RUTGERS
Cancer Institute
of New Jersey

Rutgers, The State University of New Jersey
195 Little Albany Street
New Brunswick, NJ 08903-2681

cinj.org
p. 732-235-2465

Facilitating Informed Decisions for Contralateral Prophylactic Mastectomy

Principal Investigator: Sharon Manne, Ph.D
Rutgers Cancer Institute of New Jersey
195 Little Albany Street
New Brunswick, NJ 08903
Telephone: (732) 235-6759, FAX: (732) 235-6225
Email: mannesl@cinj.rutgers.edu

Co-Principal Investigator: Laurie Kirstein, M.D.
Memorial Sloan Kettering Cancer Center
300 east 66 St.
NY, NY 10065
646-888-5403
Email: kirsteil@mskcc.org

Subinvestigators:

Barbara Smith, M.D., Ph.D
Massachusetts General Hospital

Deborah Kashy, Ph.D
Michigan State University
(statistician)

Kevin Criswell, Ph.D.
Rutgers CINJ Co-Investigator

Shawna Hudson, Ph.D
Rutgers CINJ Co-Investigator

Sara Frederick, MS
Rutgers CINJ study staff

Deborah Toppmeyer, MD
Rutgers CINJ study staff

Travis Logan, MS
Rutgers CINJ study staff

Anna Mitarotondo, BA
Rutgers CINJ Study staff

Rutgers Cancer Institute of New Jersey
Operations Center
Office of Human Research Services
Rutgers Cancer Institute of New Jersey
195 Little Albany Street
New Brunswick, NJ 08903
Telephone: (732) 235-8675
FAX: (732) 235-7690

Rutgers Cancer Institute of New Jersey
Biostatistical Center
Biometrics Division
Rutgers Cancer Institute of New Jersey
120 Albany Street, 5th Floor
New Brunswick, NJ 08903
Telephone: (732) 235-6791
FAX: (732) 235-7350

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LIST OF ABBREVIATIONS

CINJ, Cancer Institute of New Jersey

RWJMS, Robert Wood Johnson Medical School

MGH, Massachusetts General Hospital

MSKCC, Memorial Sloan Kettering Cancer Center

CPM, Contralateral Prophylactic Mastectomy

UBC, Unilateral Breast Cancer

ITX Corps, web software development company

WSC, Women With Sporadic Cancers

DA, Decision Aid

RCT, randomized controlled trial

1. Purpose/Specific Aims

Contralateral Prophylactic Mastectomy (CPM), a medically unnecessary procedure for women with sporadic cancers, is rising exponentially. The goal of this study is to develop a theoretically guided, web-based DA (CPM-DA) for women with sporadic breast cancer to promote informed decision making. A web-based intervention was selected to allow for improved options for dissemination and reach for future research. Development of the CPM-DA will be accomplished in two phases. **Phase 1** will be a developmental phase where the basic DA content will be developed based on interviews with women with sporadic breast cancer who have or have not had CPM, as well as investigator input. The CPMDA prototype will be reviewed by women who have and have not undergone CPM. In **Phase 2**, the finalized CPM-DA will be evaluated in a small randomized clinical trial for acceptability, feasibility, and preliminary efficacy among women with sporadic breast cancer considering CPM. We will conduct a small randomized trial assigning patients to receive Usual Care or the CPM-DA.

Primary Aim: Is the intervention trial feasible?

The purpose is to develop a feasible web-based DA. Thus, it is important that this trial provide evidence of feasibility. We will define feasibility as the rate of acceptance and participation. These figures will be based on the randomized trial (Phase 2 of the current study). First, we will examine acceptance as determined by consents and completed baseline interviews. Second, we will examine the length of time for completing surveys.

Secondary Aim 1:

To provide preliminary data on the impact of the CPM-DA on preparedness to make the CPM decision, decisional conflict, CPM knowledge, psychosocial factors, Perceived risk for cancer in the healthy/ breast/metastatic disease, cancer recurrence/metastasis worry, cancer distress and intention to have CPM.

2. Background and Significance

2.1. CPM among women with sporadic breast cancer. **Rates of contralateral prophylactic mastectomies (CPM) are increasing but are not associated with improved survival among women diagnosed with sporadic breast cancer.** More than 242,300 US women are diagnosed with unilateral breast cancer (UBC, or cancer in one breast) annually (American Cancer Society, 2013). The rate of women with UBC choosing removal of the non-cancerous breast, a procedure called contralateral prophylactic mastectomy (CPM) has risen exponentially (Cemal et al., 2013; Stucky et al., 2010, Arrington et al., 2009; Jones et al., 2009). The use of CPM among women with a strong family history does not account for the increase in CPM. Rather, the increase is thought to be due to women without a strong family history (henceforth referred to as women with sporadic cancers, or WSC) choosing CPM. Although a case can be made for CPM among women with a strong family history of breast cancer(van Sprundel et. al.,, 2005, Fayanju, et. al., 2014), CPM is not recommended for sporadic breast cancers because it does not reduce the risk for metastatic disease or improve survival(Peralta et. al., 2000, Herrinton et. al., 2005, Fayanju, et. al., 2014) . The Society of Surgical Oncology's position statement endorses CPM in the following situations: 1) BRCA 1-2 mutation; 2) high risk lesions (e.g.,

atypical ductal hyperplasia, lobular carcinoma in situ); 3) prior UBC; 4) difficulty following contralateral breast radiology, or; 5) cosmetic reasons (Society of Surgical Oncology, 2007).The arguments against routine CPM in patients who do not meet these criteria are: 1) the risk of systemic disease exceeds the risk of a contralateral breast cancer; 2) the risk for contralateral breast cancer is low among WSC; 3) effective adjuvant treatments such as chemotherapy, tamoxifen, and/or aromatase inhibitors for estrogen-receptive tumors reduce contralateral breast cancer risk by 50% (Bedrosian et al., 2010; Fisher et al., 1996); 4) breast surveillance with MRI is available; 5) CPM is associated with increased post-surgical infection rates(Osman et al., 2013); 6) CPM does not completely eliminate contralateral breast cancer risk(Tuttle et al., 2012). Despite these facts, an increasing percentage of WSC choose CPM, with an estimated 9,160 surgeries performed in 2014 (extrapolated from data from the American Cancer Society, 2014).

2.2. Factors contributing to CPM decisions.

Little is known about why women diagnosed with sporadic breast cancer choose CPM. The increased use of CPM among women with sporadic breast cancer is thought to be related to several factors (Yi et. al., 2010): 1) improved post-mastectomy reconstruction outcomes; 2) emotional distress about cancer, uncertainty, and the desire to reduce future cancer risk which leads to a preference for aggressive treatments; 3) decision-making urgency, and; 4) information about CPM obtained from the media and internet. Breast cancer diagnosis can trigger distress and the desire to reduce the risk for future cancer recurrence or spread. Studies suggest that women choosing CPM report higher cancer distress and general distress and greater perceived risk of recurrence at the time of CPM (King et. al., 2013). As such, a key motivation for choosing CPM among women at sporadic risk is to decrease one's risk for contralateral breast cancer, a desire to achieve peace of mind, to improve survival, and prevent cancer from spreading(Rosenberg et. al., 2013, Soran et. al., 2013).. However, CPM does not confer a significant survival advantage(Herrinton et. al., 2005) and actual risk for cancer in the healthy breast among women at sporadic cancer risk is low (Tuttle et. al., 2007). Indeed, women report knowing that CPM will not improve survival, but at the same time, they overestimate their risk of developing cancer in the healthy breast and state that they chose CPM to improve their chances of survival (Rosenberg et. al., 2013). Studies suggest that women with sporadic breast cancer estimate that 10% of patients will develop contralateral breast cancer without CPM over 5 years, which overestimates the actual risk of about 2-4% over 5 years (Tuttle et. al., 2007). A second stressor that women face is that most treatments that confer life-time benefit are initiated in the first few months after diagnosis, and the decision process about surgical options is compressed into 2-3 weeks pre-surgery (Katz & Morrow, 2013). Thus, there is pressure to make treatment decisions, which may lead patients to accept treatments regardless of their risks and benefits (Katz & Morrow, 2013). A third motivator for CPM decisions is information women receive from health professionals (Rosenberg et. al., 2013) as well as information from the internet and/or media. Even when women are informed, they may not accurately recall or relate this information to their personal situation (Yi et. al., 2010). Surgeons' input may not be a key influence in CPM decisions ((Rosenberg et. al., 2013), as research suggests that two-thirds of women indicate that their physician was not an important factor (Yi et. al., 2010). Instead, women attend to their own urgency and high-profile patients choosing this surgery (Katz & Morrow, 2013). Indeed, surgeons may acquiesce to patients because they do not wish to lose the patient (Tuttle et. al., 2007). There have been no studies evaluating how CPM is discussed with surgeons pre-operatively. The expectation that CPM will provide psychological relief is

valid. Women choosing CPM report lower levels of breast cancer concern (Geiger et. al., 2008) and greater satisfaction with their breasts compared to women who do not choose CPM (Koslow et.al., 2013). Levels of distress and quality of life, however, do not differ(Geiger et. al., 2008). Moreover, the procedure is not without adverse effects. Between 6% and 13.5% of women choosing CPM report decisional dissatisfaction (Geiger et. al., 2008),Montgomery et.al., 1999, Altschuler et. al., 2008, Borgen et. al., 1998, Frost et.al., 2005, Frist et. al., 2011). Reasons for dissatisfaction include cosmetic appearance (Rosenberg et. al., 2013, Montgomery et.al., 1999, Altschuler et. al., 2008), loss of breast sensation (Altschuler et. al., 2008_, dissatisfaction with information regarding alternative options to CPM (Altschuler et. al., 2008), and loss of femininity (Montgomery et.al. 1999, Altschuler et. al., 2008). Unfortunately, because high-risk women are also included in these studies, the levels of long-term satisfaction, decisional regret, and body image for women with sporadic cancer selecting CPM are not well-studied. CPM among women with sporadic breast cancer indicates that decisions are guided by the expectation that CPM will reduce recurrence in the healthy breast and improve survival, when this surgery is not medically recommended. Many women state they do not receive information from doctors about reasons for not having CPM, and among those who do; physician input is not a key factor in the decision. Patient anxiety may interfere with effective decision making.

Decision Support Aids are Useful. Studies suggest some women who choose CPM express decisional regret and dissatisfaction. It is difficult to form conclusions about decisional processes among women with sporadic breast cancer because studies have included both high risk and sporadic risk breast cancer patients together. Thus, it is not known whether women with sporadic breast cancer report the same levels of satisfaction and quality of life after CPM. Because there is no clear medical rationale for CPM for these women, balanced information regarding CPM, clarification of actual cancer risk, bolstering efficacy to manage cancer anxiety, and presenting alternatives to CPM may result in more informed decision-making. Patients who face difficult treatment decisions in a medical situation where information is not uniformly presented may benefit from decision support aids (DAs) to facilitate informed decision-making (Andersen et. al., 2009). DAs are used to supplement practitioners' counseling and are designed to facilitate patients' understanding of the options, help patients weigh advantages and disadvantages of each option, increase patients' awareness of the personal importance attached to the benefits and risks of each option, and encourage patients to engage with their health care providers in deciding which option to pursue (Andersen et. al., 2009, ACS). Our team has developed and piloted a decision support aid for breast cancer patients undergoing mastectomy to facilitate informed decision making about breast reconstruction. The breast reconstruction decision aid (named BRAID) was highly rated and improved knowledge about reconstruction (Manne & Kirstein, unpublished data, see Appendix E for screenshots). In the context of CPM decisions, DAs can address cancer anxiety, teach anxiety management skills, and provide personalized education about actual risk versus perceived risk. Ultimately, improved decision making can contribute to greater long-term decisional satisfaction (Fayanju et. al., 2014, Lostumbo et. al., 2010). Toward this end, we propose to develop a theoretically-guided, multiplatform, web-based DA (CPM-DA) for women with sporadic breast cancer to educate them regarding CPM. A multiplatform intervention (desktop computer/tablet) was selected to allow for improved options for dissemination and reach for future research.

2.3. Timeline for Decision Making. Once a palpable mass or radiologic finding is identified, the patient has a biopsy within 1-2 weeks. Within one week, the biopsy result is given to the patient. At that time, the surgeon presents the surgical options (lumpectomy, mastectomy), and surgery is scheduled within 1-2 weeks for lumpectomy and 2-3 weeks for mastectomy. Patients considering CPM consult a plastic surgeon, and then decide (before the mastectomy) whether they wish to proceed with CPM. The decision making timeline is brief.

2.4. Decisional processes. As noted above, there is little known about how women make the CPM decision. Although studies have shown that women choosing CPM are satisfied with their decision and many do not report regret (Geiger et al., 2008), other studies suggest that there is decisional regret and dissatisfaction in a subset of women (Rosenberg, et.al. 2013; Altschuler et al., 2008). It is difficult to form conclusions about decisional processes among WSC because studies have included both high risk and WSC patients together. Thus, it is not known whether WSC report the same levels of satisfaction and quality of life after CPM. Because there is no clear medical rationale for CPM among WSC, balanced information regarding CPM, clarification of actual cancer risk, bolstering efficacy to manage cancer anxiety and surveillance, and presenting alternatives to CPM may result in more informed decision-making.

Health information-seeking behaviors support the need for web-based approach. A review of patients undergoing CPM at CINJ in the last two years indicates that 67% were White, 22% were Hispanic, 7.4% were Asian, and 3.6% were Black. The median age was 50 with a range from 36 to 76 years of age. The population at Massachusetts General and Memorial Sloan Kettering, our other sites, is the same with regard to age, but more highly educated and primarily white. Given this age and ethnicity composition of the sample, 2013 figures suggest that between 80- 85% of patients approached for the proposed study will have internet access (Cole et.al. 2013). The internet is an increasing source of health information for healthy adults as well as patients coping with a variety of medical conditions. Among internet users, 83% report having looked online for health information (Pew Internet and American Life Project, 2011). More than two-thirds of individuals diagnosed with cancer report looking for cancer information and the most common source of information is the Internet (Pew Internet and American Life Project, 2011). Web-based information influences treatment decisions (Castleton et. al., 2011). Web-based interventions are effectively used to enhance decision support for breast cancer patients with BRCA mutations (Schwartz et. al., 2009) and to reduce distress for cancer patients (David et.al. 2013, Duffecy et. al., 2013, Gustafson et. al., 2001, Stanton et. al., 2013). Use and adherence is good, with figures ranging from 63%34 to 86% (Stanton et.al., 2013.

2.5. Multi-platform Internet Approaches. Cancer patients obtain information from their health providers, but are increasingly finding cancer information on the internet (Metz et al., 2003; Castelton et al., 2011). Indeed, about 47-63% of breast cancer patients report searching for cancer information on the internet (Metz et al., 2003, Littlechild & Barr, 2013). Internet information influences treatment decisions (Castelton et al., 2011). Internet interventions are effectively used to enhance decision support for breast cancer patients with BRCA mutations (Schwartz et al., 2009) and to reduce distress for cancer patients (David et al., 2013; Duffecy et al., 2013; Gustafson et al., 2011; Stanton et al., 2013). Use and adherence is relatively high, with figures ranging from 63% (Schwartz et al., 2009) to 86% (Stanton et al., 2013). Multiplatform interventions (desktop, pamphlet, smartphone) are currently the most common way individuals obtain information. Few studies have utilized this platform in cancer treatment, although studies use the smart phone as a delivery mode for other health issues (Hyun et al., 2013). It is thought that multiplatform applications will ultimately enhance dissemination of

health behavior interventions (Panayi et. al, 2013). Multiplatform interventions are currently the most common way individuals obtain web-based information.
Summary of Significance. CPM is a medically unnecessary procedure for women diagnosed with sporadic breast cancer and is associated with increased risk for post-surgical complications. Despite this, its use is rising in this population. We will develop a DA to facilitate well-informed and value-sensitive CPM decisions to improve decisional preparedness, improve knowledge, reduce perceived risk and anxiety about recurrence, and improve patients' ability to cope with anxiety about cancer recurrence. The web-based DA has high potential to for future dissemination.

Prior work: Facilitating informed decision making for breast reconstruction (R21 CA149531). This study evaluates the acceptability/efficacy of a breast reconstruction decision aid (BRAID) to assist women with making the decision about reconstruction. BRAID is being compared with a publicly-available pamphlet. 80% of participants logged into BRAID and it was highly rated (Manne et al., 2010; Manne et al., 2007). The goal was to evaluate the efficacy of a CD-ROM decision aid to facilitate informed consent for MSI testing. The decision aid increased knowledge and preparedness and reduced decisional conflict.

3. Research Design and Methods

The Team. Our research team has considerable expertise and experience in the following substantive and methodological areas necessary to carry out the proposed: decision support aid development (**Manne, ITX**); breast cancer surgery and oncology (**Kirstein, Smith, Toppmeyer, Brill, Grana**); health behavior theories (**Manne, Hudson**); internet interventions (**Manne, ITX**); qualitative mixed methods analysis (Hudson)and biostatistics and research methods (**Kashy, Ohman-Strickland**). Our team also includes a community advisory panel. ITX is a software product development company that will design the decision support aid for this project. ITX Corporation will program the website based on the requirements defined by the research team. They have completed necessary paperwork to partner with Rutgers Cancer Institute of New Jersey researchers on this project. Grana (Consultant) is a breast oncologist and Cooper Cancer Institute Director with personal experience with CPM. Brill (Consultant) is a breast surgeon from Cooper Cancer Institute. They will serve as Year 1 consultants on the DA. We will form a **patient advisory board** of three patients who selected CPM to ensure that the information presented is balanced. This study entails two phases: A developmental phase for the CPM-DA (Phase 1) and a pilot and feasibility test (phase 2). Phase 1 participants will be recruited from CINJ and Phase 2 participants will be recruited from CINJ, MSKCC and Massachusetts General Hospital.

3.1. Phase 1: PROTOTYPE DEVELOPMENT AND TESTING (Month1-16). The first year will be devoted to the development of the web-based DA prototype. The DA will be multiplatform, accessible via computer, tablet, and smartphone. We plan for the development to take 9 months, but the actual timeline may vary based on completion of the steps outlined. Step 1: Interview patients to obtain data about important information they would like to have and reasons why they would consider having or not having CPM. Step 2: Develop the DA prototype. Step 3: Obtain feedback from patients about the prototype.

PHASE 1 During Phase 1, we will interview 24 women (12 patients who did not have CPM in the past 5 years, but considered it; and 12 patients who selected CPM in the past 5 years) regarding CPM-DA content preferences.
Additional eligibility for Phase 1 interviewees:

1. Has a first, Primary diagnosis of unilateral Stage 0, 1, 2, or 3a breast cancer [patients with bilateral breast cancer will be excluded from participation]
2. ≥ 18 years
3. Speaks and reads English
4. WSC [does not have hereditary breast/ovarian cancer syndrome (BRCA carrier, strong family history]. If there is any uncertainty, the surgeon will use the Tyrer-Cuzick (Tyrer et al., 2004) risk model to calculate risk. The Tyrer-Cuzick model calculates a personal lifetime risk of breast cancer based on multiple factors. It has become the standard model because it incorporates not only factors such as estrogen exposure and first degree relatives, but also second degree relatives and paternal lineage. A lifetime risk of 20% or greater is considered high risk and would necessitate increased screening methods to the traditional annual mammogram. For this study, anyone with a lifetime risk up to 19% on the Tyrer-Cuzick model will be considered average risk for breast cancer. Anyone with a lifetime risk of 20% or greater will be excluded from participation.
5. Able to provide meaningful informed consent.

To ensure a heterogeneous population, we will obtain a representative sample of age, ethnicity, and post-CPM experiences (e.g., complications, no complications).

To obtain 24 women we anticipate approaching about 35 women. The acceptance rate for the interview phase of our BRAID study was > 90%.

For patients who did not have CPM, we will identify women having unilateral mastectomy or lumpectomy in the past 5 years. CINJ breast cancer surgeons will refer women who had unilateral mastectomy or lumpectomy in the past 5 years who they know considered and did not select CPM.

For patients selecting CPM in the past 5 years, we will identify women from the records of CINJ's breast surgeons. Data from 2013-2014 indicates there are approximately 50 CPMs performed annually. This will allow sufficient sampling for Step 1. Patients will be sent a study description and a toll free number to decline. If the participant does not decline, they will be contacted.

In all sub-groups, eligible women who consent will be asked to attend a 60 minute interview and paid $65 for their time and travel to the interview.

Interview: Questions ask patients about experiences with CPM, reasons they chose and did not choose CPM, and CPM satisfaction. The interviews will be audiotaped and videotaped and notes will be taken to share with the study team. Interviews will be transcribed and

recommendations tabulated. Interview tapes will be marked with a study ID #. Analysis of the Step 1 data will follow common dictates of qualitative data analysis: data reduction, data display, and conclusion drawing and verification. A template, content analysis will be conducted. Dr. Hudson will lead the proposed qualitative analyses. Specifically, themes important for DA development will be identified based on the a priori theoretical model (Social Cognitive Theory). Data will be explored in the context of the model (e.g., What are the key CPM knowledge gaps? How do the patients think about risk? How do they manage fear and take a measure of control? How do their social networks (e.g., family, partners, friends) influence their decision making? What input from the surgeon did they find helpful?). New themes that emerge from interviews will also be explored. We will engage in iterative cycles of reading, summarizing, and re-reading the data 47-48 until thematic saturation has occurred. We anticipate that a sample of 24 women (12 per group) 49 will be needed to achieve thematic saturation across and within groups. An index of themes will be applied systematically to the data and tracked using ATLAS.ti, a qualitative data analysis software. Data analyses will continue until theme saturation or no new themes emerge related to key content areas for the DA. We will use this information to guide key content areas for the DA.

We will be taking photographs of CINJ patients' surgical outcomes of their breasts to be included in the DA. All patients will be asked to sign an IRB-approved HIPAA release for the use of photographs. We will not include the patient's name, photographs of her face, or any other identifying information. We will include information on the type of surgical procedure the patient underwent.

PHASE 1, Step 2. Prototype development, Months 6-13:

Months 6-9: Patient preferences identified in Step 1 will be used as a starting point to inform and refine design and content of the DA. We will have an initial design meeting with all investigators to finalize the DA prototype's goals. Manne, Kirstein and Hudson, with assistance from ITX, will develop the initial specifications and an initial paper and wireframe design. The specifications will serve as a blueprint for the ITX programming. Prototyping is a starting point for discussions of interface "look and feel" and navigation elements. It allows for an iterative design process as it facilitates making rapid changes with minimal investment.
Step 1 interviews and analyses will overlap prototype development in Months 6-9 facilitating data collection for additional edits to the wireframes. Months 8-9: An initial draft of text and narration scripts will be created by Manne, Kirstein, and Hudson and reviewed by ITX. We will develop audio, video, and visual components appropriate to the content with assistance from ITX. Months 10-11. The team will develop the audio scripts and on-screen personal narratives (video streams of personal stories, see Module outline). Months 12-13: Content and video clips will be put into the final version.

Conceptual Frameworks Guiding the CPM-DA. Our work will be guided by the Ottawa Framework for Informed Decision Making (O'Conner et al., 1999; O'Conner et al., 1995; O'Conner et al., 1998) as well as Social Cognitive Theory (Bandura, 1986) The **Ottawa framework** (O'Conner et al., 1998; O'Conner et al., 2002) has three elements: assessing decision needs, providing decision support, and evaluating decision making and outcomes.

Assessing needs in four areas is key: 1) perceptions- level of knowledge and receptivity to making choices; 2) perceptions of others – decision support, others' opinions, and preferred role in decision making; 3) resources – coping ability and external assistance to make and implement the choice, and; 4) personal characteristics- e.g., age, ethnicity. An optimal decision is informed, consistent with personal values, acted upon, and results in high satisfaction (O'Conner et al., 1997). In the oncology context, decision support aids facilitate decisions about breast cancer risk reduction among women considering *BRCA* genetic testing (Green et al., 2004; Wakefield et al., 2008) and breast surgery (Goel et al., 2009; Jibaja-Weisset al., 2006). Our approach will include all aspects of the framework. Information will be provided to increase knowledge about options; a description of possible outcomes will be included to make expectations more realistic; augmenting decision skills by providing guidance and coaching to help bring up topics to discuss with partner and surgeon. In addition, because anxiety is the key motivating factor behind CPM, content will include management skills for worry about breast cancer recurrence as well as information about their actual risk. **Social cognitive theory** (Bandura, 1986) outlines factors that influence health decisions/behaviors and outlines cognitive and affective influences of change. Social cognitive theory constructs we will use include perceived risk of cancer recurrence, emotional representations of breast cancer (fear of recurrence), self-efficacy, and social influence. Self-efficacy is conceptualized as the confidence to manage anxiety about breast cancer in the future and the confidence to follow up with cancer surveillance. Social influence includes input from doctor, other health professionals, family, friends, internet, and media.

The Layout of the DA is as planned: **Module 1** (2 minutes) contains an orientation/tutorial program which describes the DA, how to navigate it, and provides basic training. **Module 2** (5 minutes) is a risk education module that addresses perceptions and facts about contralateral BC risk. **Module 3** (5 minutes) presents medical facts about with CPM. The section will be guided by questions including: "What does a reconstructed breast look like?" "Is there a difference in recovery time if I choose CPM?" and "Are there more complications possible if I choose CPM?" Participants can select not to view graphic illustrations. **Module 4** (10 minutes) is an anxiety assessment and self-efficacy enhancement tool. Because anxiety about recurrence in the other breast is a primary motivator for CPM, this module addresses that anxiety. Patients will rate the degree of worry about recurrence in the other breast and metastatic disease and their confidence in coping with these worries and then will be offered coping strategies. A patient video will accompany with each strategy. We will use the fear of recurrence session materials from our ongoing grant for women with gynecological cancer as a guide. **Module 5** (10-15 minutes) contains personal narratives from women who chose or did not choose CPM. Patients from CINJ will be interviewed by Manne. Women will discuss the process they went through to make the decision, including values and preferences they weighed, and other concerns they had. Four clips will be selected that provide balanced information regarding satisfaction with the decision and possible complications. **Module 6** (10 minutes). is the interactive decision section which guides participants through the advantages and disadvantages of CPM. The participant will rank and weigh motivations, consider others' opinions, and assess assistance they might want. The final screen will summarize responses. It will not specifically endorse a decision, but rather will encourage women to discuss relevant options/contraindications of CPM with their surgeon, family, and friends.

PHASE 1, Step 3, Usability Testing, Iterative feedback, and Final Alterations, Months 14-16. Step 3 will be devoted to obtaining feedback about our interactive web-based prototype and making final modifications to the intervention and programming.

Procedures. Participants from Step 1 will be asked to attend a 90 minute session at CINJ. From the 24 participants from Step 1, we will enroll 10 women, with equal representation of women who had/did not have CPM. Participants will navigate and provide feedback on modules. Participants will be paid $65.00 for their time and travel.

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Interview. The questions ask about the quality and preference for graphic illustrations, the depth and complexity of the information, what they like/do not like about the personal narratives, what knowledge, risks, and possible benefits that were missed or are not relevant, and if they have additional content suggestions. Ease of navigation will be observed and usability measures administered (ASQ)

Final Alterations (Months 14-16). The team will listen to the audiotapes of the interviews, review notes, and summarize the issues. We will discuss and implement necessary alterations to the DA as well as incorporate feedback from the usability testing. Conference calls will be planned with the team to discuss the issues identified and decide whether the DA content needs alteration.

Web accessibility. ITX will ensure that the web-site functions the same in as many Web browsers as possible. ITX will update the site content and functionality*. As a final step*, *participants who provided feedback will be asked to review the site again to assess their feedback*. ITX and Manne/Kirstein's team will perform beta and break testing which consists of performing every possible user action to ensure that the programming does not break and will function reliably under a variety of conditions. We will finalize the DA after these steps.

3.2. Phase 2: CPM-DA FEASIBILITY TRIAL (Months 17-24)

The primary goal is to evaluate whether women will participate, use the DA, and evaluate the DA positively. A second goal is to gather pilot information about the impact of the DA on knowledge, psychological constructs, decisional conflict, and preparedness. We will conduct a small randomized trial assigning patients to receive Usual Care or the CPM-DA.

3.2.1. **Phase 2 Inclusion criteria:**

1. Completed initial surgical consult with breast cancer surgeon at CINJ/MGH/MSKCC and is considering CPM, regardless of the surgical treatment of their primary breast cancer (lumpectomy/mastectomy).
2. Has home internet access.
3. Has a first, primary diagnosis of unilateral Stage 0, 1, 2, or 3a breast cancer or Stage 1-3b who is down-staged to Stage1-3a with neo-adjuvant chemotherapy
4. ≥ 18 years
5. Speaks and reads English
6. WSC [does not have hereditary breast/ovarian cancer syndrome (BRCA carrier, strong family history]. If there is any uncertainty, the surgeon will use the Tyrer-Cuzick (Tyrer et al., 2004) risk model to calculate risk. For this study, anyone with a lifetime risk up to 19% on the Tyrer-Cuzick model will be considered average risk for breast cancer. Anyone with a lifetime risk of 20% or greater will be excluded from participation.
7. Able to provide meaningful informed consent.

3.2.2. Phase 2 Participant Recruitment and Consent Procedures. Staff will identify women scheduled for a surgical consultation. Because this study targets women considering CPM, participants will be approached after the consult as the surgeon discusses options the patient is eligible for at this time. The surgeon will refer the patient if she is considering CPM. The project coordinator or designated study staff will review eligibility with the surgeon and medical staff, and, if the patient meets eligibility, provide an explanation of the study and cover all of the aspects of the consent with the patient.

FOR CINJ patients, they have 2 options to complete consent. They can sign paper consent or acknowledge consent before beginning an electronic survey. Participants will be given the option to complete the baseline and follow-up surveys electronically through Rutgers Population Science Datstat Illume Survey Software, via paper and pencil, or over the phone with research staff. If the participant prefers to complete a paper and pencil version of the survey, they will sign paper consent and be provided with the survey to complete in clinic. The baseline survey should take 15-20 minutes to complete. The research staff will collect the completed survey from the participant. Participants who are unable to complete the survey in clinic will be able to take the survey home to return via pre-paid mail or via email/fax. Participants will also be given the option to complete electronic surveys. Email will be required to route electronic surveys, but email is already collected for use with the B-Sure Decision Support Aid. For those patients wishing to complete the electronic baseline survey, the participant will be asked to acknowledge consent prior to beginning the survey. After consent and baseline survey are received, the participant will be randomly assigned to either the Usual Care or the CPM-DA arm. An email will be sent and/or a phone call will be placed to the participant from Rutgers CINJ staff notifying the participant of her random assignment. Usual Care is described below. Participants in the CPM-DA arm will be given their random assignment, the website address, a secure username & password, and website instructions delivered via email or paper and/or phone. The DA will be optimized to be accessible on desktops. We will email/text this same information as a reminder to participants to use the DA. Follow-up surveys will be delivered via paper and pencil, phone or electronically depending on patient preference.

For Memorial Sloan Kettering patients, all participants are required to sign paper consent forms. They will be given the option to complete the baseline and follow-up surveys electronically through Rutgers Population Science Datstat Illume Survey Software, via paper and pencil, or over the phone with research staff. If the participant prefers to complete a paper and pencil version of the survey, they will sign paper consent and be provided with the survey to complete in clinic. The baseline survey should take 15-20 minutes to complete. The research staff will collect the completed survey from the participant. Participants who are unable to complete the survey in clinic will be able to take the survey home to return via pre-paid mail or via email/fax. Participants will also be given the option to complete electronic surveys. Email will be required to route electronic surveys, but email is already collected for use with the B-Sure Decision Support Aid. For the electronic baseline survey, the participant will again acknowledge consent by beginning the survey- they will have already signed the paper consent as well. After consent and baseline survey are received, the participant will be randomly assigned to either the Usual Care or the CPM-DA arm. An email will be sent and/or a phone call will be placed to the participant from Rutgers CINJ staff notifying the participant of her random assignment. Usual

Care is described below. Participants in the CPM-DA arm will be given their random assignment, the website address, a secure username & password, and website instructions delivered via email or paper and/or phone. The DA will be optimized to be accessible on desktops. We will email/text this same information as a reminder to participants to use the DA. Follow-up surveys will be delivered via paper and pencil, phone or electronically depending on patient preference.

For Massachusetts General Hospital patients, all participants are required to sign paper consent forms prior to verifying eligibility. They will be given the option to complete the baseline and follow-up surveys electronically through Rutgers Population Science Datstat Illume Survey Software, via paper and pencil, or over the phone with research staff. If the participant prefers to complete a paper and pencil version of the survey, they will sign paper consent and be provided with the survey to complete in clinic. The baseline survey should take 15-20 minutes to complete. The research staff will collect the completed survey from the participant. Participants who are unable to complete the survey in clinic will be able to take the survey home to return via pre-paid mail or via email/fax. Participants will also be given the option to complete electronic surveys. Email will be required to route electronic surveys, but email is already collected for use with the Decision Support Aid. For the electronic baseline survey, the participant will again acknowledge consent by beginning the survey- they will have already signed the paper consent as well. After consent and baseline survey are received, the participant will be randomly assigned to either the Usual Care or the CPM-DA arm. An email will be sent and/or a phone call will be placed to the participant from Rutgers CINJ staff notifying the participant of her random assignment. Usual Care is described below. Participants in the B-Sure CPM-DA arm will be given her random assignment, the website address, a secure username & password, and website instructions delivered via email or paper. The DA will be optimized to be accessible on desktops. We will email/text this same information as a reminder to participants to use the DA. Follow-up surveys will be delivered via paper and pencil, phone or electronically depending on patient preference

Participants will be asked to complete a total of 3 surveys. Surveys will be administered via paper, online through an email link to the survey sent by Rutgers Population Science Datstat Illume Survey Software, or via phone with research staff. The baseline is administered when participants first enter the study, follow-up survey #1 is to be completed at the time of a post-op appointment, usually between 2-4 weeks after surgery and follow-up survey #2 is to be completed 6 months after the baseline survey. For both follow-ups, participants will be sent a link to the survey via email or they may also be contacted by telephone to complete the follow-up surveys. If requested, we can mail a copy of the follow-up survey to participants with a pre-paid envelope to return the survey. For follow-up #1 research staff will provide the participant with the follow-up survey at an appointment. The participant can complete the survey in clinic or they can take it home to return via mail in a pre-paid envelope. For patients who indicated a preference to complete the follow-up survey electronically, research staff will visit the participant at her appointment and remind her that the survey will be sent via email link. If patients take the survey home or prefer electronic surveys, staff will contact participants weekly and, if contact is not made within two weeks, the participant may be considered a survey refuser or drop. If participants skip the first follow-up survey, we will still send them the second follow-up survey at 6 months. We allow participants access to the website for the study duration. We do not anticipate that they will view the B-Sure website simply to look up answers for the follow-ups.

We will track website use to evaluate this possibility. Participants are paid $25 for each survey they complete for a total of $75. Rutgers Cancer Institute of New Jersey will provide payments to MSKCC participants in the form of gift cards which will require Rutgers staff to receive contact information (including names, address, email and phone #s) for MSKCC participants. MSKCC study consent will detail that Rutgers CINJ staff will receive their contact information to carry out study procedures. Research recruiters and site investigators Manne, Kirstein and Smith will meet bi-weekly to review study accrual and troubleshoot enrollment challenges.

Randomization Procedures: This is a randomized trial with a Usual Care and the CPM-DA condition. Patients will be assigned to condition after consent is acknowledged online or paper consent is signed and online or paper baseline packets have been completed. A Rutgers CINJ statistician will design a blocked randomization scheme and will also ensure that randomization procedures are being followed. To randomize a new patient at Rutgers Cancer Institute of New Jersey, Memorial Sloan-Kettering Cancer Center, or Massachusetts General Hospital the following procedure will be followed: Site staff will notify the coordinator at the main site (Rutgers) when a new consent and baseline have been received. The Rutgers coordinator or appropriate study staff will randomize from the master file in the order in which notification of a new consent/baseline packet was received. The master file will be updated and research staff at all sites will be notified of the randomization. Rutgers study staff will notify participants of their randomization via email or a phone call. If applicable, Rutgers staff will provide participants with the CPM-DA website address, a secure password, and website navigation instructions. MSKCC will request to collect limited data in the form of a patient refuser form that will cause no more than minimal risk to patients that decide not to participate in MSKCC protocol #16-1396. The refuser form contains no PHI. This refuser form will be completed by the research team after approaching a patient in clinic that declines to participate in the study. The refuser form will then be sent to the sponsor site, Rutgers, to help them collect information on the feasibility of patients utilizing the decision aid and the common reasons for which patients decline to participate. The data in this form will be stored in a database at Rutgers.

For enrolled patients who ultimately seek surgery at an outside institution, the recruitment script and random assignment notification documents will inform participants that they are welcome to continue on with the study by evaluating the website if applicable and by completing the follow-up surveys. Rutgers CINJ staff will make contact with the participant to obtain the date of surgery for coordination of follow-up survey schedule.

CPM Decision Aid Arm Debriefing.
Staff at Memorial Sloan Kettering Cancer Center or Massachusetts General Hospital will contact current and former participants from the B-sure decision aid arm to obtain consent to be contacted for the debriefing interview call. After consent is received, Dr. Manne or designated Rutgers Cancer Institute of New Jersey staff member will then contact participants to schedule and conduct the brief phone interview to obtain feedback on the Decision Aid. The interviewer will remind participants of the information included in each of the B-Sure decision aid modules. The interviewer(s) will elicit feedback on the most helpful aspects of the decision aid, changes, and/or additional information that would be helpful to incorporate in future iterations of the decision aid and will also discuss the patient's decision-making process. The CPM participant Interview script along with the open-ended questions is submitted to IRB for review.

Procedures for contacting former participants/conducting interviews at Memorial Sloan Kettering Cancer Center and Massachusetts General Hospital are as follows: Participants who actively

dropped out or refused further participation in the study will not be contacted. All living participants who were randomized to the DA arm who completed all aspects of the study will be approached for the debriefing interview by the recruiting institution. The recruiting institution will send a letter explaining the purpose of the debriefing component along with the updated consent form containing optional study aspects portion. Participants will also be given a phone # and email address from the site they were recruited (MSKCC or MGH) to contact to have the consent discussion or if they want to refuse participation. Participants can mail the consent back to the recruiting institution in a pre-paid envelope. Once consent is received, Rutgers study staff will contact participants via phone to explain the study and confirm their interest in participating. A tentative date for the interview will be established. Staff will confirm that all participants have signed consent, and that the consent has been returned to Rutgers staff before conducting the interviews.

3.2.3. Sample Size for RCT. We anticipate we will recruit participants for about 6months (months 17-22). Our goal is to enroll 90 to 130 women (65 in UC and 65 in CPM DA). We are anticipating a 70-75% acceptance rate based on our BRDA study. To obtain N = 130 (90 MSKCC, 10 CINJ, 30 MGH), we estimate approaching 169-182 women. Because acceptance rates are a study goal, this is only an estimate, and thus we allow 6-12 months for accrual.

3.2.4 Usual Care. Usual care consists of what traditionally occurs at both sites. At both sites, the surgical oncologist educates WSC regarding the facts about CPM, including the fact that it is not medically indicated, and does not reduce the risk of the spread of cancer. If interested, the patient is referred to a plastic surgeon.

3.3 Study Sites

Recruitment of participants and all human subjects' interactions will take place at Rutgers, Cancer Institute of New Jersey for Phase 1 and at Rutgers CINJ, Memorial Sloan Kettering Cancer Center (MSKCC) and Massachusetts General Hospital (MGH) for Phase 2. Dr. Barbara Smith's involvement in the project will be as a consultant during Phase 1 of the study where she will provide input into the development of the decision aid. MGH and MSKCC will not begin participant recruitment until year 2.

3.4 Duration of the Study

In Phase 1, Step 1: Participants will be asked to attend one 60 minute interview.
In Phase 1, Step 3: Participants from step 1 will be asked to attend one 90 minute interview to provide feedback on module and to complete a prototype evaluation.

In Phase 2: CPM-DA FEASIBILITY TRIAL participants will provide feedback over the course of 6 months.

3.5 Study Enrollment Procedures

A copy of the institution's IRB-approved informed consent document and written justification for any changes made to the informed consent for this protocol must be on file at the Rutgers Cancer Institute of New Jersey's Office of Human Research Services (OHRS) before any participating institution may enter patients. Consent forms proposed for use at a participating

institution must be reviewed and approved by the OHRS Regulatory Affairs Manager and all documents must be received (i.e., IRB approved documentation, IRB approved consent form, etc.).

Participants who complete the online surveys will be asked to acknowledge online consent in the survey program before beginning the baseline survey through Qualtrics.

To register eligible patients on this study, each site will work with the study team and the Rutgers Cancer Institute of New Jersey's Program Coordinator for completion of the signed and dated eligibility checklist, completed signature page of the consent form and additional source documents if requested. Once eligibility has been verified, a unique patient study number will be issued. This is the point that the patient is considered on study. Patients must not start any study designated items prior to registration aside from consent and following the consent procedure the completion of baseline survey. Patients must not start any other study designated items prior to registration.

4. Study Variables

4.1. Measures

A preliminary overview of the study measures is shown in Table 1. We will utilize concise, psychometrically valid measures used in our prior research or that of other research groups.

Table 1. Measures Assessed at Each Time Point	**Baseline**	**FU 1 (Around post-op appointment 2-4 weeks post-surgery)**	**FU 2 (6 months)**
Background Variables			
- Sociodemographic characteristics	✓	---	---
- Knowledge of CPM	✓	✓	✓
Psychosocial Factors	✓	✓	✓
- Risk Perception	✓	✓	✓
- Reasons for CPM	✓	✓	✓
- Self-Efficacy	✓	✓	✓
- Social influence	✓	---	---
- Importance of Input	✓	✓	✓
Decision Factors	✓	✓	✓
- Satisfaction with/Completeness of Preparation	✓	✓	✓
- Decision Conflict	✓	✓	✓
- Interest/Intention	✓	✓	✓
Process Evaluation of DA (DA arm only)	---	✓	---

4.1.1 Baseline survey (15-20 m).

4.1.2. Demographics. Basic demographics and technology skills will be assessed.
4.1.3. Knowledge. 11-items evaluate CPM knowledge (Kirstein, personal comm., September, 2013).
4.1.4. Psychosocial factors. 1) *Risk perception*- 3 items estimate risk for breast cancer in the other breast and how much CPM reduces risk (Rosenberg et al., 2013); 2) *Reasons for CPM*- 11 reasons (Rosenberg et al., 2013); will be assessed*;* 3*)Self-efficacy*–3 items assess confidence in managing worry about cancer recurrence, complying with surveillance, and worry about surveillance*. 4*) *Social influence*- Item asks how much doctors talked about reasons to have/not have CPM; 5) *Importance of input*-Items ask how important input from surgeon, nurse, family/friends, internet, media is in the decision (Rosenberg et al., 2013).
4.1.5. Decision factors: *Satisfaction with/completeness of preparation*. The Satisfaction with the Decision-making Process Survey (Barry et al., 1997) assesses satisfaction with a number of factors including the amount of information, how information was presented, and how prepared they are to make a decision.
4.1.6. **Decisional conflict.** The Decisional Conflict Scale (Anderson, 2009) is a widely used scale. CPM interest/intention. Made a CPM decision; if not, rate CPM intentions.

4.2. Follow-up Measures

4.2.1. Follow-up surveys (20m). All baseline measures except demographics will be given.
4.2.2. Process Evaluation: 1) *DA Evaluation* (DA arm only). Ratings include: extent that they used the DA, comprehensiveness of information, whether it presented material in a balanced manner, whether it influenced the decision, whether it was helpful in making the decision, whether it was helpful in understanding pros and cons, and whether they used the information in a discussion with the surgeon. Items are based on Brug (Brug et al., 2005) and previous research (Manne et al., 2010; Manne et al., 2005) 2) *DA implementation evaluation*. We will assess: a) log ins and time in DA; b) time spent in each module; c) number of pages printed out/sent to mobile device; d) ease of accessing and navigating the web-based application at home or at the center; 3) *User Interface Satisfaction* (Lund, 2001) assesses usefulness, ease of use, ease of learning and satisfaction with online tools. Feedback will be collected at the time of the first follow-up survey, but we may also contact participants by phone for a short debriefing on their experience with the site.

4.2.3 Risk and procedures for handling adverse events.
This study involves research presenting little risk. There are no physical risks or side effects associated with participation. If the participant is experiencing any psychological distress, as reported by the patient to the study staff, the study project coordinator will inform Dr. Manne. Dr. Manne will then determine if contacting the participant is necessary and/or helpful to evaluate distress levels and refer if further assistance is needed or requested. There are psychosocial resources available for patients. These procedures have been implemented successfully with our previous psychological intervention trials.

4.2.3.1. Adverse Events: In the proposed study, we define adverse events as psychological distress by the method outlined above, the following procedure for handling this event are: 1) the site PI will inform the IRB about the event; 2) the PI, Dr. Manne, will be informed and this event will be reported to the Rutgers Cancer Institute of New Jersey IRB.

As with all research that collects protected health information, there is a risk that participants' confidentiality could be compromised during the study.

4.3 Data and Safety Monitoring

Data Safety and Monitoring Advisory Board. Monitoring of this study will occur in accordance with the Rutgers Cancer Institute of New Jersey's NCI approved Data and Safety Monitoring Plan (DSMP).

In order to insure the safety of participants and the integrity of the study, a data and safety monitoring plan will be in put into effect. As part of this plan, all adverse events will be reported through Rutgers Cancer Institute of New Jersey for processing as per established policy.

The project coordinator, under the direct supervision of the principal investigator, will be responsible for reporting any adverse events that are documented on the safety/adverse events form or are reported by the study interventionist.

We will identify a group of Rutgers Cancer Institute of New Jersey Cancer Prevention and Control Program investigators who will serve as our Data Safety and Monitoring Advisory Board. This team will consist of 2 investigators from Rutgers Cancer Institute of New Jersey who will review our risk procedures, adverse event reporting procedures and quality assurance procedures in Year 2. They will review any serious adverse events reported and adherence to our eligibility rules.

4.4. Protections Against Risks

In order to preserve privacy and protect the confidentiality of participants, a series of security procedures will be undertaken. IRB and HIPAA regulations concerning confidentiality will be strictly enforced. All study personnel receive training and certification in human subjects protection and HIPAA regulations. Each study participant will be given a unique numeric identifier upon study entry. Names and other protected health information will not be stored in the same database as survey and medical information. All computers used for research purposes adhere to the institution's requirements regarding password protection, data encryption, anti-virus protection, and intrusion detection. All Internet-based data communications are encrypted. All hard copy study-related materials and data will be stored in locked file cabinets in secure locations. The research team has never previously experienced a breach of participant confidentiality in a research study.

5. Data Handling and Statistical Analysis

All patients' shadow files/research records that are housed at Rutgers will be maintained on a secure server at Rutgers CINJ. Hard copies of all files will be stored in locked file cabinets on the 5th floor of CINJ in Population Science department and will be retained until ten years after the last publication. Audiotapes of any feedback or usability interviews will be collected and will be labeled with the study ID#, no names will be included. Electronic copies of audio files will be stored on the secure hare drive, hard copies will be stored in a locked cabinet in the Population Science department. All audio files will be handled as described in the Policy and Procedure,

entitled Data Storage Management and Transfer of Audio and Video Research Data and will be retained until ten years after the last publication.

Research transcripts and data will be maintained on secure servers with restricted authorization for research team members only and will be destroyed ten years after the last manuscript has been published. The PI and the designated research team will retain the data keys that link patient names with their unique identifiers for 10 years. The retention of accurately recorded and retrievable research data is necessary in order to ensure scientific integrity. Research records will include sufficient detail to permit examination for the purpose of replicating the research, responding to questions that may result from unintentional error or misinterpretation, establishing authenticity of the records, and confirming the validity of the conclusions.

Databases for participant recruitment and tracking, medical records review data, and participant survey data will be developed and maintained by the CINJ Population Science Research Support Core using HIPAA-compliant DatStat software. Approval for use of this software in research studies has been provided by the Rutgers Biomedical and Health Sciences Institutional Review Board (IRB). (The approval process included: obtaining a Technology Professional Service Agreement and a Business Associate Agreement from DatStat; the approval of a Security Questionnaire from the Rutgers Office of Information Technology; and the completion of a Security Risk and Assessment Tool by the Rutgers CINJ Office of Information Technology.) The software allows for research study personnel to be assigned data access and privileges specific to their role on the study. Online surveys will be completed by participants using a secure website (hosted on DatStat servers) developed and maintained by the CINJ Population Science Research Support Core.

DatStat secure servers are registered with site certificates provided by AddTrust that provide for advanced encryption over the wire. As each user moves through the survey form, his/her responses are encrypted while in-transit between the browser and DatStat's server using SSL (Secure Sockets Layer) and 40, 56, or 128-bit Public Key Encryption. All servers used for data collection are highly fault-tolerant and equipped with redundant, hot-pluggable power supplies, redundant network interfaces, and RAID 5 hot-swappable disk storage. All primary servers are plugged into a monitored, uninterruptible power supply (UPS). DatStat servers are stored in a locked server cabinet/rack, which are housed in a state-of-the-art, well-ventilated data center. Physical access to servers and data backup is restricted to a minimal number of information technology professionals. The servers are secured with physical and firewall security.

5.1. Primary Aim: Is the intervention trial feasible?

Approach and Analysis

For feasibility, 2 questions will be addressed: 1) Are patients joining/staying in the trial? We judge this study feasible if the participation rate (consented and complete baseline) is equal to or greater than 70% and the retention rate at follow-up is 85%. These "yardsticks" were selected to ensure there is sufficient interest to proceed to a larger scale trial. 2) Are participants using the DA in the way that was intended? We will evaluate log-ins, pages viewed, and how long modules are viewed. If participants review more than 75% of the pages, we will consider this acceptable usage. To evaluate the acceptability, we will

examine: whether participants use the DA, to what degree they use it, and factors predicting uptake and use. We will also look at whether patients 1) opened the web aid and 2) viewed each page. First, basic descriptive information will be gathered regarding participant log-ins and number and duration of log-ins. Second, DA evaluation and User Interface Satisfaction surveys will be examined.
We will judge the DA as acceptable if 75% of participants used it and if the average score was > 5.6/7 on the DA evaluation. *Using regression analyses*, we will examine the following for association with DA use: younger age, internet familiarity, and higher education. The small sample (N = 40) and limited range of correlate categories limits options for statistical analyses. Missing values will be imputed from observed information *(SAS Procedures MI and MIANALYZE). Confidence intervals and inferential procedures will adjust for uncertainty due to imputation.*

Table 1. Probability of declaring feasibility under various assumptions

Feasibility Component	Unaccept-able Rate	Acceptable Rate	Decision rule for claiming Feasibility	Prob. Declare Feasible under Unacceptable Rates	Prob. Declare Feasible under Acceptable Rates
Acceptance Rate	65%	70%	If 80 women recruited by the 114th (inclusive) approached	5%	96%
Completion Rate	79%	85%	If 68 participants complete survey	5%	96%

***Power**. We expect to approach a maximum of 140 to enroll 100 women. If 100 women are enrolled in the study by the 140th patient approached and 85/100 participants complete the survey, then we will declare the study feasible. We chose the sample size and decision rules so that the probability of declaring feasibility would be approximately 5% under unacceptable rates of acceptance and completion and exceed 95% under acceptable rates. Power calculations are in **Table 1.** If the true acceptance and completion rates are 65% and 79%, respectively, which we consider to be too low to warrant further research, then the probability of declaring feasibility would be 5%. If the true acceptance and completion rates are 70% and 85%, respectively, which we consider large enough to warrant further research, then the probability of declaring feasibility would be 96%.These figures are based on binomial distributions*

5.2. Secondary Aim 2: What is the impact of DA on CPM knowledge, psychosocial factors, decisional conflict, completeness of preparation, and CPM intention?

Approach and Analysis. *Our outcomes are knowledge, perceived risk for recurrence, cancer worry, coping efficacy, anxiety, decisional conflict, preparedness, and intention. We anticipate that 100 women will complete the baseline and 85 will complete the follow-up. We will characterize the data using standard methods (means, medians, standard deviations, 95% confidence intervals) for the sample and separately by study arm. In exploratory analyses, we will use two sample repeated measures to compare outcomes using an intent-to-treat approach. We will assess associations among the outcome variables using Pearson's correlation coefficients. We will also characterize the patterns of missing data.*

6. Reporting Results

The policies and procedures of Rutgers University's legal department (see: Investigator's Handbook) will govern publication of the results of this trial. The results of this trial will be submitted for publication in a timely manner following its conclusion. The Rutgers Cancer

Institute of New Jersey PI and all co-authors will review any abstract of manuscript prior to its submission.

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