The Development of a Decision Aid to Promote Informed, Shared Decision Making for Contralateral Prophylactic Mastectomy (CPM)

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Dedication

To my children, Ender, and Eli, for teaching me patience and perseverance.
Be you, always.

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Abstract

Contralateral prophylactic mastectomy (CPM) is a risk-reducing surgical removal of a healthy breast to reduce the risk of developing breast cancer. Although most women diagnosed with breast cancer will never develop a contralateral breast cancer, it continues to be an area of discussion at surgical consultation. The decision point of considering CPM versus unilateral mastectomy is a patient-sensitive decision that can benefit from ongoing, shared, decision-making interventions. Decision aids (DAs) are a feasible and acceptable approach to improve the shared, decision-making process in the clinical setting. Therefore, the aims of this dissertation are (1) to explore factors and values contributing to women choosing CPM versus unilateral mastectomy, and (2) to determine the content validity and final evaluation of the modified DecisionKEYS for CPM to provide content and feedback for the continued modification of the DecisionKEYS interventions.

In the first manuscript, following the Whitemore and Knafl (2005) proposed steps, an integrative review of current DAs for the choice of CPM versus unilateral mastectomy is presented. The initial literature search was conducted in 2019 and was updated in December 2021. A comprehensive search was conducted in CINHAL, OVID Medline, PubMed, Web of Science, PsycINFO, and Cochrane databases using search terms *contralateral prophylactic mastectomy* and *decision aid*. This review yielded five articles that were pilot testing a DA for the CPM surgical decision point.

In the second manuscript, the multi-phase, mixed methodological approach for the study aims is outlined. Phase I, as presented in this dissertation, aims (1) to explore factors and values contributing to women choosing CPM versus unilateral mastectomy, and (2) to determine the content validity and final evaluation of the modified DecisionKEYS for CPM to provide content

and feedback for the continued modification of the DecisionKEYS interventions. Phase II will address study aims (3) to compare pre-post levels of decision conflict and decision-making quality, and (4) to identify later decision regret based on choice type for women using DecisionKEYS over time when choosing CPM versus unilateral mastectomy.

In the third manuscript, a mixed method approach using semi-structured interviews and two quantitative surveys, the *Decision Making Quality Scale* (DMQS) and the *Decision Regret Scale* (DRS) is presented. Four themes were identified from the qualitative data: 1) fear of cancer recurrence or a cancer diagnosis in the opposite breast, 2) empowerment and self-trust, 3) previous experiences, histories, and influences related to cancer, and 4) expressed need for increased psychosocial support at the time of initial diagnosis. Quantitative findings indicate that participants rate their decision-making quality as high (DMQS scores were high) and did not report any later regret post-surgery (DRS scores were low).

In conclusion, a DA is feasible and acceptable in the clinical setting when patients are considering CPM versus unilateral mastectomy. Breast oncology settings should consider the addition of a decision aid intervention for patients desiring CPM at the time of surgery for treatment of their primary breast cancer. Future research is also needed to test the modified version of DecisionKEYS for CPM as an intervention to improve shared decision making and compare levels of 1) decision conflict, 2) decision-making quality, 3) decision regret, and 4) risk tolerance.

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Chapter 1

Introduction

An estimated 297,790 new cases of invasive breast cancer will be diagnosed in women in the United States in 2023 (American Cancer Society, 2022). For patients that have been diagnosed with early breast cancer in one breast, without a strong family history of breast cancer or known genetic mutation, the risk of developing a new primary cancer in the opposite breast is 0.5-1.0 percent per year over their lifetime (Chagpar et al., 2018). Among this population, a subgroup of women undergoing mastectomy for the malignant breast will also elect to remove the healthy, unaffected breast to reduce future cancer risk. This procedure known as a contralateral prophylactic mastectomy (CPM) is indicated for women considered high-risk for contralateral breast cancer, such as those with a genetic mutation (American Cancer Society, 2019).

Contralateral prophylactic mastectomy (CPM) is a risk-reducing surgical removal of a healthy breast to reduce the risk of developing breast cancer. Although most women diagnosed with breast cancer will never develop a contralateral breast cancer, it continues to be an area of discussion at surgical consultation.

In the landmark Institute of Medicine (IOM) report, *Crossing into the Quality Chasm,* patient-centered care was defined as "care that is respectful of and responsive to individual patient preferences, needs, and values" and that ensures "that patient values guide all clinical decisions" (IOM, 2001, p.49). Patient-centered care dimensions highlighted in this report include dimensions of patient-centered care: (1) respect for patients' values, preferences, and expressed needs; (2) coordination and integration of care; (3) information, communication, and education; (4) physical comfort; (5) emotional support—relieving fear and anxiety; and (6) involvement of

family and friends (IOM, 2001, p.49). Subsequently, in 2012, the *New England Journal of Medicine,* published a perspective calling shared decision making the "pinnacle of patient centered care" (Barry, et al., 2012). According to Jagis and colleagues (2017), providing evidence for the need of an intervention to improve communication and informed decision making among patients considering CPM is greatly needed. Evidence exists that patients do benefit from decision interventions when making difficult treatment decisions (Stacey, et al., 2017; Hollen, et al., 2013; Jones, et al., 2013).

Decision Aids for Breast Cancer Surgery

A Cochrane review of the use of decision aids for health decisions highlights that decision aids are useful to enhance communication between patients and clinicians as well as help patients become active participants in the decision-making process (Stacey, et al., 2017). Additionally, decision aids are useful when there is not a 'best choice' and the treatment options are preference-sensitive (Stacey, et al., 2017). Breast cancer surgery options can be considered 'preference-sensitive' and CPM, is an identified preference-sensitive decision point.

With the identified complexities in breast cancer surgery decisions, there are many decision aids available for patients choosing breast cancer surgery. A systematic review demonstrated that most surgical decision aids for the breast cancer population focus on lumpectomy, axillary surgery, unilateral mastectomy, and/or reconstruction (Zdenkowski, et al., 2016). However, despite being recognized as a preference-sensitive decision, the systematic review noted there were no decision aids for CPM at the time of the review (Zdenkowski, et al., 2016).

Patient Decisional Conflict and Regret with Cancer Treatment

Decisional conflict is "the simultaneous opposing tendencies within the individual to accept and reject a given course of action" (Janis & Mann, 1977, p.46). O'Connor and colleagues have delineated eight modifiable factors: lack of knowledge, unrealistic expectations, unclear values, unclear perceptions of others, social pressure, lack of support, lack of skills or self-confidence, and lack of resources (O'Connor, et al., 2002). A systematic review of decision aids for breast cancer treatment highlighted that the decisional conflict scale (O'Conner, 2003), developed by O'Connor, was used in 13 studies to evaluate the decision aid. Along with decisional conflict or uncertainty, regret is a common emotion seen in cancer patients (Nicolai, et al., 2016). While CPM literature demonstrates that most women are satisfied with the decision to have a CPM, there is data that suggests women do feel regret after this choice (Ager et al., 2016; Bruade, et al., 2017). For example, Bruade and colleagues (Bruade, et al., 2017), highlighted women made statements such as the "choice did me a lot of harm," but did not correlate this with regret. Women that did report regret following CPM, reported the regret was related to complications that led to more surgery or delayed treatment, worsened body image, or decreased sexuality (Bruade, et al., 2017).

Theoretical Framework

In considering the key concepts and variables in depth, the Conflict Theory of Decision Making (Janis & Mann, 1977) perfectly underpins the study aims and intervention of this dissertation. According to the theory, the preconditions (risk, hope, and time) predict the degree of stress a person feels which then influences the decision-making style and quality (Janis & Mann, 1977; Hollen, et al., 2013). A clear hypothesis is that there are preconditions (personal properties, disease characteristics encompassing risk, social support encompassing hope)

influencing the amount of decisional conflict and quality decision making women considering contralateral prophylactic mastectomy (CPM) may have (see, **Figure 1**). The degree of stress can affect normal patterns of information processing (Janis & Mann, 1977). A higher degree of stress can lead to more decisional conflict or uncertainty. Decisional conflict is defined as "the simultaneous opposing tendencies within the individual to accept and reject a given course of action" (Janis & Mann, 1977, p.46). Thus, the importance of measuring decisional conflict in breast cancer patients considering CPM is crucial.

Janis and Mann (1977) further outline seven criteria for quality decision making. A major assumption within the theory is that quality decision making occurs when an individual does all of the following: must search for a wide range of alternative courses of actions, surveys objectives and values, weighs pros and cons of consequences, searches for new information, takes account of any new information even when it does not support initial preference, reexamines the pros and cons of consequences and finally makes a detailed plan for the chosen course (Janis & Mann, 1977, p. 11). If the degree of stress causes an individual to skip any of these outlined steps, it will most likely result in a decision-making style that predicts poorer decision-making quality (Janis & Mann, 1977).

Decision-making quality is the second outcome variable within this study and outlined on this conceptual model. Lastly, based on the decision-making style and quality, then the person will either feel regret or satisfaction with the decision (Janis & Mann, 1977; Hollen, et al., 2013). Post decisional regret is caused by "events or credible communications that call attention to potential financial loss, health impairments, social censure, or other undesirable consequences that might follow adhering to the course of actions to which the person committed" (Janis & Mann, 1977, p. 311). Decisional regret is the final variable measured in this pilot study, which

considers the potential financial, physical, and social consequences breast cancer surgery can have.

Additionally, the Janis and Mann Conflict Theory of Decision Making (Janis & Mann, 1977) underpins the modified intervention, DecisionKEYS, in this dissertation (see, **Figure 1,** presented with permission (Hollen et al., 2013). The intervention briefly explains the theory to patients along with giving patients time to reflect on personal values, risks, and benefits of the choices. By following the assumptions of the theory, the intervention helps participants to understand why quality decision making is important and guides them through the 7 steps of quality decision making previously described (Janis & Mann, 1977; Hollen, et al., 2013; Jones, et al., 2013). Furthermore, following the recommendations of Janis and Mann (1977), the intervention contains a balance sheet to assist the participant in weighing potential gains and losses of each choice.

Further, the direct opposing theory to Janis and Mann's Conflict Theory of Decision Making (Janis & Mann, 1977), Dijkerhuis's Unconscious Thought Theory (UTT) (Dijksterhuis, & Nordgren, 2006) was reviewed. There are 6 principles of UTT. The main principle is that conscious thought is limited and that the unconscious process has higher capacity and limited attention (Dijksterhuis, & Nordgren, 2006). Dijksterhuis and colleagues studied to prove that unconscious decisions (directing attention away from the choice prior to a final decision) led to post-choice satisfaction (Dijksterhuis, & Olden, 2006). While original UTT research indicated that participants that made a quick decision without deep introspection or deliberation reported greater post-choice satisfaction when compared to the deliberation group, UTT studies have proven difficult to replicate (Dijksterhuis, & Olden, 2006; Acker, 2008; Dehghan, et al., 2011). Wilson and colleagues still debate whether the deliberate, pro versus con deliberation improves

quality decision making (Wilson, 2002; Walton, et al., 2018). A limitation within the unconscious decision-making literature is that all studies have focused on choices of apartments, art, or other choices that would not result in a state of permanence (Dijksterhuis, & Olden, 2006; Acker, 2008; Dehghan, et al., 2011; Wilson, 2002).

In summary, the rationale is presented that the Conflict Theory of Decision Making, involving deep introspection and deliberation is best for difficult decisions with greater consequences (Janis & Mann, 1977). The Conflict Theory of Decision Making (Janis & Mann, 1977) is most applicable to the study of women choosing CPM or not, considering that CPM is a permanent surgical procedure that will result in a lifetime of consequences. It is beyond a choice result of satisfaction, it is a finite choice that potentially leads to a deeper emotion, that of regret (Janis & Mann, 1977; Hollen et al., 2013; Jones, et al., 2013). Furthermore, this theoretical underpinning has been used nationally and internationally as the basis of decision support research for patients with cancer (Hollen, 1994; Hollen et al., 2013; Jones, et al., 2013). The application of the theory in this research will predict, based on the women's decision-making style, the quality of decision making, amount of decisional conflict, or decisional regret (Janis & Mann, 1977; Hollen et al., 2013; Jones, et al., 2013).

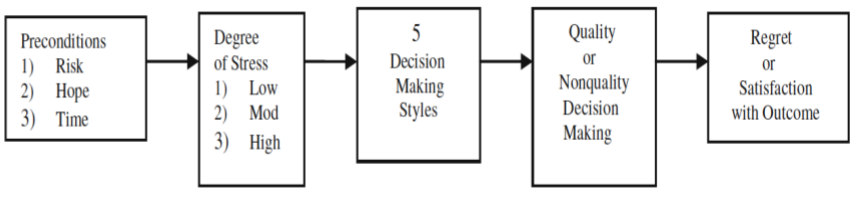
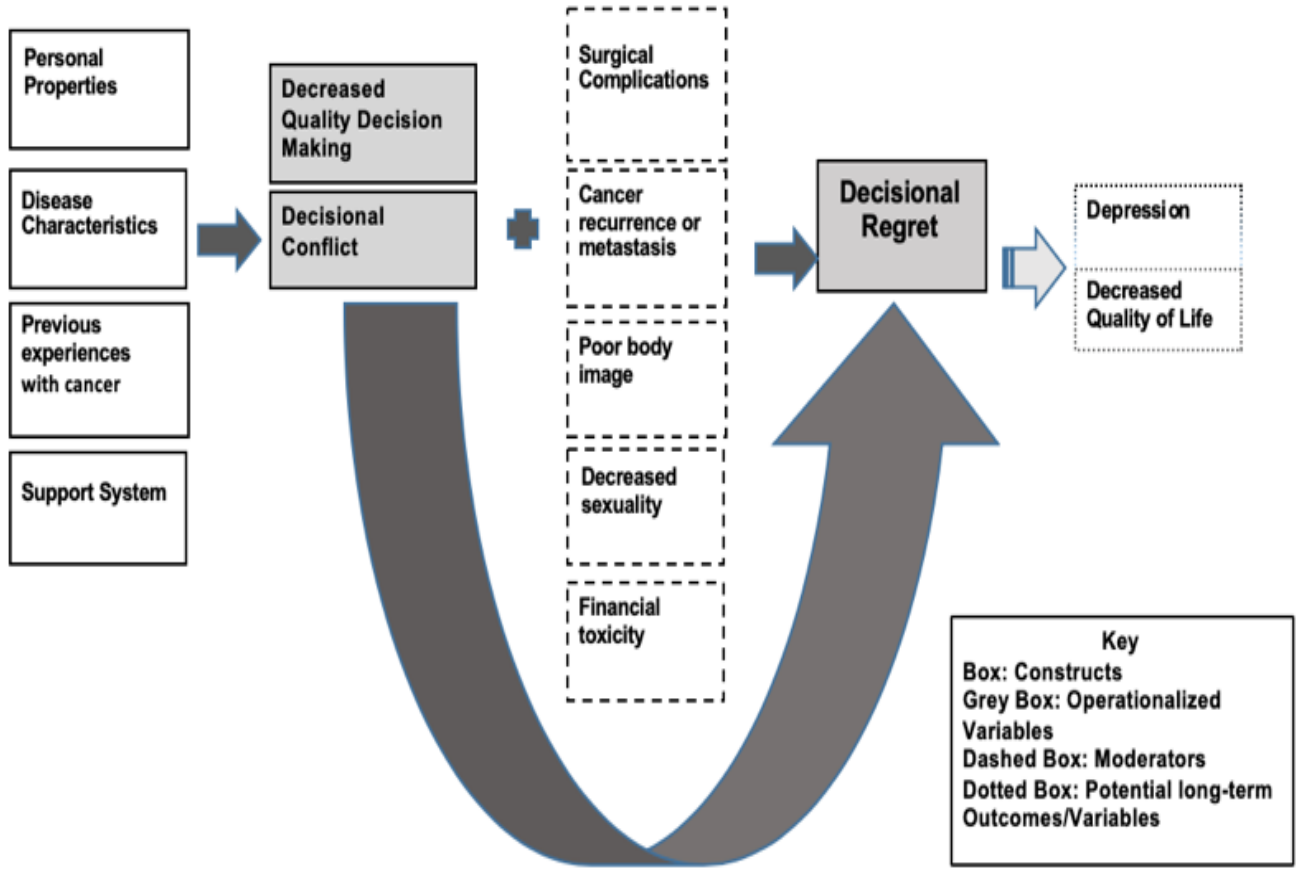


Fig. 1 Diagram of theory adapted for brief tutorial

Dissertation Conceptual Map

There are many factors that may influence a woman's decision for CPM. Based on a woman's history, values, and preferences this may influence the amount of decisional conflict and quality of decision making. **Figure 2** illustrates, within a conceptual map, how these constructs and variables interact and ultimately influence one another. In **Figure 2**, note that the constructs to the left are antecedents that may influence quality decision making and decision conflict. The first hypothesis of this study is the use of an interactive decision aid at the intersection of facing the decision (to elect CPM or not) will reduce decision conflict and improve quality decision making. Along with measuring decision conflict and decision quality, potential moderators for decisional regret will be explored: 1) surgical complications, 2) cancer recurrence, 3) poor body image, 4) decreased sexuality, and 5) financial toxicity. The second hypothesis is that this decision aid will reduce decisional regret and act as a buffer for the potential moderators preceding decisional regret (see, **Figure 2**).

Figure 2. *Dissertation Conceptual Map*



The aims of this dissertation are:

- To explore factors and values contributing to women choosing CPM versus unilateral mastectomy
- To determine the content validity and final evaluation of the modified DecisionKEYS for CPM to provide content and feedback for the continued modification of the DecisionKEYS intervention.

Future study aims are:

- To compare pre-post levels of decision conflict and decision-making quality
- To identify later decision regret based on choice type for women using DecisionKEYS over time when choosing CPM versus unilateral mastectomy.

Chapter 2 presents a review of the current literature pilot testing a DA for women choosing CPM or unilateral mastectomy. This integrative review identified current gaps and builds upon the evidence that this population could benefit from a DA in the breast surgery clinical setting. Chapter 3 outlines the multi-phased, mixed methodologic approach to achieve the aims of this dissertation and continued research that is required in this area. In Chapter 4, the findings from the Phase I mixed methods pilot study to develop the content and validity of the theory-based, interactive decision aid (DA) intervention, DecisionKEYS are presented. Lastly, in Chapter 5, a summary of the overall dissertation findings, discussion of clinical implications, and direction for future research are presented.

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Chapter 2

Title

Decision Aid Interventions for Contralateral Prophylactic Mastectomy: An Integrative Review

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Abstract

Problem Identification: The use of a decision aid (DA) for women facing the decision of contralateral prophylactic mastectomy (CPM) is limited. This article examines the pilot testing of decisions aids for CPM.

Literature Search: A comprehensive search was conducted in CINHAL, OVID Medline, PubMed, Web of Science, PsycINFO, and Cochrane databases using search terms *contralateral prophylactic mastectomy* and *decision aid*.

Data Evaluation: The studies were assessed for relevance in testing a patient decision aid for CPM and measurements used for the decision process and decision quality.

Synthesis: Five studies met the inclusion criteria**.** These studies included a pre-post cohort pilot study, one RCT, two mixed-method studies, and a qualitative study.

Implications for Research: In breast oncology surgery settings, further testing of a DA for women considering CPM should be considered**.**

Knowledge Translation

- Contralateral Prophylactic Mastectomy (CPM) is a preference-sensitive decision and clinicians should be aware of factors that patients consider when deciding between unilateral mastectomy and CPM.
- Decision aids can help guide preference sensitive clinical decision**s**.
- The use of decision aid in the oncology surgical setting is feasible and acceptable.

Approximately, 1 in 8 women will be diagnosed with an invasive breast cancer in their lifetime and it is estimated there will be 287,850 new cases annually among women in the United States (American Cancer Society, 2022). For patients that have been diagnosed with early breast cancer in one breast, without a strong family history of breast cancer or known genetic mutation, the risk of developing a new primary cancer in the opposite breast is 0.5-1.0 percent per year over their lifetime (Chagpar et al., 2018). Among this population, a subgroup of women undergoing mastectomy for the malignant breast will also elect to remove the healthy, unaffected breast to reduce future cancer risk. This procedure known as a contralateral prophylactic mastectomy (CPM) is indicated for women considered high-risk for contralateral breast cancer, such as those with a genetic mutation (American Cancer Society, 2022). CPM is known to reduce the risk of contralateral breast cancer by 90-95 percent (Ager et al., 2016; Portschy et al., 2014; American Cancer Society, 2022). However, even in patients with high-risk mutations such as BRCA1/2, there is no survival benefit to CPM (Ager et al., 2017; Portschy et al., 2014; Wong et al., 2017). Additionally, CPM does not decrease risk of metastasis from a patient's breast cancer (Ager et al., 2016; Portschy et al., 2014). In 2016, the American Society of Breast Surgeons (ASBrS) consensus statement endorsed that CPM should be discouraged among patients with average-risk but, recognize that patient preference and goals should be included in the decision-making process (Boughey et al., 2016).

About, 15-20% of bilateral mastectomies have complications; half of those complications occur in the contralateral healthy breast (Ager, et al., 2016). Clinical risks of CPM include: 1) wound healing complications, 2) the loss of reconstruction (if performed), 3) infection, 4) postoperative pain, 5) phantom breast syndrome, and 6) arm mobility limitations (Chagpar et al., 2018). Furthermore, extant research demonstrates that women report dissatisfaction or regret

following CPM due to: 1) complications, 2) poor cosmetic results, and 3) diminished sexuality (Ager et al., 2016; Bruade et al., 2017). Complications from surgery can delay adjuvant therapy for patient's known breast cancer (increasing the risk of metastasis), cause poor cosmetic results (Ager et al., 2016) as well as add cost burden to the patient. Also, at a system level, increased rate of CPMs is associated with increasing cost and morbidity among cancer centers nationwide (Jagsi et al., 2017).

Recent reports demonstrate an increase of CPMs from 3.4% in 2016 to 6.8% in 2019 (Shaheen, et al., 2022). Several systematic reviews identified factors that may influence the decision making of women choosing CPM. The most common reported factor driving the decision of CPM was fear of a future breast cancer (Ager et al., 2018; Han et al., 2011). Other factors that were identified included perception of risk, influence of others, survival data, physician feedback, and cosmetic outcomes (Ager et al., 2018; Mastaglia & Kristianson, 2001; Molenaar et al., 2004; Reaby, 1998). Research has demonstrated that women may greatly over-estimate their risk of a contralateral breast cancer (Abbott et al, 2011). Moreover, the women that reported higher perceived risk of contralateral breast cancer were also more likely to report difficulty sleeping and nervousness (Abbott et al., 2011). One qualitative study found that fear was the most expressed reason for CPM; but, it emerged in the theme of "taking control of cancer." This belief surrounded the concept that CPM would give them control to defeat cancer and guarantee long-term survival (Covelli et al., 2015).

It is well-established that decision aids are useful in helping patients become active participants in the decision-making process as well as assisting when the treatment options are 'preference-sensitive' (Stacey et al., 2017). Breast cancer surgery options can be considered 'preference-sensitive' and as previously mentioned, CPM is an identified preference-sensitive

decision point. With the identified complexities in breast cancer surgery decisions, there are many decision aids available for patients choosing breast cancer surgery.

Objective

A 2016 systematic review demonstrated that most surgical decision aids for the breast cancer population focus on the lumpectomy, axillary surgery, unilateral mastectomy, and/or reconstruction (Zdenkowski et al., 2016). However, despite being recognized as a preference-sensitive decision, the systematic review noted there were no decision aids for CPM at the time of the review (Zdenkowski et al., 2016). The purpose of this integrative literature review is to identify current research testing the use of a decision aid (DA) intervention for contralateral prophylactic mastectomy decisions.

Methods

Following the Whitemore and Knafl (2005) proposed steps of an integrative review, the identification of an increase of CPMs among an average risk population led to further investigation for greater understanding. The initial literature search was conducted in 2019 and was updated in December 2021. A comprehensive search was conducted in CINHAL, OVID Medline, PubMed, Web of Science, PsycINFO, and Cochrane databases using search terms *contralateral prophylactic mastectomy* and *decision aid*. No limits were applied to the search. Four inclusion criteria were applied: articles or reviews, any date, CPM decision, and available in English language. Two exclusion criteria were applied: 1) non-peer reviewed articles, and 2) BRCA positive or high-risk breast cancer population (the purpose of this search was to find information related to the decision to have a CPM in "average" risk breast cancer patients; not the high-risk breast cancer population). Inclusion and exclusion criteria remained broad to capture all possible literature. The search yielded 36 articles. The reference lists of reviewed

articles were also searched for relevant articles. After inclusion and exclusion criteria were applied and duplicates were removed, a total of five articles were included for final review (see **Figure 1)**. The review of the five articles organized each study by author, year, methods, population, sample size, measurements, and main findings. This allowed for comparison and synthesis of measurements for each CPM decision aid. Finally, results were summarized to provide overall analysis to identify the current state of the literature and remaining gaps.

Results

A systematic review conducted by Zdenkowski and colleagues (2016), of early breast cancer treatment decision aids, was included in the review. The purpose of including the review is to highlight that in 2016 a review of 33 decision aid articles resulted in 0 results for a specific decision aid for CPM. Following the publication of this 2016 systematic review, 5 studies aimed to develop and test a CPM decision aid were published between 2017 and 2021 (see **Table 1**).

Synthesis of Literature

All articles in this review included a newly developed decision aid to pilot for CPM (see **Table 1**). Each provided details about development of the decision aid. Four of the articles in this review utilized the OTTAWA framework to develop the pilot decision aids (Ager et al., 2018; Jansen et al., 2021; Manne et al., 2019; & Squires et al., 2019). Yao and colleagues (2018) used their own developed SCOPED framework to design their pilot DA. Inclusion criteria for all studies focused on patients with early-stage unilateral breast cancer and without genetic mutations that would increase risk of a contralateral breast cancer. Two studies further included healthcare professionals that provided direct care for patients with breast cancer (Jansen et al., 2021; Squires et al., 2019). Included studies had similar patient demographics with the majority identifying as white, married, or partnered females (Ager et al., 2018; Jansen et al., 2021; Manne

et al., 2019; & Yao et al., 2017). Patient ages ranged from 18 to over 70 years old, with reported median age ranges from 58.6, 52.7, and 47.5, respectively (Ager et al., 2018; Jansen et al., 2021; & Manne et al., 2019).

Yao and colleagues (2018) and Manne and colleagues (2019), pilot tested a decision aid (DA) with one of their primary outcome measurements being CPM knowledge. Both Yao et al., (2018) and Manne et al., (2019) indicated that their decision aids improved the knowledge about CPM in the DA groups when compared to the usual care. The DA had limited or no effects on other outcomes, such as worry, or decision preparedness. Additionally, Yao and colleagues, (2018) and Manne and colleagues, (2019) found no difference between groups in the choice to have CPM or not.

Ager and colleagues (2018) developed a decision aid with qualitative feedback from 23 participants. Their findings found that the decision aid was highly acceptable among women as well as providing feedback from women regarding DA content. Jansen and colleagues (2021) included qualitative feedback from both patients (n=31) and healthcare professionals (n=11). In addition, patients valued the DA and both clinicians and patients found the DA content balanced and useful (Jansen et al., 2021). Findings among the included literature indicate that a DA for CPM is acceptable and feasible in clinical practice when balanced information is presented (Ager et al., 2018; Manne, et al., 2019; Squires et al., 2019; & Jansen et al., 2021).

Discussion

This review provides a synthesis of DAs for contralateral prophylactic mastectomy and expands the systematic review conducted by Zdenkowski and colleagues (2016). Overall, findings support the need for a decision aid for women diagnosed with early-stage unilateral breast cancer who are considering CPM. The current studies within this review support the

conclusion that patients and clinicians both find a DA feasible and acceptable at the breast cancer surgery decision point. Neither of the studies that tested a DA found a difference in surgical decision; however, it is noted that DAs are not necessarily there to change a person's decision, but to confirm their preferred choice and improve the decision-making process as well as decrease decisional regret (Manne, et al., 2019).

Highlighting the latest guidance from Trenaman and colleagues (2021), on critically appraising trials evaluating patient decision aids, the studies included in this review were not consistent on reporting psychometric performance. Future studies should consider consistent and appropriate psychometric properties to measure performance of the decision aid on both decision process and decision quality (Trenaman et al., 2021). The included studies were consistent with documentation on the development process of the decision aids and most included clinical sensibility measurements (Ager et al., 2018; Manne, et al., 2019; Squires et al., 2019; Trenaman, et al., 2021; Jansen et al., 2021 & Yao et al., 2017).

A future study is needed to test a DA for CPM in women from a community or rural hospital setting, as well as women with less education and lower income. Further, the studies in this review did not always include long-term effects of mastectomy and CPM or psychological implications. For this preference-sensitive decision point, a DA should expand on the long-term physical and psychological effects of unilateral mastectomy versus CPM.

Limitations

Limitations of this review include that the primary author conducted the search and was a single reviewer. To increase rigor, it is best to have a cross search and second reviewer to decrease bias and the risk of inadvertently omitting pertinent studies (McDonagh et al., 2013).

Further, an expanded review of the literature could explore the reported factors for women electing CPM over unilateral mastectomy to build on the current research.

Implications for Research and Practice

In breast oncology surgery settings, further testing of a DA for women considering CPM should be considered. From this review of the literature, it is recognized that decisional support is beneficial in the oncology setting, especially when the treatment options can be driven by patient preference. Further, it is important in oncology care to ensure that patients are provided the best instruments to help make shared, informed decisions surrounding treatment next steps.

Conclusion

The decision point of considering CPM versus unilateral mastectomy will benefit from continued research. Contralateral prophylactic mastectomy continues to be a patient-sensitive decision that should require ongoing shared, decision-making interventions. Breast oncology teams should consider the addition of a decision aid intervention for patients desiring CPM at the time of surgery for treatment of their primary breast cancer.

Figure 1. *PRISMA Flowchart of Literature Search Methods*

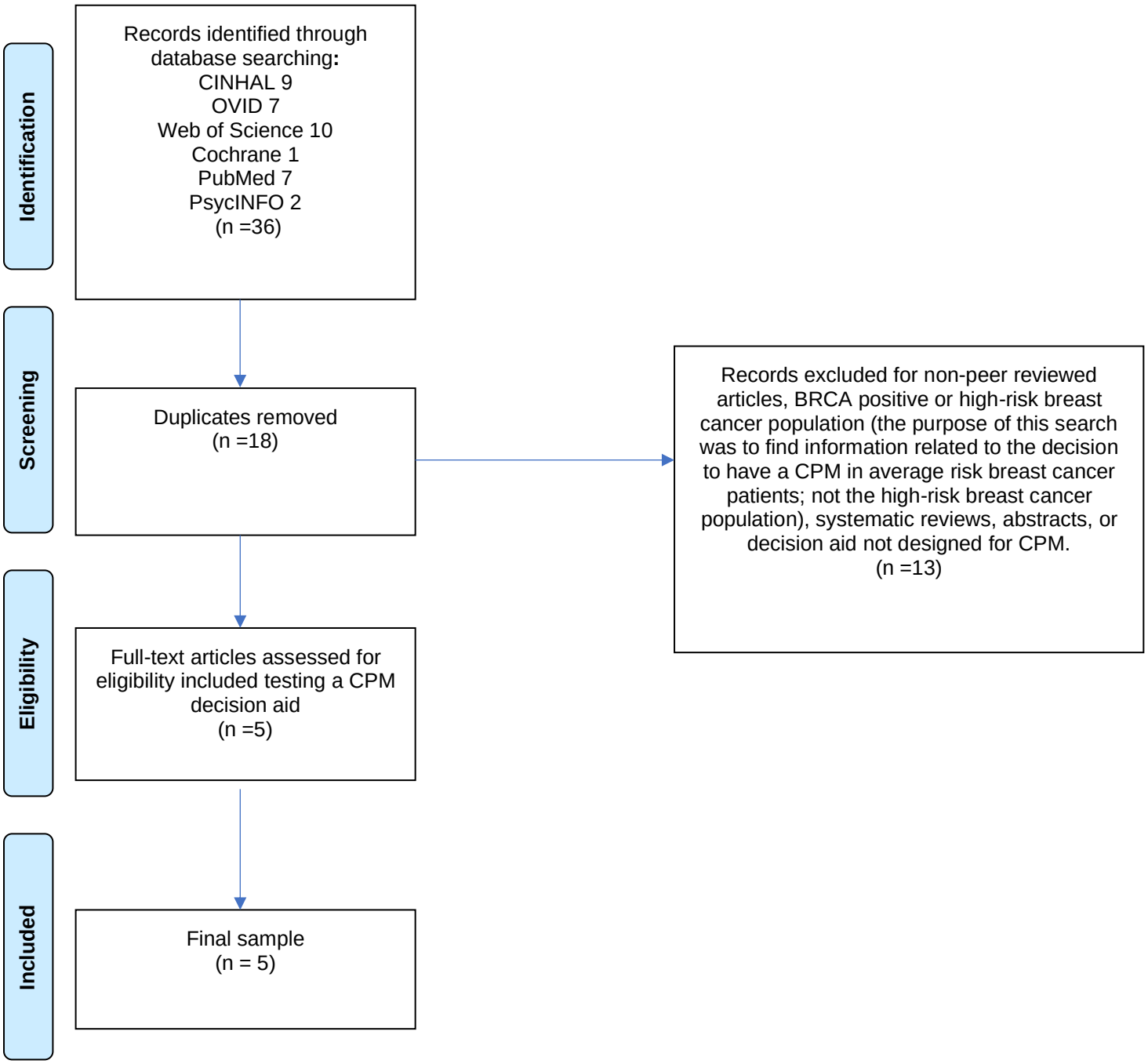

Table 1. Decision aid (DA) articles for Contralateral Prophylactic Mastectomy (CPM)

Author/Year	Study Type	Population	Sample Size	Measurements	Outcomes
Yao et al., (2017)	Pre-post cohort	Patients newly diagnosed with unilateral breast cancer and clinical AJCC Stage 0-III disease. Known BRCA mutation excluded.	Usual Care: 114 DA: 97	Two questionnaires assessing knowledge and worry. Worry about contralateral breast cancer and anxiety scale 1-10. Post-surgical consultation knowledge assessment with 9 items.	DA developed using SCOPED framework, developed by author JB. Increased knowledge in DA group; no difference in surgery decision; both groups indicated worry with no significant difference between groups. DA did not address long-term physical or psychological side effects of surgery or effect on body image.
Ager et al., (2018)	Qualitative feedback for DA	Patients self-reported previous diagnosis of early-stage breast cancer, age 40 or older, and completion of treatment. Self-reported genetic mutation excluded.	23 interviews	Qualitative analysis of DA	DA developed using OTTAWA framework. Patients reported DA acceptable, balanced information, & comprehensive. DA included pictures of surgical outcomes. Most wanted more practical information related to recovery and long-term effects.
Manne et al., (2019)	Pilot RCT of DA B-SURE	Patients 18 and older diagnosed with Stage 0-III breast cancer.	93 randomized: B-SURE DA, 46 Usual Care, 47	CPM knowledge 10-item multiple choice test, Ottawa Decisional Conflict Scale and Ottawa Preparation for DM Scale	B-SURE DA developed using OTTAWA framework. DA included pictures of surgical outcomes. Patients in DA group more knowledgeable about CPM (p=0.1); no difference in choosing CPM or not; Decision Conflict subscale (p=0.4) and no impact on preparedness.

Squires et al., (2019)	Mixed methods single arm for DA feedback	Patients with early-stage unilateral breast cancer and health care professionals involved in the care of patients with breast cancer.	51 participants: Healthcare professionals, 39 Patients,12	Surveys evaluating DA usability and acceptability	DA developed using OTTAWA framework. N=34 (87%) of healthcare professionals and N=12 (100%) of patients reported DA made sense. N=26 (67%) of healthcare professionals and N=11 (92%) of patients indicated they would share DA with others. All agreed DA was helpful to prepare for decision. DA had lack of information about psychological implications.
Jansen et al., (2021)	Longitudinal single arm pilot study of a paper form DA	Surgeons and oncologists treating patients with breast cancer and patients aged 18 and older diagnosed with unilateral breast cancer. Excluded if stage IV breast cancer or genetic mutation.	Patients: 31 Healthcare professionals: 11	Qualitative analysis of DA	DA developed using OTTAWA framework, 3 main themes emerged: Utility and impact of DA, patients valued DA, DA reported to be balanced. Target population for DA: clinicians reported only those at low risk for contralateral breast cancer and those that ask about CPM. Patients endorsed making DA available to inform about all choices. Timing of delivery of DA: most patients preferred to receive as soon as possible before surgery; clinicians preferred to give information about CPM at follow-up.

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Chapter 3

Title

Development of a Decision Aid to Promote Informed, Shared Decision Making for Contralateral Prophylactic Mastectomy: Protocol for a Pre/post Intervention Study

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Abstract

Background: Contralateral prophylactic mastectomy (CPM) is a risk-reducing surgical removal of a healthy breast to reduce the risk of developing breast cancer. Although most women diagnosed with breast cancer will never develop a contralateral breast cancer, it continues to be an area of discussion at surgical consultation.

Methods: The purpose of this on-going mixed methods pilot study is to develop and test a modified version of the DecisionKEYS decision aid in patients facing CPM. In Phase I, completed for the qualitative data, patient factors and values were explored that contribute to the increased decision to have CPM. These influenced the modification of the DecisionKEYS balance sheet and were identified through single, semi-structured interviews with patients that decide for or against a CPM. In Phase II, for the quantitative data, a pilot pre-post intervention visit comparison will compare decisional conflict and decision-making quality in women utilizing the DecisionKEYS intervention and later decision regret reported at study exit.

Discussion: The DecisionKEYS intervention for CPM is designed to include the identified factors to balance information from the patient and clinical team as well as include 'consideration of others.' The decision point of considering CPM versus unilateral mastectomy is a patient-sensitive decision that can benefit continued research and development of decision-making interventions.

Keywords: contralateral prophylactic mastectomy, decision aid, decision making

Background

Excluding skin cancer, breast cancer is the most common cancer in women in the United States (American Cancer Society, 2022). On average, 1 in 8 women will be diagnosed with breast cancer and incidence rates have increased by 0.5% in the recent years (American Cancer Society, 2022). The risk of developing a new primary cancer in the opposite breast is 0.5-1.0 percent per year over their lifetime (Chagpar et al., 2018). Despite the relatively low risk of developing a cancer in the opposite breast, women are still electing, at an increasing rate, to have a contralateral prophylactic mastectomy (CPM). A national trend study revealed an increase in bilateral mastectomy from 3.4% in 2016 to 6.8% in 2019 for patients with a unilateral breast cancer diagnosis (Shaheen, et al., 2022).

With the continued rise in CPMs, there is continued need for improved communication and decision making in patients undergoing unilateral mastectomy. There are many decision aids (DAs) available for patients choosing breast cancer surgery. A previous comprehensive systematic literature review of DAs in breast cancer care identified a gap that there were no DAs for CPM (Zdenkowski, et al., 2016). Following this, a review of the literature conducted by this researcher, found five pilot studies testing a DA for CPM (Yao et al., 2017; Ager et al., 2018; Manne, et al., 2019; Squires et al., 2019; & Jansen et al., 2021). Based on a current review, DecisionKEYS is the only theory-based decision aid that focuses on informed, shared quality decision making for breast cancer surgery. The purpose of this protocol is to develop and test a modified version of the DecisionKEYS decision aid in patients facing CPM.

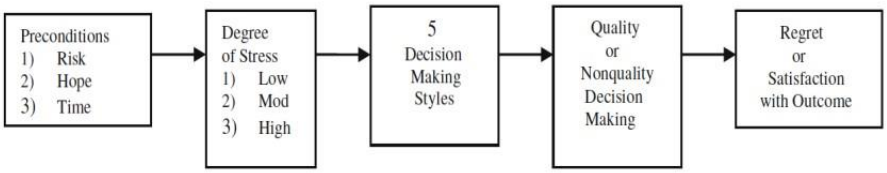
Decision Making Theoretical Framework

The Janis and Mann Conflict Theory of Decision Making underpins the intervention utilized in this mixed methods pilot study (Figure 1, presented with permission, Hollen, et al.,

2013; Janis & Mann, 1977). According to the theory, the preconditions (risk, hope, and time) predict the degree of stress a person feels which then influences the decision-making style and quality. Based on the decision-making style and quality, then the person will either feel regret or satisfaction with the decision (Hollen, et al., 2013; Janis & Mann, 1977).

The intervention includes a brief tutorial using the diagram to explain the theory to patients, along with giving patients, a copy to take home, which provides patients time to reflect on personal values, risks, and benefits of the choices. This theory has been used nationally and internationally as the basis of decision support research for women with breast cancer (Hollen, 1994; Hollen, et al., 2013).

Fig. 1 Diagram of theory adapted for brief tutorial



Methods

The purpose of this on-going mixed methods pilot study is to develop and test a modified version of the DecisionKEYS decision aid in patients facing CPM. In Phase I, for the qualitative data, patient factors and values were explored that contribute to the increased decision to have CPM. These influenced the modification of the DecisionKEYS balance sheet and were identified through single, semi-structured interviews with patients that decide for or against a CPM. In Phase II, for the quantitative data, a pilot pre-post intervention visit comparison will compare decisional conflict and decision-making quality in women utilizing the DecisionKEYS intervention and later decision regret reported at study exit. All participants will receive usual care consisting of education outlining the risks and benefits of CPM versus unilateral mastectomy.

The study setting includes two comprehensive breast cancer centers in Central Virginia: the University of Virginia (UVa) and Virginia Breast Care (VBC) collaborative with Sentara Martha Jefferson Hospital. Both settings predominately serve populations spanning the Blue Ridge Health District. Participants will enter the study at the time of seeking curative and preventative surgical treatment for a current or recent breast cancer diagnosis or those that recently completed surgery for a breast cancer diagnosis within the last 12 months. Inclusion criteria for Phase I, qualitative method, are women aged 25 or older, a diagnosis of breast cancer, breast cancer stage 0, I, II or III, have received a breast consultation within the last 12 months and are considering CPM, have had a CPM, and those that decided not to have a CPM will be included for interviews. Inclusion criteria for phase II are women aged 25 or older, have a new diagnosis of breast cancer stage 0, I, II, or III and are currently seeking a breast surgery consultation. Exclusion criteria for both phases are patients with advanced stage (IV) and/or metastatic breast cancer, not eligible for breast surgery consultation based on another advanced disease or advanced age, have a confirmed BRCA genetic mutation, and those self-reporting pregnancy. Participants will receive a $50.00 Amazon e-gift card after the completion of all study requirements.

Data Collection

The primary investigator will provide on-site training at the clinics enrolling for this study. Patients who are newly diagnosed with breast cancer seeking breast surgical consultation will be screened for eligibility. Each person who meets the eligibility criteria will be approached for participation. Eligible potential participants will be contacted by phone or in person to discuss the study in detail, answer any concerns of the participant, and to obtain the consent (if by phone, consent may be sent to participant for signature via encrypted email or postal mail).

Further, if needed, study measures may be completed by phone, video chat, or via encrypted email.

Table 1: *Study Protocol by Clinic Visit*

Study Protocol	**Visit 1 (Screening/Baseline)**	**Visit 2 (Post-Decision)**	**Visit 3 (Follow-up)**
Study Week	**1**	**2**	**8**
Informed Consent	**X**		
Review study eligibility	**X**		
Medical Record Review Form (MRRF)*	**X**		
Demographic Form (5 mins)	**X**		
Decisional Conflict Scale (DCS) (5-10 mins)**	**X**	**X**	
Decision Making Quality Scale (DMQS) (5-10 mins)	**X**		
DecisionKEYS education (20 mins)	**X**		
Interview (30-45mins)			**X**
Decisional Regret Scale (DRS) (5-10 mins)			**X**
DecisionKEYS Evaluation Form (5-10 mins)**			**X**

*Completed by the study team.
** Phase II measures only.

Study Outcome Measures

Two patient information forms developed by the PI and three validated instruments have been identified to accomplish the data collection purposes of this protocol. Estimated completion time of all forms and instruments is 30 minutes. The PI developed a one-page demographic form for sociodemographic data. The demographic form consists of 7 items for the patient to self-report. The items include age, race, marital status, education level, income, and health insurance status. Estimated completion time is 5 minutes. Dummy coding is applied for nominal data. A medical record review form was developed by the study team to capture health status of the participant. This 10-item form includes age at diagnosis, cancer diagnosis staging, hormone receptor status, genetic counseling, genetic mutation information, performance status, height, weight, family history of cancer, and social history. Estimated completion time is 15 minutes by the site's research assistant. Dummy coding is applied for reported nominal data.

The DCS, developed by O'Connor in 2003, is a 16-item scale used to measure decisional conflict (O'Conner, 2003). Reliability, test-retest correlations, and Cronbach alpha (exceeding 0.78) and construct validity discriminated between known groups, effect size ranges 0.4-0.8 are available (O'Conner, 2003). This instrument is validated and has been used in over 30 studies to test a variety of decisions (O'Conner, 2003). The DMQS, developed by Hollen in 1994, is a 7-item scale used to measure patients' decision-making quality (Hollen, 1994). The DMQS was tested in 5 studies (3 of the 5 were in the oncology population) with alpha coefficients ranging from 0.71-0.90 for internal consistency. DMQS was also reviewed by 3 experts in decision theory for content validity. This instrument was determined feasible and acceptable by participants (N=766) in the study (Hollen, 1994). The DRS is a 5-item instrument, developed by O'Connor in 1993, that is appropriate to capture post-decision regret (O'Conner, 2003). The DRS is prefaced with asking the patient to think about the decision made after talking with a health care provider. Items are given a score from 1 (strongly agree) to 5 (strongly disagree). Items 2 and 4 are reversed coded. To obtain a final score, scores are converted to a range of 1-100 by subtracting 1 from each item and then multiplying by 25 (O'Conner, 2003). A score of 0 means no regret; with 100 representing high regret. Internal consistency (Cronbach's alpha, 0.81 to 0.92) for 4 groups of patients facing prostate and breast cancer treatment decisions was reported. Convergent validity with the same 4 groups was reported for decision satisfaction ($r = -0.40$ to -0.60), decision conflict ($r = 0.31$ to 0.52), and somewhat strong for quality of life ($r = -0.25$ to -0.27). Construct validity ($F [2, 190] = 31.1$, $p<0.001$) using contrasted groups was reported with groups differing on feelings about the decision outcome and, thus, differed on regret ($F [2, 190] = 31.1$, $p<0.001$) (O'Conner, 2003).

Sample Size Considerations

For the qualitative data, the primary investigator interviewed all participants until saturation of themes was reached. The researcher identified that saturation was met when no new categories arise during analysis (Creswell & Clark, 2011). The Phase II pilot study will enroll 40 patients with 10 contingency cases, for a total of 50 subjects. The quantitative data will be used to gain preliminary data in preparation for a larger, randomized clinical trial (Polit & Beck, 2014).

Analysis Plan

Phase I: Analysis of Aims 1 and 2

Study aims are (1) to explore factors and values contributing to women choosing CPM versus unilateral mastectomy, and (2) to determine the content validity and final evaluation of the modified DecisionKEYS for CPM to provide content and feedback for the continued modification of the DecisionKEYS interventions. Statistical analysis of the qualitative data garnered from aims 1 and 2 were performed using Dedoose (Dedoose, 2018). Using Dedoose, the interview transcripts were analyzed systematically line-by-line for data reduction and theme development used an inductive open coding approach. To ensure rigor, two researchers coded separately for data triangulation and confirmability (Creswell & Clark, 2011). Additionally, for transparency, a detailed audit trail of all coding decisions was included. Themes identified during analysis informed the modification of the DecisionKEYS intervention for CPM, specifically the interactive decision balance sheet.

Phase II: Analysis of Aims 3 and 4

Study aims are (3) to compare pre-post levels of decision conflict and decision-making quality, and (4) to identify later decision regret based on choice type for women using

DecisionKEYS over time when choosing CPM versus unilateral mastectomy. Both aims provide pilot data for the usefulness of the intervention. Descriptive statistics will be used to describe the study sample and cancer characteristics for the combined sites. To determine if the proposed decision aid does influence patient decision making during breast cancer surgery consultation, simple linear regression will be employed at a significance level of 0.05. A two-tailed, non-directional test will be employed to ensure the analysis captures true significance over time.

The independent variable is the intervention use of a decision aid. This study has 3 dependent variables: 1) decisional conflict, 2) quality decision making, and 3) later regret. In models 1 and 2, to predict if the decision aid will improve patient decision making and reduce decision conflict, the DMQS and DCS will be analyzed as pre-post comparisons. Descriptive statistics will be used to report those reporting decision regret (aim 4) at the end of this study.

Potential covariates that may be explored for the larger future definitive study include: 1) age, 2) education level, and 3) reported emotional factors (such as fear or anxiety as obtained from recorded interviews). This will be accomplished by including potential covariates in the model one at a time (not cumulative) and estimating its impact. Potential covariates that are significant at the 0.15 level will be explored further in the larger study (i.e., the sample size for the definitive trial will be adjusted to look at the additional covariates). At this exploratory stage, no adjustment for multiple comparisons will be made. Participants in this study will also complete a Likert-scale form assessing the usefulness of the intervention. Descriptive statistics will be used to describe the reported evaluation outcomes for acceptability; also, the evaluation form will include space for comments. Comments included on the evaluation form will be analyzed systematically for potential theme development.

Discussion

Current literature supports the continued need for decision aids (DAs) for breast cancer surgery and further development of a DA specifically for CPM (Zdenskowski, et al., 2016; Yao et al., 2017; Ager et al., 2018; Manne, et al., 2019; Squires et al., 2019; & Jansen et al., 2021). The modified version of the DecisionKEYS intervention for CPM offers a novel approach to a complex, patient-driven decision. As highlighted in the ASBrS position statement regarding CPM, this DA balances patient preference, history, and values in the decision-making process along with clinical risk and benefit (Boughey, et al., 2016). The interactive intervention can add benefit to the shared decision-making discussion with the patient and surgeon. It is evidenced that DAs have positive effects and are acceptable during clinical consultations (Stacey, et al., 2017). The current pilot DAs found that the use of a DA for CPM is acceptable and feasible in clinical practice when balanced information is presented (Yao et al., 2017; Ager, et al., 2018; Manne, et al., 2019; Squires et al., 2019; & Jansen et al., 2021). The most common reported factor driving the decision of CPM was fear of a future breast cancer (Ager et al., 2018; Han, et al., 2011). Other factors that were identified included perception of risk, influence of others, survival data, physician feedback, and cosmetic outcomes (Reaby, 1998; Mastaglia & Kristianson, 2001; Molenaar, et al., 2004; & Ager, et al., 2018). The DecisionKEYS intervention for CPM is designed to include the identified factors to balance information from the patient and clinical team as well as include ‘consideration of others.’

The decision point for CPM will benefit from the continued research to develop and test a DA to improve the informed, shared decision making between patients and their clinical team. This intervention, designed to teach patients how to make better decisions, can provide the needed decisional support required in the breast cancer surgery setting.

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Chapter 4

Title

Development of a Decision Aid to Promote Informed, Shared Decision Making for Contralateral Prophylactic Mastectomy

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Abstract (Word count: 200/200)

OBJECTIVES: To develop a modified version of the intervention DecisionKEYS to promote informed, shared decision making for contralateral prophylactic mastectomy (CPM).

SAMPLE & SETTING: 15 patients diagnosed with early breast cancer requiring surgical intervention participated in this study from two comprehensive breast centers located in Virginia.

METHODS & VARIABLES: A mixed methods pilot study was conducted to develop the content and validity of the theory-based, interactive decision aid (DA) intervention, DecisionKEYS. Semi-structured interviews with the nurse interventionist and PI verified content and validity of the DA. The Decision-Making Quality Scale (DMQS) was completed prior to the intervention. The Decision Regret Scale (DRS) was completed post-surgical recovery.

RESULTS: Four themes were identified from the qualitative data: 1) fear of cancer recurrence or a cancer diagnosis in the opposite breast, 2) empowerment and self-trust, 3) previous experiences, histories, and influences related to cancer, and 4) expressed need for increased psychosocial support at the time of initial diagnosis. DMQS scores were high with 93% (14/15 patients) of DMQS scores equaling 15 or greater. DRS scores were low with 69% (9/13 patients) scoring 0 with no regret.

IMPLICATIONS FOR NURSING: Content and DA process validity demonstrates that a nurse interventionist is acceptable by patients.

Knowledge Translation

- Women considering unilateral mastectomy versus CPM sought in-depth information, guidance, and support.
- Patients described the decision aid as helpful in their discussions with the healthcare team.
- Fear of cancer recurrence or a second cancer diagnosis was a contributing factor for the decision to have a CPM.

Thirty percent of all new cancer cases in women is breast cancer. An estimated 297,790 new cases of invasive breast cancer will be diagnosed in women in the United States in 2023 (American Cancer Society, 2022). Among this population, a subgroup of women undergoing mastectomy for the malignant breast will also elect to have a contralateral prophylactic mastectomy (CPM) to remove the healthy, unaffected breast to reduce future cancer risk. National trends demonstrate an increase in bilateral mastectomies from 3.4% in 2016 to 6.8% in 2019 for patients with a unilateral breast cancer diagnosis (Shaheen, et al., 2022).

In 2016, the American Society of Breast Surgeons (ASBrS) consensus statement reported that CPM does not increase overall survival benefit in patients without a genetic mutation, and doubles the chance of surgical complication; thus enhanced decision-making resources are needed (Boughey, et al., 2016). A theory-based interactive decision aid (DA) intervention, DecisionKEYS for Balancing Choices, is both feasible and acceptable in the oncology setting (Hollen, et al., 2013; Jones, et al., 2013; Chu, et al., 2022). The purpose of this mixed methods pilot study was to develop a modified version of the intervention DecisionKEYS for Balancing Choices, to promote informed, shared decision making for contralateral prophylactic mastectomy (CPM).

Methods

Methodological Approach

A mixed methods design addressed the primary aim to modify the decision intervention, DecisionKEYS for Balancing Choices, for patients considering CPM. Following an exploratory sequential approach, prior to patient enrollment, the intervention was first modified using both quantitative and qualitative findings from the literature and then reviewed by clinical and decision-making experts. The main purpose of the mixed methods approach was to use semi-

structured interviews to confirm content validity, feasibility, and acceptability. For the qualitative data, patient factors and values were explored that contribute to the increased decision to have CPM. Factors and values identified through single, semi-structured interviews with patients that decide for or against a CPM provided new content and content validity to the DA intervention.

Quantitative data captured patient demographics, clinical characteristics, treatment decision, as a part of evaluating patient decision making. Patients completed two scales to evaluate decision making. The Decision-Making Quality Scale (DMQS) was completed at baseline to measure the quality of decision-making factors by the participant. The Decision Regret Scale (DRS) was completed at the end of the study, post-decision, and post-breast surgery recovery to measure later decision regret.

Participants and Setting

Through convenience sampling, patients were enrolled from two breast specialty clinics located in Central Virginia. Inclusion criteria for interviews were 1) women age 25 or older, (2) patients with a diagnosis of breast cancer, (3) breast cancer stage 0, I, II or II, (4) women that have received a breast consultation within the last 12 month, and (5) women that are considering CPM, have had a CPM, and those that decided unilateral mastectomy alone. Ineligible patients included those with known BRCA or advanced stage cancer. Patients' reasons for declining enrollment also were tracked. The Institutional Review Board at both study sites reviewed and approved the study.

Intervention

The modification and development of the DA is based on prior institutional DecisionKEYS interventions in oncology care using the Janis and Mann conflict theory of decision making as a framework (Hollen, et al., 2013; Janis, 1981; Janis & Mann, 1979). The

decision aid provides patients with a comprehensive cognitive-behavioral skills program containing information on management choices, while teaching patients how to improve quality decision making. The DA intervention is an interactive approach to balancing the choice between unilateral mastectomy and CPM with a trained study nurse interventionist. The DA is composed of 3 sections: 1) clinical background, 2) patient perspectives, history, as well as values, and 3) weighing gains and losses of CPM versus unilateral mastectomy (see **Table 1**).

Instruments

Study measures consisted of two instruments to evaluate decision making and two participant information forms.

Demographic and clinical characteristics: Participant information forms included a form to collect participant sociodemographic data (age, race, marital status, education level, income, health insurance status, and primary language). A medical record review form recorded pertinent history (age at diagnosis, date of diagnosis, breast cancer stage, hormone receptor status, genetic counseling received, genetic testing results, performance status, family history of breast cancer, alcohol consumption, tobacco use, and other substance use).

Decision Making Quality Scale (DMQS): The DMQS, developed by Hollen in 1994, is a 7-item scale used to measure patient's decision-making quality (Hollen, 1994). The DMQS was tested in 5 studies (3 of the 5 were in the oncology population) with alpha coefficients ranging from 0.71-0.90 for internal consistency. DMQS was also reviewed by 3 experts in decision theory for content validity. This instrument was determined feasible and acceptable by all participants (N=766) (Hollen, 1994). Each item is scored on a four-point scale (0 = not true at all, 3 = very true) with a possible score range from zero to 21. A score of 15 or higher is defined as high-quality decision making (Hollen, 1994).

Decision Regret Scale (DRS): The DRS is a 5-item instrument, developed by O'Connor in 1993, that is appropriate to capture post-decision regret (O'Conner, 2003). Items are given a score from 1 (strongly agree) to 5 (strongly disagree). Items 2 and 4 are reversed coded. To obtain a final score, scores are converted to a range of 1-100 by subtracting 1 from each item then multiplying by 25. A score of 0 means no regret; 100 representing high regret (O'Connor, 2003).

Data analysis

All data were coded by participants' study I.D. Primary descriptive results were based on all eligible participants that entered the study, regardless of compliance with study procedures. Descriptive statistics were calculated for participant sociodemographic data, clinical health status, and treatment decision. Statistical analysis was performed using SAS 9.4 software (Cary, NC: SAS Institute Inc., 2013). Qualitative data was captured at two separate study time points. The first study time point captured patient experience with the intervention. The primary researcher (CC) used this information to inform the final study visit that included a semi-structured interview (see **Figure 1**). This process allowed for feedback, participants the opportunity to confirm data being captured, and to explore the content for a second time to decrease the chance of researcher bias (Aurini, et al., 2022, p. 96). The semi-structured interviews were audio recorded and transcribed verbatim. Transcriptions were then reviewed and coded line-by-line using Dedoose version 9.0.62, a web application for managing, analyzing, and presenting qualitative and mixed method research data (Los Angeles, CA: SocioCultural Research Consultants, LLC). To ensure rigor, two researchers (CC and RJ) debriefed and conducted consensus of code and theme development (Aurini, et al., 2022, p. 96). Data collection

stopped when these two researchers had consensus that the data was comprehensive, and saturation was achieved (Aurini, et al., 2022, p. 98).

Results

Sociodemographic, Health Status, and Decision-Making Measures

A total of 15 patients diagnosed with early breast cancer participated (see **Table 1** for participant characteristics). Six eligible participants declined to participate. Two participants were lost to follow-up and did not complete all study measures. DMQS scores resulted in 93% (13/14 patients) with a score equaling 14 or greater. Decision Regret Scale scores were low with 69% (9/13 patients) scoring 0; no regret (N=13, min-max 0-25, mean = 6.9).

Identified Themes

Of the 15 participants enrolled, 13 provided feedback and participated in the qualitative data collection. Of the 13, 3 participants did not have access to the DA at the time of their breast surgery consult and were included to provide retrospective feedback to the content and describe their original decision-making process. Four themes were identified from the data: 1) fear of cancer recurrence or a diagnosis of cancer in the opposite breast, 2) empowerment and self-trust, 3) previous experiences, histories, and influences related to cancer, and 4) expressed need for increased psychosocial support at the time of initial diagnosis.

Theme 1: Fear of Cancer Recurrence or Developing a Second Cancer Later

During the development phase of the intervention, one qualitative study found that fear was the most expressed reason for CPM; however, it was expressed in the theme of "taking control of cancer" (Covelli et al., 2015). This belief surrounded the concept that CPM would give them control to defeat cancer and guarantee long-term survival (Covelli et al., 2015). Participants endorsed worry and fear of a cancer recurrence or potential diagnosis of a second breast cancer

in the opposite breast. One participant in this study said, " *and the constant, the constant worry. I just rather have the other one taken off*." For another, it was a joint decision between her and her spouse, *"we [spouse and patient] both kind of knew it was the right direction to go on. I don't think anybody had any second guessing going on or even today. I just need a little peace of mind, that hopefully, I will live a longer life."*

During the process of utilizing the decision aid and during the interviews, the participants understood the chances of a future cancer were relatively low and even that surgery may not prevent a cancer recurrence, however, they still endorsed this as the primary factor in choosing CPM over unilateral mastectomy. The interviews consistently were conversations centering on "what would I regret more?" and often revealed a perception that regret would be greater if they developed a second cancer. Seven participants endorsed being "very worried about a second breast cancer" and six notated being willing to "do all procedures to be sure that I do not have or develop a second breast cancer."

Theme 2: Empowerment and Self-trust

The second most common factor influencing the decision to have a CPM over unilateral mastectomy was "concern about symmetry after my unilateral mastectomy." One participant after using the DA and leaning towards the unilateral mastectomy to treat the current cancer and a CPM later, said *"I'll know when I look in the mirror [after the unilateral mastectomy surgery]."* Through the discussion of body image, symmetry, and sexuality, participants conveyed a sense of strength, empowerment, and self-trust regarding the surgical decision. Participants endorsed they do not need their breasts to be themselves or be considered feminine, one stated " *my breasts don't make me who I am*" and another, "*It depends on what the decision is over. I mean, if it's over buying a dress, or, you know if it's going to affect my husband or my*

family in any way, I certainly would have to include them. But if it's something that's just for me, then that's my choice. I am NOT my boobs."

During the interactive DA, participants spoke freely and confidently revealing a level of self-trust in their decision-making process. Another woman recounted her story of arriving at the breast surgery consult and the sign she knew she was making the right choices for herself. *"He [patient's spouse] said, 'No, come over here now.' And I went over and right at the elevators, he said look up and there was dragonflies all over the ceiling. And he said, 'if you needed a reason to believe this is where God wants you, that's it.' Because only he knew that I was not a Christian until I was in my 20s and I had adopted the dragonflies as my symbol of change between how I grew up and my Christian walk. And so, we knew that, you know, we were exactly where the Lord was wanting us at that point."*

Theme 3: Previous Experiences, Histories, and Influences related to Cancer

All participants endorsed having a previous experience, history, or influence related to cancer. A participant described an extensive relationship with cancer throughout her life, "*a friend of our family from when I was little, who died of breast cancer, about 10 years ago maybe. And then I had another again, older friend when I was a little kid who died of leukemia, back in the late 70s. And my grandfather died of pancreatic cancer. I think I was pretty convinced I was going to die, because all of those ended in that way."*

Another participant recounted being by her sister's side during cancer treatment, "*and I remember just hearing the radiation machine and seeing the mark on her [her sister]. So, I knew that after watching my sister and being with her when she died, I know there's no let's just see what happens or I want to do the least bit I can, no, we're gonna do whatever is necessary to do what I need to do."*

A middle-aged woman described **“** *[I have] been affected by cancer most of my life. My grandmother died of ovarian cancer. My father died of liver cancer. His sister had breast cancer twice. My sister had cancer. One of my good friends had died of the same type of breast cancer when it came back the second time for her. So, cancers always been a part of my life, unfortunately. My one friend, which is the pastor's wife, she had a lumpectomy. My other friend, she had a single mastectomy. So, we all talked about, you know, how things went with each of us. And, we were all confident in the decisions that we had made.”* As the participants described their experiences with cancer it was often linked to their current fear of developing a second cancer and the urge to do everything possible to treat their current cancer.

Theme 4: Expressed Need for Increased Psychosocial Support and Discussion at Initial Surgery Consult

All participants expressed the need for improved psychosocial support and communication at the initial surgical consult. A participant described her difficult initial surgery consult, *“like they stood me in the middle of the room. And basically, pretty much naked. And then doctor came in with like, five young people. I was mortified. Like, I was so embarrassed. Like to be standing as a woman and in front of an audience that I didn't know was coming in. And that just triggered the part of my like, more trauma response brain, it was more of the emotional part of my brain. That became triggered and so whatever they would have told me, my cognitive is gone. My brain wasn't even really functioning because I was thinking, how in the hell can I get out of here?”* Another participant highlighted that *“from the decision aid, we [patient and surgeon] actually had a further conversation. And in the very end with my last meeting with her [the surgeon], she was very kind and very understanding and she was very*

onboard. But for most of our [initial] meetings, it was pretty hostile because she was not in agreement with me whatsoever."

Further, participants often described that the initial consult did not flow like a conversation and did not feel patient-centered, " *[the surgeon had a] fairly generic spiel. And she doesn't really want to vary from that much, which I found kind of frustrating because I wanted sort of more specific answers. I mean, I'm sure I drive people crazy. You know I went in and I probably had 16 or 18 questions that I was gonna ask. She was like let me just do my thing first. So, I felt like it was kind of generic. And then she was sort of discouraging. I had asked her, like, is there a place I can do some kind of research to get more information and she wasn't terribly supportive of that, which I found a little frustrating. And, then I had looked on like American Cancer Society and it's all just very general info, I wanted sort of more specifics than that, so it was the first meeting was very frustrating."*

Discussion

The interview results build upon previous research exploring the patient reported factors for choosing CPM. The findings in this study confirm the reported factor that women chose CPM because of fear of recurrence, perceived risk, or "peace of mind" (Greener, et al., 2018; Huang, et al., 2018; Hawley, et al., 2018; Jagsi, et al, 2017; Covelli, et al., 2015; Brown, et al., 2017; Sando, et al, 2018; Rosenberg, et al., 2017; Altschuler, et al., 2008; Venetis, et al., 2018; D'Agostino, et al., 2018). Aligned with their theme of "fear of a second cancer" in this study, despite clinical risk discussions, Greener and colleagues (2018), provided an example of perceived risk with this quotation from a participant '*but in my mind, I thought, any percentage is bad enough'* (Greener, et al., 2018, p.151). Covelli and colleagues provided many quotations from women using the language "survival", "worry about the other side" and "risk" (Covelli, et

al., 2015). One quote from the Covelli, et al., (2015) study was *'take these two breasts off. I would be willing to take that risk so that I didn't die from breast cancer at the age of 63'* (Covelli, et al., 2015, p.387).

Secondly, the most common theme among body image was symmetry (Covelli, et al., 2015; Huang, et al., 2018; Jagsi, et al., 2017; Altschuler, et al., 2008; Rosenberg, et al., 2017; D'Agostino, et al., 2018). Covelli and colleagues (2015), had more than one participant use the word "symmetry" when providing why they chose CPM (Covelli, et al., 2015). In this quote from the Covelli 2015 study, there is a convergence of the fear of recurrence combined with body image, *'my choice would be flat, because that also gives me the peace of mind as well as the matching symmetry'* (Covelli, et al., 2015, p.387). The findings of this study confirm the convergence of fear of recurrence and a second cancer diagnosis with body image and further adds the convergence of previous histories and associations with cancer.

Implications of Nursing and Practice

Jones and colleagues identified in a previous study that DAs help patients be more involved in clinical conversations and that contact with the study nurse was helpful (Jones, et al., 2013). Participants endorsed that the DA intervention in conjunction with the trained nurse delivering the DA to be most helpful. A trained nurse interventionist to deliver a guided conversation to assist patients in balancing breast oncology surgical choices is well-received and acceptable by breast surgery patients according to the findings of this study.

Conclusion

Participants endorsed that the interaction DA was helpful in decision-making, communication with their surgeon, and provided them the opportunity to discuss their thoughts in a supportive, structured approach. Breast oncology settings should consider the addition of a

decision aid intervention for patients desiring CPM at the time of surgery for treatment of their primary breast cancer.

Table 1

Patient Decision Aid Key Components:

Background Information	Clinical risks and benefits of CPM
Understand your Perspective, History, and Values	Interactive values and perspective clarification exercise using series of contrasting statements
Compare your Options	Interactive exercise to clarify gains/losses for self/others related to CPM versus unilateral mastectomy alone
Decision Preference	Indicate decision preference or uncertainty following exercise

Table 2

Participant Characteristics:

Age	N=15, min-max 25-78, median = 51
Sex	15/15, 100% female
Married/Partnered	9/15, 60%
School (years)	N=15, Min-max 12-20, median = 16
Income (<$40,000)	6/15, 16%
English primary language	13/15, 87%
Family History of Cancer	10/15, 67%
CPM Decision Preference	11/15, 73%
Decision Regret Scale (DRS)	N=13, min-max 0-25, mean = 6.9
Decision Making Quality Scale (DMQS)	N=13, min-max 14-21, mean = 19.4

Figure 1 *Participant Interview Guide*

Semi-Structured Interview Questions

1. Can you describe what a typical day looks like for you over the past year?

2. In day-to-day life, could you describe how you make important decisions?

3. Can you describe your experience with your cancer diagnosis?

4. What experiences did you have with cancer before your diagnosis?

5. During your breast surgery consult, what information did you receive?
   - 5.1 What treatment did you decide upon after your surgery consult?
   - 5.2 When making your surgical decision, what factors did you consider?
   - 5.3 What other concerns influenced your decision (outside of what healthcare providers were telling you)?
   - 5.4 Did you include others (family, friends) in your surgical decision?
   - 5.5 What values do you think most influenced your decision?

6. How would you describe the decision-making style that was used between you and your surgeon?

7. What type of support did you receive during the time of decision making and after?

8. How did the COVID-19 pandemic influence your decision?

9. Other than what we have previously discussed, is there anything further you would like me to know about your decision experience?

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Chapter 5

Conclusion

Summary of Dissertation Findings

This dissertation provides a comprehensive understanding to the decision-making process, patient reported factors, and acceptability of DA interventions in clinical settings for patients considering CPM. Chapter 2 builds on the current literature of the use of DAs in breast cancer care, more specifically for the decision to have a CPM versus unilateral mastectomy alone and identifies the continued need to test DA interventions in this setting. Chapter 3 presents the multi-phased mixed methodological approach for the development and testing of a DA for CPM. Chapter 4 presents the content validity and acceptability of an interactive DA intervention in the setting of breast surgery consultation. Further, four identified themes provides a summary: 1) fear of cancer recurrence or a diagnosis of cancer in the opposite breast, 2) empowerment and self-trust, 3) previous experiences, histories, and influences related to cancer, and 4) expressed need for increased psychosocial support at the time of initial diagnosis. These themes are an extension of the patient report factors, influences, and histories that influence the decision to elect a CPM.

Next Steps and Future Research

As outlined in Chapter 3, further testing of the modified DA intervention, DecisionKEYS, is needed to measure the 1) fear of cancer recurrence or a diagnosis of cancer in the opposite breast, 2) empowerment and self-trust, 3) previous experiences, histories, as well as influences related to cancer, and 4) expressed need for increased psychosocial support at the time of initial diagnosis. Further, based on the finding, that the number one factor for electing CPM is the fear of developing a cancer in the contralateral breast, future research is needed in the context of measuring risk tolerance in the setting of breast cancer care. Future research is also needed to

test the modified version of DecisionKEYS for CPM as an intervention to improve shared decision making as well as compare levels of 1) decision conflict, 2) decision-making quality, 3) decision regret, and 4) risk tolerance.

This dissertation further provided foundational work to continue to explore the modification of DecisionKEYS across the breast cancer care continuum, specifically for CPM. Based on previous work, this intervention is both acceptable, feasible, and endorsed as helpful by patients (Hollen, et al., 2013; Jones, et al., 2013, Chu, et al., 2022). Over the next 5 years, this researcher plans to continue to modify and test the intervention, DecisionKEYS, across breast cancer care settings at pivotal decision care points.

Chapter 5 References

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Last updated: September 2020

Preparing your manuscript
The information below details the section headings that you should include in your manuscript and what information should be within each section.
Please note that your manuscript must include a 'Declarations' section including all of the subheadings (please see below for more information).

Title page
The title page should:

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The Abstract should not exceed 350 words. Please minimize the use of abbreviations and do not cite references in the abstract. The abstract must include the following separate sections:

- **Background:** the context and purpose of the study
- **Methods:** how the study will be performed

- **Discussion:** a brief summary and potential implications
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Keywords
Three to ten keywords representing the main content of the article.

Background
The Background section should explain the background to the study, its aims, a summary of the existing literature and why this study is necessary or its contribution to the field.

Methods/Design
The methods section should include:

- the aim, design and setting of the study
- the characteristics of participants or description of materials
- a clear description of all processes, interventions and comparisons. Generic drug names should generally be used. When proprietary brands are used in research, include the brand names in parentheses
- the type of statistical analysis used, including a power calculation if appropriate.

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This should include a discussion of any practical or operational issues involved in performing the study and any issues not covered in other sections.

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If abbreviations are used in the text they should be defined in the text at first use, and a list of abbreviations should be provided.

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All manuscripts must contain the following sections under the heading 'Declarations':

- Ethics approval and consent to participate
- Consent for publication
- Availability of data and materials
- Competing interests
- Funding
- Authors' contributions
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