s)
Son(s)
Daughter(s)
Maternal Grandmother
Maternal Grandfather
Maternal Aunt(s)
Maternal Uncle(s)
Maternal Cousin(s)
Paternal Grandmother
Paternal Grandfather
Paternal aunt(s)
Paternal Uncle(s)
Paternal Cousin(s)

Appendix B: Socio-Demographics, Personal Medical History and Family Cancer History Form (Continued)

Height (inches/ centimeters)
Weight (pounds/ kilograms)
- Any changes in weight over the past year? (yes/no)
- How much weight have you gained or lost? (amount)
- Was your change in weight intentional? (yes/no)

Have you been diagnosed with any of the following medical concerns?
(Please check all that apply.)
- Hypertension
- Heart problems
- High cholesterol
- Diabetes mellitus
- Thyroid problems
- Arthritis
- Headaches
- Depression
- Anxiety
- Endometriosis
- Uterine fibroids
- Osteoporosis
- Osteopenia
- Other:

Gynecologic History:
- Age of first menstrual period
- Last menstrual period (month/year)
- Total # of pregnancies
- # of live births
- Age at first live birth?
- Irregular menstrual periods?
- Spotting or bleeding between periods?
- Vaginal bleeding or spotting with sexual intercourse?

Are you pregnant now? (yes/no)
Have you ever breastfed? (yes/no; for how long if applicable = # of months)
Any plans for children in the future? (yes/no)

Appendix B: Socio-Demographics, Personal Medical History and Family Cancer History Form (Continued)

Any current contraception to prevent pregnancy? (yes/no)

Current contraception methods.

(Please check all that apply.)

Condoms, vasectomy, bilateral tubal ligation, IUD, diaphragm, birth control pills, Depo-provera, patch, diaphragm, tubal ligation, abstinence, other?

Current prescription medications (yes/no)

Birth control pills/ oral contraceptives
Anti-anxiety
Anti-depressants
Estrogen
Progesterone
Testosteroe
Tamoxifen/ How long have you taken Tamoxifen? (# of months)

Any other prescription medications?

Current over-the counter medication (herbs, calcium, vitamins, or supplements available without a prescription).

Have you ever smoked cigarettes? (yes/no)

Age when you started using tobacco?
How many cigarettes daily?
Other tobacco use?
Total # of years smoked?
If you have quit, age when you stopped using tobacco?

Do you drink any alcohol?

Number of drinks per week? (Beer/ Wine/ Hard liquor)

Do you exercise on a regular basis? (yes/no)

Please indicate type of exercise & # of days per week.

Genetic testing results:

BRCA 1 positive/ BRCA 2-positive /
BRCA Variant of undetermined significance/ Other

How long has it been since you received your genetic test results?

0-6 months / 6-12 months/ 1-2 years/ 2-3 years/ 3-4 years/ 4-5 years/ > 5 years

Appendix B: Socio-Demographics, Personal Medical History and Family Cancer History Form (Continued)

Did you see a Genetic Counselor prior to testing for BRCA? (yes/no)
Health care provider.

Please tell us about your health care team.

Indicate any providers you have seen in the past one year (*may select more than one).*

Primary care provider; Obstetrician/ Gynecologist; Gynecologic Oncologist; Medical Oncologist; Surgical Oncologist; Breast Surgical Oncologist; General Surgeon; Plastic Surgeon; Psychiatrist; Psychologist; Mental Health Counselor

Any other health care providers?

Are you followed in a "High-Risk" clinic setting? (yes/no)
Do you have a pelvic exam on a regular basis (with or without a Pap smear)

Yes- once yearly; Yes- every 6 months; No

Do you have pelvic sonograms (ultrasound) on a regular basis?

Yes- once yearly; Yes- every 6 months; Yes- more often; No

Do you have a CA-125 blood level checked?

Yes- once yearly; Yes- every 6 months; No

Have you ever had a bone density test? (DEXA/ bone densitometry) (Yes/no)

Do you have breast imaging (mammogram, breast MRI &/or breast ultrasound/sonogram)? (yes/no)

Type & frequency of regularly scheduled breast imaging.

Once yearly (yes/no); every 6 months (yes/no)

Have you had *any* prophylactic, risk-reducing surgery? (yes/no)
Prophylactic mastectomy (yes/no)

Procedure type / At what age.

Sentinel Lymph Node biopsy at the time of mastectomy? (yes/no)

Immediate breast reconstruction at the time of your mastectomy? (yes/no)

Type of reconstruction

Reconstruction completed? (yes/no)

Date of final procedure.

Is there any surgery pending?

Prophylactic surgery to remove fallopian tubes & ovaries (salpingo-oophorectomy) (yes/no)

Procedure type

Appendix B: Socio-Demographics, Personal Medical History and Family Cancer History Form (Continued)

Hysterectomy? (yes/no)

Procedure type; at what age? At same time as removal of tubes and ovaries?

Any other surgical procedures?

Procedure type/ At what age?

Any complications related to your surgery (or surgeries)?

What do you think was the primary reason you chose to have prophylactic, risk-reducing surgery? (What was your motivation for having surgery?)

or

What do you think is the primary reason you have decided not to have prophylactic surgery?

Do you intend to have any risk-reducing surgery in the future? (yes/no)

What surgery do you think you might have in the future?

Appendix C: Quality of Life Index
Ferrans and Powers
QUALITY OF LIFE INDEX© GENERIC VERSION - III

PART 1. For each of the following, please choose the answer that best describes how ***satisfied*** you are with that area of your life. Please mark your answer by circling the number. There are no right or wrong answers.

Response options: 1= Very Dissatisfied 2= Moderately Dissatisfied 3= Slightly Dissatisfied 4= Slightly Satisfied 5= Moderately Satisfied 6= Very Satisfied

HOW *SATISFIED* ARE YOU WITH:

1. Your health?
2. Your health care?
3. The amount of pain that you have?
4. The amount of energy you have for everyday activities?
5. Your ability to take care of yourself without help?
6. The amount of control you have over your life?
7. Your chances of living as long as you would like?
8. Your family's health?
9. Your children?
10. Your family's happiness?
11. Your sex life?
12. Your spouse, lover, or partner?
13. Your friends?
14. The emotional support you get from your family?
15. The emotional support you get from people other than your family?
17. How useful you are to others?
18. The amount of worries in your life?
19. Your neighborhood?
20. Your home, apartment, or place where you live?
21. Your job (if employed)?
22. Not having a job (if unemployed, retired, or disabled)?
23. Your education
24. How well you can take care of your financial needs?
25. The things you do for fun?
26. Your chances for a happy future?
27. Your peace of mind?
28. Your faith in God?
29. Your achievement of personal goals?
30. Your happiness in general?
31. Your life in general?
32. Your personal appearance?
33. Yourself in general?

Appendix C: Quality of Life Index (Continued)

PART 2. For each of the following, please choose the answer that best describes how ***important*** that area of your life is to you. Please mark your answer by circling the number. There are no right or wrong answers**.**

Response options: 1= Very Unimportant 2= Moderately Unimportant 3= Slightly Unimportant 4= Slightly Important 5= Moderately Important 6= Very Important

HOW *IMPORTANT* TO YOU IS:

1. Your health?
2. Your health care
3. Having no pain?
4. Having enough energy for everyday activities
5. Taking care of yourself without help
6. Having control over your life?
7. Living as long as you would like?
8. Your family's health?
9. Your children?
10. Your family's happiness
11. Your sex life?
12. Your spouse, lover, or partner?
13. Your friends?
14. The emotional support you get from your family
15. The emotional support you get from people other than your family?
16. Taking care of family responsibilities
17. Being useful to others
18. Having no worries?
19. Your neighborhood
20. Your home, apartment, or place where you live?
21. Your job (if employed)?
22. Having a job (if unemployed, retired, or disabled).
23. Your education?
24. Being able to take care of your financial needs?
25. Doing things for fun?
26. Having a happy future
27. Peace of mind
28. Your faith in God?
29. Achieving your personal goals?
30. Your happiness in general?
31. Being satisfied with life?
32. Your personal appearance?
33. Are you to yourself?

Appendix D: Self-Anchoring Striving Scale

We all desire certain things out of life. When you think about what really matters in your own life, where on the ladder would you place your life at the present time?

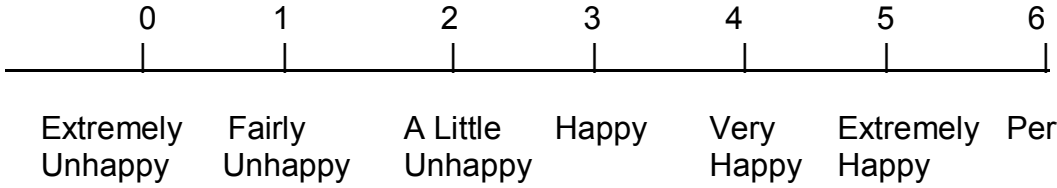
10 = the best you can imagine

10
9
8
7
6
5
4
3
2
1

1 = the worst you can imagine.

Appendix E: Dyadic Adjustment Scale
(One-item: Happiness)

There are different degrees of happiness in relationships. The middle point, "happy," represents the degree of happiness in most relationships. Please circle the number that best describes the degree of happiness, all things considered, of your relationship at the present time.



Appendix F: Body Image Quality of Life Inventory

***Instructions**:* Different people have different feelings about their physical appearance. These feelings are called "body image." Some people are generally satisfied with their looks, while others are dissatisfied. At the same time, people differ in terms of how their body-image experiences affect other aspects of their lives. Body image may have positive effects, negative effects, or no effect at all. Listed below are various ways that your own body image may or may not influence your life. For each item, circle how and how much your feelings about your appearance affect that aspect of your life. Before answering each item, think carefully about the answer that most accurately reflects how your body image usually affects you.

- 3= Very Negative Effect; -2= Moderate Negative Effect; -1=Slight Negative Effect; 0= No effect; +1= Slight Positive Effect; +2=Moderate Positive Effect; +3= Very Positive Effect

1. My basic feelings about myself—feelings of personal adequacy and self-worth
2. My feelings about my adequacy as a man or woman—feelings of masculinity or femininity.
3. My interactions with people of my own sex.
4. My interactions with people of the other sex.
5. My experiences when I meet new people.
6. My experiences at work or at school.
7. My relationships with friends.
8. My relationships with family members.
9. My day-to-day emotions.
10. My satisfaction with my life in general.
11. My feelings of acceptability as a sexual partner.
12. My enjoyment of my sex life.
13. My ability to control what and how much I eat.
14. My ability to control my weight.
15. My activities for physical exercise.
16. My willingness to do things that might call attention to my appearance.
17. My daily "grooming" activities (i.e., getting dressed and physically ready for the day).
18. How confident I feel in my everyday life.
19. How happy I feel in my everyday life.

Appendix G: Female Sexual Functioning Index

INSTRUCTIONS: These questions ask about your sexual feelings and responses during the past 4 weeks. Please answer the following questions as honestly and clearly as possible. Your responses will be kept completely confidential. In answering these questions the following definitions apply:

Sexual activity can include caressing, foreplay, masturbation and vaginal intercourse.

Sexual intercourse is defined as penile penetration (entry) of the vagina.

Sexual stimulation includes situations like foreplay with a partner, self-stimulation (masturbation), or sexual fantasy.

CHECK ONLY ONE BOX PER QUESTION.

Sexual desire or interest is a feeling that includes wanting to have a sexual experience, feeling receptive to a partner's sexual initiation, and thinking or fantasizing about having sex.

1. Over the past 4 weeks, how **often** did you feel sexual desire or interest?
   - Almost always or always
   - Most times (more than half the time)
   - Sometimes (about half the time)
   - A few times (less than half the time)
   - Almost never or never

2. Over the past 4 weeks, how would you rate your **level** (degree) of sexual desire or interest?
   - Very high
   - High
   - Moderate
   - Low
   - Very low or none at all

Sexual arousal is a feeling that includes both physical and mental aspects of sexual excitement. It may include feelings of warmth or tingling in the genitals, lubrication (wetness), or muscle contractions.

3. Over the past 4 weeks, how **often** did you feel sexually aroused ("turned on") during sexual activity or intercourse?
   - No sexual activity
   - Almost always or always
   - Most times (more than half the time)
   - Sometimes (about half the time)
   - A few times (less than half the time)
   - Almost never or never

Appendix G: Female Sexual Functioning Index (Continued)

4. Over the past 4 weeks, how would you rate your **level** of sexual arousal ("turn on") during sexual activity or intercourse?
   - No sexual activity
   - Very high
   - High
   - Moderate
   - Low
   - Very low or none at all

5. Over the past 4 weeks, how **confident** were you about becoming sexually aroused during sexual activity or intercourse?
   - No sexual activity
   - Very high confidence
   - High confidence
   - Moderate confidence
   - Low confidence
   - Very low or no confidence

6. Over the past 4 weeks, how **often** have you been satisfied with your arousal (excitement) during sexual activity or intercourse?
   - No sexual activity
   - Almost always or always
   - Most times (more than half the time)
   - Sometimes (about half the time)
   - A few times (less than half the time)
   - Almost never or never

7. Over the past 4 weeks, how **often** did you become lubricated ("wet") during sexual activity or intercourse?
   - No sexual activity
   - Almost always or always
   - Most times (more than half the time)
   - Sometimes (about half the time)
   - A few times (less than half the time)
   - Almost never or never

8. Over the past 4 weeks, how **difficult** was it to become lubricated ("wet") during sexual activity or intercourse?
   - No sexual activity
   - Extremely difficult or impossible
   - Very difficult
   - Difficult
   - Slightly difficult
   - Not difficult

Appendix G: Female Sexual Functioning Index (Continued)

9. Over the past 4 weeks, how often did you **maintain** your lubrication ("wetness") until completion of sexual activity or intercourse?
   - No sexual activity
   - Almost always or always
   - Most times (more than half the time)
   - Sometimes (about half the time)
   - A few times (less than half the time)
   - Almost never or never

10. Over the past 4 weeks, how **difficult** was it to maintain your lubrication ("wetness") until completion of sexual activity or intercourse?
   - No sexual activity
   - Extremely difficult or impossible
   - Very difficult
   - Difficult
   - Slightly difficult
   - Not difficult

11. Over the past 4 weeks, when you had sexual stimulation or intercourse, how **often** did you reach orgasm (climax)?
   - No sexual activity
   - Almost always or always
   - Most times (more than half the time)
   - Sometimes (about half the time)
   - A few times (less than half the time)
   - Almost never or never

12. Over the past 4 weeks, when you had sexual stimulation or intercourse, how **difficult** was it for you to reach orgasm (climax)?
   - No sexual activity
   - Extremely difficult or impossible
   - Very difficult
   - Difficult
   - Slightly difficult
   - Not difficult

13. Over the past 4 weeks, how **satisfied** were you with your ability to reach orgasm (climax) during sexual activity or intercourse?
   - No sexual activity
   - Very satisfied
   - Moderately satisfied
   - About equally satisfied and dissatisfied
   - Moderately dissatisfied
   - Very dissatisfied

Appendix G: Female Sexual Functioning Index (Continued)

14. Over the past 4 weeks, how **satisfied** have you been with the amount of emotional closeness during sexual activity between you and your partner?
    - No sexual activity
    - Very satisfied
    - Moderately satisfied
    - About equally satisfied and dissatisfied
    - Moderately dissatisfied
    - Very dissatisfied

15. Over the past 4 weeks, how **satisfied** have you been with your sexual relationship with your partner?
    - Very satisfied
    - Moderately satisfied
    - About equally satisfied and dissatisfied
    - Moderately dissatisfied
    - Very dissatisfied

16. Over the past 4 weeks, how **satisfied** have you been with your overall sexual life?
    - Very satisfied
    - Moderately satisfied
    - About equally satisfied and dissatisfied
    - Moderately dissatisfied
    - Very dissatisfied

17. Over the past 4 weeks, how **often** did you experience discomfort or pain during vaginal penetration?
    - Did not attempt intercourse
    - Almost always or always
    - Most times (more than half the time)
    - Sometimes (about half the time)
    - A few times (less than half the time)
    - Almost never or never

18. Over the past 4 weeks, how **often** did you experience discomfort or pain following vaginal penetration?
    - Did not attempt intercourse
    - Almost always or always
    - Most times (more than half the time)
    - Sometimes (about half the time)
    - A few times (less than half the time)
    - Almost never or never

Appendix G: Female Sexual Functioning Index (Continued)

19. Over the past 4 weeks, how would you rate your **level** (degree) of discomfort or pain during or following vaginal penetration?
    - Did not attempt intercourse
    - Very high
    - High
    - Moderate
    - Low
    - Very low or none at all

If no sexual activity during the past 4 weeks, please indicate the reason (may choose more than one):

Not really interested in sex	○
Physical problems related to sex	○
Lack of a partner	○
Partner has physical problems related to sex	○
Partner is not interested in sex	○
Other: _____	

Appendix H: Menopausal Symptom Scale

Below is a list of symptoms that you may have experienced during the week. Please rate how bothered you were each by each problem during the last week by circling one number for each symptom.

Not at all	Slightly	Moderately	Quite a bit	Extremely
1	2	3	4	5

Hot flashes
Night sweats
Vaginal dryness
Genital itching/irritation
Pain in pelvic area
Difficulty with bladder control while laughing or crying
Difficulty with bladder control at other times
Sleep problems (difficulty falling asleep, sleeping through the night, waking up early)

Appendix I: Psychological General Well-Being Index (Revised)

*Questions are to be answered for how you have felt ***during the past week***.

1. Did you feel in good spirits?
2. Have you been bothered by any illness, bodily disorder, aches or pains?
3. Have you felt depressed?
4. Have you been in firm control of your behavior, thoughts, emotions or feelings?
5. Have you been bothered by nervousness or your 'nerves'?
6. Did you have a lot of energy, pep or vitality?
7. Have you felt downhearted and blue?
8. Have you been generally tense or did you feel any tension?
9. Have you been happy, satisfied, or pleased with your personal life?
10. Did you feel healthy enough to carry out the things you like to do or had to do?
11. Have you felt sad, discouraged, hopeless, or had so many problems that you wondered if anything was worthwhile?
12. Have you been waking up feeling fresh and rested?
13. Have you been concerned, worried or had any fears about your health?
14. Have you had any reason to wonder if you were losing your mind, or losing control over the way you act, talk, think, feel or of your memory?
15. Has your daily life been full of things that were interesting to you?
16. Did you feel dull or sluggish?
17. Have you been anxious, worried, or upset?
18. Have you been feeling emotionally stable and sure of yourself?
19. Did you feel relaxed and at ease?
20. Have you felt cheerful and lighthearted?
21. Have you felt tired, worn out, used up or exhausted?
22. Have you been under, or felt you were under any strain, stress or pressure?

Response options (# 1,3,5,7,9,11,13,15,17,19,21): None of the time; A little of the time; Some of the time; A good bit of the time; Most of the time; All of the time
Response options (# 2,4,6,8,10,12,14,16,18,20,22): All of the time; Most of the time; A good bit of the time; Some of the time; A little of the time; None of the time
Scoring: Reverse items 3,4,5,6,7,10,11,12,13,17,18,20,21
Subscale composition:
Anxiety—5,8,17,19,22
Depressed Mood—3,7,11
Positive Well-Being—1,9,15,20
Self-Control—4,14,18
General Health—2,10,13
Vitality—6,12,16,21

Appendix J: BRCA Self-Concept Scale

Instructions: Below is a list of statements that people sometimes make about themselves. Please read each statement and decide if you agree or disagree and to what extent. If you strongly disagree circle 1, if you strongly agree circle 7, if you are somewhere in between circle any of the other numbers between 1 and 7, number 4 is the midpoint. If the statement does not apply to you please circle 8 for not applicable.

1. I am hopeful about myself in the future **(R)**

2. I am able to deal with my test result **(R)**

3. I feel my body has betrayed me

4. I feel like a walking time bomb

5. I feel different from others my age

6. I know my body well **(R)**

7. I feel guilty that I might pass on a cancer risk to my children

8. I feel isolated because of my test result

9. I feel I have lost my sense of privacy

10. I think about my test result a lot

11. I am worried that cancer will be found when I go for screening

12. I feel labeled

13. I feel burdened with this information

14. I distrust my body

15. I am in control of my health **(R)**

16. My test result gets in the way of who I really am

17. I have become more secretive

(R) indicates item to be recoded.

Appendix K: Satisfaction with Decision

Please answer the following questions regarding your decision on how to manage your hereditary risk for cancer.

Please indicate to what extent each statement is true for you AT THIS TIME.
Use the following scale to answer the questions.
1 = strongly disagree
2= disagree
3=neither agree nor disagree
4= agree
5= strongly agree

1. I am satisfied that I am adequately informed about the issues important to my decision.

2. The decision I made was the best decision possible for me personally.

3. I am satisfied that my decision was consistent with my personal values.

4. I expect to successfully carry out (or continue to carry out) the decision I made.

5. I am satisfied that this was my decision to make.

6. I am satisfied with my decision.