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A Lifestyle Management Coaching Intervention For Fear Of Cancer Recurrence In Young Breast Cancer Survivors

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A LIFESTYLE MANAGEMENT COACHING INTERVENTION FOR FEAR OF CANCER RECURRENCE IN YOUNG BREAST CANCER SURVIVORS

by

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Abstract

Objective: A significant challenge facing young breast cancer (BC) survivors is learning how to manage fear of cancer recurrence (FCR) during survivorship. Limited tailored FCR interventions and age-appropriate support exist. This Doctor of Nursing (DNP) project, based upon best practice guidelines, aimed to evaluate how a Lifestyle Management Coaching Intervention (LMCI) could help young female BC survivors learn how to decrease and manage their FCR more effectively and experience improved health outcomes.

Method: Eligible participants were female BC survivors aged 18-59 with Stage I-III BC demonstrating elevated baseline FCR screening scores during the extended survival period recruited from the Edward-Elmhurst Health (EEH) system located in Illinois. Pre/post-intervention testing of Fear of Cancer Recurrence Inventory Short Form (FCRI-SF) scores, the Paired *t*-test for statistical analysis, and a one-time end-of-program survey were utilized.

Intervention: The 10-week virtual FEARLESS LMCI designed by the principal investigator consisted of ten, hour-long weekly BC-specific health coaching sessions and focused on helping participants incorporate eight healthful lifestyle management pillars into their daily lives: (F) Fearing Less, (E) Eating Well/Nutrition, (A) Activity, (R) Rest/Restoration, (L) Love of Self/Purpose, (E) Environment, (S) Sleep, and (S) Stress Management. Twelve (N= 12) survivors completed the LMCI.

Results: The Paired *t*-test concluded that the FEARLESS LMCI was effective in reducing FCR among the participants with a significant mean decrease of 6.75 points in FCRI-SF scores, 95% CI [3.92, 9.58], $t(11) = 5.24$, $p < .001$. Participants met the eight FEARLESS post-intervention adaptive goals at least 75% of the time. All participants reported that the LMCI helped them learn to manage FCR more effectively, cope better, and restore health. The LMCI also enhanced perceived self-love, longevity, and legacy among the participants.

Conclusion: The FEARLESS DNP project findings provide clear evidence in support of utilizing a virtual LMCI for unmanaged FCR among young BC survivors. FCR should be screened for and addressed in the clinical setting according to best practices.

Key Words: young breast cancer survivor, fear of cancer recurrence, FCR, Fear of Cancer Recurrence Inventory Short Form, FCRI-SF, FCR factors, FCR interventions, nutrition, physical activity, exercise, rest, sleep, stress, coping, lifestyle modifications, wellness coaching, health coaching

Dedications

This FEARLESS DNP project is dedicated in honor of my late Auntie Terri Klikuszewski who passed away from breast cancer on January 20, 2004. During her beautiful 43 years of life, she brought love, happiness, and wisdom to many. She has been my spiritual guide throughout my nursing career and during the DNP project process. I love and miss her every day.

This DNP project is also dedicated to all past, present, and future young breast cancer survivors experiencing FCR. I truly understand that FCR is a significant concern affecting many of you. The FEARLESS coaching intervention was written and designed directly from my heart and represents a compilation of the evidence-based and intuitive information I have collected over nearly seventeen years of my career. It has been my honor to care for and support so many of you throughout these many years and now bring you this program. Through dissemination of the project findings, I hope to help make the first five years after breast cancer treatment some of the best years of your life. I would like to especially thank the twelve project participants for their dedication to my program. It means the world to me.

I am also dedicating this project to my mom. Mom, you are the true definition of unconditional love. Your support throughout this process is immeasurable. You taught me throughout my life that “I have incredible self-confidence” and this one statement has now taken me all the way to completing my doctorate. Every day I am grateful for you. Growing up, you gave me everything I needed to succeed. Your selflessness is what pulled me through to the finish line while I was also balancing work and new motherhood. Even during your breast cancer diagnosis and treatment, you stayed by my side throughout this process with unwavering help and loyalty. Thank you so much for taking such good care of Colin these past few years and being the best mom and Nana ever. I love you with all my heart.

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I would first like to acknowledge God, for I know He has led me to this proud moment. God, thank you. Please continue to use me as an instrument of healing moving forward and help me to enhance the lives of young breast cancer survivors both near and far.

I would also like to acknowledge my father. Dad, you encouraged me to succeed in school from the very start. During my early academic years, you worked day and night to provide me with private education and the foundation necessary to complete my academic dreams. I hope you are proud to see your hard work and dedication pay off. Thank you.

I would next like to acknowledge my loving husband. Brian, thank you for staying by my side and supporting me during the completion of three nursing degrees and agreeing to use so many family resources to complete my advanced degrees. I am so grateful to you.

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Chapter 1

Breast cancer is the most prevalent type of cancer worldwide and the second most common cause of death from cancer in women in the United States after lung cancer (American Society of Clinical Oncology [ASCO], 2022; World Health Organization [WHO], 2021). Cancer of the breast begins in the ducts or lobules of glandular tissue located within the breast. The most common site for breast cancer is in the epithelium of the ducts so it is not surprising that research indicates that 85% of breast cancers are ductal type, and 15% are of lobular origin. Breast cancers that are confined to the duct or lobule are in situ and may progress to become invasive or infiltrating. This infiltration can be localized to the surrounding breast tissue with the potential to spread to the regional lymph nodes or distant organs of the body (ASCO, 2022). The strongest breast cancer risk factor is female gender (WHO, 2021).

Due to the potential for breast cancer to progress, breast cancer survivors often experience fear of cancer recurrence (FCR). FCR is defined as fear, concern, or worry relating to the possibility that cancer will progress or return (Lebel et al., 2016). FCR is normal to a degree after a breast cancer diagnosis and treatment, and it is important to acknowledge this with patients. When left unaddressed or unmanaged, however, FCR can become dysfunctional and/or permanent resulting in lower quality of life, higher rates of depression and anxiety, preoccupation with worry and bodily symptoms, greater physical symptom burden, and psychiatric disorders among other problems (Gormley et al., 2022; Smith et al., 2020).

This Doctor of Nursing Practice (DNP) project aims to plan, develop, implement, and evaluate a lifestyle management coaching intervention (LMCI) supported by a thorough

integrated literature review that will help decrease FCR and improve several health outcomes in young breast cancer survivors demonstrating abnormally elevated FCR screening scores. These health outcomes include the creation of whole, restored health after cancer treatment, less FCR after participation in the LMCI, living a more balanced life, developing a deeper self-love/purpose and legacy, changing to an integrated healthier coping response, and becoming healthfully integrated/adapted to their new normal after breast cancer treatment. In this chapter, the background and significance of breast cancer and FCR, as well as the factors associated with clinically significant FCR scores are discussed. A thorough description of the problem, purpose, and project inquiry is provided. The theoretical frameworks that relate to FCR and will guide the project intervention for breast cancer survivors are examined.

Background and Significance

Breast Cancer is the most common type of cancer diagnosed in women, occurs in every country of the world, and accounts for more lost disability-adjusted life years (DALYs) by women globally than any other type of cancer. It is important to understand the actual numbers of women diagnosed with and surviving breast cancer at the global and national levels. At the end of 2020, 7.8 million female breast cancer survivors were living throughout the world and had been diagnosed with the disease within the past five years. Globally, the data from 2020 also revealed that breast cancer morbidity was over 2 million women, and the mortality was 685,000. The incidence of breast cancer has increased by more than 20 percent since 2008, and it now represents ¼ of all cancers in women worldwide (Breast Cancer Research Foundation, 2022; WHO, 2021).

Furthermore, about 3.8 million breast cancer survivors live in the United States (US). Nationally, the data in 2022 showed that 1 in 8 women (13%) are diagnosed with invasive breast

cancer in their lifetime, and 1 in 39 (3%) will die from it. An estimated 287,850 new cases of invasive breast cancer were diagnosed in US women in 2022 (American Cancer Society [ACS]), 2022). The average 5-year and 10-year survival rates for women in the US diagnosed with non-metastatic invasive breast cancer are 91% and 85%, respectively. Localized invasive breast cancers have a 99% 5-year survival rate, while those that spread to the regional lymph nodes have an 86% 5-year survival rate. However, young adult females and adolescents are less likely to be diagnosed in the early stages of breast cancer (ASCO, 2022). They may also experience aggressive breast cancer more frequently. For example, triple-negative breast cancer (TNBC), a type of breast cancer in which the cancer cells do not have estrogen or progesterone (ER/PR) receptors and lack the HER2 protein, is considered more aggressive and accounts for about 10-15% of all breast cancers. These cancers are more common in women younger than forty, with localized and regional survival rates of 91% and 65%, respectively (ACS, 2022).

Of the 3.8 million breast cancer survivors who live in the US, 18% are 49 years old or younger (ACS, 2022; Gormley et al., 2022). Breast cancer is the leading cause of cancer-related death for women younger than 40 years old, and early age at the time of diagnosis is associated with lower survival rates, worse prognosis, and higher recurrence rates. When compared to older women, young women are 52% more likely to die from breast cancer. Based on this information, a prevalent concern among breast cancer survivors after diagnosis and treatment is the fear that their cancer will recur (Gormley et al., 2022).

To put this further into perspective, approximately 50% of breast cancer survivors are estimated to experience moderate to severe levels of FCR, and this has been demonstrated to be as high as 70% for women 45 years old and younger (Gormley et al., 2022; Thewes et al., 2012). Nearly 7% of cancer survivors experience severe and disabling FCR, which can become

unmanaged and long-lasting without proper intervention (Butow et al., 2018). Additionally, the characteristics of clinical FCR include excessive distress, self-focused attention, difficulty making future plans, functional impairments, maladaptive coping, a prominent level of worry, rumination, preoccupation, and/or intrusive thoughts, and threat monitoring with frequent self-examination and diagnostic tests (Butow et al., 2018; Lebel et al., 2016). Identifying patients who are at greater risk of FCR can help inform tailored interventions to decrease the problem and improve patient management (Crist & Grunfeld, 2012). For these reasons, and according to best practices, FCR should be screened for and addressed in the clinical setting.

Problem Statement, Purpose, and Project Inquiry

An unmet need of breast cancer survivors is learning how to manage FCR (Smith et al., 2020). FCR is one of the greatest concerns of cancer survivors after treatment completion, and a gap in age-appropriate support exists. Hence it is not surprising that 49% of all cancer survivors experience moderate to severe FCR levels, associated with impaired functioning, distress, and lower quality of life (Smith et al., 2020). After completing the acute period of survival, or cancer treatment, breast cancer patients are faced with establishing a new normal and often feel lost in transition when doing so. This timeframe, known as the extended period of survival, can be dominated by FCR due to an abrupt stop to cancer treatment, management, and frequent examinations, particularly in younger women. Breast cancer survivors may benefit from additional support and tailored interventions during surveillance periods to help minimize potential manifestations and triggers of FCR (Gormley et al., 2022).

The purpose of the DNP project is to study the effectiveness of a DNP student-led health coaching intervention to decrease FCR among breast cancer survivors. The DNP project will address a practice gap in helping young breast cancer survivors establish a new normal of

survivorship after completing cancer treatment and transition from the acute period of survival more wholistically while decreasing FCR. The project aims to answer the proposed research inquiry: How will a ten-week DNP student-led lifestyle management-focused coaching intervention lead to decreased FCR and improved health outcomes among female breast cancer survivors demonstrating abnormally elevated screening scores during the extended survival period?

The population of interest includes female, English-speaking breast cancer survivors 18-59 years old diagnosed with invasive breast cancer. Participants will be in the extended period of survival and demonstrate a positive Fear of Cancer Recurrence Inventory Short-Form score (FCRI-SF) of 12 or above. The intervention includes a LMCI that is consistent with the National Comprehensive Cancer Network (NCCN), American Institute for Cancer Research (AICR), and American Academy of Lifestyle Medicine (ACLM) best practice guidelines. The intervention will include group coaching sessions conducted by a nationally certified health coach DNP student. The DNP project will be conducted as a quantitative pretest-posttest without a comparison group and includes a mixed-method post-program survey. The primary outcome of interest is FCRI-SF scores. Participation in this DNP student-led LMCI post-breast cancer treatment will decrease FCR in breast cancer survivors as demonstrated by improved FCRI-SF scores ideally below twelve, as well as enhance various health outcomes for program participants.

Theoretical Framework

One theoretical framework related to the topic of FCR in breast cancer survivors is the Roy Adaptation Model (RAM) by Sister Callista Roy, a nursing model based on both scientific and philosophical principles. The development of this model began in the 1960s and was first

published in 1970. RAM theorizes that a feeling and thinking person is a holistic adaptive system constantly interacting with external and internal stimuli and their environment. The human adaptive processes include automatic/unconscious responses and cognitive/emotional responses to stimuli and life processes, which maintain an individual's integrity. Three levels of adaptive processes occur in response to a changing environment or stimuli, including integrated (adapted), compensatory (attempt to reestablish adaptation), and compromised (not adapted) (Masters, 2015; Roy, 2009).

According to the RAM, a compensatory or compromised adaptation level affects the human system's ability to cope or respond positively in a situation and influences behavioral responses. The response is determined based on the environment and the current level of adaptation. Responses can be ineffective when not adaptive. An individual's behavior is the function of the input of stimuli and adaptation level, and the output consists of either adaptive or ineffective responses. Responses function as feedback to the human system, and then the individual increases or decreases efforts to cope accordingly. Furthermore, coping processes are considered innate (genetically determined and automatic) or acquired (learned or developed). Behaviors are observed in four adaptive modes: physiologic-physical mode (cellular/organ level and physical adequacy), self-concept mode (body image, personal/spiritual self), role function mode (roles in society and groups), and interdependence mode (love, values, and support systems). Behaviors reflect how the individual/group copes and adapts to a health status change (Masters, 2015; Roy, 2009).

The major concepts of RAM include Person, Environment, Health, and Nursing. The person is defined as a holistic, human adaptive system and the focus of nursing care. The environment is defined as the world around and within the human adaptive system consisting of

influences, conditions, and circumstances that affect and stimulate behavior and adaptive responses. The environment is considered a stimulus. Stimuli can be internal or external to the human adaptive system, provoke responses, and are considered the point of interaction between the human system and environment. Stimuli are focal (most present in the individual/group consciousness), contextual (not the center of attention in the consciousness), and residual (outside the consciousness). Environmental changes can strain the coping and adaptive responses of individuals/groups (Masters, 2015; Roy, 2009).

Additionally, health is defined as the process of being and becoming whole. It exists along a continuum and reflects human interaction with or adaptation to the changing environment. Nursing is defined as a profession, science, and practice focusing on human life processes. Nurses promote health, full-life potential, and integrated adaptation for patients/groups. Nurses contribute to helping individuals/groups experience quality of life, health, and dying with dignity. Nurses help patients/groups change ineffective behavior to adaptive behavior using assessment, observation, interviewing skills, intuition, enhancement of environmental factors, and accurate measures. Nurses help individuals/groups use conscious awareness and choice to create integration with the environment (Masters, 2015; Roy, 2009).

Ursavas & Karayurt (2021) utilized the Roy Adaptation Model to guide a support group intervention to investigate the effect of perceived social support, sexual adaptation, and body image after breast cancer treatment. This quasi-experimental study with pre/post-testing included 79 Turkish women from a chemotherapy unit and was conducted over a period of eleven months. Thirty-seven women were assigned to the intervention group, and forty-two were assigned to the control group with non-randomization. The intervention consisted of five 90-120-minute sessions that addressed physiologic, interdependence, self-concept, and role function modes and

needs of the breast cancer survivors and included a Living with Breast Cancer book containing all the session topics. The control group received routine nursing care that included a booklet on coping and side effects of chemotherapy. It was found that the RAM-guided support intervention produced significantly higher post-intervention scores in the intervention group than the control group in the areas of perceived body image, social support, and impact on sexual functioning. Overall, RAM theories can be applied to FCR management along with other applicable theoretical frameworks.

A second theoretical framework related to the topic of FCR in breast cancer survivors is CREATION Life, formerly known as CREATION Health, by Des Cummings Jr., Ph.D. with Monica Reed, MD. This framework was originally published in 2003. CREATION is an acronym that describes full health, whole-person care, and living a better, balanced life. It reflects God's model for health established in the creation story and has been implemented into the Adventist Health System with the goals of treating each person as a child of God, healing their mind/body/spirit, and inspiring each person to experience CREATION Life. This framework introduces people to the first and finest gift of all time, abundant and full health, which can be achieved physically, mentally, socially, and spiritually. It invites individuals to wake up without fear, live longer, and live the legacy they want to leave behind. It teaches people the best ways to eat, exercise, and create a balanced, healing environment in life and helps them achieve a state of wellness following God's prescription for living (CREATION Life, 2022; Cummings & Reed, 2005).

Cummings and Reed (2005) describe eight principles as the most powerful for improving every part of life and as a gift from God. These include Choice, Rest, Environment, Activity, Trust, Interpersonal Relationships, Outlook, and Nutrition, with the first letter of each word

making up the acronym CREATION. Choice is defined as choosing to be well and healthy as the first step. Choice can make the difference between survival and hopelessness and death. We are what we choose. Rest is defined as relaxing during the day and achieving a good night's sleep. Environment is defined as creating a healthy personal and natural environment that is positive, peaceful, nurturing, comfortable, and recharging. Activity is defined as improving health and wellness through aerobic activity, stretching, and muscle development. Trust is defined as remaining centered and stable through creating an inner world that revolves around trust in a divine power. Interpersonal Relationships are defined as improving health through good support and wholesome interpersonal relationships. Outlook is defined as using a healthy mindset to help heal the body. Nutrition is defined as eating to fuel the whole body and maximizing energy and healing using a plant and water-rich dietary pattern.

Finally, a third theoretical framework related to the topic of FCR in breast cancer survivors has been created by the principal investigator using concepts in alignment with and connection to the RAM and CREATION Life frameworks, as well as best practice guidelines put forth by various accredited health organizations. The FEARLESS Framework is a new model for breast cancer survivors developed by the DNP student to help them manage the stimuli of a breast cancer diagnosis, treatment, and subsequent FCR more effectively during the extended survival period. FCR is identified as the focal stimulus most present in the breast cancer survivor's mind after treatment through the FCRI-SF screening tool.

In alignment with the major concepts of RAM, the overall goals of this model are for the DNP student (nurse) to help breast cancer survivors (person) feel healthy and whole again (health) after breast cancer treatment and transition into a more integrated and adapted "new normal" (environment) of survivorship using the CREATION Life principles and other

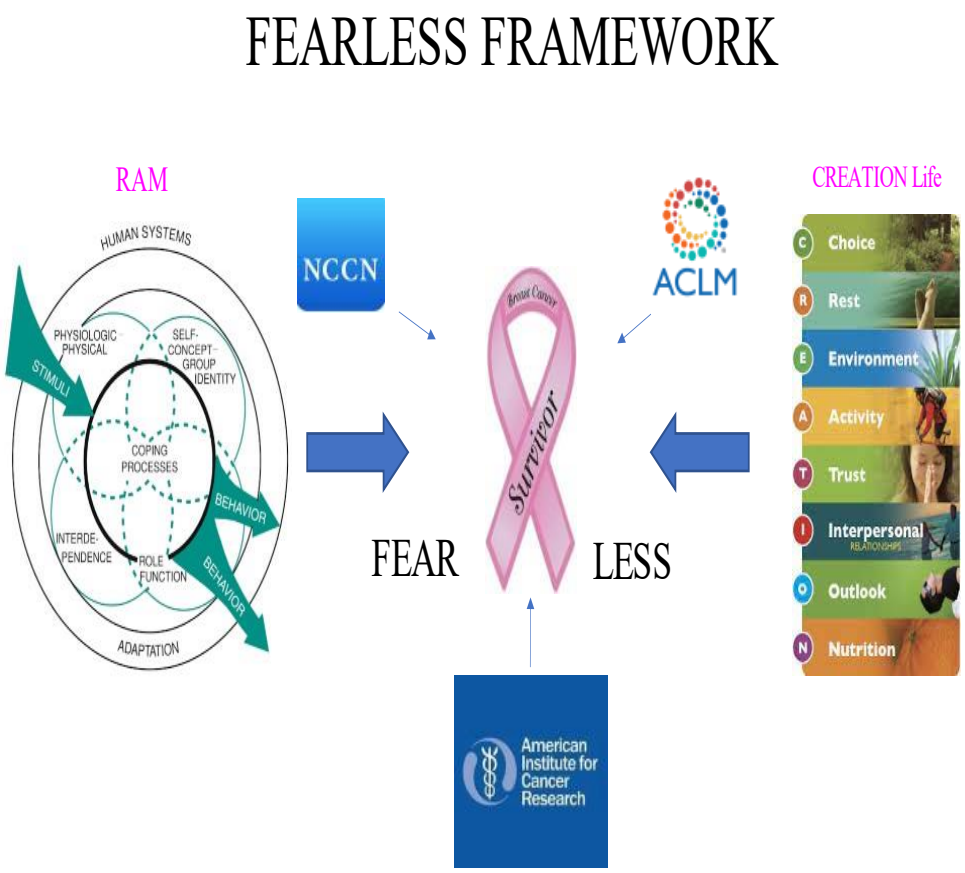
evidence-based lifestyle modifications. This will be achieved by the DNP student principal investigator helping the participating group of breast cancer survivors change their compensatory or compromised responses to having a breast cancer diagnosis and elevated FCR to an integrated/adapted "new normal" with enhanced coping behaviors and responses, as well as decreased FCR.

The DNP student-led LMCI, based on the new FEARLESS model, focuses on survival, growth, and human/environment transformations. This is important because ineffective coping can threaten survival. The LMCI will aid these individuals to seek relief from anxiety related to FCR and feel more secure. It will help them grow, develop, and transform collectively in a group setting. The nurturing LMCI will assist young breast cancer survivors to fulfill their life purpose, become whole and integrated, manage internal/external stimuli more effectively, enhance interactions with their environment, and experience improved quality of life (Roy, 2009).

CREATION Life concepts are integrated into the four adaptive modes of the RAM framework to comprise the new FEARLESS framework. This will promote lasting health, integration, and improved coping processes as the young breast cancer survivors acquire all the lifestyle modification tools necessary to better manage FCR. The eight FEARLESS pillars focus on (F) Fearing Less/FCR, (E) Eating Well/Nutrition, (A) Activity, (R) Rest/Restoration, (L) Love of Self/Purpose, (E) Environment, (S) Sleep, and (S) Stress Management.

The CREATION Life principles of nutrition, activity, and rest are integrated into the physiologic-physical mode. Additionally, the Lifestyle Medicine (LM) pillars of sleep and stress are addressed in this mode due to their impact on the cellular/organ level of the body. The CREATION Life principles of choice, trust, and outlook are integrated into the self-concept mode to help the young survivors develop their personal/spiritual selves. The CREATION Life

principle of environment is integrated into the role function mode as the survivors create a new normal in their previously existing roles. Finally, the CREATION Life principle of interpersonal relationships is integrated into the interdependence mode as the survivors learn to rely on added support systems that help them manage FCR and uncertainty more effectively (Masters, 2015; Roy, 2009). Of note, three evidence-based accredited organizations will also be used as the primary sources of information to further support the FEARLESS LMCI content including the NCCN, AICR, and ACLM.



Concepts and Definition of Terms

American College of Lifestyle Medicine (ACLM)

The medical professional society providing quality education and certification to those dedicated to clinical and worksite practice of lifestyle medicine as the foundation of a transformed and sustainable healthcare system (ACLM, 2021).

American Institute for Cancer Research (AICR)

A leading US organization and charity founded in 1982 in the field of diet, nutrition, and cancer (Butrum, 2000).

American Society of Clinical Oncology

A professional organization founded in 1964 representing physicians of all oncology sub-specialties who care for people with cancer (Wikipedia, 2023).

Fear of Cancer Recurrence (FCR)

The fear, concern, or worry relating to the possibility that cancer will progress or come back (Lebel et al., 2016).

Fear of Cancer Recurrence Inventory Short Form (FCRI-SF)

The nine-item Fear of Cancer Recurrence Inventory is a short form of the original FCRI and corresponds to the severity subscale of the FCRI (42 items). The FCRI-SF evaluates the presence and severity of intrusive thoughts associated with FCR (Peng et al., 2019).

Lifestyle Medicine (LM)

The use of evidence-based lifestyle therapeutic interventions, including a whole-food, plant-predominant eating pattern, regular physical activity, restorative sleep, stress management, avoidance of risky substances, and positive social connection as a primary modality, delivered by clinicians trained and certified in this specialty, to prevent, treat and often reverse chronic disease (ACLM, 2021).

The National Comprehensive Cancer Network® (NCCN®)

A not-for-profit alliance of thirty-two leading cancer centers devoted to patient care, research, and education. NCCN is dedicated to improving and facilitating quality, effective, equitable, and accessible cancer care so all patients can live better lives (NCCN, 2022).

Summary

A thorough discussion of the breast cancer disease process, epidemiology, FCR, and the background, significance, problem, purpose, and project inquiry of the DNP project have been provided in this chapter. Furthermore, a comprehensive theoretical framework discussion was presented demonstrating how the frameworks integrate with the project inquiry, purpose, and rationale for this project, as well as how they will guide the planning and development of the project and virtual LMCI for young breast cancer survivors as they transition from treatment to the extended survival period after breast cancer treatment. The FEARLESS Framework is a newly created model for young breast cancer survivors developed by the principal investigator to help address a practice gap of helping them establish a new normal of survivorship after cancer treatment with decreased FCR and enhanced coping behaviors and health outcomes. In subsequent chapters, an evidence-based literature review, project plan/methodology, results, and discussion are thoroughly analyzed.

Chapter 2

Review of Literature

Scholarly resources and databases used for this literature review were CINAHL Complete and PubMed, accessed through the McKee Library of Southern Adventist University. Google Scholar was also utilized. Reference lists of relevant studies were reviewed in detail, and further searches were performed on PubMed to collect additional journal articles as needed. Additionally, the American College of Lifestyle Medicine Scientific Evidence Cancer website

with links to evidence in support of Lifestyle Medicine was accessed to collect other relevant information and studies on lifestyle modifications and interventions for the project. The National Comprehensive Cancer Network and American Institute for Cancer Research practice guidelines were reviewed and used to guide the LMCI. Journal types included medical, nursing, science, cancer, nutrition, and psychology.

The search limits included English, past 5 years, randomized controlled trial, and meta-analysis. A limited number of studies over 5 years collected during previous LM courses or through the reference list reviews were utilized to guide the DNP project intervention and demonstrate the literature gap. The search words and terms included breast cancer, breast cancer incidence, breast cancer prevalence, fear of cancer recurrence, FCR, Fear of Recurrence Inventory, FCRI, lifestyle modifications, nutrition and breast cancer, physical activity/exercise and breast cancer, lifestyle interventions for breast cancer, obesity/overweight, National Comprehensive Cancer Network, American Institute for Cancer Research, American College of Lifestyle Medicine, wellness coaching, group coaching, and nurse practitioner coaching.

Presentation of Literature

The literature review established a satisfactory amount of research on defining and measuring FCR, FCR instruments, FCRI interpretation, factors associated with clinically significant FCR scores, and evidence supporting a lifestyle management intervention for FCR among breast cancer survivors. The review also confirmed the clinical suspicion that an unmet need of breast cancer survivors is learning how to manage FCR with age-appropriate support and interventions during early survivorship, and it is necessary to address this gap in clinical practice to help survivors transition to a holistic new normal after cancer treatment with well-adapted FCR.

Defining & Measuring FCR

FCR is medically defined as the fear, concern, or worry relating to the possibility that cancer will progress or come back (Lebel et al., 2016). Prior to 2016, there was a lack of published consensus among the medical community on a preferred definition. In August of 2015, expert researchers, patient advocates, trainees, and policymakers attended a two-day conference at the University of Ottawa and established an expert-based definition of FCR and defined the characteristics for when it reaches a significant clinical level after extensive discussion, voting, and use of the Delphi method structured communication technique (Lebel et al., 2016).

Various tools exist for measuring FCR. A study conducted during the early 2000s by Canadian researchers Simard & Savard (2008) sought to develop and subsequently validate a self-report screening tool that clinicians could use to evaluate FCR. The tool was designed by six experts consisting of one nurse, three psychologists, and two psychiatrists over the course of two ninety-minute meetings. The result was a 42-item, standardized, multi-step test that evaluates triggers, severity, psychological distress, coping strategies, functional impairment, insight, and reassurance associated with a cancer diagnosis called the Fear of Cancer Recurrence Inventory. The researchers found that the FCRI is a valid and reliable tool for evaluating FCR and that a higher score indicates more elevated levels of FCR.

Another tool used for measuring FCR is the Fear of Cancer Recurrence Inventory Short Form (FCRI-SF). After designing the FCRI tool, Simard & Savard (2015) aimed to create and validate a briefer and more cost-effective version of the FCRI. The FCRI-SF uses only a portion of the FCRI screening tool known as the FCRI severity subscale consisting of nine items. The researchers validated this tool using data obtained from sixty randomly selected localized prostate, breast, colorectal, and lung cancer survivors. The FCRI-SF tool was found to have a

strong correlation and high internal consistency with the total FCRI score and that optimal specificity (75%) and sensitivity (88%) rates are associated with an FCR cutoff score of 13 or higher. Specificity did increase further to 97% at a cutoff score of 16.

A more recent cross-sectional, observational study performed by Peng et al. (2019) aimed to examine if the FCRI-SF tool could also detect high FCR in breast cancer survivors. The study participants included 240 postoperative Chinese breast cancer patients aged 19-60 with stage 0-3 breast cancer. An FCR score was considered high if greater than 12. It was found that 76.81%, or 159 of the breast cancer participants experienced high FCR. The results were considered reliable at this cut-off score given a 98.6% sensitivity rate. Additionally, quality of life was assessed using The European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire C 30, and it was also confirmed that breast cancer survivors with high FCR scores also demonstrate significantly lower quality of life scores. It is important to note that while this study used a cut-off score of greater than 12, a score above 16 indicates high and/or clinically significant FCR (Mutsaers et al., 2020).

Factors Associated with FCR

Previous research has demonstrated that certain factors are associated with higher FCR. As aforementioned, Simard & Savard aimed to validate and develop the FCRI screening tool to evaluate FCR. Using a ten-participant pilot study followed by a second round of questionnaires completed by 288 French-Canadian patients with breast, prostate, colorectal, or lung cancer, the researchers found that higher FCRI scores were significantly associated with younger age, female gender, chemotherapy, radiation, surgery, and localized or metastatic cancer. Furthermore, they also found that higher levels of FCR were significantly associated with

avoidance, increased intrusive thoughts, and anxiety and depression symptoms (Simard & Savard, 2008).

Gormley et al. (2022) performed an integrative review on thirteen eligible observational and qualitative studies between 2003 and 2019 to further explore factors and themes associated with higher FCR among breast cancer survivors younger than 45 years old and found similar outcomes. Eight studies revealed a significant association between higher FCR and young age. Five studies found that motherhood/having children is also associated with higher FCR for young breast cancer survivors. Other factors associated with higher FCR among young breast cancer survivors included breast-conserving surgery, more frequent unscheduled healthcare visits and self-breast examinations, higher anxiety and depressive symptoms, stressful life events, perceived inadequate emotional and physical social support, increased cognitive processing (intrusive thoughts, avoidance), metacognition (rumination, worrying, negative thoughts), illness intrusiveness, and decreased self-efficacy. Three tools were used to evaluate FCR across studies including the Concerns About Recurrence Scale (CARS), Fear of Cancer Recurrence Inventory (FCRI), and Lasry Fear of Recurrence Index. Notably, this integrative review found that young women desire emotional support from other younger breast cancer survivors and the researchers recommended that clinicians screen all young cancer survivors for FCR and provide age-appropriate support thereafter.

A meta-analysis performed by Smith et al. (2020) aimed to study the severity and prevalence of FCR in addition to providing an overview, critique, and suggested improvements of the FCRI tool. Studies that cited the original FCRI validation paper by Simard & Savard (2008) discussed above and reported quantitative data were included in the meta-analysis. Other studies were included for a literature review. The authors found that the highest levels of FCR

prevalence were observed in breast, gynecological, and melanoma cancer survivors. Furthermore, FCR severity was assessed using the FCRI-SF cut-off scores of $\geq$ 13, $\geq$ 16, and $\geq$ 22, which revealed that between 30 and 43.3% of cancer patients appear to experience clinical levels of FCR at the $\geq$ 16 and $\geq$ 22 cut-off mark and this increases to 53.9%, or over half of survivors when scores $\geq$ 13 are included. It was found that higher FCR scores are associated with female gender, younger age, pain/physical symptoms (poor sleep, fatigue), and greater psychological morbidity (anxiety and depression), which is consistent with the long-existing FCR literature.

Another longitudinal study performed by Heidkamp et al. (2021) used survey data collected from 184 breast cancer survivors in Germany to investigate the prevalence, determinants, and individual courses of FCR in long-term breast cancer survivors. Data was collected using the Short Form of Fear of Progression Questionnaire at initial hospitalization, 10 weeks, 40 weeks, and 5-6 years post-hospital discharge. It was found that 54.8%, 31.6%, and 29.7% of participants experienced a dysfunctional level of FCR at the initial hospitalization, 40-week, and 5-6-year time points, respectively. This indicates that higher levels of dysfunctional FCR occurred closer to cancer diagnosis and that nearly one-third of the breast cancer survivors were still experiencing some level of dysfunctional FCR five-to-six years after diagnosis, further indicating there is a need for continued screening and support for patients with dysfunctional FCR even many years after diagnosis. Other findings from this study noted strong evidence again that young age is associated with higher FCR and that recurrence, being divorced or widowed, higher levels of fatigue, treatment with chemotherapy, and report of lower confidence in treatment during hospitalization/pessimism are also associated with higher risk for dysfunctional fear of cancer recurrence at the five-to-six-year mark.

Finally, two longstanding yet relevant studies that discuss the factors associated with higher FCR and demonstrate a knowledge gap in the literature include a comprehensive literature search by Crist & Grunfeld (2012) consisting of forty-three studies and a systematic review by Simard et al. (2013). Crist & Grunfeld (2012) aimed to identify the key factors associated with fear of recurrence among cancer patients and found that the most consistent predictor of high FCR is younger age. Their literature search also found that there is strong evidence for an association between poorer quality of life, poor coping responses (low self-esteem, denial coping, avoidance coping), and physical symptoms (attribute unrelated symptoms to recurrence, pain) and higher FCR.

Simard et al. (2013) concluded through a review of eighty-nine cross-sectional and a mix of other longitudinal, randomized controlled, quasi-experimental, and mixed-design studies that young age, physical symptoms, psychological distress, and lower quality of life are associated with higher FCR. Physical symptoms included fatigue and pain, and psychological distress included feelings of distress, depression, anxiety, and intrusion/avoidance. Additionally, having a high level of FCR at baseline indicated higher long-term FCR, suggesting that FCR can become chronic. This systematic review concluded that there is limited data on FCR interventions thus supporting consideration for developing a LMCI for unmanaged FCR. This could be particularly beneficial for young female breast cancer survivors given their higher FCR levels as documented in the above literature findings.

Evidence for LMCI: Best Practice Guidelines

Three evidence-based organizations that have developed best-practice lifestyle management guidelines and have been chosen to guide the LMCI to improve FCR scores and health outcomes for breast cancer survivors are the National Comprehensive Cancer Network,

the American Institute for Cancer Research, and the American College of Lifestyle Medicine. According to the NCCN Guidelines Version 3.2021 for cancer survivorship, cancer survivors should be counseled on the general principles of a healthy lifestyle since healthy habits are associated with improved quality of life, overall health, and reduced cancer recurrence risk and death. Recommendations relevant to this DNP project include setting incremental goals for diet, physical activity, and weight management, avoiding inactivity, achieving/maintaining a healthy weight, engaging in regular physical activity, maintaining a healthy nutrition pattern, consuming alcohol sparingly if at all, smoking cessation, and aiming for adequate sleep (NCCN, 2021).

Also, according to the AICR, research suggests that the same evidence-based guidelines that help prevent cancer also help guard against its return (AICR, 2020). Guidelines that are relevant to this DNP project include aiming for a healthy weight, engaging in regular physical activity, eating a diet rich in fruits, vegetables, whole grains, and beans, limiting fast and processed foods, limiting red meat consumption, limiting sugar-sweetened beverages, avoiding tobacco, limiting alcohol consumption, and following healthcare recommendations. Additionally, the AICR cancer prevention literature supports consistently using the New American Plate method and cancer prevention food list. The goal is to have vegetables, fruits, whole grains, and beans make up 2/3 (or more) of each meal and animal protein make up 1/3 (or less). The recommended food list includes apples, asparagus, blueberries, broccoli/crucifers, brussels sprouts, carrots, cauliflower, cherries, coffee, cranberries, flaxseed, garlic, grapefruit, grapes, kale, pulses (beans, peas, lentils), raspberries, soy, spinach, squash, strawberries, tea tomatoes, walnuts, and whole grains to help lower the risk of various cancers (AICR, 2020).

Finally, according to the ACLM, LM is an evidence-based approach to preventing, treating, and reversing diseases by replacing unhealthy behaviors with positive ones (ACLM,

2021). The practice of Lifestyle Medicine involves prescribing the following interventions to patients to help them change their unhealthy behaviors when applicable including a whole food, plant-predominant dietary lifestyle, regular and consistent physical activity, restorative sleep, stress management, avoidance of risky substances, and positive social connection as a therapeutic technique for treating and reversing chronic disease (ACLM Toolkit, 2020).

Evidence for LMCI: Wellness and Group Coaching Support

Various wellness and coaching interventions in the literature have been shown to improve health outcomes for breast cancer survivors. Stan et al. (2020) demonstrated that a wellness coaching intervention (WCI) after active breast cancer treatment for twenty obese or overweight breast cancer survivors aged 18 to 70 resulted in a significant increase in participants meeting American Cancer Society guidelines for exercise. This number improved from 25% of participants at baseline to 60% at 12 weeks. Furthermore, health scores increased from baseline to 12 weeks for several days completing 30 minutes of physical activity/week (3.1 to 5.2), physical activity motivation scores (6.5 to 7.4), and physical activity confidence scores (6.6 to 7). This is important because regular physical activity has been shown to be positively correlated to breast cancer survival (Lahart et al., 2015; Lee, 2019). Notably, 40% of participants achieved the 3% post-intervention weight loss goal because of participating in the intervention; however, this weight loss was not sustained at 30 weeks.

In a quasi-experimental study with pre/post testing which included 79 Turkish female participants, researchers found that a group support intervention produced significantly higher post-intervention scores in the intervention group than the control group in the areas of perceived body image, social support, and impact on sexual functioning. The participants were recruited from a chemotherapy unit, and the study was conducted over a period of eleven months. Thirty-

seven women were assigned to the intervention group, and forty-two were assigned to the control group with non-randomization. The intervention consisted of five 90-120-minute sessions that addressed physiologic, interdependence, self-concept, and role function modes and needs of the breast cancer survivors and included a Living with Breast Cancer book containing all the session topics. The control group received routine nursing care that included a booklet on coping and side effects of chemotherapy (Ursavas & Karayurt, 2021).

Evidence for LMCI: Healthy Lifestyle Behaviors

Current research explored a possible association between decreased mortality and combined healthy lifestyle behaviors in cancer survivors. A prospective study conducted by Karavasiloglou et. al (2019) looked to see how lifestyle behaviors influenced the survival of cancer patients originally included in the National Health and Nutrition Examination Survey III conducted between 1988 and 1994 in the United States. This study included 522 participants with a self-reported cancer diagnosis, and the researchers assessed their lifetime highest Body Mass Index, diet quality, physical activity level, smoking habits, and alcohol intake through interviews. A lifestyle score of zero or one was assigned to each lifestyle behavior per participant for a total score ranging from 0 to 5. Breast cancer was the highest-reported type of cancer.

The outcome of measure was all-cause mortality obtained from national death records collected after 14.5 years, in which 344 participants had died. Adherence to healthy eating was statistically significant, and adherence to each healthy lifestyle behavior, as evidenced by a high or moderate lifestyle score, was inversely associated with mortality (Karavasiloglou et. al, 2019). These findings support the inclusion of healthy lifestyle behavior management education into a LMCI for young breast cancer survivors as FCR is the outcome of measure in the DNP project, which is often associated with mortality-related fears.

Healthy Eating

Current research supports the inclusion of education on healthy eating into a LMCI for breast cancer survivors to improve health outcomes and better manage elevated FCR. A systematic review and dose-response meta-analysis of prospective cohort studies performed by Wang et al. (2014) found that of 56,423 deaths reported during a 4.6-to-26-year follow-up period ranging up to August 2013, a lower risk of all-cause mortality was found to be associated with higher fruit and vegetable consumption with a threshold occurring at approximately five servings per day. More specifically, this consisted of two fruits and three vegetables daily. This systematic review did not uncover a specific association between a lower risk of cancer death and higher fruit and vegetable intake; however, given the lower risk of all-cause mortality findings, education on healthy eating through a lifestyle management program remains relevant.

Additionally, a long-term follow-up of the Women's Health Initiative Randomized Trial of 48,835 postmenopausal women established that during five years of a dietary intervention (1993-1998) of increased fruit, vegetable, and whole-grain intake along with a reduced fat intake and cumulative follow-up of 19.6 years, there was a statistically significant decrease in deaths after breast cancer diagnosis in the dietary intervention group, as well as modest weight loss (Chlebowski et al., 2019). These findings are important as the NCCN and AICR dietary guidelines used in this DNP project are similar to those used in the above trial, and although not all project participants will be postmenopausal, the study findings are valuable for the development of the LMCI.

Furthermore, researchers from the European Prospective Investigation into Cancer (EPIC) cohort study, initially performed in Italy from 1993-1998, reviewed the dietary habits among 32,578 Italian female participants aged 36-64. After a median follow-up of 11.25 years,

approximately 1,000 breast cancers were diagnosed. The researchers found that increased consumption of raw or cooked leafy and fruiting vegetables and raw tomatoes is associated with a decreased breast cancer risk (Masala et al., 2012).

A more recent systematic review of 112 articles in PubMed published by De Cicco et al. (2019) identified that eating a consistently healthy dietary pattern particularly rich in fiber, fruits, vegetables, polyunsaturated fatty acids, and vitamins C and E may improve the overall survival of women with stage I-III breast cancer as it helps to lower inflammation and oxidative stress. Interestingly, a Mediterranean dietary pattern seems to be inversely related to breast cancer mortality, and adherence may reduce the risk of breast cancer recurrence and enhance longevity and health. The European Society for Clinical Nutrition and Metabolism now recommends a dietary pattern rich in whole grains, vegetables, and fruit, and low in dairy, red meat, alcohol, sugar, sweets, and processed meat for cancer survivors. These recommendations are consistent with current NCCN and AICR guidelines that will be used in the LMCI.

Physical Activity

Current research also supports including physical activity education in a LMCI to improve health outcomes and potentially better manage elevated FCR among breast cancer survivors. A meta-analysis by Lee (2019) of twenty-four studies with 144,244 patients, which used MEDLINE and EMBASE databases from January 1970 to February 2017, aimed to estimate associations between physical activity and risk of all-cause and breast cancer-specific mortality. It also aimed to approximate the amount and intensity of physical activity necessary to improve breast cancer outcomes. This meta-analysis found that decreased physical activity post-breast cancer diagnosis had the worst all-cause mortality risk and that moderate to high-intensity physical activity pre/post-breast cancer diagnosis had the most beneficial effect on the risk of

death compared to those with little physical activity. Both breast cancer specific and all-cause mortality had an inverse relationship with high amounts and moderate-intensity levels of physical activity leading to the recommendation for getting at least 300 minutes of moderate-intensity physical activity weekly to reduce breast cancer mortality. The amount of physical activity is defined as low (<300 minutes/week), moderate (300-500 minutes/week), and high (>500 minutes/week).

Another systematic review and meta-analysis performed by Lahart et al. (2015), comprised of twenty-two prospective cohort studies (1995-2014) and 123,574 participants, found that a high level of pre-and post-breast cancer diagnosis physical activity was associated with a significantly lower risk of breast cancer related and all-cause death. It was also found through a meta-analysis of six studies that post-diagnosis physical activity resulted in reductions in all-cause death, breast cancer-related death, and breast cancer recurrence by 41%, 34%, and 24% respectively. This research demonstrates that physical activity potentially improves survival since there was an inverse relationship between all-cause and breast cancer-related mortality and physical activity, as well as between breast cancer progression and recurrence and physical activity. Lastly, according to the systematic review by De Cicco et al. (2019), a pooled cohort project called the After Breast Cancer Pooling Project (ABCPP) reported that there is a 27% decrease in the risk of death for breast cancer survivors that engage in 3-5 hours of walking/week. Sharing these findings with young breast cancer survivors can potentially help reduce their morbidity and mortality-related fears and improve health outcomes.

Evidence for LMCI: Interventions, Uncertainty and FCR

Current research supports the inclusion of interventions to manage FCR and uncertainty in a lifestyle management program for breast cancer survivors. Based on previous research

findings indicating that FCR management is one of the greatest unmet needs for breast cancer survivors, nurse researchers systematically reviewed seven articles from 2009-2014. The articles were obtained through an extensive search of medical, nursing, and Google Scholar databases to look for evidence-based interventions that can help breast cancer survivors better manage FCR and uncertainty. The researchers found that mindfulness practices such as meditation, improved communication between the patient and her providers, interventions that address uncertainty such as distraction and relaxed breathing, and counseling and therapy interventions were shown to improve FCR and/or uncertainty for breast cancer survivors. Furthermore, the researchers reported that it is their formal recommendation that Advanced Practice Registered Nurses (APRNs) should facilitate processes for breast cancer survivors that can help them experience less anxiety, improved quality of life, and less worry about FCR (Dawson et al., 2016).

In a randomized controlled trial by Otto et al. (2016), researchers found that engaging early-stage breast cancer survivors in a 6-week online gratitude intervention led to greater well-being and psychological adaptation and a significant decrease in fear of death-related cancer recurrence when compared to a control group. Study participants in the gratitude intervention group spent ten minutes per week writing a letter of gratitude to the person of their choice, while participants in the control group listed and described twenty activities they had engaged in during that week. Study measures included weekly gratitude, positive affect, weekly goal pursuit, and FCR/fear of death worry. The participants in the control group did not experience a significant decrease in FCR/fear of death worry. Also, participants from the intervention group reported meaningful goal pursuit at higher levels and exhibited fewer worries related to death. The researchers found that gratitude can lead to decreased FCR/worry of death.

Summary and Synthesis of Literature

An extensive literature review collectively confirms the principal investigator's hypothesis that a considerable amount of young female breast cancer survivors experience an elevated level of unmanaged FCR after breast cancer diagnosis and treatment and into survivorship due to a range of factors. These women are in need of learning how to manage their clinically positive FCR more effectively during this timeframe to avoid undesirable outcomes and to attain whole health after treatment completion particularly given that breast cancer is now the most prevalent type of cancer worldwide (WHO, 2021). Longstanding research has been included in this review to demonstrate further the point of an ongoing knowledge gap in the literature on the subject and in patient care. The literature review confirms that clinicians should screen all young, female breast cancer survivors for unmanaged FCR and provide age-appropriate interventions as needed and that young women desire emotional support clinically and from other younger breast cancer survivors. This integrated review also revealed that the FCRI-SF is an evidence-based screening tool that is well validated and will therefore be used to evaluate the outcome of this DNP project.

Furthermore, the DNP project aims to provide an age-appropriate, DNP student-led LMCI for elevated FCR among young female breast cancer survivor participants in a group health coaching setting. This evidence-based intervention is grounded in best practice guidelines available through the NCCN, AICR, and ACLM organizations. The LMCI will address the need for improved management of high FCR and improved health outcomes in this population during the extended period of survival. After a thorough literature review, it was found that there is well-established research in the areas of best practice guidelines, wellness and group coaching support, healthy lifestyle behaviors, and uncertainty/FCR interventions for breast cancer survivors. This is important as these concepts will provide structure for the DNP project

intervention that will be guided by the RAM, CREATION Life, and the principal investigator's proposed FEARLESS theoretical frameworks. The FEARLESS DNP project intervention will include processes to help participants better manage their abnormal level of FCR and uncertainty related to breast cancer, as well as improve several health outcomes.

Chapter 3: DNP Project Plan

A summary of the DNP project plan and methodology is discussed. Topics of the overall project plan include the project type, stakeholders, assumptions, aims, objectives, hypotheses, essentials, organization, and financials. The methodology will be addressed from the lens of the DNP project design, scientific merit, setting and sample plan, statement of mutual agreement with the agency, measurement tools/instruments, project intervention/procedure, data collection plan, and data analysis plan. Great care has been taken to ethically protect the young breast cancer survivor project participants.

Type of Project

The DNP project type is a prospective, non-randomized quasi-experimental quantitative pretest-posttest with a mixed method post-program survey. In review, the purpose of the DNP project is to plan, develop, implement, and evaluate a DNP student-led lifestyle management coaching intervention that will help to decrease fear of cancer recurrence, enhance coping behaviors, and improve health outcomes in young female breast cancer survivors demonstrating elevated FCR screening scores. The DNP project will address the practice gap of helping young breast cancer survivors establish and transition into a new normal after cancer treatment with managed FCR using a tailored intervention in a deeply caring and nurturing virtual health coaching environment. The DNP project intervention implementation will begin on January 4, 2023, and finalize on March 8, 2023. The timeline for DNP project completion is August 2023.

Stakeholders, Champions, Community

Various individuals and hospital staff will be needed to implement the DNP project. Edward-Elmhurst Health System hospital administrators/leadership, research council, risk management, and institutional research oversight and review committees will be required to help ensure that the DNP project meets the legal and ethical requirements of the hospital system. The breast cancer survivorship APRN and nurse navigators will be needed to help recruit patients that are eligible for the study after cancer treatment. Primary care providers, surgical/medical/radiation breast oncologists, clinical psychologists, APRNs, and their support staff will be necessary to assist with recruitment and ensure the DNP project is conducted according to best practice/standards. DNP project participants will also be vital to help answer the research question as their participation in and experiences with the project will lead to the outcome. These entities are necessary for the DNP project as they will allow for the principal investigator to provide a group, lifestyle modification-focused coaching intervention to bridge the gap between the acute and permanent survival periods for young breast cancer survivors and to implement change to better meet the psychosocial needs of the breast cancer patient when transitioning to the new normal of survivorship.

Congruence of Organization's Strategic Plan

Project Assumptions

FCR is normal to a degree after a breast cancer diagnosis and treatment. However, the review of literature strongly indicated that up to half of breast cancer survivors experience unmanaged FCR, which increases for young adults. Identifying patients who are at greater risk of FCR can help inform tailored interventions to decrease FCR and improve patient management (Crist & Grunfeld, 2012; Gormley et al., 2022; Heidkamp et al., 2021; Smith et al., 2020). A

LMCI designed to help decrease FCR is another proposed tailored intervention/option for management.

Project Aims, Objectives, Hypotheses, DNP Essentials

Aims

The DNP project aims to help young female breast cancer survivors (1) create and gain abundant and restorative health physically, mentally, socially, and spiritually after cancer treatment, (2) experience less fear of cancer recurrence as evidenced by decreased FCRI-SF scores to an ideal range (< 12) after participation in a ten-week virtual group coaching intervention, (3) live a longer, more balanced life after implementation of evidence-based healthful lifestyle modifications that meet their physiologic needs with a focus on longevity, (4) learn how to develop self-love and purpose and live the legacy they want to leave behind, (5) change compensatory/compromised adaptation to an integrated healthier coping response by strengthening responses and behaviors to strenuous internal and external stimuli, and (6) learn how to adapt to their changing environment more healthfully and become integrated/adapted to their new normal after breast cancer treatment.

Objectives

1. To plan, develop, implement, and evaluate a 10-week evidence-based LMCI for young female breast cancer survivors by August 2023.
2. To evaluate Fear of Cancer Recurrence Inventory Short Form (FCRI-SF) scores using pre/post Paired *t*-testing statistical analysis.

Hypotheses

H_1 Null Hypothesis: There is no difference in baseline and post-intervention FCR scores; therefore, the intervention is ineffective.

H_2 Alternative Hypothesis: There is a positive difference in baseline and post-intervention FCR scores; therefore, the intervention is effective.

DNP Essentials

Various DNP Essentials support the DNP objectives (American Association of Colleges of Nursing, 2006).

- DNP Essential I, Scientific Underpinnings for Practice: Supports Objectives 1 and 2 as the principal investigator has developed and plans to evaluate a new practice approach to reduce FCR based on nursing theories and other evidence-based best practices to create a positive change in the health status of young breast cancer survivors.
- DNP Essential II, Organizational and Systems Leadership for Quality Improvement and Systems Thinking: Supports Objective 1 as the principal investigator has designed a care delivery approach that focuses on a genuine need of breast cancer survivors to reduce FCR and emphasizes ongoing improvement in the health outcomes and future needs of the program participants.
- DNP Essential III, Clinical Scholarship and Analytical Methods for Evidence-Based Practice: Supports Objective 2 as the principal investigator has integrated knowledge from diverse sources to design and analyze a meaningful evidence-based intervention for elevated FCR among young BC survivors.
- DNP Essential IV: Information Systems/Technology and Patient Care Technology for the Improvement and Transformation of Health Care: Supports Objective 1 as the principal investigator plans to apply the LMCI virtually through Zoom Video Communications web-based learning to improve patient care among young breast cancer survivors.

- DNP Essential V: Health Care Policy for Advocacy in Health Care: Supports Objective 1 as the principal investigator plans to educate leadership and stakeholders within the EEH system on patient care outcomes post-intervention to advocate for young breast cancer survivors experiencing elevated FCR.
- DNP Essential VI, Interprofessional Collaboration for Improving Patient and Population Health Outcomes: Supports Objective 1 as the principal investigator has employed effective communication and collaborative skills necessary for successfully developing and implementing a new practice model.
- DNP Essential VII: Clinical Prevention and Population Health for Improving the Nation's Health: Supports Objective 2 as the principal investigator has reviewed breast cancer-related epidemiological scientific data with further plans for biostatistical analysis post-intervention.
- DNP Essential VIII, Advanced Practice Nursing: Supports Objectives 1 and 2 as the principal investigator plans to design, implement, and evaluate the therapeutic intervention of a LMCI for young breast cancer survivors based on best practice guidelines.

Organization

The EEH system is an integrated healthcare system in Illinois and was created by the merger of Elmhurst Memorial Healthcare and Edward Hospital in 2013. The EEH system is a not-for-profit organization comprised of the Edward and Elmhurst hospital systems and Linden Oaks Behavioral Health. There are over 50 EEH system outpatient locations across the west/southwest suburbs of Chicago, with thousands of employees, volunteers, and nearly one

hundred medical and surgical specialties/subspecialties. Both Edwards Hospital and Elmhurst Hospital have dedicated cancer center sites (Edward-Elmhurst Health, 2022).

Financial

The Centers for Disease Control and Prevention (CDC) estimates that the total annual cost of breast care in the United States is 16.5 billion dollars comprising 13% of all cancer treatment costs (CDC, 2021). The DNP student-led LMCI can potentially reduce breast cancer costs associated with health service overuse driven by FCR, given its focus on helping young survivors manage their FCR more effectively. This DNP project intervention could potentially be sustainable if it were conducted consistently by trained oncology staff members of the EEH system as part of their annual salary/wages. Also, financial costs to the principal researcher include the cost of Zoom Video Communications monthly fee and flyer printing fees. Financial costs to the program participants include the cost of a journal.

Protection of Human Subjects

Various ethical considerations will be made during the DNP project to protect human subjects. Participation in this research is voluntary, and participants can opt out of the study at any point without penalty. Institutional reviews will be conducted. Informed consent and authorization to participate in the DNP project will be obtained and reviewed by the principal investigator for each program participant entering this study. The identity of participants will be kept protected and confidential. Program participants will be referred to by an assigned number in program documents. Zoom Communications will be used as the virtual platform to protect participant health information. Program participants will participate in the virtual coaching sessions using only their first names, and active participation in each of the sessions will be voluntary. All information containing the personal identifying information of participants will be

kept in a password-protected computer system or locked file system managed by the principal researcher.

Participants will be encouraged to build a deeper, more empowering, and trusting relationship with themselves and develop spiritually during program sessions. This information is written into the consent, and participants will be encouraged to discuss any concerns they have regarding this directly with the principal investigator prior to beginning the study, at which point they can agree to opt-in or out of the LMCI. Also, FCR is a sensitive subject after breast cancer diagnosis and treatment. This research study may trigger the risks of added feelings of sadness, worry, concern, anxiety, and depression. The potential benefits of helping participants learn how to experience less FCR, cope better, and experience restored health through creating a nurturing virtual coaching environment outweigh these risks. The DNP student principal investigator will make every effort to conduct the LMCI in a deeply caring health coaching environment so that survivors can feel entirely supported while making the transition into survivorship more effectively and healthfully.

Additionally, the principal investigator completed Collaborative Institutional Training Initiative (CITI) Program training on July 10, 2022 (see Appendix M). Training was completed in the areas of plagiarism, research involving human subjects, and research misconduct to further foster project and participant integrity (CITI, n.d.). The principal investigator completed/applied for and received approval to conduct the DNP project from Southern Adventist University (SAU) and EEH Institutional Review Boards (IRBs) (see Appendix B). First, the principal investigator successfully presented a DNP project proposal to the SAU faculty on June 30, 2022, and subsequently received permission from the SAU IRB to proceed with the project on October 17, 2022 (see Appendix A). The principal investigator also successfully presented a DNP project

presentation to EEH Nursing Research and Evidence-Based Practice Council on July 26, 2022, and the EEH Institutional Research Oversight Committee (EEH IROC) on September 15, 2022, in which it was determined that the project could move forward for review by the EEH IRB (see Appendix A). Final EEH IRB approval was received on November 1, 2022, granting full permission to proceed with the project at the EEH system (see Appendix A).

Methodology

Project Design

The DNP project will be conducted as a prospective, non-randomized quasi-experimental quantitative pretest-posttest design without a comparison group. It will include a mixed method post-program survey. It will evaluate a LMCI for FCR. The project will include pre/post-testing and utilize quantitative methodology through the Paired *t*-test to measure the differences between pre-and post-intervention FCR scores. The Paired *t*-test was selected for this DNP project as it allows for data analysis of before and after measurements on a single group of participants, in this case, FCR scores of young breast cancer survivors (Elliott & Woodward, 2020).

The FCRI-SF will be used to assess this project's primary outcome of measure, the FCR score. Simard & Savard (2015) created and validated the FCRI-SF to provide a briefer and more cost-effective alternative to the larger 42-item FCRI screening tool. The FCRI-SF screening tool is strongly correlated to and has high internal consistency with the original FCRI tool. Based on these findings, the FCRI-SF was chosen as the FCR screening tool for this DNP project.

Furthermore, FCRI-SF data points will be collected at baseline and ten weeks post-intervention. The program participants will be recruited after breast cancer treatment during the extended survival period adjunct to the breast cancer survivorship care plan whenever possible. There will also be a one-time survey administered to each participant at the end of the program

to track accountability and participation in the program and to evaluate program objectives, adaptive goals/learning outcomes, and voluntary post-intervention feedback (see Appendix K).

Scientific Merit

The DNP project demonstrates scientific merit. It addresses formal research requirements and includes a plan for adhering to human subject ethical guidelines. It includes a problem statement of a phenomenon (FCR in young breast cancer survivors), a frame of reference arising from the discipline of the researcher (DNP student with extensive breast cancer experience), a discussion of related literature (a thorough literature review), a clearly stated research question (How will a ten-week DNP student-led LMCI lead to decreased FCR and improved health outcomes among female breast cancer survivors demonstrating abnormally elevated screening scores during the extended survival period?), a description of participants (young female breast cancer survivors with specific inclusion criteria), a clearly defined analysis-synthesis process, and a clear plan for interpretation and dissemination of study findings. The DNP project also demonstrates evidence of integrity in the research process (Parse, 2016).

Sampling Plan

Population/Sample, Setting, Recruitment

The ten-week DNP student-led LMCI will take place virtually via Zoom Video Communications. This will eliminate the potential for COVID-19 or other infectious disease-related disruptions to in-person sessions, as implementation will occur during the fall/winter seasons. The participants will be recruited from the EEH system in Illinois. Recruitment sites for young breast cancer survivor participants will include primary care, surgical/medical/radiation oncology, and weight management outpatient clinics. Implementing the intervention in these community hospital settings will allow for the development and refinement of the intervention to

move this change process forward and deliver best practices to the study participants (Johnson, n.d.). The principal investigator will primarily follow up with the oncology staff for ongoing recruitment support and flyers designed by the principal investigator will be displayed at individual outpatient care sites (see Appendix N).

DNP project eligibility criteria include female, English-speaking breast cancer survivors between 18 and 59 years old diagnosed with invasive breast cancer (Stage I-III). Eligible participants will be in the extended period of survival, demonstrate a positive FCRI-SF score above 12, and must have had health-related care in the EEH system. If recruitment proves challenging to meet an adequate sample size, inclusion criteria may be extended into the permanent/chronic survival period greater than five years post-breast cancer treatment. This remains to be determined.

Exclusion criteria include non-English speaking females less than 18 and greater than 60 years old with in-situ (Stage 0) or metastatic (Stage IV) breast cancer and those in the acute survival period. Although the literature tends to define the young cancer survivor as less than 40-45 years old, the exact age criteria considered “young” for having breast cancer varies. Given that reproduction, having young children, having children later in life, and family life disruptions are common concerns of young breast cancer survivors, the age criterion has been extended to 59 years old to be more inclusive and sensitive to these matters without age discrimination (Gormley et al., 2022). Participants will be recruited from November 2, 2022, through January 2, 2023. Informed consent and authorization to participate in the DNP project will be obtained and reviewed by the principal investigator for each participant entering the LMCI.

The sample size was calculated using the general power analysis program (G*Power) software 3.1.9.7 Copyright © 1992-2020. This program was chosen because it supports sample

size and power analysis calculations for the Paired *t*-test. Calculating an adequate sample size is essential to the DNP project, as studies with inappropriate sample sizes and power can make evidence-based practice change decisions or judgments challenging and inaccurate (Kang, 2021). The protocol of power analyses includes *t*-test means difference testing between two dependent means (matched pairs) with the input of two tails, effect size 0.5, α err prob 0.05, and power (1-β err prob) 0.80 and output of non-centrality parameter δ 2.9154759, Critical t 2.0345153, and degrees of freedom (df) 33. According to G*Power, the adequate total sample size will be 34 and an actual power of 0.807.

Statement of Mutual Agreement with the Agency

A statement of mutual agreement to conduct the study through the EEH system has been provided by both the IROC and IRB in letter format (see Appendix A). A statement of mutual agreement to utilize the FCRI-SF screening tool has been provided by the tool designer and validator Sebastien Simard in email format (see Appendix G). Consent for participation in the DNP project will be obtained by the principal investigator for each participant prior to the program start date of January 4, 2023 (see Appendix C).

Measurement Tools/Instruments

The FCRI-SF is the primary instrument that will be used for the DNP project to assess and compare the means of baseline and post-intervention FCR scores of program participants (see Appendix F). This tool is a shortened version of the 42-item Fear of Cancer Recurrence Inventory previously discussed at length in Chapter 2. The FCRI-SF consists of nine items that aim to understand worries associated with cancer recurrence using a rating scale from 0 to 4. Question five is a reversed score item. Higher scores indicate greater FCR, with 0 to 15 indicating low to moderate FCR severity, 16 to 21 indicating high FCR severity, and $\geq$ 22

indicating clinically significant FCR severity. Clinically significant severity warrants a referral to a psychosocial cancer care specialist. The maximum FCR score is 36 (Mutsaers et al., 2020). Measurement through the FCRI-SF score will show how well the participants have adapted to their changing survivorship environment post-intervention. There will also be a one-time survey that will be administered to each participant at the end of the program as previously mentioned.

Permission to use the FCRI-SF tool has been granted by the tool developer and validator Sebastien Simard provided he and his team receive appropriate acknowledgment of their work. A free PDF of the FCRI-SF screening tool was provided by Simard to the principal investigator in an email granting permission for use in this project. Potential project participants will be administered the FCRI-SF tool and screened by the principal investigator in person or through e-mail. If a score above 12 is obtained at baseline, participants will become eligible to participate in the project provided they meet all other eligibility criteria. Previous research by Peng et al. (2019) has identified an FCRI-SF cutoff score above 12 to establish validity and reliability with high sensitivity, while earlier research by Simard and his team established a cutoff level of 13 (Simard & Savard, 2015).

Project Intervention, Procedure

Intervention

The FEARLESS LMCI will help young breast cancer survivors decrease FCR and enhance health, self-love, longevity, and legacy. The overall goals of this model are for the DNP student to help breast cancer survivors feel healthy and whole again after breast cancer treatment and transition into a more integrated and adapted “new normal” of survivorship that is focused on developing decreased FCR, restored health, and enhanced coping behaviors. Participation in

the FEARLESS intervention will help breast cancer survivors manage the stimuli of a breast cancer diagnosis and subsequent FCR more effectively during the extended survival period.

A positive psychology coaching approach will be utilized to create an intervention atmosphere that enables participants to flourish and feel engaged, fulfilled, and happy using strategies based on developing longevity, optimism, gratitude, and positive emotions (Moore et al., 2016). Information will be delivered directly to patients in the format of a ten-week DNP student-led virtual health coaching intervention. The DNP student principal investigator is a nationally certified health coach through the National Board for Health & Wellness Coaching (NBHWC). The intervention will include ten 1-hour-long weekly sessions. The sessions will empower survivors through the eight pillars of the FEARLESS Framework: Fearing Less, Eating Well/Nutrition, Activity, Rest/Restoration, Love of Self/Purpose, Environment, Sleep, and Stress Management (see Appendix H). Each week time will be set aside for small group discussion related to the pillar(s) of interest and tips for success by CREATION Life. There will also be an introduction and a conclusion session (Sessions 1 and 10). DNP project session objectives will be utilized to guide the intervention (see Appendix I).

Sessions. During program sessions related to the pillar of Fearing Less, participants will learn about the most current survival statistics, including that most women will survive their breast cancer. FCR will be discussed including its definition, impact, common fears, triggers, potential targets, and coping and management strategies. Additional resources utilized for FCR management include ASCO/Cancer.Net, ACS, and The Comprehensive Survivorship Guide 2nd edition given to the participants at their survivorship appointment. CREATION Life information on choice, outlook, and trust will be provided, including the incorporation of the Optimist's Creed and/or Serenity Prayer and making a conscientious choice every day to have less fear, live

a healthy and balanced life, transform fear to trust, and manage the healing process with a healthier outlook.

The program session Eating Well/Nutrition will include coaching the participants on how to incorporate a healthy nutrition pattern into everyday life and maintain it. This will include a full discussion of NCCN, AICR, and LM guidelines focusing on AICR recommendations. Participants will be encouraged to eat a diet rich in fruits, vegetables, whole grains, and lentils, limit fast and processed foods, limit red meat consumption, limit sugar-sweetened beverages, avoid tobacco when applicable, and limit alcohol consumption. They will be encouraged to use the New American Plate Method and cancer prevention food list to eat to heal and create energy.

Participants will also participate in a Whole Food, Plant-Based clean eating, and lifestyle modification challenge to help them acknowledge the link between lifestyle and health outcomes, replace unhealthy behaviors with positive ones, and provide a cleansing reset for the body post-cancer treatment. This challenge will pull together and encourage active participation in all the FEARLESS principles. The participants will be provided with an overview of the nutritional aspects of detoxification in clinical practice. This includes information on the detoxification and biotransformation pathways including phases I and II of liver detoxification, supportive nutrients, and the elimination processes (Cline, 2015; Liska, 1998).

The program session Activity will include coaching the participants on maintaining a healthy exercise pattern in everyday life. This will include a full, combined review of NCCN, AICR, ASCO, and ACLM guidelines for engaging in regular physical activity of at least 150-300 minutes of moderate-intensity or 75-150 minutes of vigorous-intensity activity weekly, along with two or more days weekly of strength training. Topics of discussion will include physical activity benefits, activity types, activity levels, plans, and tips for survivors. The meta-analysis

by Lee (2019) of twenty-four studies with 144,244 patients which found that decreased physical activity post-breast cancer diagnosis had the worst all-cause mortality risk and that both breast cancer-specific and all-cause mortality had an inverse relationship with high amounts and moderate-intensity levels of physical activity will be discussed. This information will be provided to help motivate the program participants.

The program sessions Rest/Restoration and Sleep will include coaching the participants on how to incorporate a restorative rest and sleep pattern into everyday life and maintain it, as anxiety and fear are the opposite of rest. This will include a full discussion of NCCN and ACLM guidelines along with CREATION Life information on rest and sleep. Participants will be encouraged to incorporate 7-9 hours of sleep per night and carve out one day per week to include at least one full hour of rest. Discussion topics will include stages of sleep, sleep disrupters, tips for better sleep, sleep management goals, daily rest, weekly rest, recreation, annual rest, tips for success, and more.

The program session Love of Self/Purpose will teach participants how to develop purpose and self-love beyond measure. This session will focus on the CREATION Life principles of choice, trust, and outlook to help the survivors develop their personal/spiritual selves. Through small group discussions and journaling, participants will be encouraged to learn how to live the legacy they want to leave behind. They will be encouraged to transform their fear into courage and courage into purpose. This session will allow participants to create and gain abundant and restorative health physically, mentally, socially, and spiritually through its teachings and activities, such as practicing letting go, forgiveness, making better choices, optimism, and trust in spirituality. This session will focus on the co-creation and enhancement of self-love, longevity,

and legacy. The participants will be led through a one and five-year wellness vision exercise to help them develop a good vision of the meaning and purpose of their lives moving forward.

The program session Environment will include coaching breast cancer survivors on how to build a healthy internal and external environment and create a new normal in their previously existing roles. Program participants will surround themselves with a group of women also experiencing breast cancer survivorship. They will learn how to develop interpersonal relationships and rely on added support systems to help them better manage FCR and uncertainty. CREATION Life will be the primary resource for information on Environment and will include small group discussions on how to create a positive home environment and engage with nature to improve outlook and immunity. Participants will be encouraged to remove things that trigger fear and anxiety from their environment and instead include things that promote a positive, nurturing, clean, joyful, comfortable, and restorative one. ACLM recommendations on forming and strengthening social connections will also be discussed.

The final program session Stress will include coaching breast cancer survivors on effectively managing their stress, as unmanaged stress can manifest as an expression of fear. Session topics include a full discussion of NCCN and ACLM guidelines, including good stress/bad stress, self-management tips, and how to effectively manage stressful triggers and events. The participants will develop a mindful gratitude practice and participate in a DNP student-guided breast cancer survivor willow tree meditation for stress reduction purposes. Healthy strategies for coping will also be reviewed.

DNP project session objectives will be utilized to guide the intervention (see Appendix I). After the final session, participants will receive a survey to track accountability and participation in the program and evaluate program adaptive goals/learning outcomes. Voluntary post-

intervention feedback questions will also be a part of this survey. The goal is for participants to reach specific, measurable, achievable, relevant, and timely learning outcomes by the end of the program (see Appendix J). Also, post-FCRI-SF screening scores greater than or equal to 22 will generate a referral back to the oncologist for further psychosocial support. The DNP-student health coach will also be available to participants individually as needed for additional support and to discuss the support available to them through the hospital and nearby cancer wellness center.

Procedure

- Discuss the DNP project with stakeholders.
- Request and receive permission to use the FCRI-SF screening tool from the tool developer and validator Sebastien Simard.
- Present and receive approval from EEH Nursing Research and Evidence-Based Practice Council to advance the DNP project proposal to EEH IROC.
- Write a letter of agreement and submit it to EEH leadership to include a detailed project plan (see Appendix E).
- Obtain signatures from EEH leadership to pursue EEH IROC and IRB approval processes.
- Develop the DNP project intervention including the session content, objectives, and learning outcomes/goals to promote adaptation to the extended survival period.
- Write the DNP project consent.
- Write a letter of introduction to program participants (see Appendix D).
- Create a DNP project flyer for recruitment purposes.
- Submit and receive approval from EEH IROC.

- Submit and receive approval from EEH and SAU IRBs.
- Review the DNP project with stakeholders as described above.
- Recruit participants.
- Assess the FCR behaviors of participants using the FCRI-SF screening tool.
- Assess/categorize stimuli for those behaviors using the FCRI-SF screening score.
- Make FCR diagnosis (elevated FCRI-SF score).
- Collect data and consent to participate in the DNP project from eligible and agreeable project participants.
- Implement the virtual FEARLESS LMCI aimed at managing stimuli to promote adaptation into survivorship to include ten breast cancer specific weekly sessions based upon the 8 FEARLESS pillars (includes one introduction and one conclusion session).
- Reassess the FCR behaviors of participants using the FCRI-SF screening tool.
- Analyze pre- and post-FCRI-SF scores.
- Evaluate achievement of and engagement in the program and adaptive goals/learning outcomes through the end-of-program survey.
- Analyze the qualitative survey responses on the end-of-program survey.
- Disseminate the DNP project findings.

Plan for Data Collection

The data collection process will begin after DNP Project approval from EEH System Nursing Research and Evidence-Based Council, EEH IROC, and the SAU/EEH IRBs are obtained. The data described below will be collected during participant recruitment and continue over 12-14 weeks as needed during the DNP project intervention timeframe. Demographics that will be collected include first/last name, age, gender, phone number, and e-mail. FCRI-SF

scores, cancer stage, survival period, and data from post-program surveys will also be collected. Data will be stored in the principal investigator's password protected EEH laptop computer, statistical software, and locked file system and managed by the principal investigator. The principal investigator will screen potential participants for elevated FCR pre-intervention and then re-screen eligible participants post-intervention at ten weeks. The principal investigator will collect the participants' end-of-program learning outcomes and responses.

Plan for Data Analysis

Data analysis will be performed using IBM SPSS Statistics software. The Paired *t*-test will be used to measure the differences between pre- and post-intervention FCR scores with normal distribution. The Paired *t*-test is useful for analyzing differences and comparing two means of samples that are related in some way. The nonparametric alternative to the Paired *t*-test will be the Wilcoxon Test as needed (Elliott & Woodward, 2020). The primary outcome of interest is FCRI-SF scores. The predictor variable is participation in the LMCI. Other variables of interest are age (scale), female gender (nominal categorical), pre/post intervention weight (scale), pre/post intervention BMI (scale), cancer stage (categorical/ordinal), extended survival period (binary, y/n), and post-program qualitative survey completed (binary, y/n).

The DNP project will compare FCRI-SF score measurements of the study participants before and after the LMCI at baseline and ten weeks. The rejection criterion (alpha) will be set at .05, and a *p*-value less than .05 will reject the null hypothesis. For example, if the *p*-value is > .05, there is no significant difference between the two group means, and the null hypothesis will not be rejected. This will indicate that there is no difference in baseline and post-intervention FCRI-SF scores; therefore, the intervention is ineffective. However, if the *p*-value is < .05, there is a significant difference between the group means, and the null hypothesis will be rejected.

This will indicate that there is a positive difference in baseline and post-intervention FCRI-SF scores and, therefore, the intervention is effective (Elliott & Woodward, 2020).

The confidence interval (CI) will also be examined to determine whether it includes zero, as this will indicate no significance between the FCRI-SF means. A CI that does not include zero will indicate that there is a statistically significant difference in the population means (Elliott & Woodward, 2020). Cohen's *d* will be measured. A positive difference in baseline and post-intervention FCRI-SF scores will indicate to the principal investigator that the LMCI effectively decreases FCR among young breast cancer survivors. The post-intervention survey will also be analyzed (see Appendix K). Data analysis will include the assistance of a statistician Dr. Jones from Dissertation Genius for accuracy.

Summary

In this chapter, a thorough discussion of the DNP project and methodology has been provided. The data collected and analyzed from this DNP project will help advance knowledge in additional support and tailored interventions for young female breast cancer survivors after treatment and during the extended survival surveillance period to help minimize potential manifestations and triggers of FCR. The data collected and analyzed will also help address a practice gap by helping young breast cancer survivors establish a new normal of survivorship after cancer treatment with decreased FCR and enhanced coping behaviors and health outcomes.

Chapter 4: Results

The purpose of the DNP project was to plan, develop, implement, and evaluate a DNP student-led LMCI that would help to decrease FCR, enhance coping behaviors, and improve health outcomes in young breast cancer survivors demonstrating high FCR screening scores. In this chapter, a detailed discussion of the data analysis will be provided. This includes the

quantitative and qualitative DNP project results. Data collection procedure, a description of the sample and demographics, the project data analysis, and incidental findings are discussed.

Discussion of Results

The DNP project recruitment period took place from November 2022-January 2023 after the principal investigator received IRB approval to conduct the project from both SAU and EEH. The FEARLESS intervention was implemented from January 4, 2023, to March 8, 2023, after the participants provided consent for participation. Quantitative FCRI-SF statistical and demographic analysis was performed by Dr. Jones from Dissertation Genius, LLC using SPSS Version 29. The post-program survey goals/learning outcomes and participant responses were analyzed by the principal investigator. The following objectives and null/alternative hypotheses were addressed:

- *Objective 1:* To complete and evaluate the 10-week evidence-based LMCI by August 2023.
- *Objective 2:* To evaluate FCRI-SF scores using pre/post Paired *t*-testing statistical analysis.
- H_1 *Null Hypothesis:* There is no difference in baseline and post-intervention FCR scores; therefore, the intervention is ineffective.
- H_2 *Alternative Hypothesis:* There is a positive difference in baseline and post-intervention FCR scores; therefore, the intervention is effective.

Description of Sample

The group of participants in the FEARLESS intervention was recruited from the EEH system in Illinois from various outpatient clinics. Participants were female, English-speaking breast cancer survivors between 18 and 59 years old diagnosed with invasive breast cancer stage

I, II, or III. Participants were in the extended period of survival, demonstrated a pre-intervention positive FCRI-SF score above 12, and received health-related care in the EEH system at some point. Nineteen women initially expressed interest in participating in the DNP project. One woman did not meet the eligibility criteria. Four eligible women opted not to participate.

There were fourteen participants in the original sample, however, two participants dropped out of the LMCI. One participant dropped out because she felt the program differed from her expectations, and another dropped out as she was unable to complete the eligibility criteria for attending 8/10 sessions. The resulting dataset included $N = 12$ participants that completed the program, pre-and post-intervention FCRI-SF, and the post-intervention survey.

Demographics

Demographic descriptions included frequencies and percentages for categorical (nominal) variables and mean and standard deviations measured at the interval level of measurement. The sample consisted of 12 females with ages ranging from 41 to 57 years ($M = 49.50$, $SD = 4.96$). The height of participants ranged from 62.00 to 69.50 inches ($M = 65.13$, $SD = 3.13$), and weight (in pounds) ranged from 106.00 to 237.00 ($M = 166.67$, $SD = 38.73$) for participants that opted to provide this information to the principal investigator. There were seven (58.3%) participants with Stage 1 breast cancer and five (41.7%) with Stage 2 breast cancer. Table 1 depicts this information.

Table 1

Sample Demographics (N = 12)

Variable	Min	Max	*M*	*SD*	*n*	%
Age	41	57	49.50	4.96		
*Height	62.00	69.50	65.13	3.13		
**Weight	106.00	237.00	166.67	38.73		
Stage cancer						
Stage 1					7	58.3%
Stage 2					5	41.7%

*Excludes four participants that opted out of providing pre-intervention height

**Excludes three participants that opted out of providing pre-intervention weight

Project Data Analysis

The FCRI-SF was the primary instrument that was used for the DNP project to assess and compare the means of baseline and post-intervention FCR scores of program participants. The FCRI-SF consisted of 9 items that aimed to understand worries associated with cancer recurrence using a rating scale from 0 to 4. The sum of the responses of the Likert items was formed and served as an overall measure of FCR. Also presented are the testing of parametric assumptions for the statistical analysis, the results of statistical testing, and post-intervention survey findings.

FCRI-SF Scores

FCR scores were measured before and after the FEARLESS intervention and are provided in Table 2. The categorical percentages of initial FCRI-SF scores were 0% (0-15 low to moderate severity), 25% (16-21 high severity), and 75% (> 22 clinically significant severity). The post-intervention scores improved to 25%, 58%, and 17% respectively. Before the intervention, FCRI-SF scores ranged from 17.00 to 30.00 with a mean of $M = 23.92$ ($SD = 3.32$).

After the intervention, there was a decrease in FCRI-SF scores that ranged from 8.00 to 26.00 with a mean of *M* = 17.17 (*SD* = 5.57). This is a mean percent decrease of 28.22%. The bar chart in Figure 1 illustrates this reduction in mean FCR from pre- to post-intervention.

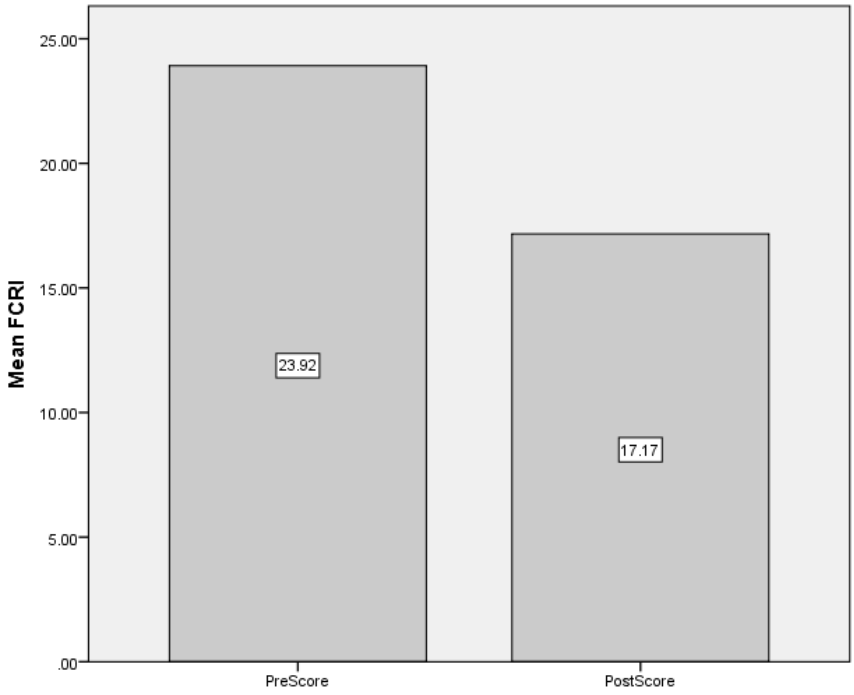
Table 2

FCR Scores Pre- and Post-LMCI Intervention

	Min	Max	*M*	*SD*
Pre-FCR Score	17.00	30.00	23.92	3.32
Post FCR Score	8.00	26.00	17.17	5.57

Figure 1

Bar Chart Comparing Pre- and Post-FEARLESS Intervention FCR Scores



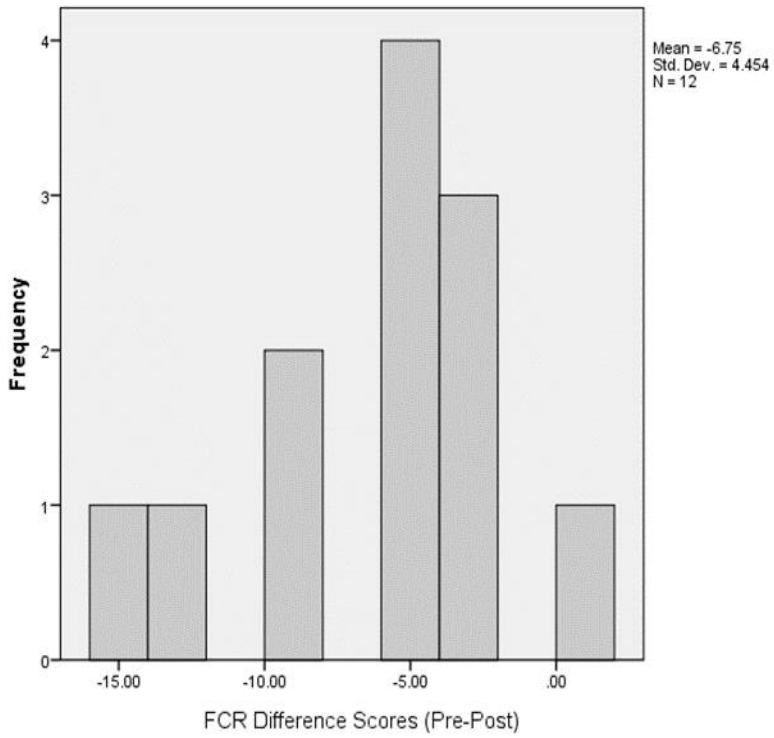
Testing of Parametric Assumptions

To determine if the change in mean FCR score was significant, a Paired *t*-test was conducted. However, before the analysis, the parametric assumptions had to be verified. These

assumptions included the normality of the difference scores and the absence of outliers in the difference scores (Field, 2018). Normality was assessed in the following three ways: (a) calculating skewness and kurtosis statistics, (b) Shapiro-Wilk's test of normality, and (c) visual inspection of a histogram. The skewness of the difference scores was -0.710 and the kurtosis was -0.055. Hair et al. (2010) and Bryne (2010) argued that data is considered normal if skewness is between -2 to +2 and kurtosis is between -7 to +7. Thus, the skewness and kurtosis values were within an acceptable range. Also, the Shapiro-Wilk's test for normality was not significant ($p = .313$); thus, there was no violation of the normality assumption. Lastly, visual inspection of a histogram of the difference scores indicated an approximately normal distribution (Figure 2).

Figure 2

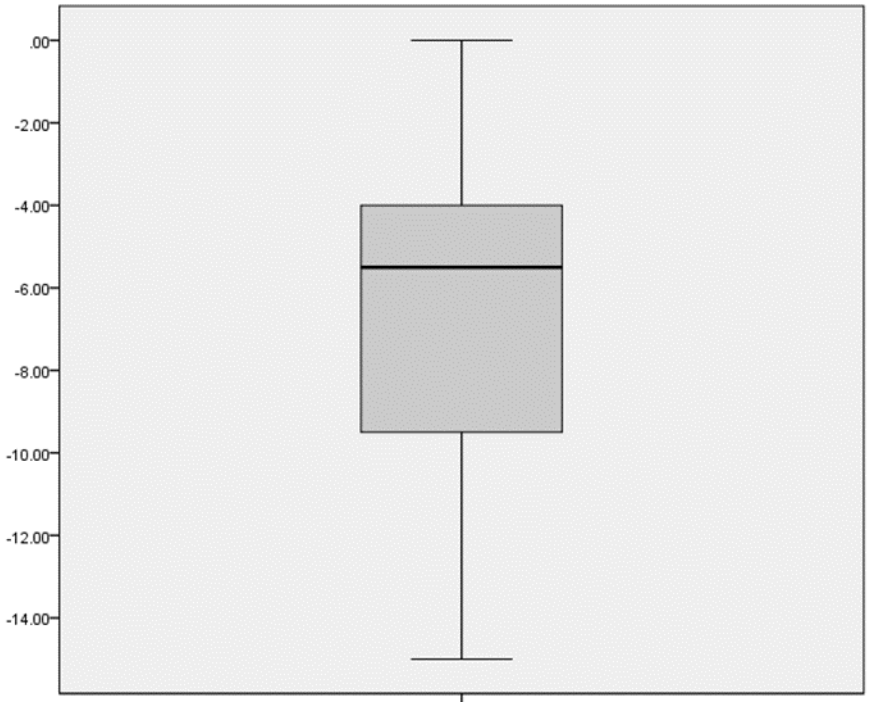
Histogram of Difference Scores (Pre-Post)



Regarding outliers, the difference scores were standardized and ranged from -1.85 to 1.51. Standardized values outside -3 to +3 standard deviations are considered possible outliers, thus, there were no outliers in the difference scores. Additionally, a box plot was created with SPSS, which indicated no outliers (see Figure 3).

Figure 3

Boxplot of FCR Difference Scores



Results

FCRI-SF

A Paired *t*-test was conducted with SPSS to determine if there was a significant mean decrease in baseline and post-intervention FCR scores. Prior to the intervention, the mean FCRI-SF score was $M = 23.92$ ($SD = 3.32$). After the FEARLESS LMCI intervention, there was a

decrease in the FCRI-SF score with a mean of M = 17.17 (SD = 5.57). This was a significant mean decrease of 6.75 points, 95% CI [3.92, 9.58], $t(11) = 5.24$, $p < .001$. Table 3 provides this information. This also indicates a large Cohen's d (effect size): d > 0.8 (d = 6.75/4.45 = 1.52), further noting a meaningful difference in the statistical significance (Elliott & Woodward, 2020).

Table 3

Paired Samples Test

M_{diff}	SD	SE	95% CI of the Difference		t	df	p
			Lower	Upper			
6.75*	4.45	1.29	3.92	9.58	5.24	11	<.001

*Significant at the .01 level.

The results of the Paired t-test were significant. As such, the null hypothesis that there is no difference in baseline and post-intervention FCR scores was rejected. It was concluded that there is a positive difference in baseline and post-intervention FCR scores; therefore, the intervention was effective for reducing FCR in young breast cancer survivors. Objective two was met.

Post-Program Survey

A post-program survey was also provided to the participants at the conclusion of the DNP project intervention to track accountability and participation in the program and to evaluate the percentage of participants that met the post-program adaptive goals/learning outcomes. It was found that the percentage of participants that met the eight post-intervention adaptive goals was at least 75% for all eight FEARLESS pillars. Table 4 summarizes this information.

Table 4

Percentage of Participants that Met Adaptive Goals Post-FEARLESS LMCI Intervention

Goal 1 (F): Read the Optimist's Creed and/or Serenity Prayer nightly before bed at least 5/7 nights a week.	75%
Goal 2 (E): Eat a whole food, plant-based diet that includes 5 servings of fruits and vegetables per day from the American Institute of Cancer Research food list.	83%
Goal 3 (A): Participate in 150-300 minutes of moderate-level physical activity weekly as tolerated.	83%
Goal 4 (R): Take a 1-hour cancer vacation every week.	92%
Goal 5 (L): Journal/describe the legacy you want to leave behind and start living it.	75%
Goal 6 (E): Attended at least 8/10 program sessions to ensure adequate social support during program intervention.	100%
Goal 7 (S): Aim for 7-9 hours of sleep every night.	75%
Goal 8 (S): Write 3 things you're grateful for each night before bed.	92%

Participants were also asked to provide further feedback in the end-of-program survey consisting of six follow-up questions. The data collected demonstrated that 100% of participants felt that the FEARLESS LMCI helped them learn how to manage their FCR more effectively, cope better, and learn how to better restore their health physically, mentally, socially, and/or spiritually as breast cancer survivors. Table 5 summarizes these findings.

Table 5

*Post-FEARLESS LMCI Intervention FCR, Coping, and Health Restoration Percentages *Yes/No*

Question 1: Do you think participation in this coaching program helped you learn how to manage your Fear of Cancer Recurrence more effectively as a breast cancer survivor?	*100%
Question 3: Do you think this program helped you learn how to cope better as a breast cancer survivor?	*100%
Question 5: Do you think this program helped you learn how to better restore your health (physically, mentally, socially, and/or spiritually) as a breast cancer survivor?	*100%

**Indicates Yes*

Participants were also asked to voluntarily elaborate on these end-of-program survey questions. Follow-up questions 2, 4, and 6 asked the participants "If so, how?" Table 6 provides a summary of the most notable feedback from the DNP project participants. See Appendix L for the full transcript. Objective one was met.

Table 6

Most Notable Qualitative Feedback from Participants Post-FEARLESS LMCI Intervention

Participant 1: Provided no additional feedback.

Participant 2: N/A- Dropped out of the DNP project.

Participant 3:

-Question 2: "I learned some new techniques to continue to help manage my fears and live my best life."

-Question 4: "I think this would be a great tool for that sweet spot when you are done with treatment and are feeling lost…"

Participant 4:

-Question 2: "…I'm also thanking my body every day…"

-Question 4: "The study…reminded me that I need to give myself time and grace in dealing with all of this."

Participant 5:

-Question 2: "I am spending more time on my nutrition and working out that I have less time to worry about fear of cancer returning. I am taking the time to plan long-term goals for my life..."

-Question 4: "…I feel more positive about myself, and my mind feels much more clear…This time felt like a gift for my soul."

-Question 6: "…Journaling has provided for me the nice time for myself to slow down and reflect on my day. I feel now that it is always okay for me to allow myself the grace and patience I need and that it is always okay to take time for myself. My mental health is just as important as my body..."

Participant 6:

-Question 2: "I am better able to stay positive and not dwell on what is beyond my control or the "what ifs?"…listening to other survivors' journeys helped me feel less alone."

-Question 4: "I feel more empowered to create a healthier future for myself. We set goals for our legacy, and I want to be able to look back knowing I did all I could."

-Question 6: "During treatment, I didn't really feel in control of my life…I was not leading. I finally feel like the roles are switching with myself in the lead it's very empowering…focusing on being FEARLESS keeps the cancer thoughts at bay. The program gave me tools to move forward..."

Participant 7:

-Question 2: "…I realized how much stress can contribute to illness, and stressing over recurrence can be so counterproductive."

-Question 4: "The sense of community always helps me cope better…"

Participant 8:

-Question 2: "…I enjoyed hearing what others do to help calm their fears. Made me feel less alone in this journey."

-Question 4: "The Creed and Serenity Prayer really helped to bring a calm to my day and writing in the journal provided a positive mindset to my day."

Participant 9:

-Question 2: "…The Optimist Creed is a game changer... I like having "goals" to achieve..."

-Question 4: "…I am so much more prepared and confident I WILL survive."

-Question 6: "I have a better understanding of the science behind making healthy food choices..."

Participant 10:

-Question 2: "It helped me focus on the present and what I can do to be healthier in the present rather than the fear of an unknown future."

-Question 4: "Being together with other young BC survivors helped me feel that I wasn't alone. It helped me focus on investing in myself and my health and well-being**...**"

-Question 6: "It helped me become more intentional about the aspects of my health that I can control such as diet, physical activity, practicing gratitude and mindfulness, etc. It helped me view myself as a worthy investment..."

Participant 11:

-Question 2: "…I love the Optimist's Creed and the Serenity Prayer and the practice of doing those daily along with the gratitude journal..."

-Question 4: "I would say the biggest thing for me was knowing that some of the feelings and emotions that I have been dealing with are not unique to me but are shared by other survivors… it was helpful to interact with this group of women who have been diagnosed in the past couple of years."

-Question 6: "The focus on cancer-fighting foods was very helpful…(and) the difference between sleep and rest..."

Participant 12:

-Question 2: "…Motivation to increase my exercise activities; Motivation to practice self-love/self-care."

-Question 4: "Reading the Optimist's Creed and/or Serenity Prayer has helped; Journaling more frequently; Meditation."

Participant 13:

-Question 2: "I learned how to manage fear of recurrence by implementing lifestyle changes based on the 8 pillars of the FEARLESS framework."

-Question 4: "The program helped me to learn how to cope..."

-Question 6: "After 9 sessions of the program, I am equipped with the tools and knowledge to better restore not only my health, but my mental state. Program offers healthy ways for managing my fears..."

Participant 14: N/A- Dropped out of the DNP project.

Incidental Findings

Due to the sensitive nature of FCR, the principal investigator planned to generate a referral back to the oncologist for further psychosocial support for post-FCRI-SF screening scores greater than or equal to 22 as this score indicates a clinically significant FCR severity. There were 9/12, or 75% of participants that screened above or equal to a score of 22 before participating in the FEARLESS LMCI intervention. This improved to 2/12, or 17% of participants post-intervention. The need for further clinical therapy was communicated to the two participants that demonstrated clinically significant scores by the principal investigator so they could seek out additional psychological resources as needed. The other seven participants no longer needed a referral for clinical therapy, which was unexpected, yet remarkable.

Also, the principal investigator initially intended to obtain a pre-and post-LMCI weight and height for all participants to look for improvement in Body Mass Index when applicable and to potentially use these results to guide weight loss and management care in future practice. However, it was revealed by one participant that this request generated emotional distress and she declined to submit these demographics. Two other participants did not provide a pre-intervention weight and height and one other participant did not provide a pre-intervention height for reasons unknown despite repeated requests for the information by the principal investigator. Additionally, four participants were actively receiving care for weight loss and management at the principal investigator's clinic when the program concluded, which could have resulted in

misleading improvements in unhealthy weight gain unrelated to the LMCI. The principal investigator thus elected not to collect post-intervention weights as originally planned.

Summary

A thorough statistical analysis of the DNP project concluded that the FEARLESS LMCI was effective in decreasing FCR among young breast cancer survivors. The null hypothesis was rejected. Furthermore, participants achieved a percentage of at least 75% for meeting the eight post-intervention adaptive goals, and all participants reported that the FEARLESS LMCI helped them learn how to manage their FCR more effectively, cope better, and better restore their whole health. The qualitative analysis revealed that the participants provided extensive feedback on how the program helped them. Two DNP project participants that demonstrated clinically significant FCR scores post-FEARLESS LMCI intervention were referred to their oncologist for further psychological management. Objectives one and two of the DNP project were met.

Chapter 5: Discussion

Practice Inquiry and Purpose Discussion

The FEARLESS DNP project aimed to answer the proposed research inquiry of how a ten-week DNP student-led lifestyle management-focused coaching intervention would lead to decreased FCR and improved health outcomes among young female breast cancer survivors demonstrating abnormally elevated screening scores during the extended survival period. Other aims of the DNP project were to help participants (1) create and gain abundant and restorative health, (2) experience less FCR as evidenced by decreased FCRI-SF scores, (3) live a longer, more balanced life after implementation of evidence-based healthful lifestyle modifications, (4) learn how to develop self-love and purpose and live their legacy, (5) change compensatory/compromised adaptation to an integrated healthier coping response, and (6) learn

how to adapt to their changing environment and their new normal after breast cancer treatment more healthfully. The two objectives of the FEARLESS DNP project were to complete this process by August 2023 and to evaluate FCRI-SF scores using pre/post Paired *t*-testing statistical analysis. This chapter provides a thorough discussion of the quantitative and qualitative DNP project results relating to the FCRI-SF scores, adaptive goals/learning outcomes, and post-intervention survey. Demographic characteristics, observations and limitations, impact on the DNP degree, application to the theoretical framework, evidence-informed practice, and implications for future DNP projects relating to this project are discussed.

Discussion of Findings

FCRI-SF Scores

Learning how to effectively manage FCR is an unmet need of many young breast cancer survivors after diagnosis and completion of subsequent treatment. This DNP project demonstrated through a Paired *t*-test statistical analysis that the virtual FEARLESS LMCI developed and implemented by the DNP student principal investigator significantly decreased FCR in young, early-stage breast cancer survivors during the extended survival period. This was further evidenced by a mean percent decrease of 28.22%, or 6.75 points in FCRI-SF scores. The null hypothesis that there is no difference in baseline and post-intervention FCR scores was rejected and it was concluded that the LMCI was effective for reducing FCR in young breast cancer survivors.

All participants initially screened positive for abnormally high FCRI-SF scores. The severity of FCR decreased substantially across all levels (low to moderate, high, and clinically significant) as previously described. Two participants achieved a normal FCRI-SF score of less than 12 and seven participants reversed clinically severe FCR after participating in the

intervention indicating that the FEARLESS LMCI successfully managed FCR at moderate, high, and clinically significant levels in this study. One participant's score remained unchanged post-intervention. Eleven out of twelve (92%) participants experienced a reduction in FCRI-SF scores again demonstrating the effectiveness of the LMCI.

Furthermore, the initial pre-intervention FCRI-SF screening concluded that eighteen out of nineteen (95%) women initially interested in participating in the study were experiencing moderate to severe FCR as evidenced by an eligible FCRI-SF score including five out of five (100%) of those women 45 years old or younger. This is well above the documented literature findings of approximately 50% and 70% of BC survivors respectively that are estimated to experience these same levels of FCR (Gormley et al., 2022; Thewes et al., 2012). Also, fourteen out of nineteen (74%) of those initially screened exhibited an FCRI-SF score in the clinically significant range $\geq$ 22 indicating a need for clinical management of FCR. This is significantly above the documented literature findings indicating that approximately 7% of cancer survivors generally experience severe and disabling FCR (Butow et al., 2018).

The FEARLESS DNP project findings confirmed that unmanaged FCR is a significant problem facing young breast cancer survivors for at least five years after treatment completion and the extent of the problem may be greater than previously thought. These findings also collectively provided evidence in support of using the FEARLESS LMCI for reducing and managing FCR among young breast cancer survivors. The DNP project aim of helping participants experience less FCR as evidenced by decreased FCRI-SF scores was met. The objectives of the DNP study to complete this process by August 2023 and to evaluate FCRI-SF scores using pre/post Paired *t*-testing statistical analysis were also met. Again, the null hypothesis was rejected.

Adaptive Goals

The DNP project results also demonstrated that the participants achieved 75% or higher for each of the eight post-intervention adaptive goals after participating in the virtual FEARLESS LMCI indicating accountability and loyal participation in the program. Among the highest goals achieved were Environment/8/10 sessions attended (100%), Rest/participating in a weekly cancer vacation (92%), and Stress Management/participating in a daily grateful exercise (92%). Next were Eating Well/aiming for five AICR fruits/vegetables daily (83%) and Activity/engaging in 150-300 minutes of moderate level exercise daily (83%). The lowest goals achieved were Fearing Less/daily optimist's creed/serenity prayer (75%), Love/journaling legacy (75%), and Sleep/aiming for adequate hours nightly (75%). These results indicated that the DNP project aims of helping participants live a more balanced life after the implementation of evidence-based healthful lifestyle modifications, learning how to develop self-love and purpose and live their legacy, and learning how to adapt to their changing environment and their new normal after breast cancer treatment more healthfully were met at least ¾ of the time.

Furthermore, given that the Paired *t*-test statistical analysis concluded that the FEARLESS LMCI was effective for reducing FCR in young breast cancer survivors, these results are consistent with the evidence presented by the principal investigator in the literature review in support of an LMCI for elevated FCR among young female survivors using best practice guidelines, wellness and group health coaching, healthy lifestyle behaviors, mindfulness practices, and other lifestyle management and oncologic recommendations and resources.

Post-Intervention Survey: Quantitative & Qualitative Feedback

The DNP project results demonstrated that the virtual FEARLESS LMCI helped participants learn how to manage their FCR more effectively, cope better, and restore their health

physically, mentally, socially, and/or spiritually. The participant responses on the yes/no questions 1, 3, and 5 of the post-intervention survey showed that 100% of participants reported feeling this way in all three areas indicating that the DNP project aims of helping participants experience less FCR, change compensatory/compromised adaptation to an integrated healthier coping response, and create and gain abundant and restorative health were met.

Furthermore, the extensive qualitative feedback provided by the DNP project participants in questions 2, 4, and 6 indicated that the principal investigator's goal to help participants experience enhanced self-love, longevity, and legacy was also met. For example, Participant 5 reported, "I feel more positive about myself, and my mind feels much more clear…This time felt like a gift for my soul." Participant 6 reported, "I feel more empowered to create a healthier future for myself. We set goals for our legacy, and I want to be able to look back knowing I did all I could." Participant 10 wrote, "It helped me view myself as a worthy investment…It helped me become more intentional about the aspects of my health that I can control."

Among some of the factors mentioned by the participants which helped them learn how to manage FCR more effectively, cope better, and restore their health were the Optimist's Creed, Serenity Prayer, journaling, other survivors/group support, nutrition, exercise, goal setting, positivity, a sense of community, mindfulness, practicing gratitude, self-care, meditation, self-love, and healthy lifestyle modifications. There was also extensive participant feedback supporting a LMCI for elevated FCR consistent with the evidence presented by the principal investigator in the literature review. Participant 12 wrote, "The program helped me to learn how to cope..." Participant 3 stated, "I learned some new techniques to continue to help manage my fears and live my best life." Participant 9 reported, "I am so much more prepared and confident I

WILL survive." Participant 6 wrote, "The program gave me tools to move forward..." And finally, Participant 7 stated, "The sense of community always helps me cope better."

Demographic Characteristics

As previously mentioned, 95% of women that were initially interested in participating in the DNP project screened positive for moderate to severe FCR. Only one of the nineteen women was ineligible for the study based on her low FCRI-SF score. Previous research has demonstrated that certain demographic characteristics are associated with higher FCR. The literature review performed by the principal investigator revealed that young age and female gender are consistently associated with elevated FCR. One study noted that younger age is the most consistent predictor of high FCR (Crist & Grunfeld, 2012; Gormley et al., 2022; Heidkamp et al., 2021; Simard & Savard, 2008; Simard et al., 2013; Smith et al., 2020). This DNP project also determined that young age and female gender are predictors of elevated FCR. The mean age of the study participants was 49.5 years old and all participants were female.

Observations and Limitations

Strengths

The DNP project had significant strengths. First, the FEARLESS LMCI was planned, developed, and implemented by the principal researcher with over seventeen years of clinical experience working with young breast cancer survivors. The blending of LM, CREATION Life, best practice guidelines, and sound clinical knowledge led to the creation of an intervention capable of reducing FCR, improving coping, and restoring the whole health of the FEARLESS program participants. Also, the small sample size coupled with a supportive and nurturing virtual health coaching environment allowed for a more intimate experience for the DNP project participants.

Another strength of the DNP project is that the participants in the LMCI were active during the weekly sessions and loyal to the program. The DNP project retention rate was 86%. This was likely due to the sensitive and vulnerable nature of FCR, which kept the participants engaged. Finally, the FEARLESS intervention was conducted virtually. This eliminated the concern for possible infectious disease/COVID interruptions or limitations and ensured that the sessions remained confidential. This worked well since the ten-week LMCI was run during the wintertime and proved very convenient for the participants.

Limitations

A limitation of this DNP project included a brief recruitment period lasting only approximately 1.5-2 months. This resulted in a smaller than ideal sample size. An adequate sample size was calculated to be 34, and 12 participants completed the FEARLESS LMCI. Fortunately, a large Cohen's d (effect size) was still calculated. Also, while the virtual nature of the LMCI allowed for convenience and limited session disruptions, it did not allow for the more personal contact that in-person sessions provide. Some of the participants said that they wished they could have met in person. For this reason, delivery of the LMCI in person could prove valuable.

Barriers & Unique Challenges

A barrier to the DNP project was recruitment. The principal investigator did not work in the oncology department during the recruitment period. Recruitment initially relied upon the random dissemination of DNP project flyers in offices and waiting areas located within various outpatient clinics across the EEH system, an oral presentation by the principal investigator given at the EEH breast conferences, and the ongoing efforts of the oncology support staff. A decision by the EEH research department to count the number of DNP project participants towards 2023

clinical trial accrual cases for accreditation by the Commission on Cancer (COC) and National Accreditation Program for Breast Centers (NAPBC) helped improve recruitment efforts, increase the number of participants, and overcome this barrier.

The DNP project also had noteworthy unique challenges. The ten-week duration of the program, the lengthy program sessions, and the extensive planning and development required to implement the DNP project proved to be a significant undertaking for the principal researcher, which was challenging. Also, three participants were unable to attend session 6, which focused extensively on developing purpose/self-love, longevity, and legacy along with enhancing healthy social relationships, outlook, choice, and trust to experience less fear. Due to the importance of receiving this session content, a one-time individual make-up session was provided to the participants who missed this session after permission from the DNP project advisor was received by the principal investigator to conduct the additional sessions. Of note is that the individual coaching sessions were conducted in the same manner as the group sessions.

Lessons Learned

Various lessons were learned during the DNP project process. First, virtual group health coaching was efficient, and participants appreciated the support they received from their peers during the sessions. It also allowed for the FEARLESS LMCI content to reach a larger audience more quickly than individual health coaching could. Also, conducting a mini pre and post educational content coaching session worked well. The participants were able to review the content from the previous week at the beginning of each session, as well as discuss the new content they learned at the end of the session. This allowed them to remain engaged in the sessions and broke up the time spent on presenting the educational content. Finally, due to its effectiveness, the FEARLESS LMCI or a similar evidence-based intervention should be

considered for use as an extension of the survivorship care plan for survivors experiencing elevated FCR.

Impact on the Doctor of Nursing Practice Degree

The FEARLESS DNP project found that unmanaged FCR after breast cancer treatment is a significant problem facing young survivors. FCR is palpable. It is real. It has the potential to manifest into a chronic nature without proper clinical intervention. The findings of this DNP project are important because they have provided additional confirmation of the severity of this issue, as well as an evidence-based solution for use in clinical practice. There were approximately four million women living with a history of invasive breast cancer in January 2022 in the US (ACS, 2022). Empowering young breast cancer survivors in nursing clinical practice using the FEARLESS LMCI can help them experience less FCR and better health outcomes when applicable.

The principal investigator collected and compiled evidence-based best practice guidelines from major health organizations and fused them with nursing theory to provide the young survivors with an effective, compassionate, and evidence-based LMCI to help them learn how to manage their whole health after treatment. The FEARLESS LMCI positively impacted the young breast cancer survivor participants. The participants learned how to better manage their fears associated with cancer recurrence, engage in evidence-based lifestyle modifications that promote longevity and restoration of health, cope more effectively, and adapt to their new normal after breast cancer treatment more healthfully. Utilizing the FEARLESS LMCI during the DNP project translated evidence-based practice into evidence-informed practice and can serve as a model for care for oncology nurses and APRNs moving forward.

Additionally, various DNP Essentials aligned with the FEARLESS DNP project and created meaning and context. The principal researcher developed, implemented, and evaluated the new FEARLESS LMCI practice approach to reduce FCR based on nursing theories to create a positive change in the health status of young breast cancer survivors in alignment with DNP Essentials I and VIII. The LMCI used advanced virtual communication skills through Zoom technology to reduce FCR and emphasize the ongoing improvement in health outcomes and future needs of young breast cancer survivors in alignment with DNP Essentials II and IV. The principal researcher also integrated knowledge from diverse sources such as the NCCN, AICR, and ACLM evidence-based guidelines to plan and design the meaningful FEARLESS evidence-based practice guidelines to address elevated FCR management among young breast cancer survivors in alignment with DNP Essentials III and VIII (American Association of Colleges of Nursing, 2006).

Furthermore, the principal investigator employed effective communication and collaborative skills necessary for successfully developing and implementing the new FEARLESS LMCI with the EEH breast oncology team and plans to educate them on project outcomes at the next planned hospital breast conference on September 8, 2023. This is to continue to improve FCR-related patient outcomes and optimal care in alignment with DNP Essentials V, VI, and VIII. The principal investigator also analyzed epidemiological, biostatistical, and scientific data related to breast cancer, FCR, best practice guidelines, wellness/health coaching, and diverse lifestyle management data to address gaps in care related to the young breast cancer survivor experience in alignment with DNP Essential VII. Finally, the principal investigator demonstrated advanced levels of clinical judgment and systems thinking as evidenced by designing,

implementing, and evaluating a statistically significant and successful DNP project intervention in alignment with DNP Essential VIII (American Association of Colleges of Nursing, 2006).

Application to Theoretical Framework

The principal investigator developed and applied the FEARLESS theoretical framework and subsequent LMCI to help accomplish the aims and objectives of the DNP project and address a primary challenge that many young breast cancer survivors face, which is learning how to manage their FCR effectively after diagnosis and treatment. The framework and LMCI were also developed and applied to help this population experience decreased FCR, improved coping, and restored health after demonstrating an elevated FCRI-SF score. The FEARLESS model and LMCI are based upon several theories, principles, and evidence-based best practice guidelines, which are important to the project findings and collectively supported the DNP project at several key points of the process including the planning, development, implementation, and evaluation phases.

During the planning and development phase of the FEARLESS theoretical framework, the principal investigator aimed to create an eight-pillar model and intervention that introduced the DNP project participants to abundant and full health in alignment with NCCN, AICR, ACLM, CREATION Life, and RAM theories, principles, and guidelines. The FEARLESS framework theorized that enhanced adaptive coping responses and behaviors observed in the four RAM modes can be learned and acquired with the right support and resources. Furthermore, the FEARLESS LMCI provided an evidence-based solution to theoretically improve the participants' adaptation and coping responses to the stimuli of a breast cancer diagnosis, treatment, and FCR while helping them learn how to manage these stimuli more effectively. It also theoretically provided the support and resources necessary for restoring their health.

Additionally, the LMCI provided the participants with a potential method to enhance their self-love and purpose, longevity, and survival experience/legacy through the creation of a balanced and healed life after breast cancer treatment (CREATION Life, 2022; Cummings & Reed, 2005; Masters, 2015; Roy, 2009).

During the implementation phase of the FEARLESS theoretical framework and LMCI, the principal investigator (nurse) successfully facilitated the process of helping the DNP project participants (person) feel healthy and whole again (health) after cancer treatment and transition into a more integrated and adapted "new normal" (environment) of survivorship with decreased FCR, improved coping responses, and increased participation in evidence-based healthful lifestyle modifications. In this phase, the FEARLESS theory was further applied during the implementation of the eight FEARLESS pillars and weekly virtual group LMCI. This led to favorable health outcomes for all participants that completed the ten-week intervention.

During the evaluation phase of the FEARLESS theoretical framework and LMCI, it was evident that the chosen theories, principles, and best practice guidelines were important to the DNP project findings and that the FEARLESS model and LMCI were applied correctly given the favorable DNP project outcomes. All participants reported that the intervention improved their ability to manage FCR, helped them cope more effectively, and helped restore their health. There was a significant mean decrease in the FCRI-SF scores indicating a statistically significant decrease in FCR.

Additionally, greater than 75% of the participants met their adaptive goals indicating that they were in fact participating in evidence-based healthful lifestyle modifications. Finally, 100% of the participants answered yes to the survey questions at program end-time demonstrating that coping processes can be learned and acquired as initially theorized in the FEARLESS framework

and that the eight pillar LMCI was in fact an evidence-based solution to help reduce FCR and improve health outcomes among young breast cancer survivors. This is in alignment with RAM which theorizes that well-adapted behavior reflects a person's ability to cope or positively respond to a health status and CREATION Life which asserts that abundant and full health can be achieved physically, mentally, socially, and spiritually with holistic support and resources (CREATION Life, 2022; Cummings & Reed, 2005; Masters, 2015; Roy, 2009).

Evidence-Informed Practice and Stakeholders

Consistent with the existing literature, this DNP project confirmed that unmanaged FCR is a problem facing young breast cancer survivors after their treatment. The FEARLESS DNP project demonstrated that healthcare providers and their supporting staff have an opportunity to help enhance the first five years after treatment for young survivors. The FEARLESS DNP project confirmed that a DNP student-led virtual group LMCI helped reduce FCR after participants learned adapted coping strategies and participated in improved lifestyle modifications.

A suggested evidence-informed practice change is to screen breast cancer survivors between the ages of 18-59 for FCR using the FCRI-SF after treatment completion and during their survivorship care plan meeting conducted by the survivorship APRN. Patients that screen positive on the FCRI-SF should be provided with the FEARLESS LMCI to help them transition into survivorship with the tools necessary to improve their health physically, emotionally, socially, and spiritually. The FEARLESS LMCI could function as an extension of cancer treatment in a survivorship and/or LM clinic. The necessary stakeholders to implement and champion this type of evidence-informed practice change include breast surgeons, medical and radiation oncologists, nurse navigators, clinical psychologists, APRNs, and other medical

support staff. For example, the FEARLESS LMCI could be run on a regular basis in an outpatient setting conducted by designated staff after adequate LMCI training.

Dissemination and Sustainability Plan

There are several ways the principal investigator plans to disseminate the DNP project findings and make the FEARLESS LMCI sustainable. An educational poster and final PowerPoint presentation summarizing the DNP project findings has been created for use as needed at student/professional meetings and conferences. The DNP project findings were presented to students and faculty at the Southern Adventist University DNP seminar on Tuesday, August 15, 2023. The results were also presented to the breast oncology team of EEH, the site of participant recruitment, during their quarterly breast conference on Friday, September 8, 2023. This included a discussion on how to potentially implement the findings into clinical practice across the EEH system. Other potential means for dissemination include publishing the project findings and implementing the FEARLESS LMCI into the principal investigator's current APRN and health coaching practices.

Implications for Future DNP Projects

This FEARLESS DNP project found that young breast cancer survivors experiencing an unhealthy level of FCR desire tailored emotional support in addition to the clinical care they receive during the extended survival period. This includes receiving emotional support from other young survivors. Future DNP projects should focus on helping young breast cancer survivors collectively heal the trauma and fears associated with their cancer diagnosis and treatment and attain whole health after treatment completion in group settings. Conducting the FEARLESS LMCI with a larger sample size and as a larger scale study should be considered

virtually and/or in person given the potential to help a wider range of young survivors manage their FCR more effectively.

It appears from the review of literature and FEARLESS DNP project findings that learning the rationale behind and empowering young female breast cancer survivors to implement clean eating, increased exercise, improved rest and sleep, stress management, and coping and fear reduction techniques can help alleviate FCR and restore health. Future FCR-related DNP projects should focus on screening for unmanaged FCR and providing young breast cancer survivors with the LM tools necessary for also enhancing self-love and purpose, longevity, and legacy according to best practices. If future FCR-related DNP projects are not conducted, this could result in missing a significant opportunity for helping to create a more whole and healed young breast cancer survivor during and after the transition into survivorship.

Conclusion

The DNP project findings indicate that the FEARLESS LMCI can be used to address the practice gap of helping young breast cancer survivors establish and transition to a new normal after cancer treatment more holistically physically, emotionally, socially, and spiritually with less FCR. Using the tailored FEARLESS intervention in a deeply caring and nurturing virtual health coaching environment helped participants decrease and manage FCR more effectively, cope better, and attain whole, restored health after a cancer diagnosis and treatment. Post-program survey feedback noted that the participants also experienced enhanced self-love, longevity, and legacy after participating in the LMCI. The FEARLESS DNP project findings provide clear evidence in support of implementing a virtual group lifestyle management health coaching intervention for unmanaged FCR among young female breast cancer survivors.

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Appendix A: Permission Letters

September 15, 2022

Lisa Murphy, APRN

Family Nurse Practitioner

Elmhurst Memorial Hospital

[via email]

Dear Ms. Murphy:

Thank you for presenting your study, "A Lifestyle Management Coaching Intervention for Fear of Cancer Recurrence (FCR) in Young Breast Cancer Survivors" to the Edward-Elmhurst Health Institutional Research Oversight Committee (EEH IROC) on September 15, 2022.

The materials submitted for IROC committee review were as follows:

- IROC Application, fully signed 8/10/22
- Protocol (#2: Student Intervention, 9/6/2022)
- Dear Participant Letter (#4, dated 9/6/22)
- To Whom It May Concern Letter (#5 dated 9/6/2022)
- Fear of Cancer Recurrence Inventory – Short Form (FCRI-SF) ©Simard, S & Savard, J (2015), used with permission
- Post-Program Survey & Additional Questions (#8, dated 9/2/22)

After hearing the presentation and reviewing the submitted documents, the EEH IROC determined that the project could move forward for review by the EEH Institutional Review Board (EEH IRB) with the following stipulations:

1) Please replace all student-related contact information with Edward-Elmhurst Health contact information (phone number, address, etc.) in your study materials. Because you will be conducting this study with EEH patients and you are employed by EEH, your investigator credentials need to reflect your affiliation with EEH.

   Completed. Study materials have been updated to reflect Edward-Elmhurst Health contact information.

2) In regard to the school requirement to incorporate religious/spiritual elements in your research at a secular institution, the committee asks that you revise the protocol to describe how you will ascertain the spiritual/religious comfort of

study group participants during meetings and how you will adjust session methods to address any subject who is not comfortable with such religious elements.

Completed. Patient consent has been updated as follows on page # 2: Will there be any discomforts and/or risks? You will also be encouraged to build a deeper, more empowering, and trusting relationship with yourself and develop spiritually during particular program sessions. If this makes you uncomfortable, please discuss your concerns directly with the principal researcher Lisa Murphy prior to beginning the study so that you can better decide if you would like to still participate in the study.

Also, the intervention/protocol now contains the following statement for clarification: Consent to participate in the DNP program intervention will be obtained for each program participant. In this study, participants will be encouraged to build a deeper, more empowering, and trusting relationship with self and develop spiritually during program sessions. This information is written into the consent and participants will be encouraged to discuss any concerns they have regarding this directly with the principal researcher Lisa Murphy prior to beginning the study at which point they can agree to opt-in or out of the study.

3) During your presentation, you indicated that there were still some elements in the list of interventions that were still being finalized. Please submit the finalized version of the protocol for IRB review. The EEH IRB may ask additional questions based on the protocol submitted for their review.

Completed. The finalized version of the intervention/protocol was submitted on Thursday 10/13/2022 with all necessary updates and/or changes.

Once the above materials are received, the EEH IRB will be in contact to relay next steps. If you have any questions, please contact the Office of Research Administration at iroc@eehealth.org.

Gayle Lee SP (for GL)

Chair, EEH Institutional Research Oversight Committee

Stephanie Pittman, MS, CIP

System Manager, Research Regulatory Operations

Healthy Driven
Edward-Elmhurst HEALTH

November 1, 2022

Lisa Murphy, APRN
Family Nurse Practitioner
Elmhurst Memorial Hospital
[via email]

Protocol Title: A Lifestyle Management Coaching Intervention for Fear of Cancer Recurrence in Young Breast Cancer Survivors

Dear Ms. Murphy:

A representative of the Edward-Elmhurst Health Institutional Review Board (EEH IRB) has reviewed and the above project and approved your study as it meets the requirements for an expedited review found at 45 CFR 46.110 in that it involves no more than minimal risk to research subjects and meets the following regulatory categories for expedited review:

> *Category 7 - Research on individual or group characteristics or behavior (including, but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.*

The following documents were reviewed as part of the approval:

- IROC Application, fully signed 8/10/22
- Protocol (undated, but updated 10/07/22)
- Dear Participant Letter (revised and received 10/31/22)
- To Whom It May Concern Letter (revised and received 10/31/22)
- Fear of Cancer Recurrence Inventory – Short Form (FCRI-SF) ©Simard, S & Savard, J (2015), *used with permission*
- Post-Program Survey & Additional Questions
- EEH Informed Consent & Authorization to Participate in a Research Study (Version #2, dated 10/25/22)

Should the scope of the project change beyond what is described in the above document or there are unanticipated problems involving risks to subjects or others, please notify the EEH IRB with the relevant information and materials before proceeding further. Additionally, if your affiliation with Southern Adventist University and/or employment by EEH changes, all research activity must stop and the EEH Office of Research Administration must be notified immediately.

In complying with Federal regulations, the EEH IRB will be notified that this study received expedited approval.
The EEH IRB will be responsible for the continuing review and approval of the aforementioned study until we receive written notice of study closure. If you anticipate your study continuing beyond the expiration of IRB approval (**October 31, 2023**), please complete the Edward-Elmhurst Health IRB *Continuing Review Form for Studies Reviewed by EEH IRB* (located on the Edward-Elmhurst Health Intranet under "Office of Research Administration") and submit it to the EEH IRB 30 days prior to expiration of IRB approval.

Should you have any further questions, feel free to contact the EEH IRB at IRB@eehealth.org.

Sincerely,

Stephanie Pittman, MS, CIP
System Manager (South Region), Research Regulatory Operations
Director, Edward-Elmhurst Health Institutional Review Board (EEH IRB)

SOUTHERN ADVENTIST UNIVERSITY — INSTITUTIONAL REVIEW BOARD

SOUTHERN ADVENTIST UNIVERSITY
Power for Mind & Soul

IRB
Institutional Review Board

October 17, 2022

Principal Investigator: Lisa Murphy

Research Project: A Lifestyle Management Coaching Intervention for Fear of Cancer Recurrence (FCR) in Young Breast Cancer Survivors

IRB Tracking Number: 2022-2023-023

Dear Lisa,

The Institutional Review Board has examined your research study proposal, **A Lifestyle Management Coaching Intervention for Fear of Cancer Recurrence (FCR) in Young Breast Cancer Survivors**, with supporting documents at the IRB committee level and it is a delight to inform you has approved your research request as expedited**.** This level of approval is for classroom usage only meaning data collected cannot be used for anything other than a class project**.** We wish you the very best as you move forward with this study and look forward to reading your findings when your study is completed.

As you move forward with your study, if there is a need to make minor changes to this research, before making those changes please notify us by completing and submitting a FORM B (Certification of Modification, Annual Review, Research Termination, or Research Completion). Please submit all applications to irb@southern.edu. If substantial changes are planned, you, as the principal investigator, should submit a new IRB FORM A application.

Many blessing to you as you move forward. Please let us know if there is anything additional, we can do to assist you with this research study.

Always in His service,

Robert Overstreet

Robert Overstreet, Ph.D. IRB
Chair
Southern Adventist University 423-
236-2285
robertoverstreet@southern.edu

"I applied my mind to **study** and to explore by wisdom all that is done under the heavens…" - Ecclesiastes 2:13

"Research is to see what everyone else has seen and to think what nobody else has thought." - Albert Szent-Gyorgy

Appendix B: Institutional Review Boards

SOUTHERN ADVENTIST UNIVERSITY
Power for Mind & Soul

IRB Institutional Review Board FORM A
Version 01/01/2021

RESEARCH APPROVAL
NOT REQUIRED FOR
LITERATURE REVIEW OR ACADEMIC EXERCISE

IRB Tracking #	**2021-2022-**Reserved for IRB Committee
Date of Approval:	Reserved for IRB Committee
Research Request:	☐ Exempt ☒ Full Review ☐ Expedited ☐ Animal/Plant
Type of Research (Check all that apply)	☒ DNP SCHOLARLY PROJECT ☐ APPLYING FOR ARC FUNDING ☐ GRAD. STUDENT RESEARCH ☐ FUNDED FACULTY RESEARCH ☐ UNDERGRAD. STUDENT RESEARCH ☐ GENERAL FACULTY RESEARCH ☐ THESIS

1. RESEARCH PRINCIPLE INVESTIGATOR

1.1. TITLE: **A Lifestyle Management Coaching Intervention for Fear of Cancer Recurrence (FCR) in Young Breast Cancer Survivors**

1.2. PRINCIPAL INVESTIGATOR: **Lisa R. Murphy**	CITI TRAINING[1] ☒ YES ☐ NO	EMAIL ADDRESS: **lisarmurphy@southern.edu**	PHONE #: **7732971687**	SCHOOL/DEPARTMENT: **Nursing**
CO-INVESTIGATOR: **N/A**	☐ YES ☐ NO	EMAIL ADDRESS: Email Address	PHONE #: Phone Number	FACULTY SUPERVISOR: Dr. Jill Buchholz
CO-INVESTIGATOR: **N/A**	☐ YES ☐ NO	EMAIL ADDRESS: Email Address	PHONE #: Phone Number	STARTING DATE: **01/03/2023**
CO-INVESTIGATOR: **N/A**	☐ YES ☐ NO	EMAIL ADDRESS: Email Address	PHONE #: Phone Number	ESTIMATED COMPLETION DATE: **03/14/2023**
MORE CO-INVESTIGATORS. LIST THEIR NAMES, EMAILS, PHONE NUMBERS, AND CITI TRAINING COMPLETION		**N/A**		

1.3. IS THIS RESEARCH BEING DONE WITH ANY INSTITUTIONS, INDIVIDUALS, OR ORGANIZATIONS NOT AFFILIATED WITH SAU? ☒ YES ☐ NO
If yes, please provide information of authorized officials below

NAME OF INSTITUTION: **Edward-Elmhurst Health System**

ADDRESS: **1200 S York Rd**	CITY: **Elmhurst**	STATE: **IL**	ZIP CODE: **60126**
CONTACT NAME: **Lisa Murphy**	POSITION: **APRN**	EMAIL ADDRESS: **Lisa.murphy2@eehealth.org**	PHONE #: **7732971687**
EXTERNAL FUNDING AGENCY: **N/A**		IDENTIFICATION # *(if applicable)*: **N/A**	GRANT SUBMISSION DEADLINE *(if any)*: Date

1.4. APPLICATION CHECKLIST. ATTACH (INSERT OR PASTE) ALL CHECKED ITEMS TO SECTION #9 (*CHECK ALL THAT APPLY*)

RESEARCH INSTRUMENTS: ☒ TESTS ☒ SURVEYS ☒ QUESTIONNAIRES ☒ PROTOCOLS
☐ OTHER FORMS ELSE USED TO COLLECT DATA

☒ INFORMED CONSENT DOCUMENTS

☒ PERMISSIONS FROM APPLICABLE AUTHORITIES *(such as principals of schools, teachers of classrooms, etc. to conduct your research at their facilities on their Letterhead)*

☒ RECRUITING MATERIALS AND TEXT OF E-MAIL OR WEB-BASED SOLICITATIONS

☒ ALL LINKS AND/OR QR CODES MUST BE ATTACHED AS COPIES

SUBMIT via irb@southern.edu ☐ *Signed by the faculty advisor, then scanned and submitted*
☐ *Submitted directly by the faculty advisor (no signature required)*

YOU CANNOT BEGIN YOUR RESEARCH UNTIL IT HAS BEEN OFFICIALLY APPROVED BY THE IRB

2. Research Project Description

2.1. Background and Rationale for the Study

This section should present the context of the work by explaining the relation of the proposed research to previous investigations in the field. Include citations for relevant research.

Breast Cancer (BC) survivors often experience fear of cancer recurrence (FCR). FCR is defined as the fear, concern, or worry that cancer will progress or come back (Lebel, et al., 2016). FCR is associated with impaired functioning, distress, and lower quality of life. Approximately 50% of BC survivors experience moderate to severe levels of FCR, and this can be as high as 70% for women 45 years old and younger (Gormerly et al., 2022; Thewes et al., 2012; Smith et al., 2020). Furthermore, approximately 7% of cancer survivors experience severe and disabling FCR (Butow et al., 2018).

Previous research has identified that an unmet need of BC survivors is learning how to manage FCR. FCR is one of the greatest concerns of cancer survivors after treatment completion and a gap in age-appropriate support exists. BC patients are faced with establishing a new normal after completing cancer treatment and often feel lost in transition when doing so. This timeframe, the extended survival period, can be dominated by FCR. Young BC survivors may benefit from additional support and tailored interventions during surveillance periods to help minimize potential manifestations and triggers of FCR and to help them transition into survivorship more effectively (Gormerly et al., 2022).

References

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Thewes, B., Butow, P., Bell, M.L., Beith, J., Stuart-Harris, R., Grossi, M., Capp, A., & Dalley, D. (2012). Fear of cancer recurrence in young women with a history of early-stage breast cancer: a cross-sectional study of prevalence and association with health behaviours. Support Care Cancer, 20, 2651–2659. https://doi:10.1007/s00520-011-1371-x

2.2. Purpose/Objectives of the Research

Briefly state, in non-technical language, the purpose of the research and the problem to be investigated. When possible, state specific hypotheses to be tested or specific research questions to be answered. For pilot or exploratory studies, discuss the way in which the information obtained will be used in future studies so that the long-term benefits can be assessed.

The purpose of the DNP project is to conduct an APRN-led lifestyle management coaching intervention designed by the researcher to help to decrease Fear of Cancer Recurrence (FCR) and improve health outcomes in young

breast cancer survivors demonstrating high FCR screening scores. The DNP project inquiry: How will a ten-week APRN-led lifestyle management-focused practice intervention lead to decreased FCR among young female BC survivors demonstrating abnormally elevated screening scores during the extended survival period?

The project aims to help young female breast cancer survivors (a) gain restorative health physically, mentally, socially, and spiritually after cancer treatment, (b) experience less FCR as evidenced by decreased FCR-SF scores to an acceptable range (< 12) after participation in a 10-week virtual group coaching intervention, (c) live a longer, more balanced life after implementation of evidence-based healthful lifestyle modifications that meet their physiologic needs, (d) learn how to develop self-love and purpose and live the legacy they want to leave behind, (e) change compensatory/compromised adaptation to an integrated healthier coping response, and (f) learn how to adapt to their changing environment more healthfully and become better integrated into their new normal after breast cancer treatment.

The project objectives are (a) To plan, develop, implement, and evaluate a 10-week evidence-based lifestyle management virtual coaching intervention for young female breast cancer survivors by August 2023 and (b) To evaluate Fear of Cancer Recurrence Inventory Short Form (FCRI-SF) scores using pre/post Paired T-Testing statistical analysis.

The DNP project will help to address a practice gap by helping young BC survivors establish a new normal of survivorship after completing cancer treatment with enhanced coping behaviors and health outcomes in a deeply caring and nurturing virtual health coaching environment.

2.3. Methods and/or Procedures

Briefly discuss, in non-technical language, the research methods which directly involve use of human subjects. Discuss how the methods employed will allow the investigator to address his/her hypotheses and/or research question(s).

The DNP project will be conducted as a prospective, non-randomized, quasi-experimental small-scale pilot project without a comparison group. The project will include pre/post-testing and utilize quantitative methodology through the Paired T-Test to measure the differences between pre-and post-intervention FCR scores. There will also be a qualitative component to the project. A one-time google survey will be administered to each participant at the end of the program to track accountability and participation in the program, evaluate program adaptive objectives/goals, and provide voluntary qualitative post-intervention feedback (see attached survey).

The Fear of Cancer Recurrence Inventory Short Form (FCRI-SF) will be used to assess FCR scores (see attached tool). The FCRI-SF is a brief version of the original 42-item FCRI screening tool. The FCRI-SF tool uses only a portion of the FCRI screening tool known as the FCRI severity subscale consisting of 9-items. FCRI-SF data points will be collected at baseline and ten weeks post-intervention. Permission to use the FCRI-SF tool has been granted by the tool developer and validator Sébastien Simard providing he and his team receive appropriate acknowledgment of their work. A free PDF of the FCRI-SF tool was provided by Sébastien Simard to the principal investigator in the e-mail granting permission for use in this project (see attached e-mails). Potential project participants will be administered the FCRI-SF tool and screened by the principal investigator and/or hospital breast cancer survivorship APRN in person or through e-mail. If a score above 12 is obtained at baseline, participants will become eligible to participate in the study. Demographics that will be collected include first/last name, age/DOB, gender, phone number, and e-mail.

The pilot group of participants will be recruited through the Edward-Elmhurst hospital system in Illinois after attending a one-time survivorship care plan visit at the treatment endpoint and/or upon being identified at follow-up visits during the extended survival period after breast cancer treatment. Informed consent and authorization to participate in the DNP project will be obtained and reviewed by the principal investigator for each participant entering the pilot project.

DNP Project eligibility criteria include female, English-speaking breast cancer survivors between 18 and 59 years old diagnosed with invasive breast cancer (Stage I-III). Participants will be in the extended period of survival and demonstrate a positive FCRI-SF score above 12. If recruitment proves challenging to meet an adequate sample size, inclusion criteria may be extended into the permanent/chronic survival period greater than five years post breast cancer treatment. This remains to be determined. Exclusion criteria include non-English speaking females less than 18 and greater than 60 years old with in-situ (Stage 0) or metastatic (Stage 4) breast cancer in the acute survival period. Participants will be recruited over the course of 1-3 months as needed. The sample size goal of the project is 34, which was calculated using the general power analysis program (G*Power) software 3.1.9.7 Copyright © 1992-2020.

The 10-week APRN-led lifestyle management coaching intervention will take place virtually via Zoom Video Communications. This will eliminate the potential for COVID-19 or other infectious disease-related disruptions to in-person sessions as implementation will occur during the fall/winter seasons (see the attached detailed description of the study intervention for further details). Data will be gathered over a period of 12-14 weeks as needed and will include this 10-week intervention timeframe. Data will be stored in the principal investigator's personal computer and home, as well as in statistical software.

Data analysis will be performed using IBM SPSS Statistics software. The project will compare FCRI-SF score measurements of the study participants before and after the group coaching intervention at baseline and 10 weeks. The Paired T-Test will be used to measure the differences between the pre-and post-intervention FCRI-SF scores. The primary outcome of interest is FCRI-SF scores. Previous research by Peng et al. (2019) has identified an FCRI-SF cutoff score above 12 to establish validity and reliability with high sensitivity, while earlier research by Simard and his team established a cutoff level of 13 (Simard & Savard, 2015).

The predictor variable is participation in the Lifestyle Management Coaching Intervention. Other variables of interest are stated below. The rejection criterion (alpha) will be set at 0.05. The confidence interval (CI) will be examined. The Cohen's d effect size will be measured. A positive difference in baseline and post-intervention FCR-SF scores will indicate to the investigator that the lifestyle management health coaching intervention is effective for decreasing FCR among young breast cancer survivors. The post-intervention survey will also be analyzed. Data analysis will include the assistance of a statistician for accuracy, Dr. Jones from Dissertation Genius.

References

Peng, L., Huang, W., Zhang, W., Xu, Y., Lu, F., Zhong, L., Chen, X., Xu, S., Chen, W., & Li, M. (2019). Psychometric properties of the short form of the fear of cancer recurrence inventory (FCRI) in Chinese breast cancer survivors. Frontiers in Psychiatry, 10(537), 1-7. https://doi:10.3389/fpsyt.2019.00537

Simard, S. & Savard. (2015). Screening and comorbidity of clinical levels of fear of cancer recurrence. Journal of Cancer Survivorship Research and Practice, 9(3), 481-91. https://doi: 10.1007/s11764-015-0424-4

3. Description of Research Sample

3.1. Approximate Number of Subjects: **34**

3.2. Type of human subjects that are involved:
If human subjects are involved, check all that apply

☐ MINORS
if minors are involved, attach a Childs Assent Form

☐ PRISON INMATES

☐ MENTALLY IMPAIRED

☐ PHYSICALLY DISABLED

☐ INSTITUTIONALIZED RESIDENTS

☐ HEALTH CARE DATA INFORMATION
if this line is checked, attach any necessary HIPAA forms

☐ VULNERABLE OR AT-RISK GROUPS *e.g. poverty, pregnant women, substance abuse population*

☐ ANIMALS OR PLANTS

☒ OTHER: Female, English-speaking breast cancer survivors between 18 and 59 years old diagnosed with invasive breast cancer (Stage I-III). Participants will be in the extended period of survival, demonstrate a positive Fear of Cancer Recurrence Inventory Short-Form score (FCRI-SF) above 12, and receive care at the Edward-Elmhurst (EEH) health system.

☐ ANYONE UNABLE TO MAKE INFORMED DECISIONS ABOUT PARTICIPATION

3.3. PARTICIPANT RECRUITMENT

Describe how participant recruitment will be performed. Include how potential participants are introduced to the study. Check all that apply

☐ SAU DIRECTORY

☒ POSTINGS, FLYERS

☐ RADIO, TV

☐ PARTICIPANT POOL
Specify

☐ WEB-BASED SOLICITATION
List the site(s): Specify

☒ E-MAIL SOLICITATION
How addresses obtained: EEH Health System e-mails as approved by hospital administration

☒ OTHER: Study participants will be recruited from the Edward-Elmhurst Hospital (EEH) system in Illinois. Recruitment sites will include primary care, surgical/medical/radiation oncology, and weight management outpatient clinics. Flyers will be used at individual sites. The Breast Cancer Survivorship APRN will be needed to help recruit patients after the survivorship care plan meeting post-cancer treatment. Primary care providers, surgical/medical/radiation breast oncologists, APRNs, and their support staff will be necessary to help with recruitment and ensure the scholarly project is conducted according to best practice/standards. Hospital system marketing may assist with recruitment e-mails as agreeable.

Attach any recruiting materials you plan to use at the end of the document.

4. Content Sensitivity, Privacy, and Confidentiality	
Efforts will be made to keep personal information confidential. We cannot guarantee absolute confidentiality. Personal information may be disclosed if required by law. Identities will be help in confidence in reports in which the study may be published and databases in which results may be stored	
4.1. Does your research address culturally or morally sensitive issues? *If Yes, describe*	☒ Yes ☐ No ☐ N/A
4.2. Will personal identifiers be collected? *If Yes, describe* **Name, age, female gender, pre/post intervention weight, pre/post intervention BMI, cancer stage, extended survival period (y/n), and end of program survey completion (y/n)**	☒ Yes ☐ No ☐ N/A
4.3. Will identifiers be translated to a code? *If Yes, describe* **A number will be assigned to each participant in the order in which they enter the study beginning with number one. First/last names of participants will be limited to an assigned number on all documentation.**	☒ Yes ☐ No ☐ N/A
4.4. Will recordings be made (audio, video)? *If Yes, describe* **Intervention Sessions 1-10 may be recorded in case a participant is unable to attend in real-time for consistency of information.**	☒ Yes ☐ No ☐ N/A
4.5. Does your research include any human health-related information? *If Yes, your research must address HIPAA requirements. Refer to the IRB Manual for more information*	☒ Yes ☐ No ☐ N/A
4.6. How are you planning to protect sensitive/personal/HIPAA information? *Please explain* **There is a risk of loss of confidentiality for the participants. Participation in this research is voluntary and participants can opt out of the study at any point without penalty. Consent for participation will be obtained prior to the start of the study (see attached consent). The identity of participants will be kept protected and confidential. Program participants will be referred to by an assigned number in program documents. Zoom Communications will be used as the virtual platform to protect participant health information. Program participants will participate in the virtual coaching sessions using only their first names and participation in the coaching sessions will be voluntary. All information containing personal identifying information of participants will be kept in a password-protected computer system or locked file system.**	☐ N/A
4.7. Who will have access to data (survey, questionnaires, recordings, interview records, etc.)? *Please list* **Principal Investigator Lisa R. Murphy and the statistician, Dr. Jones, from Dissertation Genius as needed.**	
5. Funding, Costs, and Participant Compensation	
5.1. Is Funding being sought to support this research? ☐ Internal ☐ External *If Yes, describe* Enter	☐ Yes ☒ No ☐ N/A
5.2. Is there a funding risk? *If Yes, describe* Enter	☐ Yes ☒ No ☐ N/A
5.3. Who will keep the financial records? Specify	
5.4. Are participants to be compensated for the study? * Amount $ Enter $ *If Yes, describe* * Type Enter * Source Enter	☐ Yes ☒ No ☐ N/A
5.5. Will participants who are students be offered class credit? *If Yes, describe* Enter	☐ Yes ☐ No ☒ N/A
5.6. Are other inducements planned to recruit participants? *If Yes, describe* Enter	☐ Yes ☒ No ☐ N/A
5.7. Are there any costs to participants? *If Yes, explain* **The cost of Zoom Video Communications' monthly fee for virtual participation and a journal**	☒ Yes ☐ No ☐ N/A
6. Animals/Plants	
6.1. Are the animals/plants being studied on the endangered list?	☐ Yes ☐ No ☒ N/A
6.2. Are Scientific Collection Permits required, i.e. Tennessee Wildlife Resources Agency?	☐ Yes ☐ No ☒ N/A
6.3. Have the animal(s) of this study already been used in a previous study (non-naïve animals)?	☐ Yes ☐ No ☒ N/A
6.4. Will the animal(s) used in this study be used in a future study?	☐ Yes ☐ No ☒ N/A

6.5. WHERE WILL THE ANIMALS BE HOUSED?	☐ YES ☐ NO ☒ N/A
6.6. WILL THE RODENTS (IF APPLICABLE) BE HOUSED IN WIRE BOTTOM CAGES?	☐ YES ☐ NO ☒ N/A
6.7. WILL PLANTS BE USED FOR INSTRUCTIONAL PURPOSES AS PART OF TEACHING A COURSE?	☐ YES ☐ NO ☒ N/A

7. RISKS

Risk is any potential damage or adverse consequences to researcher, participants, or environment. These might include physical, psychological, social, or spiritual risks whether as part of the protocol or a remote possibility.

7.1. ARE THERE ANY RISKS INVOLVED WITH THIS STUDY? ☒ YES ☐ NO ☐ N/A

If Yes, check all that apply

☐ PHYSICAL RISK

May include pain injury, and impairment of a sense such as touch or sight. These risks may be brief or extended, temporary or permanent, occur during participation in the research or arise after.

If Selected, describe Enter

☒ PSYCHOLOGICAL RISK

Can include anxiety, sadness, regret and emotional distress, among others. Psychological risks exist in many different types of research in addition to behavioral studies.

If Selected, describe **Fear of Cancer Recurrence is a sensitive subject after breast cancer diagnosis and treatment. This research study may trigger added feelings of sadness, worry, concern, anxiety, and depression. Every effort will be made by the researcher to ensure that this is a positive and beneficial experience for the participants and that they learn how to experience less fear of cancer recurrence, cope better, and experience restored health through the creation of a nurturing virtual coaching environment.**

Each hour-long session will accommodate a dedicated timeframe for health coaching participants to be able to express their concerns, fears, and questions in a supportive group setting. Pre or post-FCRI-SF screening scores greater than or equal to 22 will generate a referral back to the oncologist for further psychosocial support. The APRN health coach will also be available to participants individually as needed for additional support and to discuss the support available to them through the hospital and nearby cancer wellness center.

☐ SOCIAL RISK

Can exist whenever there is the possibility that participating in research or the revelation of data collected by investigators in the course of the research, if disclosed to individuals or entities outside of the research, could negatively impact others' perceptions of the participant. Social risks can range from jeopardizing the individual's reputation and social standing, to placing the individual at-risk of political or social reprisals.

If Selected, describe Enter

☐ LEGAL RISK

Include the exposure of activities of a research subject "that could reasonable place the subjects at risk of criminal or civil liability."

If Selected, describe Enter

☐ ECONOMIC RISK

May exist if knowledge of one's participation in research, for example, could make it difficult for a research participant to retain a job or find a job, or if insurance premiums increase or loss of insurance is a result of the disclosure of research data.

If Selected, describe Enter

☐ SPIRITUAL RISK

May exist if knowledge of one's spiritual beliefs or lack of, could be exposed which in turn could invoke an economic, social and or psychological risk.

If Selected, describe Enter

7.2. IN YOUR OPINION, DO BENEFITS OUTWEIGH RISKS? ☒ YES ☐ NO ☐ N/A

If Yes, explain

Fear of Cancer Recurrence is a sensitive subject after breast cancer diagnosis and treatment. This research study may trigger the risks of added feelings of sadness, worry, concern, anxiety, and depression. The potential benefits of helping participants learn how to experience less fear of cancer recurrence, cope better, and experience restored health through the creation of a nurturing virtual coaching environment outweigh these risks.

7.3. EXPLAIN HOW YOU PLAN TO MINIMIZE THE RISKS IDENTIFIED ABOVE

The APRN health coach/investigator will make every effort to conduct the lifestyle management coaching intervention in a deeply caring and nurturing health coaching environment so that survivors can feel entirely supported while making the transition into survivorship more effectively and healthfully.

8. RESULTS

8.1. HOW WILL THE RESULTS BE DISSEMINATED?

☒ CLASSWORK ONLY ☐ PUBLISHED ARTICLE ☐ STUDENT CONFERENCE ☐ PROFESSIONAL CONFERENCE

☒ OTHER Poster; Published article, Student, and/or Professional conference if given the opportunity.

Additional Special Requirements or Attachments to the Application

Approvals from other IRBs

Cooperative research projects involve research that involves more than one institution. In these instances, federal law holds each institution responsible for safeguarding the rights and welfare of human subjects and for complying with federal policy; therefore, SAU IRB applications must be made even if there is another institution conducting a review of the same research project. When a study is being carried out at a non-USA site, and approval from other institutional review boards at the foreign site must be sought. The IRB recommends that a copy of each IRB approval be submitted.

Questionnaires/Other Instruments

Any questionnaires, tests, survey instruments or data collections sheets which are not standard and well known must be submitted as part of the application. Structured interview questions and outlines for unstructured interviews also must be included.

Advertisements/Notices/Recruitment Flyers

The text of any advertisement, video display, notice, sign, brochure or flyer used to recruit subjects either should be included as an attachment. It includes documents to which there are Links and/or QR-Codes.

9. APPENDICES AND ATTACHMENTS

Insert all Research appendices and/or attachments. These include the checked in the #1.4 items.
To add an attachment, click inside the insert-frame below and paste your material. To add several attachments: before pasting your material, click on the frame below and use the "+" button (see the pictured below) to add as many frames as many attachments you have. Paste your material.

Start each attachment on a new page by using "Enter" (Windows) or "Return" (Mac) to move to the next page.

Signatures: If submitted by a faculty member, electronic (typed) signatures are acceptable. If submitted by a student, please print out completed form, obtain the faculty advisor's signature, scan completed form, and submit it via e-mail. Only Word Form or PDF files are acceptable submissions.

Lisa R. Murphy
Principal Investigator (PI) or Student

10/4/2022
Date

Faculty Advisor (for student applications)

Click dropdown to enter date
Date

All student applications must be either signed by the faculty advisor then scanned and submitted electronically, or submitted directly by the faculty advisor. All applications should be submitted by email to: irb@southern.edu

[1] Did the investigator complete CITI Training?

SOUTHERN ADVENTIST UNIVERSITY
Power for Mind & Soul

IRB Institutional Review Board FORM B

Version 01/01/2021

RESEARCH PROJECT MODIFICATION

Current Tracking #	Research Tracking #
Date of Approval:	Date of Research Approval by IRB
Category of Approval:	☐ Exempt ☒ Full Review ☐ Expedited ☐ Animal/Plant
Request for	☒ Modification ☐ Research Termination ☐ Annual Review ☐ Research Completion
Date Received:	Reserved for IRB Committee
Date Approval Sent:	Reserved for IRB Committee

PRINCIPLE INVESTIGATOR

RESEARCH TITLE: **A Lifestyle Management Coaching Intervention for Fear of Cancer Recurrence in Young Breast Cancer Survivors**

PRINCIPAL INVESTIGATOR:	EMAIL ADDRESS:	PHONE #:	SCHOOL/DEPARTMENT:
Lisa R. Murphy	**lisarmurphy@southern.edu**	**773-297-1687**	**Nursing**
FACULTY ADVISOR (IF APPLICABLE):	EMAIL ADDRESS:	PHONE #:	
Dr. Jill Buchholz	**jbuchholz@southern.edu**	**423-236-2343**	

Provide the required information in the space available. If additional space is needed, attach a separate sheet or expand that section of the form. Both scanned original signatures and typed electronic signatures are acceptable. All forms and research instruments should be submitted by email to irb@southern.edu.

INCOMPLETE SUBMISSIONS WILL BE RETURNED TO THE APPLICANT WITH REVIEW

MODIFICATIONS

PROJECT STATUS

Select the status of the project

☒ ACTIVE – Project ongoing

☐ COMPLETE – Project Completed!

Select changes status for the project

☐ NO CHANGES are planned and the project will continue as previously approved by the IRB

☒ CHANGES ARE PLANNED. Please complete the section below

NOTIFICATION OF CHANGES

Check the appropriate boxes below and provide additional information where appropriate (e.g. new title, new PI, description of changes, etc.). If no changes are planned or project is completed, please leave blank.

☐ CHANGE TO THE PROJECT TITLE

If different from your last approval letter, please provide new title:
Add Title

☐ CHANGE OF INVESTIGATORS

If there are change(s) in regard of principal or co-principal investigators(s), other collaborators, or change in faculty advisor(s), provide their name(s):
List Names

Version 01/01/2021

☐ CHANGE AFFECTING PARTICIPATION OF HUMAN SUBJECTS

If there is changes(s) to project which will affect participation of human subjects, revise and amend any relevant sections of Form A and submit these changes with a Form B. This requires a new Form A as well as this Form B. Remember, there is no change too small to report to IRB:

Outline the Change(s)

☐ CHANGE TO RESEARCH INSTRUMENTS

If there is change(s) to informed consent forms and/or assent forms(s), submit new consent Forms with this Form B.

☐ CHANGE TO LOCATION

If there are any additional locations for conducting project, submit with this Form B a copy of the letter(s) from these organizations which have given permission for you to conduct your research in their institution. The letters should be on the institution's own letterhead. List the new locations where research is being completed:

List New Locations

☐ CHANGE IN RISKS TO SUBJECTS

If you have encountered unexpected risks to research Subjects (e.g., breaches of confidentiality) or to yourself (e.g., angry parents, threats of violence), submit a copy of the Incident Report Form(s) with this Form B and describe how you have or will resolve the problem:

Describe the Change(s)

☒ OTHER CHANGE(S)

If there are any other changes, explain these changes:

A request has been made by the Edward-Elmhurst Health (EEH) System to use this DNP project/study for hospital accreditation. The accrediting bodies for the Commission on Cancer (COC) and NAPBC (National Accreditation Program for Breast Centers) have a standard for number of patients enrolled in clinical trials. In order to meet this standard for each, there are percentages of our analytical cases (or those diagnosed at EEH) who must be enrolled in clinical trials. The plan is to use the participant numbers from this study, to count toward their clinical trial accrual for both accreditation bodies. Contact for EEH: Jessica Schnase, Systems Manager EEH Cancer Center Research- Jessica.schnase@eehealth.org, 630-646-6072

Signatures: If submitted by a faculty member, electronic (typed) signatures are acceptable. If submitted by a student, please print out completed form, obtain the faculty advisor's signature, scan completed form, and submit it via e-mail. Only Word Form or PDF files are acceptable submissions. All forms should be submitted by email to: irb@southern.edu

Lisa R. Murphy
Principal Investigator (PI) or Student

1/10/2023
Date

Faculty Advisor (if applicable)

Click dropdown to enter date
Date

Edward-Elmhurst HEALTH *Healthy* Driven

Institutional Review Board Application for a New Study

I. Project & Investigator Information	
This form should not be used for approval of Humanitarian Use Device (HUD) use at EEH.	
1. Project (Protocol) Title: A Lifestyle Management Coaching Intervention for Fear of Cancer Recurrence (FCR) in Young Breast Cancer Survivors	
2. Principal Investigator Name: Lisa R. Murphy, APRN	3. Principal Investigator (check one): [X] is an Edward-Elmhurst Health Employee [ ] has staff privileges at Edward-Elmhurst Health
4. Mailing Address: (Street, City, State, Zip) Edward-Elmhurst Medical Group 1200 S. York Rd Elmhurst, IL 60126 331-221-6140	5. Contact Phone Number: 331-221-6140 24-HOUR: 773-297-1687 6. Email: LISA.MURPHY2@EEHEALTH.ORG LISARMURPHY@SOUTHERN.EDU

7. Name(s) Of Sub-Investigators	Department	Email Address
N/A		
8. Name(s) Of Research Staff	Department	Email Address
N/A		

9. Is this research sponsored by any research grant or contract? [ ] Yes [X] No
*If yes, please disclose names of all sponsoring agencies/organizations funding this research?
(list name, contact name, telephone and email)
N/A

10. Have you submitted this research project to any other IRB (besides the Edward-Elmhurst Health IRB)?

[X] **Yes [ ] No**

*if yes, please provide the name(s) of the other IRB(s)

Southern Adventist University School of Nursing
4881 Taylor Circle
Collegedale, TN 37315

111. About This Research Project

1. **Date of EEH Institutional Research Oversight Committee (IROC} approval:** 09/15/2022

2. **Study Abstract:** Provide a brief description of the study's purpose, objectives, and hypothesis in 200 words or less.
The purpose of the DNP Project is to conduct an APRN-led lifestyle management coaching intervention designed by the researcher to help to decrease Fear of Cancer Recurrence (FCR) and improve health outcomes in young breast cancer (BC) survivors demonstrating high screening scores.

   The DNP Project Inquiry: How will a ten-week APRN-led lifestyle management-focused practice intervention lead to decreased FCR among young female BC survivors demonstrating abnormally elevated screening scores during the extended survival period?

   The project aims to help young female breast cancer survivors (a) gain restorative health physically, mentally, socially, and spiritually after cancer treatment, (b) experience less FCR as evidenced by decreased FCR-SF scores to an acceptable range(< 12) after participation in a 10-week virtual group coaching intervention, (c) live a longer, more balanced life after implementation of evidence-based healthful lifestyle modifications that meet their physiologic needs, (d) learn how to develop self-love and purpose and live the legacy they want to leave behind, (e) change compensatory/compromised adaptation to an integrated healthier coping response, and (f) learn how to adapt to their changing environment more healthfully and become better integrated into their new normal after breast cancer treatment.

   The project objectives are (a) To plan, develop, implement, and evaluate a 10-week evidence-based lifestyle management virtual coaching intervention for young female breast cancer survivors by August 2023 and (b) To evaluate Fear of Cancer Recurrence Inventory Short Form (FCRI-SF) scores using pre/post Paired T-Testing statistical analysis.

   The project will help to address a practice gap by helping young BC survivors establish a new normal of survivorship after completing cancer treatment with enhanced coping behaviors and health outcomes in a deeply caring and nurturing virtual health coaching environment.

   The project hypothesis: There is a positive difference in baseline and post-intervention FCR scores; therefore, the intervention is effective. The null hypothesis: There is no difference in baseline and post-intervention FCR scores; therefore, the intervention is ineffective.

3. **Summary of Methods:** Describe the study design and methods in simple language. This description should include Inclusion/exclusion criteria and a complete list study methods/treatments, procedures, measurements, and data analyses (statistical methodology) that are planned. Include how any questionnaires, surveys and other instruments will be employed. Insert additional pages as necessary.
   The DNP Project will be conducted as a prospective, non-randomized, quasi-experimental small-scale pilot project without a comparison group. The project will include pre/post-testing and utilize quantitative methodology through the Paired T-Test to measure the differences between pre and post-intervention FCR scores. There will also be a qualitative component to the project. A one-time google survey will be administered to each participant at the end

of the program to track accountability and participation in the program, evaluate program adaptive objectives/goals, and provide voluntary qualitative post-intervention feedback (see attached survey).

The Fear of Cancer Recurrence Inventory Short Form (FCRI-SF) will be used to assess FCR scores. The FCRI-SFis a brief version of the original 42-item FCRI screening tool. The FCRI-SFtool uses only a portion of the FCRI screening tool known as the FCRI severity subscale consisting of 9-items. FCRI-SF data points will be collected at baseline and ten weeks post-intervention. Permission to use the FCRI-SF tool has been granted by the tool developer and validator Sebastien Simard providing he and his team receive appropriate acknowledgment of their work. A free PDF of the FCRI-SF tool was provided by Sebastien Simard to the principal investigator in the e-mail granting permission for use in this project (see attached e-mails). Potential project participants will be screened by the principal investigator using the FCRI-SF tool and if a score above 12 is obtained at baseline, they will become eligible to participate in the study.

The pilot group of participants will be recruited through the Edward-Elmhurst hospital system in Illinois after attending a one-time survivorship care plan visit at the treatment endpoint and/or upon being identified at follow-up visits during the extended survival period after breast cancer treatment. Informed consent and authorization to participate in the DNP project will be obtained and reviewed by the principal investigator for each participant entering the pilot project.

DNP Project eligibility criteria include female, English-speaking BC survivors between 18 and 59 years old diagnosed with invasive breast cancer (Stage 1-111). Participants will be in the extended period of survival and demonstrate a positive FCRI-SF score above 12. If recruitment proves challenging to meet an adequate sample size, inclusion criteria may be extended into the permanent/chronic survival period greater than five years post breast cancer treatment. This remains to be determined. Exclusion criteria include non-English speaking females less than 18 and greater than 60 years old with in-situ (Stage O) or metastatic (Stage 4) breast cancer in the acute survival period. Participants will be recruited over the course of 1-3 months as needed. The sample size goal of the project is 34, which was calculated using the general power analysis program (G*Power) software 3.1.9.7 Copyright© 1992-2020.

The 10-week APRN-led lifestyle management coaching intervention will take place virtually via Zoom Video Communications. This will eliminate the potential for COVID-19 or other infectious disease-related disruptions to in-person sessions as implementation will occur during the fall/winter seasons (see the attached detailed description of the study intervention for further details). Data will be gathered over a period of 12-14 weeks as needed and will include this 10-week intervention timeframe. Data will be stored in the principal investigator's personal computer and home, as well as in statistical software.

Data analysis will be performed using IBM SPSS Statistics software. The project will compare FCRI-SF score measurements of the study participants before and after the group coaching intervention at baseline and 10 weeks. The Paired T-Test will be used to measure the differences between the pre-and post-intervention FCRI-SF scores. The primary outcome of interest is FCRI-SF scores. Previous research by Peng et al. (2019) has identified a FCRI-SF cut off score above 12 to establish validity and reliability with high sensitivity, while earlier research by Simard and team established a cutoff level of 13 (Simard & Savard, 2015).

The predictor variable is participation in the Lifestyle Management Coaching Intervention. Other variables of interest are name, age, female gender, pre/post intervention weight, pre/post intervention BMI, cancer stage, extended survival period (y/n), and end of program survey completion (y/n). The rejection criterion (alpha) will be set at 0.05. The confidence interval (Cl) will be examined. The Cohen's d effect size will be measured. A positive difference in baseline and post-intervention FCR-SF scores will indicate to the investigator that the lifestyle management health coaching intervention is effective for decreasing FCR among young breast cancer survivors. The post-intervention survey will also be analyzed. Data analysis will include the assistance of a statistician for accuracy, Dr. Jones from Dissertation Genius.

References

Peng, L., Huang, W., Zhang, W., XL:, Y., Lu, F., Zhong, L., Chen, X., Xu, S., Chen, W., & Li, M. (2019). Psychometric properties of the short form of the fear of cancer recurrence inventory (FCRI) in Chinese breast cancer survivors. Frontiers in Psychiatry, 10(537), 1-7. https://doi:10.3389/fpsyt.2019.00537

Simard, S. & Savard. (2015). Screening and comorbidity of clinical levels of fear of cancer recurrence. Journal of Cancer Survivorship Research and Practice, 9(3), 481-91. https://doi: 10.1007/sll764-015-0424-4

1. **Benefits:** Describe the benefits to the individual and/or mankind.

Breast Cancer survivors often experience fear of cancer recurrence (FCR). FCR is defined as the fear, concern, or worry that cancer will progress or come back (Lebel, et al., 2016). FCR is associated with impaired functioning, distress, and lower quality of life. Approximately 50% of BC survivors experience moderate to severe levels of FCR, and this can be as high as 70% for women 45 years old and younger (Gormerly et al., 2022; Thewes et al, 2012; Smith et al., 2020). Furthermore, approximately 7% of cancer survivors experience severe and disabling FCR (Butow et al., 2018).

Previous research has identified that an unmet need of BC survivors is learning how to manage FCR. FCR is one of the greatest concerns of cancer survivors after treatment completion and a gap in age-appropriate support exists. BC patients are faced with establishing a new normal after completing cancer treatment and often feel lost in transition when doing so. This tim:=frame, the extended survival period, can be dominated by FCR. Young BC survivors may benefit from additional support/tailored interventions during surveillance periods to help minimize potential manifestations and triggers of FCR. This DNP project will aim to address this survivorship concern in a deeply caring and nurturing health coaching environment so that survivors can make the transition into survivorship more effectively while also experiencing enhanced coping and health, which is a benefit to this population.

References

Butow, P., Sharpe, L., Thewes, B., Turner, J., Gilchrist, J., & Beith, J. (2018). Fear of cancer recurrence: A practical guide for clinicians. TheOncologyJournal.com, 32-38

Gormley, M., Ghazal, L., Fu, M.R., Van Cleave, J.H., Knobf, T., & Hammer, M. (2022). An integrative review on factors contributing to fear of cancer recurrence among young adult breast cancer survivors. Cancer Nursing, 45(1), E10-E26. https://doi:10.1097/NCC.0000000000000858

Lebel, S., Ozakinci, G., Humphris, G., Mutsaers, B, Thewes, B., Prins, J., Dinkel, A., Butow, P. (2016). From normal response to clinical problem: Definition and clinical features of fear of cancer recurrence. Supportive Care in Cancer, 24, 3265-3268. https://doi:10.1007/s00520-016-3272-5

Smith, A.B., Costa, D. Galica, J., Lebel, S., Tauber, N., Jasperine van Helmondt, S., Zachariae, R. (2020). Spotlight on the fear of :ancer recurrence inventory (FCRI). Psychology Research and Behavior Management, 13, 1257-1268

Thewes, B., Butow, P., Bell, M.L., Beith, J., Stuart-Harris, R., Grossi, M., Capp, A., & Dalley, D. (2012). Fear of cancer recurrence in young women with a history of early-stage breast cancer: a cross-sectional study of prevalence and association with health behaviours. Support Care Cancer, 20, 2651-2659. https://doi:10.1007/s00520-011-1371-x

2. **Risks:** Describe the risks to the subject and the precautions that will be taken to minimize them. Note that the concept of risk goes beyond physical risk and includes psychological, social and financial risk(s).

Fear of Cancer Recurrence is a sensitive subject after breast cancer diagnosis and treatment. This research study may trigger added feelings of sadness, worry, concern, anxiety, and depression. Every effort will be made by the

researcher to ensure that this is a positive and beneficial experience for the participants and that they learn how to experience less fear of cancer recurrence, cope better, and experience restored health through the creation of a nurturing virtual coaching environment. Each hour-long session will accommodate a dedicated timeframe for health coaching participants to be able to express their concerns, fears, and questions in a supportive group setting. Pre or post-FCRI-SF screening scores greater than or equal to 22 will generate a referral back to the oncologist for further psychosocial support. The APRN health coach will also be available to participants individually as needed.

There is also a risk of loss of confidentiality for the participants. Participation in this research is voluntary and participants can opt out of the study at any point without penalty. Consent for participation will be obtained prior to the start of the study. The identity of participants will be kept protected and confidential. Program participants will be referred to by an assigned number in program documents. Zoom Communications will be used as the virtual platform to protect participant health information. Program participants will participate in the virtual coaching sessions using only their first naml?s and participation in the coaching sessions will be voluntary. All information containing the personal identifying information of participants will be kept in a password-protected computer system or locked file system.

1. **Alternative Therapy:** Describe any alternative therapy(ies) available to the subject.
   The alternative therapies available to the participants include guided meditation, journaling, and health coaching.

7. Please list each item for which you are requesting IRB review and approval *(including, but not limited to, the study protocol, lnvestigational Drug/Device Brochure, recruitment materials, educational materials, consent form(s), data collection tools, etc.).* Each document should be labeled with a version number and date.	
• IRB Application #1	• Screening Tool Permission for Use E-mail #7
• Protocol/Intervention #2	• Contents of end of program survey #8
• Informed Consent #3	• Flyer #9
• Participant Introduction Letter #4	• Meditation & Wellness Vision #10 & #11
• Letter of Agreement (EEH) #5	• CITI Certificate #12
• FCR-SFScreening Tool #6	• Intervention Supporting Documents #13

III. Subject Enrollment Information

Total number of sites/ total number of subjects to be enrolled at ALL sites:	**2 / 34**
Total number of subjects to be enrolled at Edward-Elmhurst Health:	**34**

1. **How will you recruit research subjects to participate in this study? (Check all that apply)**
   [X] From your own patient population.
   [ ] By accessing records for patients other than your own which requires a partial waiver of authorization
   [ ] Using a database other than the Principal Investigator's contacts.
   Please describe the type of database (i.e. disease registry, CRO/SMO,) being used, the protections for subject confidentiality and the method by which subjects will be contacted:

   Study participants will be recruited from the Edward-Elmhurst Hospital (EEH) system in Naperville and Elmhurst, IL. Recruitment sites will include primary care, surgical/medical/radiation oncology, and weight management outpatient clinics. Flyers will be used at individual sites. The Breast Cancer Survivorship APRN will be needed to help recruit patients after the survivorship care plan meeting post-cancer treatment. Primary care providers, surgical/medical/radiation breast oncologists, APRNs, and their support staff will be necessary to help with recruitment and ensure the scholarly project is conducted according to best practice/standards. Marketing will assist with recruitment e-mailc; as agreeable.

2. **I will be recruiting and interacting with the following vulnerable populations as part of this study:**

[X] Edward-Elmhurst Health employees	Minors (under 18)	Nursing Home Residents
Persons with Known Mental Illness	Pregnant women	Cognitively impaired
Illiterate or Non-English speaking	Neonates	None of the above

   Please note that the EEH /RB is not constituted to review and approve research that involves prisoners.

3. **If any of the above vulnerable populations will be included in your study, please describe the safeguards that will be used to sufficiently protect them?** EEH employees may wish to participate in this study and will be eligible. See Section II, question #5 for details on safeguards that will be used to protect them.

4. **Will you be using any advertising or recruitment materials for this study? [X] Yes [ ] No**
   If yes, please disclose all methods of advertising and recruitment (i.e. brochures, emails, flyers, newsletters, newspaper, TV, radio, phone screens, internet, etc.) and ensure these documents are included in the materials to be approved (Section II, Question 7): Flyer, Participant Introduction Letter for E-mails, and additional E-mails as approved by EEH Marketing Department (to be determined) during the recruitment period.

5. **Will subjects be compensated for their participation in the study? [ ] Yes [X] No**
   If yes, please attach a schedule of payment (i.e. amount per visit, when payment will occur): N/A

IV. Informed Consent Process

1. Please check one of the following *(either a, b or c)*:

a. [X] My consent form is attached for IRB review and approval. As a reminder, the draft consent must be prepared using the Edward-Elmhurst Health consent template. *Before submitting any consent to the Edward-Elmhurst Health /RB, please obtain prior approval of the draft consent by the study Sponsor.*

i. [ ] I am recruiting minors and have attached an assent for IRB review and approval

ii. [ ] I am recruiting non-English speaking subjects and have attached a certified translated consent form (and other translated study- related documents) for IRB review and approval

b. [ ] I am requesting an alteration of consent by using a "Letter of Introduction" in lieu of a formal consent form. Additionally, my survey (or other subject data collection tool) discloses the statement, "Your completion of this survey/form demonstrates your consent to participate in this research project."

c. [ ] I am requesting a waiver of consent/authorization as *(Check all that apply)*

i. [ ] No protected health information will be collected **OR** all data will first be de-identified before collection

ii. [ ] The research could not practicably be conducted without the waiver of consent/authorization due to difficulty in obtaining individual subject authorizations

2. What opportunity will be afforded to the prospective subject (or the subject's legally authorized representative) to consider whether or not to participate? *(check all that apply):*

[X] Review informed consent information in detail with potential subject

[X] Provide opportunity for subjects to review consent information and ask questions at a later time

[ ] Mail consent document in advance of visit to allow extra time for review

[ ] Other (please specify):

3. Where will the consent process take place? Zoom and/or in-person-whichever is most convenient for the participant

V. Provisions for Safety Monitoring

1. All research requires safety monitoring, but not necessarily by a formal research committee. Describe the provisions for safety monitoring for this project: Each hour-long session will accommodate a dedicated timeframe for health coaching for participants to be able to express their concerns, fears, and questions in a supportive group setting. Pre or post-FCRI-SF screening scores greater than or equal to 22 will generate a referral back to oncologist for further psychosocial support. The APRN health coach will also be available to participants individually as needed for additional support.

VI. HIPAA/ Privacy and Confidentiality of Data

1. What Protected Health Information (PHI)] will be collected, used or disclosed for your research project?

[X] Names

[ ] Addresses or Geographic Subdivisions smaller than a State

[X] Telephone/Fax Numbers

[X] E-Mail Addresses

[X] Any elements of date(s), except year, directly related to an individual (birth date, admission/discharge date, date of death, etc.)

[ ] All ages over 89 and all elements of dates (including year) indicative of such age except when aggregated into a single category of "age over 90"

[ ] Medical Record Numbers

[ ] Account or Insurance (Health Plan) Identification Numbers

[ ] Social Security Numbers

[ ] Certificate/License Numbers

[ ] Vehicle/Device Identifiers and/or serial numbers, including license plate numbers

[ ] Biometric identifiers, including voiceprints and fingerprints

[ ] Full-face photographic images and any comparable images

[X] Any other unique identifying number, characteristic or code not listed above. Please explain: Fear of Cancer Recurrence Inventory Short Form (FCRI-SF) scores, age, female gender, pre/post intervention weight, pre/post intervention BMI, cancer stage, extended survival period, and end of program survey

[ ] No data elements collected will be identifiable.

2. What is the source of the individual identifiers/PHI for your research? The participants and EEH support staff as described in Section Ill, Question 1. Each participant will be assigned a number beginning at #1 in the order that they enter into the study. All subseque11t collected information including other variables: Fear of Cancer Recurrence Inventory Short Form (FCRI-SF) scores, age, female gender, pre/post intervention weight, pre/post intervention BMI, cancer stage, extended survival period, and end of program survey will be associated with this number.

3. Identify anyone outside of Edward-Elmhurst Health who will receive the individual identifiers/PHI. (i.e. *researchers from other institutions collaborating on this research, research sponsors*, etc.). 1. Statistician support (Dissertation Genius/University faculty Dr. Bob Chase and Dr. Jill Buchholz), 2. Siemard Sebastien and team (FCRI-SF tool developer/validator). They have requested that in order to continue the validation processes on the FCRI-SF in different populations and languages, they would like me to transmit my FCRI-SF data to them at the end of the study if it is possible to obtain a data share agreement. They would also like to be kept informed of study findings when they are available.

4. What precautions will be used to maintain the confidentiality of the individual identifiers/PHI *(check all that apply)?*

[X] Paper based records will be kept in a secured location and only accessible to personnel involved in the study

[X] Computer based files will only be made available to personnel involved in the study through the use of access privileges and passwords.

[X] Identifiers will be removed from study-related information once all data is collected and verified.

[ ] PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project or for other research for which the use or disclosure of PHI would be permitted by HIPAA.

[X] Other (specify): See Section 11, Question 5

VII. IRB Submission Reminders

Incomplete and/or handwritten submissions will be returned to the study team without further review.

Required Human Subjects' Protection Training

Online training is required for all individuals involved in the design, implementation or analysis of research with human subjects. Training must be completed via the CITI program (www.citiprogram.org). Instructions for registering and completing CITI training are available within the Office of Research Administration page located on the EEH intranet. // ***you are uncertain as to which CIT/ course to take, please contact the Office of Research Administration.***

CITI refresher courses are required every 3 years. No IRB approval can be issued until the assigned CITI training is completed.

Conflict of Interest Disclosure and Conflict of Interest Training

Conflict of Interest disclosures are reouired for any individual conducting or supporting research that qualifies as a clinical trial[1]. Conflict of Interest disclosures are managed by Edward-Elmhurst Health Corporate Compliance. Complete the "COi Fax Notification of a New Research Study" (available on the EEH intranet under "Office of Research Administration") and follow the submission directions on the form.

Individuals who must disclose Conflicts of Interest (as described above) must also complete the "Conflict of Interest" CITI Course in addition to the required human subjects' protection training.

How to Submit the Completed Application

1. Email the completed application to irb@eehealth.org along with electronic copies of all study documents for which you are seeking approval (consents, surveys, letters, data collection tools, etc.) or support the study (drug/device brochures, letters of support, etc.)
2. Mail the signed copy of the completed application to the EEH Office of Research Administration, the offices of which are located at Edward Hospital in the Education Center.

VIII. Name of Person Completing This Form

LISA R MURPHY, APRN
Printed name of person completing this form

ELMHURST HOSPITAL/BARIATRICS AND WEIGHT MANAGEMENT/FAMILY NURSE PRACTITIONER
Organization/Department and Title

10/7/2022
Date

[1] *a study, regardless of funding, where human participants are prospectively assigned specific interventions according to a research plan or protocol so that researchers can evaluate the effects of the intervention on biomedical or health-related outcomes.*

Edward-Elmhurst HEALTH *Healthy* Driven

Appendix A
Principal Investigator's Statement of Compliance Assurance

As Principal Investigator, I have ultimate responsibility for the performance of this study, the protection of the rights and welfare of the human subjects, and strict adherence by all sub-investigators and research staff to all Edward-Elmhurst Health Institutional Review Board (EEH IRB) requirements, institutional policies and procedures, federal regulations, and state statutes for human subject research. I hereby assure the following:

1. The information provided in this application is accurate to the best of my knowledge.

2. All individuals involved in the design, implementation or analysis of the protocol are listed in this application are qualified by education, training, and experience to perform his/her respective task and have been adequately trained in good clinical practice and the protection of human subjects in research through completion of CITI modules. Additional study team members will be added to protocol via amendment when necessary in order to include the appropriate expertise for carrying out the protocol.

3. All individuals listed in this application as study team members have been provided training in the study procedures (as outlined in this application and study protocol). All study procedures involving human subjects will be performed under my supervision or the supervision of a sub-investigator listed on this application. For clinical investigations sponsored by industry, members of the study team will be compliant with all requirements set forth in the clinical protocol and contract. This includes the performance of all protocol-required testing, maintenance of complete and accurate records as per the sponsor's requirements, and complete and timely communication with the sponsor and EEH IRB.

4. I will not engage in any research activities involving human subjects without obtaining initial IRB approval nor will I implement any changes to the IRB-approved protocol, except where necessary to eliminate immediate hazards to the subjects.

5. I will ensure the rights and welfare of research subjects is protected; the health, safety and privacy of the individual patient/subject must be the first priority throughout the study.

6. Any Protected Health Information (PHI) used and disclosed in connection with this research will not be reused or disclosed to any person or entity other than those authorized to receive it, except as required by law and/or for authorized oversight of the research.

7. All recruiting and advertising materials will be approved by the EEH IRB prior to use. Additionally, in accordance with American Medical Association ethical guidelines and Illinois law, no member of the study team, including myself, will make or accept any payments for referral of patients to research studies.

1. When applicable, the most recently approved version of the consent form will be used when consenting a subject. Additionally, the informed consent process will conducted in a manner as to ensure that the person consenting to the research has had all questions answered to their satisfaction. The original signed consent form(s) should be retained in a secure file separate from the subject's study records.

2. The EEH IRB will be provided with accurate and up-to-date information regarding the research, including progress reports to secure renewal of the research at intervals specified by the EEH IRB and federal regulations.

3. All unanticipated problems and events that present risks to subjects or others, including protocol violations/deviations and their outcomes/resolution, will be reported to the EEH IRB in compliance with EEH policies and procedures.

4. I will report, and ensure that all members of the research team report, all changes in financial disclosure and Conflicts of Interest to Edward-Elmhurst Health Corporate Compliance.

I further understand that:

1. Failure to comply with any of the above may result in immediate closure of this study.
2. This study will be subject to routine audits by the EEH IRB or designee thereof, and the results of such audits may be shared with, but limited to, appropriate Department Chairpersons and/or the Edward-Elmhurst Health Institutional Official at the discretion of the EEH IRB.
3. Study records must be maintained for a minimum of 3 years after closure, or as specified by the sponsor of the research, whichever is longer.

Please read the following statement and acknowledge by signing below:

I accept full responsibility for the ethical and scientific conduct of this research and assure that all applicable Edward-Elmhurst Health and federal regulations, policies and procedures relative to the protection of human subjects involved in this research will be followed.

Lisa K Murph, APRN — 01/7/22

Principal Investigator Signature **Date**

Edward-Elmhurst Health Administrator Signature **Date**

(authorized representative of the clinical area where the research will occur)

Appendix C: Informed Consent

Edward-Elmhurst HEALTH | Healthy Driven

INFORMED CONSENT & AUTHORIZATION TO PARTICIPATE IN A RESEARCH STUDY

TITLE OF RESEARCH STUDY: **A Lifestyle Management Coaching Intervention for Fear of Cancer Recurrence (FCR) in Young Breast Cancer Survivors**

Principal Investigator:

Lisa R. Murphy, APRN

Edward-Elmhurst Medical Group

Phone: 331-221-6140 (work) or 773-297-1687 (cell)

Lisa.murphy2@eehealth.org

Introduction

You are being asked to participate in a research study that is being conducted by the Principal Investigator to fulfill the educational requirements to obtain a Doctor of Nursing Practice (DNP) from Southern Adventist University. Please take the time to read the information in this form carefully. You should feel free to ask any questions you may have. Your decision on whether or not to participate will not affect your current or future medical care at Edward Hospital or Elmhurst Memorial Hospital.

Why is this study being done?

This study aims to address an unmet need that some young breast cancer survivors experience, which is learning how to effectively manage their Fear of Cancer Recurrence (FCR), or the fear, concern, or worry that their cancer will progress or come back. You are eligible to participate in this study because you are a female, English-speaking breast cancer survivor aged 18-59 that has completed treatment for invasive

breast cancer (Stage I-III) and screened positive for unmanaged Fear of Cancer Recurrence (FCR) on the study screening tool called the Fear of Cancer Recurrence Inventory Short Form (FCRI-SF).

The purpose of the research study is to use a lifestyle management-focused group coaching intervention to help young breast cancer survivors transition into a "new normal" of survivorship after breast cancer treatment which is focused on developing decreased fear of cancer recurrence, restored health, and enhanced coping after participation in a group virtual lifestyle management coaching intervention. The intervention to be used is consistent with the National Comprehensive Cancer Network (NCCN), American Institute for Cancer Research (AICR), American Academy of Lifestyle Medicine (ACLM) guidelines, and other trusted lifestyle management resources. The intervention and study procedures are described below.

How many people will take part in the study?

The aim is to have at least 34 participants in this study.

How long will I be in the study?

The lifestyle management-focused group coaching intervention will last approximately 10 weeks with weekly group coaching along with other young breast cancer survivors.

What will happen if I take part in this research study?

The group coaching intervention will be led by the Principal Investigator, who is an Advanced Practice Nurse nationally certified health coach, and take place in a confidential virtual environment called Zoom over 10 weeks. You must have access to Zoom via computer, smartphone, or tablet to participate in this study.

The group coaching intervention will include a total of 10, 1-hour-long weekly group sessions that will focus on empowering survivors through the 8 pillars of the FEARLESS Framework: Fearing Less, Eating Well/Nutrition, Activity, Rest/Restoration, Love of Self/Purpose, Environment, Sleep, and Stress Management.

Each weekly group session will focus on 1 of the 8 pillars of the FEARLESS Framework for a total of 10 sessions. At each session, you will receive evidence-based education and participate in health coaching and activities designed to help decrease your fear of cancer recurrence, restore your health, and help

you cope after breast cancer treatment. You will also be asked to complete the FCRI-SF screening tool at the introduction and conclusion sessions.

You will also be asked to participate in a 10-day clean eating and lifestyle modification challenge. More information regarding the modification challenge will be provided by the Principal Investigator during the study.

You will be asked to complete a survey when the study ends. This survey will track your accountability and participation in the intervention as well as evaluate the project goals.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the principal investigator if you are thinking about stopping or decide to stop. The principal investigator may stop you from taking part in this study at any time for the following reasons:

- if she believes it is in your best interest;
- if you do not follow the study rules;
- if the study is stopped

Will there be any discomforts and/or risks?

Fear of Cancer Recurrence is a sensitive subject after breast cancer diagnosis and treatment. This research study may trigger added feelings of sadness, worry, concern, anxiety, and depression. Every effort will be made by the principal investigator to ensure that this is a positive and beneficial experience for you and that you learn how to experience less fear of cancer recurrence, cope better, and experience restored health.

You will also be encouraged to build a deeper, more empowering, and trusting relationship with yourself and develop spiritually during particular program sessions. The intervention includes some faith-based activities required by Southern Adventist University (the principal investigator's graduate school). If any activity makes you uncomfortable, please discuss your concerns directly with the principal researcher Lisa Murphy so that you can better decide if you would like to still participate in the study.

Risk of loss of confidentiality

There is a risk of loss of confidentiality if your medical information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. Your personal information will be stored in the Edward-Elmhurst Health encrypted server/computer or locked file system.

Are there benefits to taking part in the study?

You may experience benefits physically, mentally, socially, and spiritually from being in this study and may experience decreased Fear of Cancer Recurrence. We anticipate you will experience enhanced coping and restored health after participation in the FEARLESS lifestyle management coaching intervention.

What other choices do I have if I do not take part in this study?

You do not have to take part in this research study. Participation is voluntary.

Will my medical information be kept private?

Federal privacy laws require the researchers conducting this study to ask for permission from research participants to use and share their protected health information for the purposes of this research study. Generally, only people on the research team will know that you are in the research study and will see your information

The people working on the study will collect information about you, as described in this consent form. To conduct this study, the principal investigator will be collecting your first and last name, age, phone number, and e-mail. You will be referred to by an assigned number in program documents. Other study participants will be able to see you during the group virtual coaching sessions via Zoom, but you will be asked to participate using only your first name.

We will do our best to make sure that your personal information collected and shared as part of this study will be kept private. However, we cannot guarantee total privacy.

Your personal information may be given out if required by law. It may also be shared with representatives of government organizations, ethics and/or institutional review boards, and other persons who are required to watch over the safety and conduct of research.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. No information that may identify you will be shared outside of Edward-Elmhurst Health, including with any agent or representative of Southern Adventist University.

Please note that:

- You do not have to consent to this Authorization to use or disclose protected health information, but if you do not, you will not be allowed to participate in the Research.
- You (or your legally authorized representative) may change your mind and revoke this authorization at any time. To revoke this Authorization to use or disclose protected health information, you must write to ***Lisa R. Murphy; Edward-Elmhurst Medical Group, 1200 S York Rd, Elmhurst, IL 60126, or lisa.murphy2@eehealth.org***. However, if you revoke this Authorization, you will no longer be allowed to participate in the Research. Also, even if you revoke this Authorization to use or disclose protected health information, the information already obtained by the principal investigator may be used and disclosed as permitted by this Authorization and the Informed Consent.

This Authorization to use or disclose protected health information does not have an expiration (ending) date.

What are the costs of taking part in this study?

You may be asked to purchase items to meet session goals such as a journal, groceries, and other lifestyle modification items of your choice. Additionally, you will be responsible for any service provider/internet costs to access the Zoom group meetings.

Will I be paid to participate in this study?

You will not receive any compensation for being in this research study.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you, and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

If you withdraw completely from the study, no further information will be collected, and your participation will end. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

Who can answer my questions about the study?

You have the right to ask any questions you may have about this research. If you have questions or concerns or believe you may have developed an injury while participating in this research, contact Lisa R. Murphy, at 773-297-1687 (cell) or 331-221-6140 (work).

If you have questions or concerns regarding your rights as a research participant or about your privacy and the use of your personal health information, you may contact the Edward-Elmhurst Health Institutional Review Board Office at irb@eehealth.org.

Signature and Consent/Permission to be in the Research

The purpose of this study, procedures to be followed, and risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have additional questions. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed copy of this consent form.

Participant: By signing this consent form, you indicate that you are voluntarily choosing to take part in this research.

_____	_____	_____
Signature of Participant	Date	Printed Name

Person Explaining the Research: Your signature below means that you have explained the research to the participant/participant representative and have answered any questions he/she has about the research.

_____	_____	_____
Signature of person who explained this research	Date	Printed Name

Appendix D: Participant Letter

Dear Participant Name:

My name is Lisa R. Murphy. I am a Doctor of Nursing Practice (DNP) student currently working on my DNP Project entitled "A Lifestyle Management Coaching Intervention for Fear of Cancer Recurrence (FCR) in Young Breast Cancer Survivors." This project is a required component of my doctoral education and aims to address an unmet need that some young breast cancer survivors experience, which is learning how to effectively manage their fear of cancer recurrence, or the fear, concern, or worry that their cancer will progress or come back. The purpose of my DNP Project is to help young breast cancer survivors transition into a "new normal" of survivorship after breast cancer treatment with a focus on developing decreased fear of cancer recurrence, enhanced coping, and restored health after participation in a group virtual lifestyle management coaching intervention.

The intervention will be conducted in a confidential and nurturing virtual environment over ten weeks. The intervention will include ten, one-hour-long weekly group sessions conducted by an Advanced Practice Nurse health coach. The sessions will focus on empowering survivors through the eight pillars of the FEARLESS Framework: Fearing Less, Eating Well, Activity, Rest/Restoration, Love of Self/Purpose, Environment, Sleep, and Stress Management. Each week participants will receive evidence-based education and participate in health coaching and activities designed to help decrease the fear of cancer recurrence and improve health outcomes.

Eligible participants and data collected for the project include female, English-speaking breast cancer survivors ages 18-59 that have completed treatment for invasive breast cancer (Stage I-III) and screened positive for unmanaged fear of cancer recurrence. Participation in this research is voluntary and participants can opt out of the study at any point without penalty. Consent for participation will be obtained prior to the start of the study. The identity of participants will be kept protected and confidential. Program participants will be referred to by an assigned number in program documents. Zoom Communications will be used as the virtual platform to protect participant health information. Program participants will participate in the virtual coaching sessions using only their first names and participation in the coaching sessions will be voluntary.

If you feel that you are eligible for and are interested in participating in this DNP Project, please call 773-297-1687 or e-mail lisa.murphy2@eehealth.org for more details. Please accept my sincere thanks for your consideration.

Sincerely,

Lisa R. Murphy, APRN

Appendix E: Letter of Agreement

To Whom It May Concern:

My name is Lisa R. Murphy. I am a Doctor of Nursing Practice (DNP) student currently working on my DNP Project entitled "A Lifestyle Management Coaching Intervention for Fear of Cancer Recurrence (FCR) in Young Breast Cancer Survivors." This project is a required component of my doctoral education and aims to address an unmet need that some young breast cancer survivors experience, which is learning how to effectively manage their fear of cancer recurrence, or the fear, concern, or worry that their cancer will progress or come back. The purpose of my DNP Project is to help young breast cancer survivors transition into a "new normal" of survivorship after breast cancer treatment with a focus on developing decreased fear of cancer recurrence, enhanced coping, and restored health after participation in a group virtual lifestyle management coaching intervention.

The intervention will be conducted in a confidential and nurturing virtual environment over ten weeks. The intervention will include ten, one-hour-long weekly group sessions conducted by an Advanced Practice Nurse health coach. The sessions will focus on empowering survivors through the eight pillars of the FEARLESS Framework: Fearing Less, Eating Well, Activity, Rest/Restoration, Love of Self/Purpose, Environment, Sleep, and Stress Management. Each week participants will receive evidence-based education and participate in health coaching and activities designed to help decrease the fear of cancer recurrence and improve health outcomes.

Eligible participants and data collected for the project include female, English-speaking breast cancer survivors ages 18-59 that have completed treatment for invasive breast cancer (Stage I-III) and screened positive for unmanaged fear of cancer recurrence. Participation in this research is voluntary and participants can opt out of the study at any point without penalty. Consent for participation will be obtained prior to the start of the study. The identity of participants will be kept protected and confidential. Program participants will be referred to by an assigned number in program documents. Zoom Communications will be used as the virtual platform to protect participant health information. Program participants will participate in the virtual coaching sessions using only their first names and participation in the coaching sessions will be voluntary.

If you have any questions, concerns, or feedback, please call 773-297-1687 or e-mail lisa.murphy2@eehealth.org. Please accept my sincere thanks for your consideration of my project.

Sincerely,

Lisa R. Murphy, APRN

Appendix F: Instrument

Fear of Cancer Recurrence Inventory- Short Form (FCRI-SF)

Screening

Most people who have been diagnosed with cancer are worried, to varying degrees, that there might be a recurrence of the cancer. **By <u>recurrence</u>, we mean the possibility that the cancer could <u>return</u> or <u>progress</u> in the same place or in another part of the body.** This questionnaire aims to better understand the experience of worries about cancer recurrence. Please read each statement and indicate to what degree it applied to you **DURING THE PAST MONTH** by circling the appropriate number.

0	**1**	**2**	**3**	**4**
Not at all	A little	Somewhat	A lot	A great deal

1. I am worried or anxious about the possibility of cancer recurrence.
   0 1 2 3 4

2. I am afraid of cancer recurrence.
   0 1 2 3 4

3. I believe it is normal to be worried or anxious about the possibility of cancer recurrence.
   0 1 2 3 4

4. When I think about the possibility of cancer recurrence, this triggers other unpleasant thoughts or images (such as death, suffering, the consequences for my family).
   0 1 2 3 4

5. I believe that I am cured and that the cancer will not come back.
   0 1 2 3 4

6. In your opinion, are you at risk of having a cancer recurrence?

0	**1**	**2**	**3**	**4**
Not at all at risk	A little at risk	Somewhat at risk	A lot at risk	A great deal at risk

7. How often do you think about the possibility of cancer recurrence?

0	**1**	**2**	**3**	**4**
Never	A few times a month	A few times a week	A few times a day	Several times a day

8. How much time <u>per day</u> do you spend thinking about the possibility of cancer recurrence?

0	**1**	**2**	**3**	**4**
I don't think about it	A few seconds	A few minutes	A few hours	Several hours

9. How long have you been thinking about the possibility of cancer recurrence?

0	**1**	**2**	**3**	**4**
I don't think about it	A few weeks	A few months	A few years	Several years

---

Information : sebastien.simard@criucpq.ulaval.ca

Appendix G: Instrument Permission Sébastien Simard

Dear Lisa
First of all, I want to apologize for the delay of my response. I have lost control of my mail box.

It is a real pleasure to learn that you wish to use the FCRI.

You will find in attachment the original paper of the development of the French version (*Fear of Cancer Recurrence Inventory: development and initial validation of a multidimensional measure of fear of cancer recurrence),* the English validation of the FCRI and the validation of a shorter version for rapidly screening clinical level of fear of cancer recurrence (*Screening and comorbidity of clinical levels of fear of cancer recurrence*).

You will find attached the last English version of the FRCI (long and short form). I give to you the permission to use our questionnaire, providing appropriate acknowledgement of our work.

As I will continue the validation processes on the FCRI in different populations and languages, I will ask you to transmit to me your data on the FCRI at the end of your study (if it is possible to obtain a data share agreement). Also, I would like you to keep me informed of your findings when they will be available.

Finally, do not distribute the questionnaire to others without my permission. I am the one who distributes the FCRI (in any language) to follow the use and the development of the questionnaire. This is for me the only way to avoid having a multiplication version of the questionnaire and to ensure its fidelity. I hope you understand that my approach is scientific and guided by the concern to better help cancer survivors in any country.

You can find below the FCRI score procedure. If you need any information or help, ask for me. I collaborate with several teams in different projects on FCR, thus if you need my expertise it will be a pleasure for me.

Questionnaire quotation:
Data verification

- Participants who have a response pattern of “0” to all questions are excluded. Since item 13 is reversed item, this is an indication that the person probably answered mechanically without taking the time to read the items.
- Participants for whom more than half (more than 50%) of the items are missing are also excluded. The validity of the questionnaire is then compromised.
- For participants who have some missing data, I suggest "imputing" data. To do this, I use the mean score of the participant's questionnaire subscale and not that of the total sample.
    - For participants who completed less than half of the items on the subscale, it is not possible to impute the items. It will therefore be missing data. It is therefore possible that after the exercise of imputing the data you have to exclude other participants.

FCRI
A total score can be obtained for each subscale and for the total scale by SUMMING the items.
CAUTION: the quotation of item 13 (I believe that I am cured and that the cancer will not come back) must be reversed before summation.
Subscales:

- Triggers: Sum items 1 to 8

- Severity: Sum items 9 to 17 (reversed item 13 before)
- Psychological distress: Sum items 18 to 21
- Functioning impairments: Sum items 22 to 27
- Insight: Sum items 28 to 30
- Reassurance: Sum items 31 to 33
- Coping strategies: Sum items 34 to 42
- Total FCRI score: Summing items 1 to 42 (reversed item 13 before)

FCRI-SF (short form)

Severity subscale only

Reverse item 5 and after sum all items

Best regards

Sébastien

Sébastien Simard, Ph. D.

Professeur agrégé en psychologie
Département des Sciences de la Santé, local V2-1060
Université du Québec à Chicoutimi (UQAC)
555, boul. de l'Université, Chicoutimi (Québec) Canada, G7H 2B1
418-545-5011 poste 6108
Sebastien1_Simard@uqac.ca

Chercheur régulier
Centre intersectoriel en santé durable (CISD) de l'UQAC
CIUSSS Saguenay-Lac-St-Jean
Équipe de Recherche Michel-Sarrazin en Oncologie psychosociale et Soins palliatifs (ERMOS)
Chercheur associé
Centre de recherche de l'Institut universitaire de cardiologie et de pneumologie de Québec (IUCPQ)
Réseau québécois de recherche en soins palliatifs et de fin de vie (RQSPAL)

Appendix H: DNP Project Intervention Session Outline

Session 1- Introduction

Introduction of APRN Health Coach: Lisa R. Murphy

-Doctor of Nursing Practice, Lifestyle Medicine, Southern Adventist University, Collegedale, TN, Pending

-Bachelor of Science Nursing (12/2005) and Master of Science Nursing/Family Nurse - Practitioner (5/2015) Rush University College of Nursing, Chicago, IL

-Bachelor of Science Community Health/Healthcare Administration (5/2002)

-Board Certified & Licensed Family Nurse Practitioner

-Nationally Certified Health Coach, National Board for Health & Wellness Coaching

-Oncology RN 10 years Rush University Medical Center

-Family Nurse Practitioner Little Company of Mary Hospital (02/2016-02/2019)

-Bariatric and Weight Management APRN Elmhurst Hospital (02/2019-Current)

Discussion of Lifestyle Management Coaching Intervention:

Purpose:

The purpose of the DNP Project is to conduct an APRN-led lifestyle management coaching intervention that will help to decrease FCR and improve health outcomes in young breast cancer survivors demonstrating high FCR screening scores.

Aims:

The project aims to help young female breast cancer survivors (a) gain restorative health physically, mentally, socially, and spiritually after cancer treatment, (b) experience less fear of cancer recurrence as evidenced by decreased FCR-SF scores to an acceptable range (< 12) after participation in a 10-week virtual group coaching intervention, (c) live a longer, more balanced

life after implementation of evidence-based healthful lifestyle modifications that meet their physiologic needs, (d) learn how to develop self-love and purpose and live the legacy they want to leave behind, (e) change compensatory/compromised adaptation to an integrated healthier coping response, and (f) learn how to adapt to their changing environment more healthfully and integrate into their new normal after breast cancer treatment.

Objectives:

3. To plan, develop, implement, and evaluate a 10-week evidence-based lifestyle management virtual coaching intervention for young female breast cancer survivors by August 2023.
4. To evaluate Fear of Cancer Recurrence Inventory Short Form (FCRI-SF) scores using pre/post Paired T-Testing statistical analysis.

Discussion of Frameworks & Supporting Organizations for lifestyle management guidelines: RAM, CREATION Life, FEARLESS

Upcoming Sessions:

Fearing Less, Eating Well/Nutrition, Activity, Rest/Restoration, Love of Self/Purpose, Legacy, Longevity, Environment, Sleep, Stress Management

Adaptive Goals: Give instructions to start working on these

Introduction of Participants (Voluntary)

Discussion of specific NCCN Healthy Lifestyle Survivorship Guidelines

10 to 20-Minute Group Coaching Session

Home Activity:

Journal Questions:

Journal. Table 1 Canadian article

How often do I have thoughts related to cancer returning?

How long do these thoughts last?

Do I find these thoughts difficult to control?

How have these thoughts affect my life?

What are some healthy ways that I can manage these fears?

Journal and write down any additional thoughts and fears.

Goals:

Write 3 Things you are grateful for each night for the duration of the program

Recite Optimist's Creed and/or Serenity Prayer nightly

Session 2- Fearing Less- Fear cannot exist without your permission (Judy C. Kneece)

-BC survivors often experience fear of cancer recurrence (FCR), or fear, concern, or worry that cancer will progress or come back.

-FCR is one of the greatest concerns of cancer survivors after treatment completion.

-FCR is inevitable and normal to a degree after a breast cancer diagnosis and treatment.

-Up to half of breast cancer survivors experience some level of unmanaged FCR and this number increases to 70% for young adults.

-When left unaddressed or unmanaged, FCR can become permanent and/or dysfunctional.

-FCR is associated with impaired functioning, distress, depression, lower quality of life, and behaviors such as avoidance or intense surveillance.

-BC patients are faced with establishing a new normal after completing cancer treatment and often feel lost in transition when doing so.

-This timeframe, the extended survival period, can be dominated by FCR.

-An unmet need of BC survivors is learning how to manage FCR.

-I am here to help you learn how to manage FCR.

-You can adjust to and lead a fulfilling life after cancer.

-You can choose to have less fear and live a healthy, balanced life.

-Transform fear to faith.

-Trust in yourself and your body. Faith “is a vital aspect of wholeness.” Keeps us strong even at our weakest.

-Switch on the lights of hope.

-Fear can paralyze the development of a healthy outlook.

-Our outlook/attitude manages the healing process.

-Our world and experiences are shaped by the way we think.

-Everything we do is a result of making a choice. Choice is the first step toward improving well-being. Healthy choices help balance our life. Take this opportunity to choose a new beginning- one free of fear, worry, and concern that your cancer will come back (CREATION Life).

-I cannot control recurrent B.C., but I can control my outlook.

Survival Statistics: The survival rate is increasingly improving.

a. According to the American Cancer Society, the 5-year survival rate has improved from 63% in 1960 to 90% presently.
b. There are 3.8 million BC survivors currently living in the US.
c. Approximately 18% of BC survivors are 49 years old or younger.
d. Average survival rates for non-metastatic invasive cancer are 91% and 85% at 5 and 10 years, respectively.

Common Fears/Triggers & Potential Targets:

Follow-up visits, Ruminating thoughts/What Ifs, Aches/pains/symptoms, Anniversaries (date of diagnosis, surgery date), Learning someone was diagnosed with BC, Death of someone with BC, Appointments, Scans, Mammograms, Birthdays

Coping & Management Interventions:

One day at a time philosophy (Time helps), Stay informed (power comes from information- study your survivorship care plan), Stay connected, Comply with treatment, Report worrisome symptoms, Understand personal cancer and situation, Regain physical function (PT, exercises), Acknowledge fears, Write down questions for the medical team in between visits, Practice healthy lifestyle choices (relax, healthy weight, good sleep, stress relief, exercise, nutrition, live healthfully, quit substances, daily schedule, Seek

emotional support: (peer support (power comes from a support network that fits you), support groups, therapy), Practice awareness (of fears, not judgment), Practice expressing and letting go, Use energy to focus on wellness, Relieve stress (Reiki, Meditation, Tai Chi, Gratitude, Yoga, Journaling), Engage in open dialogue with trusted family and friends (pg. 6).

Cancer.net app & podcast:

https://www.cancer.net/blog/2019-12/how-cope-with-fear-cancer-recurrence

Coping:

https://www.cancer.net/survivorship/life-after-cancer/coping-with-fear-recurrence

https://media.cancercare.org/publications/original/253-2022_Coping_with_the_Fear_of_Recurrence.pdf

Coping with Uncertainty:

https://www.cancer.net/coping-with-cancer/managing-emotions/coping-with-uncertainty

Life After Cancer Treatment:

https://www.cancer.org/treatment/survivorship-during-and-after-treatment/long-term-health-concerns/recurrence/can-i-do-anything-to-prevent-cancer-recurrence.html

Can I Do Anything to Prevent Cancer Recurrence:

https://www.cancer.org/treatment/survivorship-during-and-after-treatment/long-term-health-concerns/recurrence/can-i-do-anything-to-prevent-cancer-recurrence.html

Review- Breast Cancer Survivorship Handbook Judy Kneece, Chapter 2 pg. 5 & 6

Optimist's Creed/Serenity prayer

20-minute health coaching session: Review of Journal Questions, session material, I cannot control recurrent BC, but I can control my outlook.

Activity:

All that I am arises from my thoughts: fear cannot exist without my permission.

Butterfly Letter of Release/Letting Go: Draw a butterfly, they cannot speak, let them carry your deepest cancer-related fears, secrets, prayers, and wishes away.

Journal-

What fears are holding me back?

What do I need to do to be able to move forward on this journey with less fear?

Goal: Read the Optimist's Creed and/or Serenity Prayer nightly before bed at least 5/7 nights a week.

Session 3- Eating Well/Nutrition

NCCN general

AICR The New American Plate

AICR Food List

-Eat a diet rich in fruits, vegetables, whole grains, and lentils.

-Limit fast and processed foods, limit red meat consumption, and limit sugar-sweetened beverages.

-Avoid tobacco when applicable, and limit alcohol consumption.

-10-Day Lifestyle Modification Challenge.

-Information on the detoxification and biotransformation pathways including phase I and phase II liver detoxification, supportive nutrients, and the elimination processes

Goal: Eat a whole-food, plant-based diet that includes 5 servings of fruits and vegetables per day from the AICR food list.

Review LM hand-out as needed.

10 to 20-Minute Group Coaching Session

Session 4- Activity

AICR Guidelines

https://www.aicr.org/cancer-prevention/recommendations/be-physically-active/

NCCN Guidelines

https://www.nccn.org/patients/guidelines/content/PDF/survivorship-hl-patient.pdf

LM Exercise Hand-out

-How to incorporate a healthy exercise pattern into everyday life and maintain it.

-Engage in regular physical activity of at least 150-300 minutes of moderate-intensity or 75-150 minutes of vigorous-intensity activity weekly along with two or more days weekly of strength training.

-Topics of discussion will include physical activity benefits, activity types, activity levels, plans, and tips for survivors.

Tips for Survivors:

https://www.cancer.net/survivorship/healthy-living/physical-activity-tips-survivors

-Review The meta-analysis by Lee (2019)

10 to 20-Minute Group Coaching Session

LM Exercise Hand-out

Goal: Participate in 150-300 minutes of moderate-level physical activity weekly.

Session 5- Rest/Restoration

- Anxiety and fear are the opposite of rest.

-Refreshes, rejuvenates, regenerates, rebuilds mind, body, soul.

-Empowers.

-Includes good sleep, time to relax and rejuvenate.

-Daily rest, Weekly Rest, Recreation, Annual Rest.

-How to incorporate a restorative rest pattern into everyday life.

Tips for success: page 48-49- CREATION Life

Deep Breathing Exercise: Page 51- CREATION Life

10 to 20-Minute Group Coaching Session

Goal: Carve out one day per week to include at least one full hour of rest

Session 6- Love of Self/Purpose, Legacy, Longevity

-CREATION HEALTH principles of choice, trust, and outlook to help the survivors develop their personal/spiritual selves.

-Learn how to live the legacy they want to leave behind through small group discussions and journaling.

-Transform fear into courage and courage into purpose. This session will allow for participants to

-Create and gain abundant and restorative health physically, mentally, socially, and spiritually: letting go, the power of forgiveness (page 137 CREATION Health), making better choices, optimism, and trust in the divine.

-Focus on the co-creation and enhancement of self-love, longevity, and legacy.

-Gratitude, Vision, Hope (CREATION Life)

Tips For Success: CREATION Life page 146 (faith-based participants)

Tips For Success: How to Make Better Choices

Optimism page 189 & Tips for Success: Improve Your Outlook on Life page 201 CREATION Life

Review of Optimist's Creed & Serenity Prayer (faith-based participants)

Activity: APRN health coach led Wellness Vision

Home Activity: Journal activity: self-purpose, legacy, longevity

10 to 20-Minute Group Coaching Session

Goal: Journal/describe the legacy they want to leave behind and start living it.

Session 7- Environment

-How to build a healthy internal and external environment and create a new normal in their previously existing roles.

-Surround themselves with a group of women also experiencing breast cancer survivorship.

-Learn how to develop interpersonal relationships and rely on added support systems that can help them manage FCR and uncertainty more positively.

-How to create a positive home environment and engage with nature to improve outlook and immunity.

-Remove things that trigger fear and anxiety from their environment and instead include things that promote a positive, nurturing, clean, joyful, comfortable, and restorative one.

LM hand-out social connections

EEH Emotional Support Resources

Activity: Skill Builder Forgive One Another

Tips for Success: Improve your relationships

10 to 20-Minute Group Coaching Session

Goal: Attend at least 8 out of 10 sessions to ensure adequate social support during program intervention.

Session 8- Sleep

5 stages of sleep- page 37 CREATION Life

Chemistry of sleep- page 36-37 CREATION Life

LM Sleep Hand-out: sleep disrupters, tips for better sleep, and sleep management goals.

10 Tips to help you fall asleep- page 52 CREATION Life

Create a good sleep environment- page 50 CREATION Life

Goal: Incorporate 7-9 hours of sleep per night.

Session 9- Stress Management

LM hand-out Stress Reduction

Strategies for Coping pg. 57 Breast Cancer Survivorship Handbook

Activity: Meditation

10 to 20-Minute Group Coaching Session:

Goal: Write 3 things they are grateful for each night before bed.

Session 10- Conclusion

Repeat/Review FCR content.

Discuss any remaining content.

Open Health Coaching.

Final words, thank you.

Items needed: Journal, pen, education materials, Zoom access

Appendix I: DNP Project Session Objectives

Fearing Less

- Participants will express 4 triggers for Fear of Cancer Recurrence during the group health coaching session.
- Participants will identify at least 1 coping strategy for Fear of Cancer Recurrence during the group health coaching session.
- Participants will choose to read the Optimist's Creed or Serenity Prayer at least 5/7 nights before bed by the end of the program.

Eating Well/Nutrition

- Participants will describe 5 foods on the American Institute of Cancer Research food list during the group health coaching session.
- Participants will incorporate a whole-food, plant-based diet that includes 5 servings of fruits and vegetables per day from the American Institute for Cancer Research food list by the end of the program.
- Participants will prepare for and complete a whole food, plant-based clean eating, and lifestyle modification challenge to help them acknowledge the link between lifestyle and health outcomes, replace unhealthy behaviors with positive ones, and provide a cleansing reset for the body post-cancer treatment by the end of the program.

Activity

- Participants will describe 3 benefits of physical activity during the group health coaching session.
- Participants will design and engage in a personal exercise plan of 150-300 minutes of moderate-level physical activity weekly by the end of the program as tolerated.

Rest/Restoration

- Participants will propose 3 possible options for taking a 1-hour cancer vacation every week during the group health coaching session.

Love of Self/Purpose

- Participants will write the legacy they want to leave behind and start living it by the end of the program.

Environment

- Participants will state and prioritize 3 possible ways to form and strengthen their social connections during the group health coaching session.
- Participants will attend at least 8 out of 10 sessions to ensure adequate social support during program intervention.

Sleep

- Participants will explain 2 possible sleep disrupters during the group health coaching session.
- Participants will create a plan to aim for 7-9 hours of sleep every night by the end of the program.

Stress Management

- Participants will summarize stress management tips during the group health coaching session.
- Participants will write 3 things they are grateful for each night before bed by the end of the program.

Appendix J: Adaptive Goals/Learning Outcomes

Fearing Less: Read the Optimist's Creed and/or Serenity Prayer nightly before bed at least 5/7 nights a week.

Eating Well/Nutrition: Eat a whole-food, plant-based diet that includes 5 servings of fruits and vegetables per day from the AICR food list.

Activity: Participate in 150-300 minutes of moderate-level physical activity weekly as tolerated.

Rest/Restoration: Take a 1-hour cancer vacation every week.

Love of Self/Purpose: Journal/describe the legacy they want to leave behind and start living it.

Environment: Attend at least 8 out of 10 sessions to ensure adequate social support during program intervention.

Sleep: Aim for 7-9 hours of sleep every night.

Stress Management: Write 3 things they are grateful for each night before bed.

Appendix K: DNP Post-Program Survey

Name:

Please complete the end-of-program survey below.

You can check directly into the text box next to your choice for Yes/No questions.

Please complete all questions to the best of your ability and e-mail the completed survey back to me upon completion: lisa.murphy2@eehealth.org

Please aim to complete the form by Tuesday, March 7, 2023.

Thank you, Lisa R. Murphy, APRN 773-297-1687

Post Program Survey & Additional Questions

Please indicate if you have met the following learning outcomes by answering Y/N.

Please answer the additional questions below for additional feedback.

Fearing Less- Yes☐ or No ☐

Read the Optimist's Creed and/or Serenity Prayer nightly before bed at least 5/7 nights a week.

Eating Well/Nutrition- Yes ☐ or No ☐

Eat a whole-food, plant-based diet that includes 5 servings of fruits and vegetables per day from the American Institute of Cancer Research food list.

Activity- Yes ☐ or No ☐

Participate in 150-300 minutes of moderate-level physical activity weekly as tolerated.

Rest/Restoration- Yes☐ or No ☐

Take a 1-hour cancer vacation every week.

Love of Self/Purpose- Yes☐ or No ☐

Journal/describe the legacy you want to leave behind and start living it.

Environment- Yes☐ or No ☐

Attended at least 8 out of 10 sessions to ensure adequate social support during program intervention.

Sleep- Yes☐ or No☐

Aim for 7-9 hours of sleep every night.

Stress Management- Yes☐ or No☐

Write 3 things you are grateful for each night before bed.

Additional Questions:

1. Do you think participation in this coaching program helped you learn how to manage your Fear of Cancer Recurrence more effectively as a breast cancer survivor?

   Yes☐ or No☐

2. If so, how?
3. Do you think this program helped you learn how to cope better as a breast cancer survivor?

   Yes☐ or No☐

4. If so, how?
5. Do you think this program helped you learn how to better restore your health (physically, mentally, socially, and/or spiritually) as a breast cancer survivor?

Yes☐ or No☐

6. If so, how?

Appendix L: Post-Survey Transcripts

Participant 1: Provided no additional feedback.

Participant 2: N/A- Dropped out of DNP project.

Participant 3:

-Question 2: “I learned some new techniques to continue to help manage my fears and live my best life.”

-Question 4: “I think this would be a great tool for that sweet spot when you are done with treatment and are feeling lost because you don’t know what to do without being scheduled full of treatments and post-op and such. Also, that’s the sweet spot where starting therapy or joining a group would be super helpful.”

-Question 6: “I did learn some things. This would be great for someone who again is earlier in their recovery.”

Participant 4:

-Question 2: “I was already doing many of the recommended strategies (eating fairly well, exercising, etc.). It was more some of the simple, little strategies or tidbits I learned that I can add to the arsenal. The gratitude journal is one of the best strategies I implemented through this study. I had a gratitude journal prior to my diagnosis but had stopped using it. I’ve really noticed a difference in maintaining this journal. I’m also thanking my body every day and trying to get in more vegetables in my diet.”

-Question 4: “This study reinforced that I was already doing many of the proven strategies to help me cope with my breast cancer diagnosis, treatment, and fear of recurrence. The study and Lisa reminded me that I need to give myself time and grace in dealing with all of this.”

-Question 6: “I have always eaten fairly healthy, but the eating challenge took everything to the next level. It helped to show me healthy recipes and additional vegetarian alternatives.”

Participant 5:

-Question 2: “I am spending more time on my nutrition and working out that I have less time to worry about fear of cancer returning. I am taking the time to plan long-term goals for my life and not scared that my health could be a barrier. I feel I am more intentional with my actions.”

-Question 4: “I learned so many tools needed for better health, nutrition, and well-being. Tools that will carry me through my journey. I feel more positive about myself and my mind feels much more clear. The ladies on this group were very kind. This time felt like a gift for my soul.”

-Question 6: “Proper nutrition in a manageable way. I learned so much during the 10-day food challenge. Journaling has provided for me the nice time for myself to slow down and reflect on my day. I feel now that it is always okay for me to allow myself the grace and patience I need and that it is always okay to take time for myself. My mental health is just as important as my body. Thank you for this amazing opportunity to connect with such a wonderful group.”

Participant 6:

-Question 2: I am better able to stay positive and not dwell on what is beyond my control or the “what ifs?” Although I haven’t felt lonely often in my cancer battle, listening to other survivors’ journeys helped me feel less alone.”

-Question 4: “I feel more empowered to create a healthier future for myself. We set goals for our legacy, and I want to be able to look back knowing I did all I could.”

-Question 6: “During treatment, I didn’t really feel in control of my life. Yes, I did my reading and discussed everything with my healthcare team, but I was not leading. I finally feel like the roles are switching with myself in the lead it’s very empowering. I have a ways to go, but each positive step will get me to a healthier lifestyle. I can’t do it all at once and focusing on being FEARLESS keeps the cancer thoughts at bay. The program gave me tools to move forward. I did enjoy participating although it would have been nice to have met in person. It’s hard to truly connect via Zoom.”

Participant 7:

-Question 2: “Others sharing their stories helped me put things into perspective. I believe it is knowing that you are not alone. Also, I realized how much stress can contribute to illness, and stressing over recurrence can be so counterproductive.”

-Question 4: “The sense of community always helps me cope better. Having someone else around that shares your feelings or understands what you have been through always helps me feel better and cope better.”

-Question 6: “The various topics during every meeting emphasized the importance of the various factors that contribute to being “healthy.” I loved having each session focused on various topics, sleep, stress, eating well, etc.”

Participant 8:

-Question 2: “Allowed me to meet and talk with others around my age who have experienced the same thing…and are pushing forward with hope and positivity. I enjoyed hearing what others do to help calm their fears. Made me feel less alone in this journey.”

-Question 4: “The Creed and Serenity Prayer really helped to bring a calm to my day…and writing in the journal provided a positive mindset to my day.”

-Question 6: “Specifically learning about the meditation and relaxation techniques.”

Participant 9:

-Question 2: “I have better tools now. The Optimist Creed is a game changer. I had never heard of it prior to attending these sessions. I have a better understanding of some clear guidelines that can help keep me mentally and physically healthy. I like having “goals” to achieve, such as 150 minutes of activity or 5 servings of fruits and vegetables. Sleep is a struggle but much better than prior to starting the program. I am hoping to get Lisa’s meditation- your voice is easy to hear. Thank you for all you do and I liked being included in the program.”

-Question 4: “The tools that have been shared- breathing, meditating, sleep strategy, and on and on. I am so much more prepared and confident I WILL survive.”

-Question 6: “I have a better understanding of the science behind making healthy food choices, which has helped me already start making better food choices. I have referenced back to the materials that Lisa has supplied us. It was a lot of information every week, so I like having the slides for reference.”

Participant 10:

-Question 2: “It helped me focus on the present and what I can do to be healthier in the present rather than the fear of an unknown future.”

-Question 4: “Being together with other young BC survivors helped me feel that I wasn’t alone. It helped me focus on investing in myself and my health and well-being on a daily basis. It helped me strategize on how to eat better and get more physical activity amidst the hectic demands of daily life.”

-Question 6: “It helped me become more intentional about the aspects of my health that I can control such as diet, physical activity, practicing gratitude and mindfulness, etc. It helped me view myself as a worthy investment. Thank you so much Lisa for everything.”

Participant 11:

-Question 2: “I think the program did help me. It highlighted some things I already knew were important, like nutrition, sleep, and activity, but gave me more focused information in those areas to make positive changes in my habits. I love the Optimist’s Creed and the Serenity Prayer and the practice of doing those daily along with the gratitude journal. I started a positivity journal at the beginning of the year, so all of those things together have been very impactful to me.”

-Question 4: “I would say the biggest thing for me was knowing that some of the feelings and emotions that I have been dealing with are not unique to me but are shared by other survivors. I know many women who are survivors, but they are generally farther along on their journey than I am, so it was helpful to interact with this group of women who have been diagnosed in the past couple of years.”

-Question 6: “The focus on cancer-fighting foods was very helpful. I don’t remember ever seeing that list. I switched my oncologist from Amita to Elmhurst right after my radiation treatments were complete and at the time I needed a maintenance plan put in place. The other thing that was interesting to me that I never thought about before was the difference between sleep and rest. I’m a busy person and did not really give much credence to the importance of the downtime and rest in my health, but I have been really trying to keep that in mind. My Oura ring is helpful with that as it lets me know when my body might need additional rest to restore itself. Keeping rest as an important component of health was a huge takeaway for me.”

Participant 12:

-Question 2: “Awareness of various resources; Motivation to a healthier eating lifestyle; Motivation to increase my exercise activities; Motivation to practice self-love/self-care.”

-Question 4: “Reading the Optimist’s Creed and/or Serenity Prayer has helped; Journaling more frequently; Meditation.”

-Question 6: “Same responses as above; Practicing many of the exercises we learned with every session.”

Participant 13:

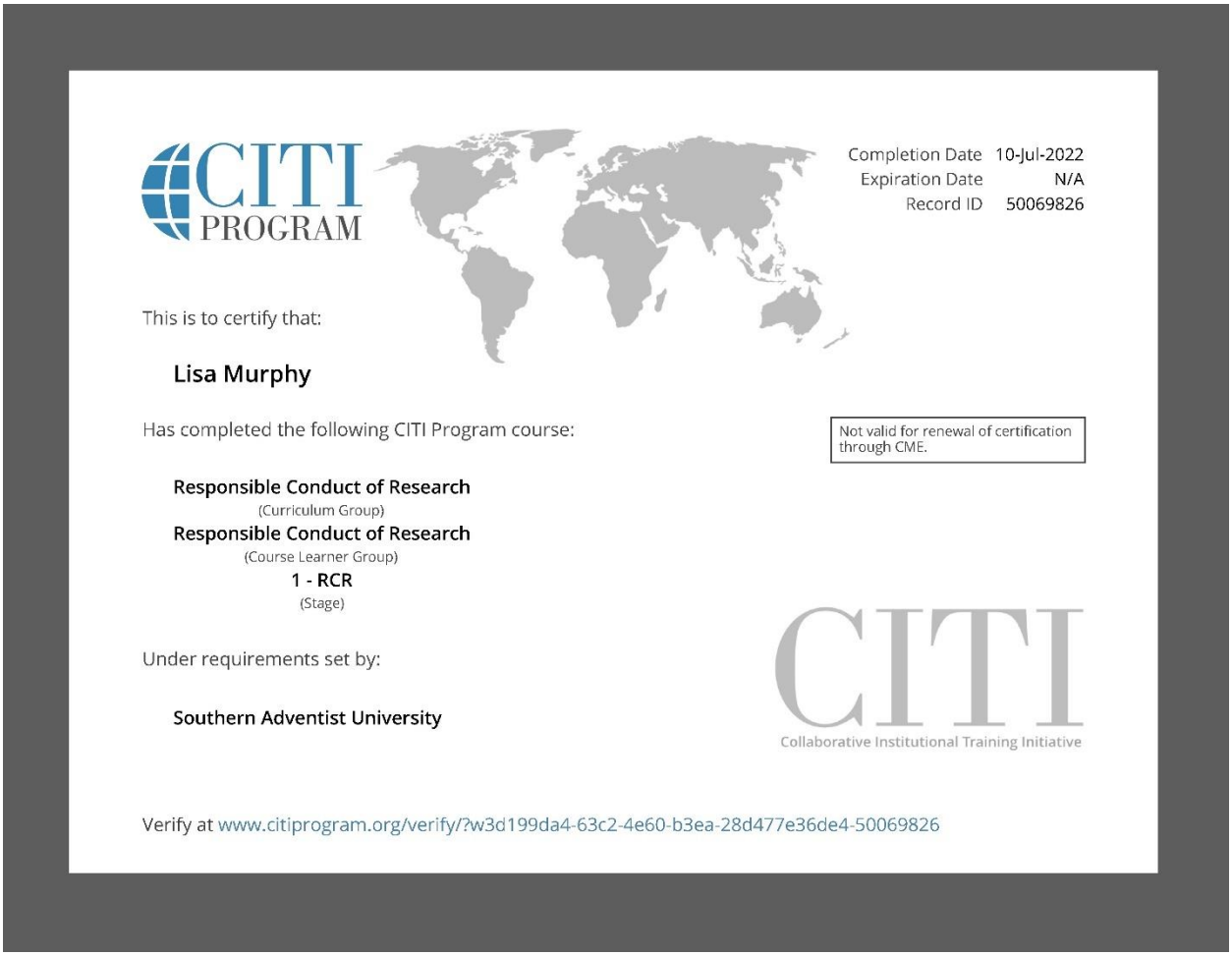
-Question 2: “I learned how to manage fear of recurrence by implementing lifestyle changes based on the 8 pillars of the FEARLESS framework.”

-Question 4: “The program helped me to learn how to cope. I did implement changes in my day-to-day life, however not all changes, but I will continue to incorporate the pillars after the end of the program.”

-Question 6: “After 9 sessions of the program, I am equipped with the tools and knowledge to better restore not only my health, but my mental state. Program offers healthy ways for managing my fears. Personally, I am still not mastering what I have learned and will be working on applying the knowledge after the program ends.”

Participant 14: N/A- Dropped out of DNP project.

Appendix M: Collaborative Institutional Training Initiative Certificate



CITI PROGRAM

Completion Date 10-Jul-2022
Expiration Date N/A
Record ID 50069826

This is to certify that:

Lisa Murphy

Has completed the following CITI Program course:

Not valid for renewal of certification through CME.

Responsible Conduct of Research
(Curriculum Group)
Responsible Conduct of Research
(Course Learner Group)
1 - RCR
(Stage)

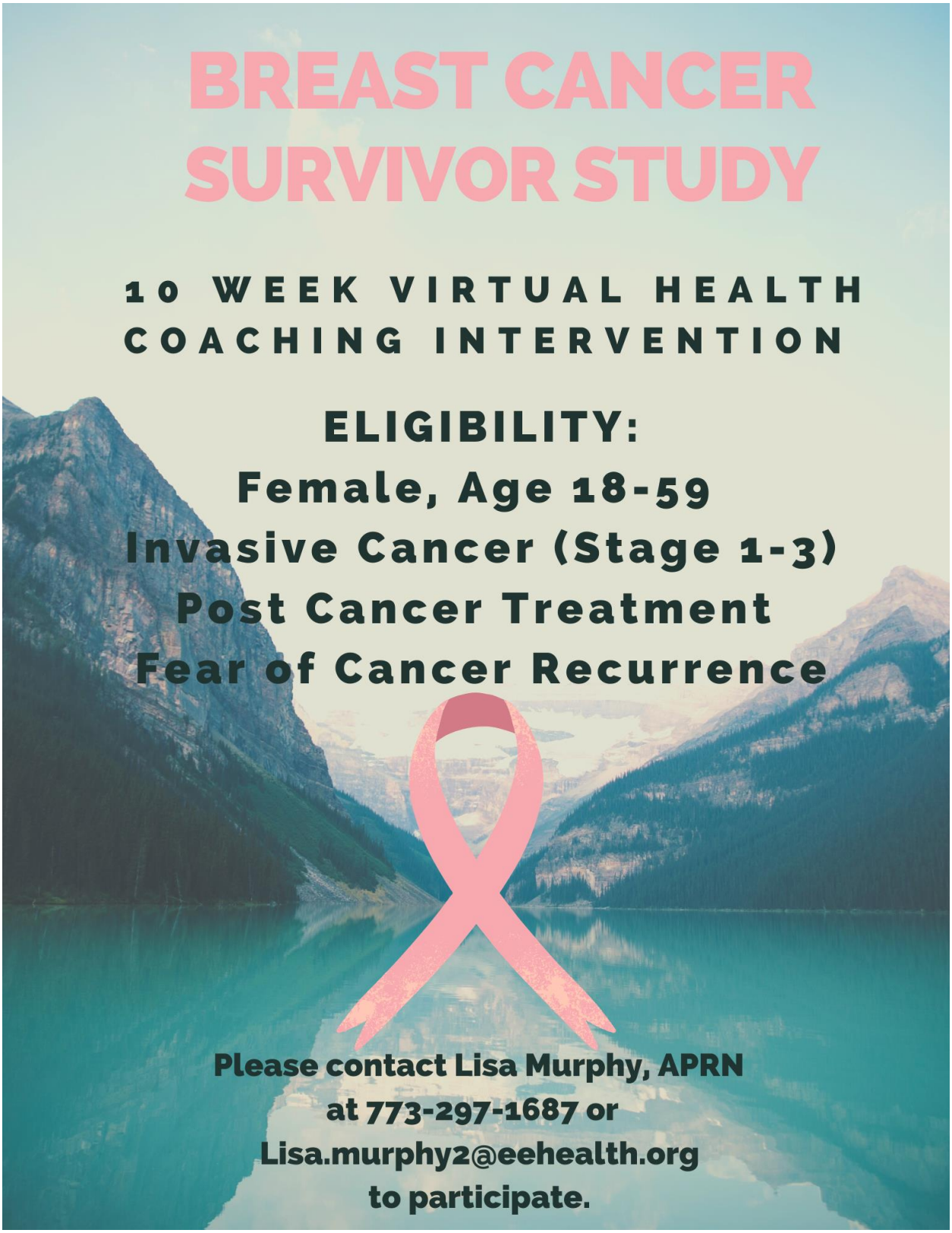
Under requirements set by:

Southern Adventist University

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w3d199da4-63c2-4e60-b3ea-28d477e36de4-50069826

Appendix N: DNP Project Flyer



Appendix O: Scholarly Project EOP SLO Synthesis

The DNP project showed competency of each of our program Student Learning Outcomes (SLOs) including Cultural Competence, Evidence-Based Practice, Health Promotion, Patient-Centered Care, Quality and Safety, Informatics and Innovation, Teamwork and Collaboration, and Professionalism.

The DNP project demonstrated Cultural Competence and Health Promotion as the FEARLESS lifestyle management practice intervention was based upon the Christian CREATION Life concepts and helped participants achieve a state of wellness following God's prescription for living. It promoted full health, whole person care, better living, and a balanced life according to the framework concepts (Cummings & Reed, 2005). Utilization of this holistic framework educated and empowered young breast cancer survivors to practice healthy lifestyle choices after cancer treatment that helped reduce fears associated with their disease. The project intervention was inclusive of females from all racial, cultural, and religious backgrounds.

The DNP project also demonstrated Evidence-Based Practice (EPB) and Quality and Safety as it utilized an EBP tool, the Fear of Cancer Recurrence Inventory Short-Form score (FCRI-SF) to identify and measure fear of cancer recurrence (FCR) pre/post intervention scores. It also utilized Lifestyle Medicine (LM), National Comprehensive Cancer Network (NCCN), American Institute for Cancer Research (AICR), CREATION Life, and other reputable cancer resources and recommendations to guide the development and implementation of the FEARLESS practice intervention. FCR is a sensitive subject for breast cancer survivors and the practice intervention may have temporarily or unintentionally caused more distress for them. The project was implemented with a goal of minimizing risk of harm and promoting quality and safe care.

The DNP project also demonstrated Patient Centered Care as it aimed to address a primary, unmet need of breast cancer survivors, which is learning how to decrease and manage FCR using a compassionate, holistic approach for a very delicate patient concern. Also demonstrated is Informatics and Innovation as the databases used to complete the literature search were CINAHL Complete and PubMed located in the McKee Library of Southern Adventist University. Google Scholar was also used. This allowed for analyzation of evidence-based best practices and information. Furthermore, the group coaching sessions were conducted using Zoom, which ensured patient confidentiality and avoided delays related to in-person sessions given the ongoing COVID-19 pandemic concerns.

The DNP project also demonstrated Teamwork and Collaboration. Implementation of the project required effective teamwork and collaboration, namely with the oncology departments within the Edward-Elmhurst Hospital system located in Illinois, particularly for the participant recruitment process. This included working closely with the staff of the medical, surgical, and radiation oncology departments including the Breast Cancer Survivorship APRN, physicians, nurses, medical assistants, and other support staff.

Finally, the DNP project demonstrated Professionalism. The DNP project has led to sustained therapeutic relationships between the principal investigator, breast cancer survivors, and oncology staff. The FEARLESS Lifestyle Management Coaching Intervention (LMCI) aimed to improve patient health outcomes while providing optimal care for young breast cancer survivors experiencing elevated FCR. The LMCI proved successful as the Paired *t*-test concluded that the FEARLESS LMCI was effective in reducing FCR among the DNP project participants. Extensive post-LMCI qualitative feedback also demonstrated the participants experienced perceived physical, emotional, social, and spiritual health benefits experienced again

demonstrating Professionalism as the tailored FEARLESS LMCI was designed by the principal investigator with whole person care as the top priority.

References

Cummings, D & Reed, M. (2005). *CREATION HEALTH Discovery*. Florida Hospital Publishing.