

FRUIT AND VEGETABLE INTAKE AND QUALITY OF LIFE
AMONG BREAST CANCER SURVIVORS

BY

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THESIS

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ABSTRACT

Background: With advances in breast cancer detection and treatment, survivors now have a 5-year survival rate > 90%. This has led to a shift in focus to improving not only survival, but also health-related quality of life (HR-QoL) after diagnosis, including physical, social, emotional, functional, and general well-being. High fruit and vegetable (FV) intake may improve HR-QoL, possibly through anti-inflammatory mechanisms, but previous research findings are mixed. The purpose of this study was to determine how FV intake is associated with HR-QoL among breast cancer survivors.

Methods: This was a cross-sectional pilot study of 82 breast cancer survivors who completed an online survey disseminated through breast cancer support groups. Participants completed the NIH dietary screener questionnaire (DSQ), which was used to estimate average daily servings of FV intake. The Functional Assessment of Cancer Therapy-Breast Cancer (FACT-B) was used to assess HR-QoL. Scores for overall HR-QoL, as well as for individual subscales of physical, social/family, emotional, and functional QoL, were computed. Covariates included self-reported age, body mass index (BMI), cancer stage, and income. Total daily servings of FV were categorized into above and below median of intake (< 2 Cups FV/day and ≥ 2 Cups FV/day) and examined in multivariable linear regression models to evaluate their relationship with overall and subscale-specific HR-QoL scores.

Results: After controlling for age, BMI, disease stage, and income, there were no significant associations observed between total FV intake and overall or subscale-specific HR-QoL scores.

Conclusion: FV intake was not associated with HR-QoL in this breast cancer survivor population. The small sample size may have lacked adequate power to detect a significant

association. Further research to understand how diet quality may influence HR-QoL in breast cancer survivors is needed.

Keywords: diet quality, fruits and vegetables, breast cancer, cancer survival, quality of life

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Dedication

To my mother, I love you for giving me your eyes.

To Auntie Elieen, for staying back, and watching me shine.

To my family, for providing support in more ways than I can tell.

To Auntie Kitty and Uncle David, for sharing life-long stories and being my life coach.

To my girls, Christy, Natalie, and Christine, for together we walk through the journey they call adulthood.

To Puffy, my dearest poodle doggie, although you will not be able to read this, you have ignited my life.

To my friends, we are young forever.

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CHAPTER 1: INTRODUCTION

Breast cancer is the most common cancer in women worldwide. About one in eight US women will develop invasive breast cancer over the course of her lifetime.¹ In 2019, an estimated 271,270 new cases of breast cancer are expected,² and female breast cancer represents 15.3% of all new cancer cases in the United States.³ With the advances in early diagnosis of the disease and better treatment, the 5-year survival rate based on 2008-2014 data from the American Cancer Society across all breast cancer stages is now increased to 90%.³ The death rates have lowered to 20.6 per 100,000 female breast cancer cases based on data from 2011-2015.³ The increasing survival time of breast cancer patients and the earlier stage at diagnosis lead to a concern of health-related quality of life (HR-QoL) problems which can persist long after initial treatment.⁴ Breast cancer survivors might face 1.) physical well-being concerns, including pain and fatigue; 2.) social/family well-being concerns, such as ability in connecting with friends and family also maintaining a healthy sex life; 3.) emotional well-being concerns, including fear of recurrence and confidence level in coping with the disease; 4.) functional well-being concerns, such as inability to work; and 5.) some other additional breast cancer related concerns, such as hair loss and feeling confident as a woman.⁴ Therefore, there is an increasing need for identifying modifiable factors that could potentially affect breast cancer survivors' quality of life.

Evidence for the effects of lifestyle factors, such as diet, on breast cancer survivors' HR-QoL is not well understood and findings are mixed. A previous study showed that physical exercise and high fruit and vegetable (FV) intake are positively associated with HR-QoL in breast cancer survivors.⁵ However, an analysis resulting from a clinical trial conducted at the Ohio State University Comprehensive Cancer Center suggested that there were no significant

associations between diet quality, as measured by the Healthy Eating Index-2010, and HR-QoL outcomes.⁶ Disagreement in results of similar studies suggests the need for more rigorous investigations into the association of FV intake and HR-QoL in breast cancer survivors.

Dietary intake, including FV intake, has been shown to influence various health outcomes which could have implications for HR-QoL.⁷ Several potential mechanisms might explain a potential protective effect of FVs on breast cancer survivors' disease status and HR-QoL. Dietary flavones and isoflavones might inhibit breast cancer development by decreasing estrogen production, inhibiting breast cancer cell proliferation, and decreasing reactive oxygen species production.⁸ A higher intake of fiber has been previously associated with a reduction in blood estrogen level and a higher dietary folate consumption might alter gene expression of critical tumor suppressor and proto-oncogenes through its' role in DNA methylation.⁹ Such micronutrients are commonly found in FV and are suggested to be associated with better HR-QoL outcomes and improving disease status in breast cancer survivors.

The purpose of this thesis research was to determine how FV intake is associated with HR-QoL among breast cancer survivors enrolled in a cross-sectional survey study. It is anticipated that the results of this study will inform the development and testing of dietary interventions for breast cancer survivors with the goal of improving HR-QoL. The hypothesis was that FV intake would be positively associated with overall and subscale-specific HR-QoL scores, including physical quality of life (P-QoL), social/family quality of life (S-QoL), emotional quality of life (E-QoL), functional quality of life (F-QoL), and some other additional breast cancer-related concerns.

CHAPTER 2: SYSTEMATIC REVIEW

Nutritional status and dietary intake play an important role in breast cancer survivors' disease prognosis and could have implication for HR-QoL.¹⁰ Higher diet quality has been associated with lower markers of systemic inflammation, which in turn may improve multiple aspects affecting survivors' HR-QoL.⁶ Several widely used indices to assess diet quality have been developed and validated, including the Healthy Eating Index (HEI) and the Diet Quality Index (DQI).¹¹ The HEI is a measure of diet quality that estimates adherence to the United States Dietary Guidelines for Americans and can be used to monitor changes in dietary patterns at the individual and population level; it is also commonly used in epidemiological research to evaluate the association between diet and health outcomes.¹² The DQI was developed based on the dietary guidelines outlined in a 1989 publication on Diet and Health from the National Academy of Sciences.^{11,13} HEI and DQI score reflect consumption on different food items. Generally, a diet high in FV, whole grains, dairy, seafood, plant proteins, and mono-unsaturated fatty acids would have a better HEI and DQI score.^{13,14} It has been hypothesized that better diet quality may be associated with better self-reported HR-QoL in breast cancer survivors, but the evidence is unclear. Therefore, the purpose of this work is to systematically review existing evidence on the association between measures of overall diet quality and HR-QoL among breast cancer survivors.

2.1. Methods

2.1.1. Study Selection Criteria

PubMed, Web of Science, and Scopus databases were searched to ensure all relevant literature were included in the review. Searches were done on the week of May 28th, 2018. Studies that met all of the following PICO (Table 1) criteria were included in the review: (1)

studies must include human subjects diagnosed with breast cancer; (2) participants must be women at least 18 years old; (3) participants must have survived any type of cancer treatment (chemotherapy, radiotherapy, or surgery); (4) in any clinical setting (inpatient or outpatient); (5) studies must address overall post-diagnosis diet quality as an exposure, and HR-QoL as an outcome; (6) full-text articles must be from peer-reviewed journals; (7) papers must have been published in English. Studies were excluded from the review if one or more of the following criteria were met: (1) studies not written in English; (2) studies that included animal subjects; (3) participants that were not diagnosed with breast cancer ; (4) women that are younger than 18 years; (5) participants have not received and completed a cancer therapy (chemotherapy, radiotherapy, or surgery); (6) overall post-diagnosed diet quality not an exposure, and HR-QoL not an outcome of interest; (7) grey literatures such as review, letters, editorials, dissertations, and conference abstracts.

Table 1. PICOS characteristics

Question: Is there any association between diet quality and health-related quality of life in Breast Cancer Survivors?		
Acronym	Definition	Description
P	Patient or problem	Human subjects with a breast cancer diagnosis
I	Intervention	Subjects that have completed and survived from any type of cancer treatment
C	Comparison	Not applicable
O	Outcomes	How diet quality is associated with health-related HR-QoL in breast cancer survivors
S	Study design	Quantitative studies

2.1.2. Search Strategy

The systematic review protocol described in the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement and previous systematic review methods utilized by our research team were adopted to guide the review process.¹⁵ A keyword search was performed in PubMed, Scopus, and Web of Science. The search algorithm included all possible combinations of keywords (1) “breast cancer,” or “breast neoplasm,” or “breast carcinoma,” or “breast cancer survivors”; (2) “diet quality,” or “diet,” or “nutrition,” or “dietary pattern,” or “fruit and vegetable intake,” or “fruit and vegetable,” or “prudent dietary pattern,” or “HEI,” or “Healthy Eating Index,” or “Alternate Healthy Eating Index,” or “AHEI,” or “Mediterranean Diet Score,” or “alternate Mediterranean Diet Index,” or “Healthy Food Index,” or “HFI,” or “Dietary Guidelines Index,” or “DGI,” or “DASH diet score” ; (3) “Quality of life,” or “QOL,” or “pain,” or “fatigue,” or “sleep,” or “emotional quality of life,” or “emotional QOL,” or “functional quality of life,” or “functional QOL,” or “social quality of life,” or “social QOL,” or “physical quality of life,” or “physical QOL.”

The specific search algorithm for each database is provided in Appendix A. All titles and abstracts of the articles identified through keyword search were screened based on the study’s inclusion and exclusion criteria. Articles that were potentially relevant were retrieved for full-text evaluation.

A cited reference search (i.e., forward reference search) and a reference list search (i.e., backward reference search) based on the articles that met the study selection criteria, were further screened and evaluated using the same study selection criteria. A trained second reviewer screened 100 randomly selected titles/abstracts for inclusion/exclusion. An inter-rater kappa of 0.98, which qualified as “excellent agreement,” was considered adequate to continue for a

systematic review.¹⁶ Two trained researchers jointly determined the inclusion/exclusion of all articles retrieved in full text, and discrepancies were resolved through discussion.

2.1.3. Data Extraction

Data extraction was used to collect the following methodological and outcome variables from each included study: author(s), study design, population/location, sample size, participants characteristics including participants' age and stage/type of cancer, diet quality assessment tools (index and food measurement tool used), outcome (instrument used), adjusted variables, and findings.

2.1.4. Data Analysis

Two trained researchers, independently read and recorded the details of the selected studies. Each selected article was analyzed for key findings. Study details and results were grouped into areas of similarity, and findings were reported. A meta-analysis was not appropriate because the included studies did not include the same study design.

2.2. Results

2.2.1. Study Selection

Utilizing Scopus, PubMed, and Web of Science database, 1,869 articles were identified through keywords. After removing duplicate titles, 1,433 articles remained for title and/or abstract screening. 1,415 of those articles did not meet eligibility for this systematic review. Out of the 18 articles remaining, 13 articles were excluded after full-text review. Three studies did not measure dietary pattern specifically, seven studies did not have HR-QoL as an outcome dependent variable, one study was written in Mexican, and two studies did not assess the relationship between diet quality and HR-QoL. The remaining five studies selected for inclusion

were published between 2006-2018. The stages of the review process, including study identification, inclusion, and exclusion, are shown in Figure 1.

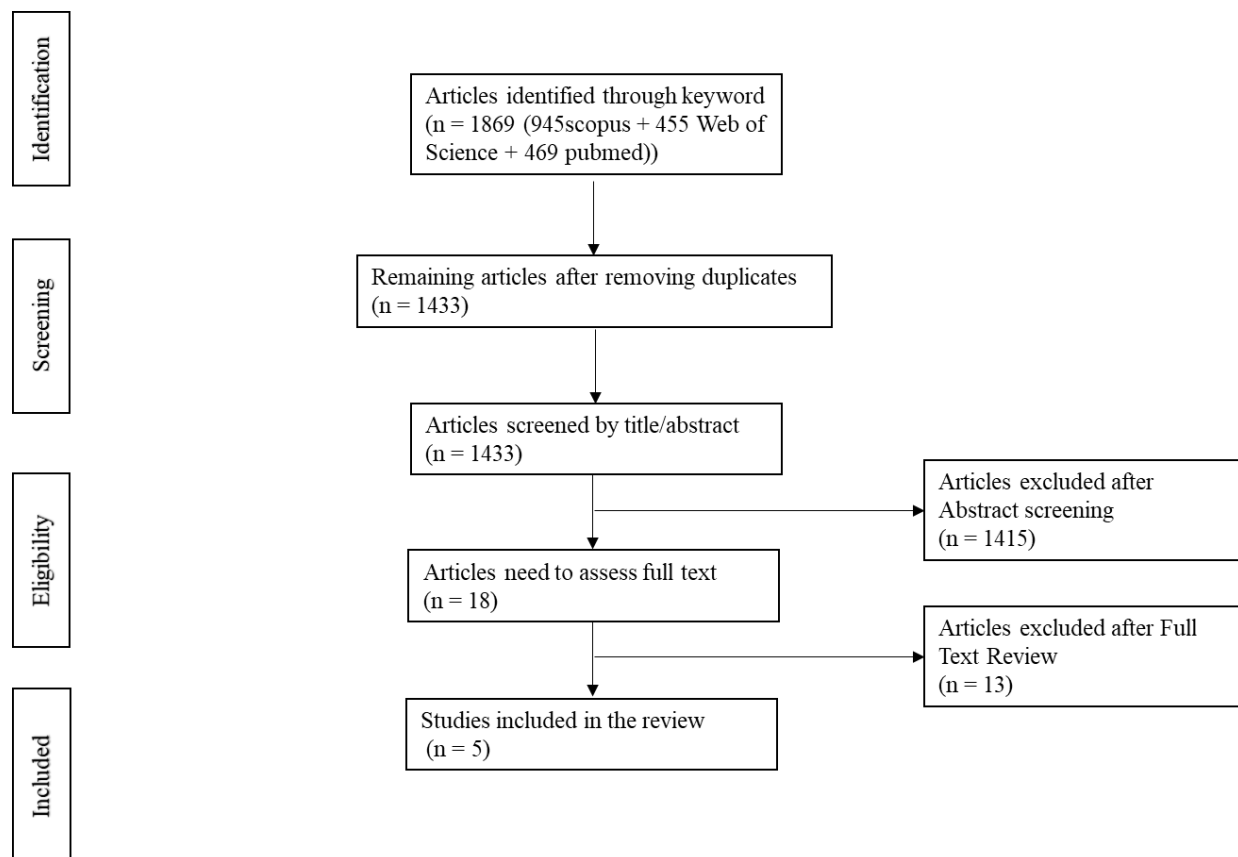


Figure 1. Study Selection Flow Chart

2.2.2. Basic Characteristics of Selected Study

Table 2 reports the basic characteristics of the five articles included in the review. The studies selected for the systematic review came from a variety of locations. Four of the studies were conducted in regions in the United States. One study was conducted in Korea. The studies were published in 2006-2018. All five of the included studies had cross-sectional designs. Every study assessed post-diagnosis diet quality using a different form of a food frequency questionnaire (FFQs) and 24-hr diet recall. Different HR-QoL assessments were used as well,

generally using questionnaires or surveys. All studies reported the status of the survivor's breast cancer (i.e. stage 1-3). Three articles gave detail about the survivor's cancer treatments and two articles gave the comorbidities. The sample sizes of the studies ranged from 41 – 770 female survivors that were 18+ years old.

2.2.3. Predictor of Interest

Breast cancer survivors' post-diagnosis diet quality as a predictor was determined in the initial review process.

HEI-2005 and HEI-2010 score: The HEI was developed by the National Cancer Institute (NCI) and the US Department of Agriculture (USDA).¹⁷ Both HEI-05 and HEI-2010 include 13 components that are classified into two main groups, adequacy components (dietary components to increase) and moderation components (dietary components to decrease).¹⁸ Adequacy components (FV, whole-grains, dairy, total protein foods, seafood, plant proteins, and mono- or poly-unsaturated fatty acids) represent the dietary elements that are encouraged, and moderation components (refined grains, sodium, added sugars, and saturated fats) represent the dietary elements that are recommended limit to consumption.¹⁴ For adequacy components, a higher score reflects higher intake which is desirable; and for moderation components, a higher score reflects lower intake which is also desirable.¹⁴ Overall, a higher HEI score represents a diet that is better aligned with the dietary recommendations.

DQI score: The DQI was developed by the National Academy of Sciences based on the dietary guidelines outlined in a 1989 publication on Diet and Health.¹³ It measures dietary consumption in total fat including saturated fat and cholesterol, FV, complex carbohydrates, protein, sodium, and calcium.¹¹ The score is stratified into three levels: 1.) lower cut-off, 2.) intermediate-range, and 3.) upper boundary, based on the dietary recommendations.¹¹ Total score ranges from 0

(excellent diet) to 16 (poor diet). Higher intake of FV, complex carbohydrates, protein and calcium would be given a lower score, and higher intake of saturated fat, cholesterol, and sodium would be given a higher score.¹³

2.2.4. Outcome of Interest

The outcomes selected were the HR-QoL and its subsets, which included physical quality of life (P-QoL), emotional quality of life (E-QoL), social quality of life (S-QoL), and functional quality of life (F-QoL). Instruments used to measure HR-QoL across various studies include Piper Fatigue Scale, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30, Quality of Life Questionnaire Breast Cancer Module 23, the Medical Outcomes Survey Short Form-36, and Functional Assessment of Cancer Therapy-Breast and Endocrine Subscale,

Table 2. Studies Basic Characteristics (p.16-17)

Authors	Study design	Population/Location	Sample size	Participants Characteristics		Diet Quality Assessment	
				1.) Age	2.) Stage of cancer (Or type of cancer)	1.) Index	2.) Food Measurements
George, S.M. et al, 2014	cross-sectional, secondary analysis of baseline data	New Mexico, Los Angeles County, and Western Washington	770	54 to 60 years	Stages 0 to IIIA	HEI-2010	FFQ
Kim, Na-Hui et al., 2018	Cross-sectional	Korea	232	21 to 79 years	Stages from I to III	Self-defined diet quality: a.) Healthy Dietary Pattern; b.) Western Dietary Pattern	A non-consecutive 3-day dietary record on 2 weekdays and 1 weekend day
Mosher, Catherine et al., 2009	Baseline telephone interviews eligibility assessment for a later on diet and exercise intervention trial.	Surveys administered by the Diet Assessment Center at Pennsylvania State University	753	≥ 65	In situ, localized, regional, distant or unknown cancer types	HEI-2005	24- recall
Orchard et al., 2017	cross-sectional, secondary analysis of baseline data	Ohio State University Comprehensive Cancer Center	44	59 - 61	Stage I to III endocrine receptor-positive breast cancer survivors	HEI-2010	FFQ
Wayne et al., 2006	cross-sectional, secondary analysis of baseline data	North-central New Mexico, Los Angeles County, CA, and western Washington state	714	15 - 64	in situ or Stage I to IIIA disease Breast Cancer	DQI	FFQ

Table 2. (cont.)

Authors	Outcome (Instrument Used)	Adjusted Variables	Findings
George, S.M. et al, 2014	Fatigue (measured with the Piper Fatigue Scale)	Age, caloric intake, alcohol, physical activity, BMI, treatment, race/ethnicity, antidepressant use, and comorbidities	Postdiagnosis diet quality was inversely and independently associated with fatigue
Kim, Na-Hui et al., 2018	HR-QoL (European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 and Quality of Life Questionnaire Breast Cancer Module 23)	Age at diagnosis, BMI at diagnosis, energy intake, marital status, education, stage at diagnosis, physical activity, time since surgery, and menopausal status	Healthy dietary patterns were associated with lower dyspnea scores and higher insomnia scores but not associated with overall HR-QoL
Mosher, Catherine et al., 2009	HR-QoL (The Medical Outcomes Survey Short Form-36)	Age, education, and comorbidities	Diet quality was positively associated with physical functioning and vitality. Greater BMI was associated with worse physical QOL
Orchard et al., 2017	Inflammation and HR-QoL (IL-6, TNFR-2, IL-17; Stanford Health and Disability Questionnaire + Functional Assessment of Cancer Therapy-Breast and Endocrine Subscale)	BMI	Higher HEI was associated with lower IL-6 and TNFR-2. No significant correlation between HEI-2010 and HR-QoL.
Wayne et al., 2006	HR-QoL (The Medical Outcomes Survey Short Form-36)	Age, race, BMI, education, stage of disease, time from diagnosis	Better diet quality associated with higher mental health and physical health.

2.2.5. Post-Diagnosis Diet Quality and HR-QoL

Three out of five studies included used the HEI to assess participants' diet quality. George et al. (2014) in the cohort of the HEAL study used HEI-2010 to assess the diet quality of 770 breast cancer survivors in a multiethnic prospective cohort study.¹⁹ The results concluded that diet quality based on the HEI scores are inversely and independently related to fatigue. Mosher et al. (2009) used the HEI-2005 in baseline telephone interviews to determine if there is an association between diet quality and HR-QoL among 753 breast cancer survivors.²⁰ The study's results showed that better diet quality combined with exercise was associated with better P-QoL ($p \leq 0.05$). Orchard, Andridge, Yee, and Lustberg (2017) did a cross-sectional, secondary analysis using the HEI-2010 on 44 breast cancer survivors.⁶ Based on the study's results after adjustments, there was no significant correlation between HEI scores and HR-QoL scores.

One out of five studies included used the DQI to assess participants' diet quality. Wayne et al. (2006) conducted a cross-sectional, secondary analysis within the cohort of the HEAL study on 714 cancer survivors and collected data using the DQI, which measures if participants eat the optimal amount of fats, sodium, fruits, vegetables, grains, proteins, and calcium.²¹ The results of this analysis showed that an "excellent score" on the DQI was associated with improving physical functioning, bodily pain, social functioning, role-emotional, and mental health.

One out of five studies included used a self-defined and adjusted dietary patterns model to assess participants' dietary intake and HR-QoL. Kim et al. (2018) conducted a study in Korea gathering dietary records of 232 Korean women diagnosed with stage I-III breast cancer between the ages of 21 and 79 years.²² There were two major dietary patterns found in this cross-sectional

study. A healthy dietary pattern characterized by high intakes of fruits, vegetables, and whole-grain intake with less saturated fat and refined grain intake and a western dietary pattern characterized by high intake of refined grains and saturated fat. The healthy dietary pattern was significantly inversely associated with dyspnea score ($p=0.005$). However, no association between either the healthy or western dietary pattern and overall or subscale-specific HR-QoL were found.

2.3. Overall Conclusion

In conclusion, it is suggested from the two analyses of the HEAL study that HEI-2010 score was inversely and independently associated with fatigue level, and DQI score was positively associated with subsequent mental and physical functioning in breast cancer survivors. It is also suggested from the Mosher et al., 2009 study that the HEI-2005 score was observed positively associated with physical functioning and vitality in older, long-term breast, prostate, and colorectal cancer survivors. This suggested following the dietary guidelines recommendation may improve some components of HR-QoL. However, study from the Orchard et al., 2017 observed no significant correlation between HEI-2010 score and HR-QoL. Also, study from the Kim et al., 2018 observed no statistical association between dietary pattern and overall and subscale specific HR-QoL score. The disagreements between study results suggested the need for more investigations to assess the association between diet quality and HR-QoL.

CHAPTER 3: METHODS

3.1. Subjects, Recruitment and Data Collection

This was a cross-sectional pilot study of 82 breast cancer survivors who completed an online survey that included self-reported assessments of diet, HR-QoL, demographics, behavioral factors other than diet, and clinical data on cancer stage, hormone status and treatment. From August 2018 to January 2019, 441 breast cancer survivors were recruited and completed the online survey. The inclusion criteria were 1.) diagnosed with ductal carcinoma in situ (DCIS) or Stage I – IV breast cancer, and 2.) 18+ years of age. To achieve a representative population sample for this study, no exclusions based on tumor stage, treatment modalities and/or current stage of disease were made.

The online survey was developed through the Research Electronic Data Capture (REDCap) system hosted at Carle Foundation Hospital. REDCap is a Health Insurance Portability and Accountability Act (HIPAA) compliant and secure web application for building and managing online survey and databases.²³ REDCap provides secure, web-based applications that are flexible enough to be used for a variety of research. It provides an intuitive interface for users to enter data and has real-time validation rules at the time of entry.²⁴ It also saves time for the researcher to retrieve data from the system. An online survey link was specifically built for our breast cancer study through REDCap and disseminated along with a recruitment message via the following methods: 1.) The University of Illinois Extension's social media network, such as Facebook, Instagram, and Twitter; 2.) The University of Illinois' eWeek Broadcast Newsletter; 3.) Dr. Anna Arthur's cancer and nutrition epidemiology lab website; and 4.) A variety of online social media breast cancer support groups. Potential participants who were interested in the study would click on the survey link and complete the survey. Two screening questions, 1. Do you

have a history of breast cancer? and 2. Are you 18 years old or older? were asked to ensure participants' eligibility before accessing the online survey. The consent process and HIPAA authorization (an authorization form that requires a signature from participants for use or disclosure of protected health information) were completed online before participants accessed and completed the survey. A \$10 Amazon gift card was offered to participants who completed the survey in full and provided the study team with their contact information (first and last name, mailing address or email address).

3.2. Survey instruments

To assess fruit and vegetable intake, participants completed the NIH dietary screener questionnaire (DSQ), which was used to estimate average daily servings of FV intake.²⁵ The DSQ includes 26 items that query the frequency of consumption in the past month of selected foods and drinks. It has been validated for capturing intakes of “dairy intake in cup equivalent per day, added sugars in teaspoon equivalent per day, whole grains in ounce equivalent per day, fiber in grams, calcium in milligrams, and red meat and processed meat in times per day.”²⁶ The FV food items were as follow: 1. 100% pure fruits juices; 2. Fruits, either fresh or frozen; 3. green leafy or lettuce salad; 4. potatoes or sweet potatoes, restricted to prepared by baked, boiled, and mashed; 5. beans such as baked beans, beans in soup, pork and beans, or any other type of cooked dried beans; and 6. other types of vegetables.²⁶ Scoring algorithms provided by the NCI were then applied to estimate participants' total FV intake in cup equivalent.

To assess HR-QoL, participants completed the Functional Assessment of Cancer Therapy-Breast Cancer (FACT-B).²⁷ FACT-B has been previously validated for measuring multidimensional HR-QoL in patients with breast cancer.²⁸ It includes statements pertaining to various domains of HR-QoL for participants to rate, including physical well-being, emotional

well-being, social/family well-being, and functional well-being with an additional set of statements specific to breast cancer-focused concerns.²⁷ The overall HR-QoL score, as well as for each individual subscale were computed.

3.3. Survey Screening

Two trained research personnel independently screened 441 completed surveys to assess survey responses for relative reliability. Previous research suggests that participants willing to provide some form of personal information can be considered more reliable.²⁹ Personal information such as first and last name, zip code, date of birth and age were assessed. Specifically, trained survey raters evaluated whether the date of birth given matched the age provided. Some questions were also built into the survey for being asked repeatedly to include within the screening process. Previous research suggests that consistent responses to repeated questions are essential to improve relative reliability.²⁹ Participants' responses on two separate HR-QoL statements asking about lack of energy and fatigue level were evaluated since lack of energy is relatable with fatigue. Another HR-QoL statement querying nausea level was asked twice to evaluate responses' reliability. The screening criteria mentioned above were used to ensure the survey responses relative reliability. Completed surveys from 82 participants were recognized as reliable and included in the final analysis.

3.4. Data Management and Analysis

REDCap was used for data management and storage. All information was kept confidential by maintaining data in password-protected storage platforms.

Statistical analysis was performed using Statistical Analysis System (SAS) version 9.4 software (license purchased from SAS Institute Inc. Cary, NC).

The predictor of interest, participants' FV intake, was estimated in cup equivalents based on their frequency of consumption in a month, in a week, or in a day, as reported in the DSQ. Participants' FV intake was organized into two categories: 1.) below the population median, <2 Cups FV/day and 2.) above the population median, ≥ 2 Cups FV/day. According to the Centers for Disease Control and Prevention (CDC), federal guidelines recommend that adults eat at least 1 ½ to 2 cups per day of fruits and 2 to 3 cups per day of vegetables as part of a healthy eating pattern.³⁰ The CDC recommendation for FV intake was not selected for categorizing FV intake in this sample to avoid the distribution being heavily skewed as the median of FV intake among this sample (2 cups/day) was significantly lower than the amount set forth by federal guidelines.

Epidemiologic characteristics assessed were age, race, body mass index (BMI), education, employment, income, smoking and drinking status, stage of disease, treatment modality, comorbid health conditions, and hormone status. Frequencies and percentages of all epidemiologic variables were calculated. The distribution of FV intake according to demographic, clinical and behavioral characteristics were computed.

The outcome of interest, overall HR-QoL, and subscale-specific scores, were estimated based on participants' responses on the FACT-B survey. The highest possible score for overall HR-QoL was 148, while the highest possible score for physical QoL, social QoL, and functional QoL was 28, for emotional QoL the highest possible score was 24, and for the breast cancer subscale the highest possible score was 40.

Multivariable linear regression models were examined to evaluate the association between FV intake and overall HR-QoL and subscale-specific scores. The models were adjusted for self-reported age, BMI, stage of disease, and income.

CHAPTER 4. RESULTS

4.1. Demographics

The results of sociodemographic and clinical characteristics are displayed in Table 3.

The mean age of the study population was 41.0 years old $\pm$ 8.4 years, with the youngest age of 23 and eldest age of 75. A majority were white. BMI ranged from 14.9 kg/m² to 31.3 kg/m², and average BMI was 21.4 kg/m². The majority were classified as normal weight. Most participants reported earned a bachelor's degree. The majority of the sample, 57%, reported they work fulltime, while 18% have a part-time job and the rest were either homemakers, people with disabilities, retired or unemployed. Most participants have an income level between \$65,000 to \$74,999. The majority of participants were former smokers and former drinkers. The largest proportion of the study population, 44%, were diagnosed with invasive lobular or invasive ductal breast cancer while 32% were diagnosed with DCIS. The most common comorbid conditions were cardiovascular-related issues including heart disease, stroke, blood clots, and hypertension while the second most common was diabetes. The mean time since breast cancer diagnosis was 1.9 years $\pm$ 2.3 years. Most participants were diagnosed with hormone-receptor positive tumors (estrogen receptor positive and/or progesterone receptor positive).

Table 3: Sociodemographic and clinical characteristics (n=82)	
Characteristic	N (%)
Age (y)	
Mean $\pm$ SD	41.0 $\pm$ 8.4
Min/Max	23.0/75.0
Race ^a	
Black or African-American	20 (24.4)
Caucasian or White	51 (62.2)
Other	10 (12.2)
BMI (kg/m²)^b	
Mean $\pm$ SD	21.4 $\pm$ 3.1
Min/Max	14.9/31.3
Education ^c	
Less than high school	0(0.0)
High school	1 (1.2)
Some college (no degree)	24 (29.6)
2-year degree	18 (22.2)
Bachelor's degree	31 (38.3)
Graduate degree	7 (8.7)
Employment ^d	
Full-time	47 (57.3)
Part-time	15 (18.3)
Other ^e	18(21.9)

Table 3. (cont.)

Income(\$)	
< \$15,000	11 (13.4)
\$15,000 - \$34,999	8 (9.8)
\$25,000 - \$49,999	14 (17.1)
\$50,000 - \$64,999	13 (15.9)
\$65,000 - \$74,999	21 (25.6)
\$75,000 - \$99,999	8 (9.7)
> \$10,0000	2 (2.4)
Prefer not to answer	5 (6.1)
Smoking Status	
Current	5 (6.1)
Former	52 (63.41)
Never	25 (30.5)
Drinking Status ^f	
Current	10 (12.2)
Former	63 (76.8)
Never	8 (9.8)
Stage	
DCIS	26 (32.1)
Invasive	36 (44.4)
Don't know/missing	20 (24.4)

Table 3. (cont.)

Time since diagnosis (in years) ^g	
Mean $\pm$ SD	1.9 $\pm$ 2.3
Min/Max	0.4/11.5
Treatment	
Surgery	5 (6.1)
Chemotherapy	1 (1.2)
Radiation therapy	5 (6.1)
Surgery + Chemotherapy + Radiation therapy	14 (17.1)
Other _h	57 (69.6)
Health comorbidities ⁱ	
Cardiovascular related ^j	22 (34.4)
Diabetes	12 (18.8)
None	30 (46.9)
Hormone-receptor status (HR+ or HR-) ^k	
HR+ (ER+ and/or PR+)	34(41.5)
HR- (ER- AND PR-)	2(2.4)
Don't know/Not discussed	27(32.9)

Missing:

a=1, b = 15, c = 1, d = 2, f = 1, g = 42, i = 18, k = 19

e = homemaker, disabled, retired, unemployed

h = hormonotherapy, Immunotherapy, others, none, missing

j = heart disease, stroke and blood clots, and hypertension

4.2. Epidemiologic Characteristics of Women by Total FV Intake

The results of epidemiologic characteristics of women by total fruit and vegetable intake are displayed in Table 4.

Age, BMI, education, and employment were not significantly associated with breast cancer survivors' FV intake. Income was significantly associated with participants' FV intake (p-value = 0.00). Participants who reported an income level of < \$15,000 also reported consuming < 2 cups of FV per day while participants reporting an income $\geq$ \$15,000 reported consuming $\geq$ 2 cups FV per day.

Smoking or drinking status, time since breast cancer diagnosis, treatment modality, comorbid health conditions, and hormone-receptor status were not significantly associated with survivors' FV intake. Stage of disease was the only clinical characteristic found to be significantly associated with survivors' FV intake (p-value = 0.02). Participants who were diagnosed with invasive breast cancer were more likely to consume $\geq$ 2 cups of FV per day compared to those with a DCIS diagnosis.

Table 4. Epidemiologic characteristics of women by total fruit and vegetable intake					
	< 2 Cups/day		≥ 2Cups/day		
	No.	%	No.	%	P-value
Number of participants n =80 ^a	40	50.0	40	50.0	
Age (y)					0.51
Mean ± SD	40.4 ± 6.7		41.6 ± 9.7		
BMI (kg/m2) ^b					0.17
Mean ± SD	20.8 ± 2.8		21.9 ± 3.1		
Education					0.80
2 year degree or Less	23	57.5	19	47.5	
Bachelor's degree or more	17	42.5	21	52.5	
Employment ^c					0.14
Full-time	22	55.0	25	64.1	
Part-time	11	27.5	4	10.3	
Other _d	7	17.5	10	25.6	
Income(\$)^e					0.00*
< \$15,000	11	28.2	0	0	
≥ \$15,000	28	71.8	37	92.5	
Smoking Status					0.80
Smoker	28	70.0	29	72.5	
Never	12	30.0	11	27.5	
Drinking Status^f					0.12
Current	2	5.1	8	20.0	
Former	34	87.2	28	70.0	
Never	3	7.7	4	10.0	
Stage ^g					0.02*
DCIS	12	30.8	14	35.0	
Invasive	13	33.3	22	55.0	
Don't Know/missing	14	35.9	4	10.0	
Time since diagnosis ^h					0.19
Mean ± SD	1.4 ± 1.0		2.4 ± 2.9		
Treatment					0.36
Surgery	2	5.0	3	7.5	
Chemotherapy	1	2.5	0	0	
Radiation therapy	1	2.5	4	10.0	
Surgery + Chemotherapy + Radiationtherapy	5	12.5	8	20.0	
Other _i	31	77.5	25	62.5	
Health comorbidities ^j					0.23
Cardiovascular related	10	29.4	12	41.4	
Diabetes	5	14.7	7	24.1	
None	19	55.9	10	34.5	

Table 4. (cont)

Hormone-receptor status (HR+ or HR-) ^k					0.17
HR+ (ER+ and/or PR+)	17	100.0	17	89.5	
HR- (ER- AND PR-)	0	0	2	10.5	

Missing : a = 2, b = 14, c = 1, e = 4, f = 1, g = 1, h = 40, j = 17, k = 44

d = homemaker, disabled, retired, unemployed

i = hormonotherapy, Immunotherapy, others, none, missing

4.3. Multivariable Linear Regression

Table 5. displays the results of multivariable adjusted least square means (SE) of HR-QoL score by FV intake after adjusting for BMI, age, stage of disease, and income. FV intake was not significantly associated with overall HR-QoL or any subscale-specific scores. However, a non-significant inverse association was observed between FV intake and overall and subscale-specific HR-QoL.

Table 5. Multivariate adjusted least square means (SE) of HR-QoL score by fruits and vegetables intake ^a						
	Overall HR-QoL score	Physical Quality of Life	Emotional Quality of Life	Social Quality of Life	Functional Quality of Life	Breast cancer concern-focused Quality of Life
<2 Cups	96.3 (4.1)	20.7 (1.1)	17.2 (0.8)	16.4(1.1)	15.5(1.0)	26.5(1.2)
≥ 2 Cups	92.9(4.4)	20.1(1.2)	16.7 (0.9)	16.4 (1.2)	15.2 (1.1)	24.4 (1.3)
p-Contrast above	0.50	0.63	0.61	0.95	0.84	0.16

a = adj. for age, BMI, stage of disease, and income

CHAPTER 5. DISCUSSION

5.1. Trends and Interpretations

In summary, FV intake in cup equivalents was not associated with overall or subscale specific HR-QoL in a sample of 82 female breast cancer survivors. However, some interesting associations were observed among participants' demographic characteristics, FV intake, and HR-QoL scores.

The mean age of the study population was 41.0 ± 8.4 , with the youngest age of 23 and the eldest age of 75. According to the NCI, the median age of breast cancer diagnosis in the United States is 62.³¹ The mean age in this study was explicitly younger than what was reported by the NCI. This average age was also significantly younger than the average age and standard deviation reported in previous research studies. The ages reported in the HEAL study ranged from late 40s to early 60s.^{19,21} Possible reasons behind the exceptionally lower average age in this sample could be explained by our recruitment of breast cancer survivors through social media support groups, some of which specifically targeted young breast cancer survivors. Additionally, this study was limited to participants who have access to the internet and were able to use an electronic device to complete an online survey. Younger breast cancer survivors may be more likely to own and use an electronic device, have access to the internet, and have the technological knowledge and skills to complete a survey through an online application.

The mean BMI of study participants was 21.4 kg/m^2 , indicating most participants were classified as normal weight, and this is substantially lower than the mean BMI reported in previous literature of breast cancer survivors. From a previous pooled analysis that investigated the association between BMI and cancer survival, a total of 11,702 cancer patients from 22 clinical trials were identified, and among the 5201 breast cancer patients, 3767 of them (72.4%)

had a BMI ≥ 25 kg/m², indicating most of the breast cancer survivors were overweight or obese.³² The average BMI reported in the HEAL study and mean BMI reported in the Diet Quality, Inflammation, and Quality of Life in Breast Cancer Survivors study was ≥ 29 kg/m², indicating most survivors were obese.^{19,21} The reason behind the lower mean BMI value in the current study is unclear, but one possible explanation is that most participants in this study were younger breast cancer survivors and there was also a high prevalence of self-reported current or former smoking. Cigarette smoking is usually associated with lower BMI, and previous studies have shown that current or former cigarette smokers were generally leaner than never smokers of the same age and sex.³³ It was also demonstrated from previous animal studies that nicotine decreased appetite and energy intake, and cigarette smoking increased resting metabolic rate in female rats.³⁴

In previous research, higher education and socioeconomic status (SES) was suggested to have a positive association with FV intake among whites, blacks, and Hispanics in the United States.³⁵ It was also reported that lower education and/or lower SES was associated with less fish and vegetable consumption, but more fried foods, pasta, potatoes, table sugar, and beer consumption.³⁶ Our results also showed higher attained education and working full-time were each associated with higher FV intake. Moreover, income level was positively associated with participants' FV intake.

Stage of disease was significantly associated with participants' FV intake. Participants with an invasive breast cancer diagnosis were more likely to have higher FV intake. The reason for this is unclear; however, FV has been suggested to have a protective effect on breast cancer disease status.³⁷ A previous study has shown that adherence to a higher quality diet that emphasized high FV intake was associated with reduced risk of non-breast cancer mortality and

better HR-QoL.³⁸ We hypothesize that perhaps participants who have an invasive breast cancer diagnosis were experiencing issues related with lower HR-QoL, and those participants were adopting a health behavioral change such as increasing their FV intake in order to improve their HR-QoL.

The mean time since breast cancer diagnosis in this sample was 1.9 ± 2.3 years with the shortest time being 0.36 year and the longest time 11.45 years. Based on our participant demographics, it appears that a majority of the sample were younger breast cancer survivors and were within 5 years of their initial breast cancer diagnosis. Even though time since breast cancer diagnosis was not significantly associated with survivors' FV intake, survivors who have a longer time since diagnosis had a greater FV intake.

It is suggested that FV intake is associated with hormone-receptor status in breast cancer survivors. Previous literature concluded that vegetable consumption was inversely associated with risk of estrogen receptor-negative breast cancer in a large pooled analyses,³⁹ and women who scored higher in various diet quality indexes had a lower risk of estrogen receptor-negative breast cancer.⁴⁰ While FV intake may modify the risk of estrogen receptor-negative breast cancer, FV intake was also suggested to moderate hormonal level in affecting tumor growth and progression and to improve breast cancer survival and HR-QoL in physically active women.⁴¹ However, differences in FV intake within both groups in HR+ and HR- were not significant in this study population.

5.2. Summary of Results

To conclude, FV intake was not associated with participants' overall or sub-scale specific HR-QoL scores. However, non-significant, inverse associations were observed between FV intake and all HR-QoL scores, where participants reporting FV intake ≥ 2 cups per day reported

lower overall and sub-scale HR-QoL scores. This study result is consistent with the result from a cross-sectional, secondary analysis of baseline data collected from 44 breast cancer survivors after completion of primary therapy, where there were no significant associations observed between diet quality, as measured by the HEI-2010 and emphasized FV, and HR-QoL outcomes.⁶ Results from this study are also consistent with a cross-sectional analysis of 232 breast cancer survivors who completed breast cancer surgery at least 6 months prior to the baseline evaluation, where a healthy dietary pattern characterized by higher FV intake was not significantly associated with overall HR-QoL.²² In contrast, results from two analyses of the HEAL study suggested that better post-diagnosis diet quality measured by the HEI-2010 and DQI, which included higher FV intake, was directly associated with mental and physical functioning and less cancer-related fatigue while improving P-QoL in breast cancer survivors.^{19,21} The discrepancy between results from this study and previous literature suggests the need for more robust investigations into the relationship of FV intake and breast cancer survivors' HR-QoL.

5.3. Strengths and Limitations

Some strengths were identified in this study. The assessment tools used in evaluating participants' FV intake and HR-QoL are survey instruments that are widely used and previously validated. The DSQ was developed by the NCI and validated for estimating frequency in consuming common food items.⁴² The DSQ has been used in various epidemiologic studies, including the National Health and Nutrition Examination Survey (NHANES).²⁵ The DSQ is a shortened version of a traditional total dietary assessment food frequency questionnaire (FFQ), such as the Harvard FFQ or Block FFQ.⁴² It has been shortened into 26 items, and the common food items were selected based on common food items in the typical American diet.⁴² The DSQ

requires a shorter time to complete compared to a traditional FFQ, and questions are written in simple language to improve ease of completing the questions.⁴³

The Functional Assessment of Cancer Therapy (FACT) survey was validated for assessing cancer survivors' HR-QoL in four main domains: P-QoL, S-QoL, E-QoL, and F-QoL.⁴⁴ It is also suggested that the FACT-B survey is appropriate for use in oncology clinical trials, as well as in clinical practice to evaluate breast cancer survivors' HR-QoL; “it demonstrates the ease of administration, brevity, reliability, validity, and sensitivity to change.”⁴⁵ The FACT-B survey has been widely used in the cancer epidemiology research field.²⁸

The online survey platform allowed the study to be advertised through various breast cancer support social media groups that spread throughout the United States and reached a diverse population within a short period of time, which is an additional strength of the study. Furthermore, an online survey study also saves time for the research team to collect, manage and retrieve data from the survey and reduces cost. The traditional paper survey requires printing of the physical survey, which can be costly, particularly if it is also mailed to participants.

Four main limitations have been identified in this study. First, FFQs are susceptible to measurement error and systematic biases in estimating usual dietary intake. It is also limited in the ability to provide detail on quantification of food items, and as the FFQ is composed of a list of food items that were pre-specified, it may not reflect cultural differences in dietary patterns of some populations.⁴⁶ Moreover, detailed information on food preparation, exact food, and beverages consumed and brands, and contextual information during which food and beverages are consumed at the same meal is lacking.⁴⁶

Second, in order to adhere with the privacy policy, the study team had no information on participants' online identity such as IP address to evaluate the reliability of participants' eligibility and survey responses and ensure the survey was only completed one time. However, a set of criteria was developed and used to strengthen the likelihood of only including reliable survey responses.

Third, due to the small sample size, this analysis may have lacked statistical power to detect significant results. It is our ongoing plan to re-open the survey portal and recruit another set of participants to enlarge the sample size and make further statistically powerful interpretations.

Lastly, this sample was biased toward younger participants and those who have access to the internet. The analysis showed that the mean age among this sample was relatively younger than the average median age of breast cancer diagnosis in the United States. Since recruitment has been done mostly in younger breast cancer survivor social media groups, younger breast cancer survivors from those groups were more exposed to the recruitment message and online survey link. Younger participants may also be more likely to own an electronic device and complete a survey on an online application.⁴⁷ As most breast cancer survivors in the United States are older survivors, selection bias towards younger participants gives rise to non-comparability for the interpretation of results between older survivors and younger survivors.⁴⁸ Future research will need to include data from a wider age range, including older breast cancer survivors to draw conclusions that are generalizable to typical breast cancer survivors within the United States.

5.4. Expected Outcomes

Due to the small sample size, analysis of this sample may have lacked statistical power in detecting significant results. However, with a larger sample size that includes older breast cancer survivors, which is a more reflective breast cancer population in the United States, we may observe a significant association between FV and HR-QoL. In a study of 3344 Chinese breast cancer survivors, with a mean age of 59.3, it was demonstrated that physical exercise and high FV intake were positively associated with HR-QoL as measured by the Treatment of Cancer Quality of Life and its breast cancer module (EORTC QLQ-C30/+BR-23) and the Functional Assessment of Cancer Therapy-General (FACT-G).⁵ Another study that utilized the same HR-QoL evaluation tools also showed that higher FV intake was positively associated with overall HR-QoL, social, emotional, and cognitive functions in 100 Malaysian breast cancer survivors.⁴⁹ However, demographics from this study included primarily white and black breast cancer survivors. Differences according to racial and ethnic groups may have a disparate impact on results. Yet, since similar study design, dietary intake and HR-QoL assessment tools were adopted, we posit that significant associations would be observed with the desired sample size and statistical power.

5.5. Future Directions

Our next step is to reopen the survey portal and collect more data from a clinical population of cancer survivors identified through the Carle Foundation Hospital Cancer Center registry. We plan to collect 400 completed surveys and conduct further statistical analysis from a larger and more diverse population of female cancer survivors with access to more detailed and reliable clinical data.

We also plan to analyze dietary factors in relation to HR-QoL other than FV intake. It is suggested that other dietary factors such as fat intake, sugar intake, and red meat and processed meat consumption may affect cancer survivors' HR-QoL.⁵⁰ The NIH DSQ allows for the estimation of “dairy intake in cup equivalent per day, added sugars in teaspoon equivalent per day, whole grains in ounce equivalent per day, calcium in milligram equivalent, fiber in gram equivalents, and red meat and processed meat times per day.”²⁶ Investigating the associations of other dietary factors would enhance the comprehensiveness of literature on common food items that affect breast cancer survivors' HR-QoL. Furthermore, the study team will be more confident in making conclusions on different dietary patterns that affect breast cancer survivors' HR-QoL.

CHAPTER 6. CONCLUSION

In conclusion, FV intake was not associated with participants' overall or sub-scale specific HR-QoL scores. However, non-significant, inverse associations were observed between FV intake and all HR-QoL scores, where participants reporting FV intake ≥ 2 cups per day reported lower overall and sub-scale HR-QoL scores. Due to the small sample size and bias towards younger participants, the study team was not able to detect significant results that are generalizable to the overall United States breast cancer survivor population. In order to improve the statistical power of this study, we are currently collaborating with the Carle Foundation Hospital to recruit more participants and collect more reliable and comprehensive data. It is our goal to collect 400 completed surveys and conduct further statistically powerful analysis from the larger sample size.

Results from this study contribute to the fields of nutrition and breast cancer research. Dietary intake is one essential modifiable factor that may impact breast cancer survivors' HR-QoL. There is currently a limited body of literature examining associations between diet and HR-QoL among breast cancer survivors. Investigating the association between other dietary factors would expand the literature on how dietary factors that might influence breast cancer survivors' HR-QoL. It is our future plan to conduct further statistical analysis on other dietary factors that may affect survivor's HR-QoL. Such research will inform dietary interventions that aim to improve breast cancer survivors' diet and potentially improve their HR-QoL. Other clinical variables, such as tumor stage and time since disease diagnosis, may modify the association between dietary intake and HR-QoL and should be explored further. Finally, we plan to further investigate and clarify other clinical characteristics' effects on breast cancer survivors' HR-QoL.

CHAPTER 7. REFERENCES

1. Breast Cancer Facts. National Breast Cancer Foundation.
<https://www.nationalbreastcancer.org/breast-cancer-facts>. Updated March 1,2019.
Accessed March 1, 2019.
2. Female Breast Cancer. Cancer Stat Facts.
<https://seer.cancer.gov/statfacts/html/breast.html>. Updated March 1,2019. Accessed March 1, 2019.
3. Breast Statistics. American Cancer Society. Cancer Facts and Statistics.
https://cancerstatisticscenter.cancer.org/?_ga=2.2367288.945741990.1524496556-953946105.1524496556#!/cancer-site/Breast. Updated March 1,2019. Accessed March 1, 2019.
4. van Leeuwen M, Husson O, Alberti P, et al. Understanding the quality of life (QOL) issues in survivors of cancer: towards the development of an EORTC QOL cancer survivorship questionnaire. *Health Qual Life Outcomes*. 2018;16(1):114.
doi:10.1186/s12955-018-0920-0. <https://www.ncbi.nlm.nih.gov/pubmed/29866185>.
Accessed May 1, 2019.
5. Gong X-H, Wang J-W, Li J, et al. Physical exercise, vegetable and fruit intake and health-related quality of life in Chinese breast cancer survivors: a cross-sectional study. *Qual Life Res*. 2017;26(6):1541-1550. doi:10.1007/s11136-017-1496-6.
<https://www.ncbi.nlm.nih.gov/pubmed/28229328>. Accessed May 1, 2019.
6. Orchard TS, Andridge RR, Yee LD, Lustberg MB. Diet Quality, Inflammation, and Quality of Life in Breast Cancer Survivors: A Cross-Sectional Analysis of Pilot Study Data. *J Acad Nutr Diet*. 2018;118(4):578-588.e1. doi:10.1016/J.JAND.2017.09.024.

- <https://www.ncbi.nlm.nih.gov/pubmed/29233615>. Accessed May 1, 2019
7. Demark-Wahnefried W, Rock CL. Nutrition-related issues for the breast cancer survivor. *Semin Oncol*. 2003;30(6):789-798. <http://www.ncbi.nlm.nih.gov/pubmed/14663779>. Accessed March 1, 2019.
 8. Fink BN, Steck SE, Wolff MS, et al. Dietary Flavonoid Intake and Breast Cancer Survival among Women on Long Island. *Cancer Epidemiol Biomarkers Prev*. 2007;16(11):2285-2292. doi:10.1158/1055-9965.EPI-07-0245. <http://cebp.aacrjournals.org/content/16/11/2285>. Accessed May 1, 2019
 9. Pirouzpanah S, Taleban F-A, Mehdipour P, Atri M. Association of folate and other one-carbon related nutrients with hypermethylation status and expression of RARB, BRCA1, and RASSF1A genes in breast cancer patients. *J Mol Med*. 2015;93(8):917-934. doi:10.1007/s00109-015-1268-0. <https://www.ncbi.nlm.nih.gov/pubmed/25805039>. Accessed May 1, 2019.
 10. Demark-Wahnefried W, Rock CL. Nutrition-related issues for the breast cancer survivor. *Semin Oncol*. 2003;30(6):789-798. <http://www.ncbi.nlm.nih.gov/pubmed/14663779>. Accessed June 26, 2019.
 11. Fransen HP, Ocké MC. Indices of diet quality. *Curr Opin Clin Nutr Metab Care*. 2008;11(5):559-565. doi:10.1097/MCO.0b013e32830a49db. <https://www.ncbi.nlm.nih.gov/pubmed/18685450>. Accessed June 26, 2019.
 12. Overview and Background of The Healthy Eating Index. <https://epi.grants.cancer.gov/hei/>. Updated June 26, 2019. Accessed June 26, 2019.
 13. Patterson RE, Haines PS, Popkin BM. Diet quality index: capturing a multidimensional behavior. *J Am Diet Assoc*. 1994;94(1):57-64.

- <http://www.ncbi.nlm.nih.gov/pubmed/8270756>. Accessed June 27, 2019.
14. How the HEI Is Scored. USDA-FNS. <https://www.fns.usda.gov/how-hei-scored>. Updated June 27, 2019. Accessed June 27, 2019.
 15. Moher D, Shamseer L, Clarke M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst Rev*. 2015;4(1):1. doi:10.1186/2046-4053-4-1. <https://systematicreviewsjournal.biomedcentral.com/articles/10.1186/2046-4053-4-1>. Accessed June 27, 2019.
 16. McHugh ML. Interrater reliability: the kappa statistic. *Biochem medica*. 2012;22(3):276-282. <http://www.ncbi.nlm.nih.gov/pubmed/23092060>. Accessed June 3, 2019.
 17. Overview and Background of The Healthy Eating Index. <https://epi.grants.cancer.gov/hei/>. Updated June 27, 2019. Accessed June 27, 2019.
 18. Comparing the HEI-2015, HEI-2010 and HEI-2005. <https://epi.grants.cancer.gov/hei/comparing.html>. Updated June 27, 2019. Accessed June 27, 2019.
 19. George SM, Alfano CM, Neuhouser ML, et al. Better postdiagnosis diet quality is associated with less cancer-related fatigue in breast cancer survivors. *J Cancer Surviv*. 2014;8(4):680-687. doi:10.1007/s11764-014-0381-3. <https://www.ncbi.nlm.nih.gov/pubmed/25001403>. Accessed June 27, 2019.
 20. Mosher CE, Sloane R, Morey MC, et al. Associations between lifestyle factors and quality of life among older long-term breast, prostate, and colorectal cancer survivors. *Cancer*. 2009;115(17):4001-4009. doi:10.1002/cncr.24436. <https://www.ncbi.nlm.nih.gov/pubmed/19637244>. Accessed June 27, 2019.

21. Wayne SJ, Baumgartner K, Baumgartner RN, Bernstein L, Bowen DJ, Ballard-Barbash R. Diet quality is directly associated with quality of life in breast cancer survivors. *Breast Cancer Res Treat*. 2006;96(3):227-232. doi:10.1007/s10549-005-9018-6. <https://www.ncbi.nlm.nih.gov/pubmed/16538543>. Accessed June 27, 2019.
22. Kim N-H, Song S, Jung S-Y, et al. Dietary pattern and health-related quality of life among breast cancer survivors. *BMC Womens Health*. 2018;18(1):65. doi:10.1186/s12905-018-0555-7. <https://link.springer.com/article/10.1186/s12905-018-0555-7>. Accessed June 27, 2019.
23. REDCap (Research Electronic Data Capture). Harvard Catalyst. <https://catalyst.harvard.edu/services/redcap/>. Updated June 6, 2019. Accessed June 6, 2019.
24. Patridge EF, Bardyn TP. Research Electronic Data Capture (REDCap). *J Med Libr Assoc*. 2018;106(1):142. doi:10.5195/JMLA.2018.319. <http://jmla.pitt.edu/ojs/jmla/article/view/319>. Accessed June 26, 2019.
25. NHANES. About the National Health and Nutrition Examination Survey. https://www.cdc.gov/nchs/nhanes/about_nhanes.htm. Updated May 31, 2019. Accessed May 31, 2019.
26. Dietary Screener Questionnaire (DSQ) in the NHANES 2009-10: Relationship Between Dietary Factors and Food Items on the DSQ. <https://epi.grants.cancer.gov/nhanes/dietscreen/relationship.html>. Updated May 31, 2019. Accessed May 31, 2019.
27. Webster K, Cella D, Yost K. The Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System: properties, applications, and interpretation. *Health Qual*

- Life Outcomes*. 2003;1:79. doi:10.1186/1477-7525-1-79.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC317391/>. Accessed June 13, 2019
28. Matthies LM, Taran F-A, Keilmann L, et al. An Electronic Patient-Reported Outcome Tool for the FACT-B (Functional Assessment of Cancer Therapy-Breast) Questionnaire for Measuring the Health-Related Quality of Life in Patients With Breast Cancer: Reliability Study. *J Med Internet Res*. 2019;21(1):e10004. doi:10.2196/10004.
<https://www.ncbi.nlm.nih.gov/pubmed/30668517>. Accessed June 26, 2019.
 29. Wright KB. Researching Internet-Based Populations: Advantages and Disadvantages of Online Survey Research, Online Questionnaire Authoring Software Packages, and Web Survey Services. *J Comput Commun*. 2006;10(3):00-00. doi:10.1111/j.1083-6101.2005.tb00259.x. <https://onlinelibrary.wiley.com/doi/full/10.1111/j.1083-6101.2005.tb00259.x>. Accessed June 26, 2019.
 30. Lee-Kwan SH, Moore L V., Blanck HM, Harris DM, Galuska D. Disparities in State-Specific Adult Fruit and Vegetable Consumption in the United States, 2015. *MMWR Morb Mortal Wkly Rep*. 2017;66(45):1241-1247. doi:10.15585/mmwr.mm6645a1.
<https://www.cdc.gov/mmwr/volumes/66/wr/mm6645a1.htm>. Accessed June 26, 2019.
 31. Breast Cancer Risk in American Women. National Cancer Institute.
<https://www.cancer.gov/types/breast/risk-fact-sheet>. Updated March 14, 2019. Accessed March 14, 2019.
 32. Greenlee H, Unger JM, LeBlanc M, Ramsey S, Hershman DL. Association between Body Mass Index and Cancer Survival in a Pooled Analysis of 22 Clinical Trials. *Cancer Epidemiol Biomarkers Prev*. 2017;26(1):21-29. doi:10.1158/1055-9965.EPI-15-1336.
<https://www.ncbi.nlm.nih.gov/pubmed/27986655>. Accessed June 26, 2019.

33. Akbartabartoori M, Lean MEJ, Hankey CR. Relationships between cigarette smoking, body size and body shape. *Int J Obes*. 2005;29(2):236-243. doi:10.1038/sj.ijo.0802827. <https://www.ncbi.nlm.nih.gov/pubmed/15505632>. Accessed June 26, 2019.
34. Miyata G, Meguid MM, Varma M, Fetissov SO, Kim H-J. Nicotine alters the usual reciprocity between meal size and meal number in female rat. *Physiol Behav*. 2001;74(1-2):169-176. doi:10.1016/S0031-9384(01)00540-6. <https://experts.syr.edu/en/publications/nicotine-alters-the-usual-reciprocity-between-meal-size-and-meal->. Accessed June 26, 2019.
35. Dubowitz T, Heron M, Bird CE, et al. Neighborhood socioeconomic status and fruit and vegetable intake among whites, blacks, and Mexican Americans in the United States. *Am J Clin Nutr*. 2008;87(6):1883-1891. doi:10.1093/ajcn/87.6.1883. <https://www.ncbi.nlm.nih.gov/pubmed/18541581>. Accessed June 26, 2019.
36. Galobardes B, Morabia A, Bernstein MS. Diet and socioeconomic position: does the use of different indicators matter? *Int J Epidemiol*. 2001;30(2):334-340. doi:10.1093/ije/30.2.334. <https://academic.oup.com/ije/article/30/2/334/713793>. Accessed June 26, 2019.
37. He J, Gu Y, Zhang S. Consumption of vegetables and fruits and breast cancer survival: a systematic review and meta-analysis. *Sci Rep*. 2017;7(1):599. doi:10.1038/s41598-017-00635-5. <https://www.ncbi.nlm.nih.gov/pubmed/28377568>. Accessed June 26, 2019.
38. Izano MA, Fung TT, Chiuve SS, Hu FB, Holmes MD. Are diet quality scores after breast cancer diagnosis associated with improved breast cancer survival? *Nutr Cancer*. 2013;65(6):820-826. doi:10.1080/01635581.2013.804939. <https://www.ncbi.nlm.nih.gov/pubmed/23909725>. Accessed June 26, 2019.

39. Jung S, Spiegelman D, Baglietto L, et al. Fruit and Vegetable Intake and Risk of Breast Cancer by Hormone Receptor Status. *JNCI J Natl Cancer Inst.* 2013;105(3):219-236. doi:10.1093/jnci/djs635. <https://www.ncbi.nlm.nih.gov/pubmed/23349252>. Accessed June 26, 2019.
40. Fung TT, Hu FB, McCullough ML, Newby PK, Willett WC, Holmes MD. Diet Quality Is Associated with the Risk of Estrogen Receptor–Negative Breast Cancer in Postmenopausal Women. *J Nutr.* 2006;136(2):466-472. doi:10.1093/jn/136.2.466. <https://europepmc.org/abstract/med/16424129>. Accessed June 26, 2019.
41. Pierce JP, Stefanick ML, Flatt SW, et al. Greater survival after breast cancer in physically active women with high vegetable-fruit intake regardless of obesity. *J Clin Oncol.* 2007;25(17):2345-2351. doi:10.1200/JCO.2006.08.6819. <https://www.ncbi.nlm.nih.gov/pubmed/17557947>. Accessed June 26, 2019.
42. Dietary Screener Questionnaire in the NHANES 2009-10: Background. <https://epi.grants.cancer.gov/nhanes/dietscreen/>. Updated May 31, 2019. Accessed May 31, 2019.
43. Dietary Screener Questionnaire in the National Health Interview Survey Cancer Control Supplement 2015. <https://epi.grants.cancer.gov/nhis/2015-screener/>. Updated June 25, 2019. Accessed June 25, 2019.
44. Benefits of the FACIT Measurement System. <https://www.facit.org/FACITOrg/Overview/WhyFACIT/Benefits>. Updated May 31, 2019. Accessed May 31, 2019.
45. Brady MJ, Cella DF, Mo F, et al. *Reliability and Validity of the Functional Assessment of Cancer Therapy-Breast Quality-of-Life Instrument.*; 1997. www.jco.org. Accessed May

- 28, 2019.
46. Food Frequency Questionnaire at a Glance. Dietary Assessment Primer.
<https://dietassessmentprimer.cancer.gov/profiles/questionnaire/>. Updated July 8, 2019.
Accessed July 8, 2019.
 47. Olson KE, O'Brien MA, Rogers WA, Charness N. Diffusion of Technology: Frequency of use for Younger and Older Adults. *Ageing Int.* 2011;36(1):123-145. doi:10.1007/s12126-010-9077-9. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3370300/>. Accessed July 1, 2019.
 48. Biases and Confounding. Health Knowledge. <https://www.healthknowledge.org.uk/public-health-textbook/research-methods/1a-epidemiology/biases>. Updated June 25, 2019.
Accessed June 25, 2019.
 49. Mohammadi S, Sulaiman S, Koon PB, Amani R, Hosseini SM. Impact of healthy eating practices and physical activity on quality of life among breast cancer survivors. *Asian Pac J Cancer Prev.* 2013;14(1):481-487. <http://www.ncbi.nlm.nih.gov/pubmed/23534778>.
Accessed May 29, 2019.
 50. Beeken RJ, Williams K, Wardle J, Croker H. What about diet?: A qualitative study of cancer survivors' views on diet and cancer and their sources of information. *Eur J Cancer Care (Engl).* 2016;25(5):774-783. doi:10.1111/ecc.12529.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4995727/>. Accessed May 29, 2019.

APPENDIX A: SYSTEMATIC REVIEW SEARCH ALGORITHM

1. PubMed Algorithm

((“breast cancer” OR “breast cancer [MeSH Terms]” OR “breast neoplasm” OR “breast neoplasm [MeSH Terms]” OR “breast carcinoma” OR “breast carcinoma [MeSH Terms]” OR “breast cancer survivors”) AND (“diet quality” OR “diet” OR “nutrition” OR “dietary pattern” OR “fruit and vegetable intake” OR “fruit and vegetable” OR “prudent dietary pattern” OR “HEI” OR “Healthy Eating Index” OR “Alternate Healthy Eating Index” OR “Alternative Healthy Eating Index” OR “Alternate-Healthy Eating Index” OR “AHEI” OR “A-HEI” OR “Alternative Healthy Eating Index 2010” OR “Alternate Healthy Eating Index 2010” OR “AHEI 2010” OR “A-HEI 2010” OR “AHEI-2010” OR “Mediterranean Diet Score” OR “Mediterranean diet” OR “MDS” OR “alternate Mediterranean Diet Index” OR “aMED” OR “Healthy Food Index” OR “HFI” OR “Dietary Guidelines Index” OR “DGI” OR “DASH diet score” OR “DASH Diet Score”) AND (“Quality of Life” OR “Quality of Life [MeSH Terms]” OR “QOL” OR “QOL [MeSH Terms]” OR “QoL” OR “QoL [MeSH Terms]” OR “pain” OR “fatigue” OR “sleep” OR “emotional QOL” OR “emotional quality of life” OR “functional quality of life” OR “functional OQL” OR “social QOL” OR “social quality of life” OR “physical QOL” OR “physical quality of life”))

2. Web of Science Algorithm

TS=((“breast cancer” OR “breast neoplasm” OR “breast carcinoma” OR “breast cancer survivors”) AND (“diet quality” OR “diet” OR “nutrition” OR “dietary pattern” OR “fruit and vegetable intake” OR “fruit and vegetable” OR “prudent dietary pattern” OR “HEI” OR “Healthy Eating Index” OR “Alternate Healthy Eating Index” OR “Alternative Healthy Eating Index” OR “Alternate-Healthy Eating Index” OR “AHEI” OR “A-HEI” OR “Alternative Healthy Eating Index 2010” OR “Alternate Healthy Eating Index 2010” OR “AHEI 2010” OR “A-HEI 2010” OR “AHEI-2010” OR “Mediterranean Diet Score” OR “Mediterranean diet” OR “MDS” OR “alternate Mediterranean Diet Index” OR “aMED” OR “Healthy Food Index” OR “HFI” OR “Dietary Guidelines Index” OR “DGI” OR “DASH diet score” OR “DASH Diet Score”) AND (“Quality of Life” OR “QOL” OR “QoL” OR “pain” OR “fatigue” OR “sleep” OR “emotional QOL” OR “emotional quality of life” OR “functional quality of life” OR “functional OQL” OR “social QOL” OR “social quality of life” OR “physical QOL” OR “physical quality of life”))

3. Scopus Algorithm

TITLE-ABS-KEY-AUTH(("breast cancer" OR "breast neoplasm" OR "breast carcinoma" OR "breast cancer survivors") AND ("diet quality" OR "diet" OR "nutrition" OR "dietary pattern" OR "fruit and vegetable intake" OR "fruit and vegetable" OR "prudent dietary pattern" OR "HEI" OR "Healthy Eating Index" OR "Alternate Healthy Eating Index" OR "Alternative Healthy Eating Index" OR "Alternate-Healthy Eating Index" OR "AHEI" OR "A-HEI" OR "Alternative Healthy Eating Index 2010" OR "Alternate Healthy Eating Index 2010" OR "AHEI 2010" OR "A-HEI 2010" OR "AHEI-2010" OR "Mediterranean Diet Score" OR "Mediterranean diet" OR "MDS" OR "alternate Mediterranean Diet Index" OR "aMED" OR "Healthy Food Index" OR "HFI" OR "Dietary Guidelines Index" OR "DGI" OR "DASH diet score" OR "DASH Diet Score") AND ("Quality of Life" OR "QOL" OR "QoL" OR "pain" OR "fatigue" OR "sleep" OR "emotional QOL" OR "emotional quality of life" OR "functional quality of life" OR "functional QOL" OR "social QOL" OR "social quality of life" OR "physical QOL" OR "physical quality of life"))

APPENDIX B: SURVEY INSTRUMENTS

1.) NIH dietary screener questionnaire (DSQ)

These questions are about foods you ate or drank during the **past month**, that is, the **past 30 days**. When answering, please **include meals** and **snacks** at home, at work or school, in restaurants, and any place else.

Please mark to indicate your answer.

1. During the past month, how often did you eat **hot or cold cereals**? Please mark the appropriate answer.

- ☐ Never
- ☐ 1 time last month
- ☐ 2-3 times last month

- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3-4 times per week
- ☐ 5-6 times per week

- ☐ 1 time per day
- ☐ 2 or more times per day

2. During the past month, what kind of cereal did you usually eat? – Print cereal, if none leave blank.

3. If there was another kind of cereal that you usually ate during the past month, what kind was it? – Print cereal, if none leave blank.

4. During the past month, how often did you have any **milk** (either to drink or on cereal)? Include regular milks, chocolate or other flavored milks, lactose-free milk, buttermilk. Please **DO NOT** include soy milk or small amounts of milk in coffee or tea. Please mark the appropriate answer.

- ☐ Never -> go to question 6
- ☐ 1 time last month
- ☐ 2-3 times last month

- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3-4 times per week
- ☐ 5-6 times per week

- ☐ 1 time per day
- ☐ 2-3 times per day
- ☐ 4-5 times per day
- ☐ 6 or more times per day

5. During the past month, **what kind of milk** did you usually drink? Please mark the appropriate answer.

- ☐ Whole or regular milk
 - ☐ 2% fat or reduced-fat milk
 - ☐ 1%, ½%, or low-fat milk
 - ☐ Fat-free, skim or nonfat milk
 - ☐ Soy milk
 - ☐ Other kind of milk – Print milk.
-

6. During the past month, how often did you drink **regular soda or pop** that contains sugar? **DO NOT** include diet soda. Please mark the appropriate answer.

- ☐ Never
- ☐ 1 time last month
- ☐ 2-3 times last month

- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3-4 times per week
- ☐ 5-6 times per week

- ☐ 1 time per day
- ☐ 2-3 times per day
- ☐ 4-5 times per day
- ☐ 6 or more times per day

7. During the past month, how often did you drink **100% pure fruit juices** such as orange, mango, apple, grape and pineapple juices? **DO NOT** include fruit-flavored drinks with added sugar or fruit juice you made at home and added sugar to. Please mark the appropriate answer.

- ☐ Never
- ☐ 1 time last month
- ☐ 2-3 times last month

- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3-4 times per week
- ☐ 5-6 times per week

- ☐ 1 time per day
- ☐ 2-3 times per day
- ☐ 4-5 times per day
- ☐ 6 or more times per day

8. During the past month, how often did you drink coffee or tea that had **sugar or honey** added to it? Include coffee and tea you sweetened yourself and presweetened tea and coffee drinks such as Arizona Iced Tea and Frappuccino. **DO NOT** include artificially sweetened coffee or diet tea. Please mark the appropriate answer.

- ☐ Never
- ☐ 1 time last month
- ☐ 2-3 times last month

- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3-4 times per week
- ☐ 5-6 times per week

- ☐ 1 time per day
- ☐ 2-3 times per day
- ☐ 4-5 times per day
- ☐ 6 or more times per day

9. During the past month, how often did you drink **sweetened** fruit drinks, sports or energy drinks, such as Kool-Aid, lemonade, Hi-C, cranberry drink, Gatorade, Red Bull or Vitamin Water? Include fruit juices you made at home and added sugar to. **DO NOT** include diet drinks or artificially sweetened drinks. Please mark the appropriate answer.

- ☐ Never
- ☐ 1 time last month
- ☐ 2-3 times last month

- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3-4 times per week
- ☐ 5-6 times per week

- ☐ 1 time per day
- ☐ 2-3 times per day
- ☐ 4-5 times per day
- ☐ 6 or more times per day

10. During the past month, how often did you eat **fruit**? Include fresh, frozen or canned fruit. **DO NOT** include juices. Please mark the appropriate answer.

- ☐ Never
- ☐ 1 time last month
- ☐ 2-3 times last month

- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3-4 times per week
- ☐ 5-6 times per week

- ☐ 1 time per day
- ☐ 2 or more times per day

11. During the past month, how often did you eat a green leafy or lettuce **salad**, with or without other vegetables? Please mark the appropriate answer.

- ☐ Never
- ☐ 1 time last month
- ☐ 2-3 times last month

- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3-4 times per week
- ☐ 5-6 times per week

- ☐ 1 time per day
- ☐ 2 or more times per day

12. During the past month, how often did you eat any kind of **fried potatoes**, including french fries, home fries, or hash brown potatoes? Please mark the appropriate answer.

- ☐ Never
- ☐ 1 time last month
- ☐ 2-3 times last month

- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3-4 times per week
- ☐ 5-6 times per week

- ☐ 1 time per day
- ☐ 2 or more times per day

13. During the past month, how often did you eat any **other kind of potatoes**, such as baked, boiled, mashed potatoes, sweet potatoes, or potato salad? Please mark the appropriate answer.

- ☐ Never
- ☐ 1 time last month
- ☐ 2-3 times last month

- ☐ 1 time per week
- ☐ 2 times per week

- ☐ 3-4 times per week
- ☐ 5-6 times per week

- ☐ 1 time per day
- ☐ 2 or more times per day

14. During the past month, how often did you eat refried beans, baked beans, beans in soup, pork and beans or any other type of cooked dried beans? **DO NOT** include green beans. Please mark the appropriate answer.

- ☐ Never
- ☐ 1 time last month
- ☐ 2-3 times last month

- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3-4 times per week
- ☐ 5-6 times per week

- ☐ 1 time per day
- ☐ 2 or more times per day

15. During the past month, how often did you eat brown rice or other cooked whole grains, such as bulgur, cracked wheat, or millet? **DO NOT** include white rice. Please mark the appropriate answer.

- ☐ Never
- ☐ 1 time last month
- ☐ 2-3 times last month

- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3-4 times per week
- ☐ 5-6 times per week

- ☐ 1 time per day
- ☐ 2 or more times per day

16. During the past month, not including what you just answered about (green salads, potatoes, cooked dried beans), how often did you eat **other vegetables**? Please mark the appropriate answer.

- ☐ Never
- ☐ 1 time last month
- ☐ 2-3 times last month

- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3-4 times per week
- ☐ 5-6 times per week

- ☐ 1 time per day
- ☐ 2 or more times per day

17. During the past month, how often did you have Mexican-style **salsa** made with tomato? Please mark the appropriate answer.

- ☐ Never
- ☐ 1 time last month
- ☐ 2-3 times last month

- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3-4 times per week
- ☐ 5-6 times per week

- ☐ 1 time per day
- ☐ 2 or more times per day

18. During the past month, how often did you eat **pizza**? Include frozen pizza, fast food pizza, and homemade pizza. Please mark the appropriate answer.

- ☐ Never
- ☐ 1 time last month
- ☐ 2-3 times last month

- ☐ 1 time per week
- ☐ 2 times per week

- ☐ 3-4 times per week
- ☐ 5-6 times per week

- ☐ 1 time per day
- ☐ 2 or more times per day

19. During the past month, how often did you have **tomato sauces** such as with spaghetti or noodles or mixed into foods such as lasagna? **DO NOT** include tomato sauce on pizza. Please mark the appropriate answer.

- ☐ Never
- ☐ 1 time last month
- ☐ 2-3 times last month

- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3-4 times per week
- ☐ 5-6 times per week

- ☐ 1 time per day
- ☐ 2 or more times per day

20. During the past month, how often did you eat any kind of **cheese**? Include cheese as a snack, cheese on burgers, sandwiches, and cheese in foods such as lasagna, quesadilla, or casseroles. **DO NOT** include cheese on pizza. Please mark the appropriate answer.

- ☐ Never
- ☐ 1 time last month
- ☐ 2-3 times last month

- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3-4 times per week
- ☐ 5-6 times per week

- ☐ 1 time per day
- ☐ 2 or more times per day

21. During the past month, how often did you eat **red meat**, such as beef, pork, ham, or sausage? Include red meat you had in sandwiches, lasagna, stew, and other mixtures. Red meat may also include veal, lamb, and any lunch meats made with these meats. **DO NOT** include chicken, turkey or seafood. Please mark the appropriate answer.

- ☐ Never
- ☐ 1 time last month
- ☐ 2-3 times last month

- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3-4 times per week
- ☐ 5-6 times per week

- ☐ 1 time per day
- ☐ 2 or more times per day

22. During the past month, how often did you eat any **processed meat**, such as bacon, lunch meats, or hot dogs? Include processed meats you had in sandwiches, soups, pizza, casseroles, and other mixtures.

Processed meats are those preserved by smoking, curing, or salting, or by the addition of preservatives. Examples are: ham, bacon, pastrami, salami, sausages, bratwursts, frankfurters, hot dogs, and spam. Please mark the appropriate answer.

- ☐ Never
- ☐ 1 time last month
- ☐ 2-3 times last month

- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3-4 times per week
- ☐ 5-6 times per week

- ☐ 1 time per day
- ☐ 2 or more times per day

23. During the past month, how often did you eat **whole grain bread** including toast, rolls, and in sandwiches? Whole grain breads include whole wheat, rye, oatmeal and pumpernickel. **DO NOT** include white bread. Please mark the appropriate answer.

- ☐ Never
- ☐ 1 time last month
- ☐ 2-3 times last month

- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3-4 times per week
- ☐ 5-6 times per week

- ☐ 1 time per day
- ☐ 2 or more times per day

24. During the past month, how often did you eat **chocolate** or any other types of candy? **DO NOT** include sugar-free candy. Please mark the appropriate answer.

- ☐ Never
- ☐ 1 time last month
- ☐ 2-3 times last month

- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3-4 times per week
- ☐ 5-6 times per week

- ☐ 1 time per day
- ☐ 2 or more times per day

25. During the past month, how often did you eat **doughnuts**, sweet rolls, Danish, muffins, pan dulce, or pop-tarts? **DO NOT** include sugar-free items. Please mark the appropriate answer.

- ☐ Never
- ☐ 1 time last month
- ☐ 2-3 times last month

- ☐ 1 time per week

- ☐ 2 times per week
- ☐ 3-4 times per week
- ☐ 5-6 times per week

- ☐ 1 time per day
- ☐ 2 or more times per day

26. During the past month, how often did you eat **cookies, cake, pie or brownies**? DO NOT include sugar-free kinds. Please mark the appropriate answer.

- ☐ Never
- ☐ 1 time last month
- ☐ 2-3 times last month

- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3-4 times per week
- ☐ 5-6 times per week

- ☐ 1 time per day
- ☐ 2 or more times per day

27. During the past month, how often did you eat **ice cream or other frozen desserts**? DO NOT include sugar-free kinds. Please mark the appropriate answer.

- ☐ Never
- ☐ 1 time last month
- ☐ 2-3 times last month

- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3-4 times per week
- ☐ 5-6 times per week

- ☐ 1 time per day
- ☐ 2 or more times per day

28. During the past month, how often did you eat **popcorn**? Please mark the appropriate answer.

- ☐ Never
- ☐ 1 time last month
- ☐ 2-3 times last month

- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3-4 times per week
- ☐ 5-6 times per week

- ☐ 1 time per day
- ☐ 2 or more times per day

2.) Functional Assessment of Cancer Therapy-Breast Cancer (FACT-B)

Below is a list of statements that other people with your illness have said are important. **Please circle or mark one number per line to indicate your response as it applies to the past 7 days.**

	<u>PHYSICAL WELL-BEING</u>	Not at all	A little bit	Some- what	Quite a bit	Very much
1	I have a lack of energy	0	1	2	3	4
2	I have nausea	0	1	2	3	4
3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
4	I have pain	0	1	2	3	4
5	I am bothered by side effects of treatment	0	1	2	3	4
6	I feel ill	0	1	2	3	4
7	I am forced to spend time in bed	0	1	2	3	4

<u>SOCIAL/FAMILY WELL-BEING</u>		Not at all	A little bit	Some- what	Quite a bit	Very much
8	I feel close to my friends	0	1	2	3	4
9	I get emotional support from my family	0	1	2	3	4
10	I get support from my friends	0	1	2	3	4
11	My family has accepted my illness	0	1	2	3	4
12	I am satisfied with family communication about my illness	0	1	2	3	4
13	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
14	<i>Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please mark this box ☐ and go to the next section</i>					
15	I am satisfied with my sex life	0	1	2	3	4

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

<u>EMOTIONAL WELL-BEING</u>		Not at all	A little bit	Some- what	Quite a bit	Very much
16	I feel sad	0	1	2	3	4
17	I am satisfied with how I am coping with my illness	0	1	2	3	4

18	I am losing hope in the fight against my illness	0	1	2	3	4
19	I feel nervous	0	1	2	3	4
20	I worry about dying	0	1	2	3	4
21	I worry that my condition will get worse	0	1	2	3	4

FUNCTIONAL WELL-BEING

		Not at all	A little bit	Some- what	Quite a bit	Very much
22	I am able to work (include work at home)	0	1	2	3	4
23	My work (include work at home) is fulfilling	0	1	2	3	4
24	I am able to enjoy life	0	1	2	3	4
25	I have accepted my illness	0	1	2	3	4
26	I am sleeping well	0	1	2	3	4
27	I am enjoying the things I usually do for fun	0	1	2	3	4
28	I am content with the quality of my life right	0	1	2	3	4

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

	<u>ADDITIONAL CONCERNS</u>	Not at all	A little bit	Some- what	Quite a bit	Very much
29	I have been short of breath	0	1	2	3	4
30	I am self-conscious about the way I dress	0	1	2	3	4
31	One or both of my arms are swollen or tender	0	1	2	3	4
32	I feel sexually attractive	0	1	2	3	4
33	I am bothered by hair loss	0	1	2	3	4
34	I worry that other members of my family might someday get the same illness I have	0	1	2	3	4
35	I worry about the effect of stress on my illness	0	1	2	3	4
36	I am bothered by a change in weight	0	1	2	3	4
37	I am able to feel like a woman	0	1	2	3	4
38	I have certain parts of my body where I experience pain	0	1	2	3	4

Below is a list of statements that other people with your illness have said are important.
Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

		Not at all	A little bit	Some- what	Quite a bit	Very much
39	I have a lack of energy	0	1	2	3	4
40	I have pain	0	1	2	3	4
41	I feel ill	0	1	2	3	4
42	I have been short of breath	0	1	2	3	4
43	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
44	I feel fatigued	0	1	2	3	4
45	I have bone pain	0	1	2	3	4
46	I am sleeping well	0	1	2	3	4
47	I worry that my condition will get worse	0	1	2	3	4
548	I have nausea	0	1	2	3	4
49	I have mouth sores	0	1	2	3	4
50	I am bothered by side effects of treatment	0	1	2	3	4

51	I am bothered by hair loss	0	1	2	3	4
52	I am able to work (include work at home)	0	1	2	3	4
53	I am able to enjoy life	0	1	2	3	4
54	I am content with the quality of my life right now	0	1	2	3	4

APPENDIX C: IRB APPROVAL LETTERS



Carle Foundation Hospital Institutional Review Board

DATE: November 18, 2016

TO: Anna Arthur, PhD, MPH, RD

FROM: Kyle L. Galbraith, PhD
Manager, Human Subject Protection
On behalf of the Carle IRB

PROJECT TITLE: Counseling and programming preferences for a combined nutrition and physical activity intervention for breast cancer survivors

IRB NO: 16082

SUBMISSION TYPE: Initial Review

ACTION: Approved

APPROVAL DATE: November 18, 2016

EXPIRATION DATE: **November 17, 2017**

RISK DETERMINATION: No More than Minimal Risk

REVIEW TYPE: Expedited Review

Thank you for submitting the above study for initial review. The Carle Institutional Review Board has approved the submission per the regulatory guidelines stated in 45 CFR 46.110 Categories 5 and 7, and 45 CFR 46.111 for a period of one year. The following study documents are now approved for use:

- Protocol, v. 09/08/2016
- HIPAA Authorization, v. 09/08/2016
- Partial Waiver of HIPAA Authorization, dated 09/08/2016, signed 11/18/2016
- Pre-Survey Information Sheet, v. 09/08/2016
- Breast Cancer Survey, v. 09/08/2016
- Medical Record Data Collection Form, v. 09/08/2016
- Appendix K: Co-Investigators and Key Research Personnel, dated 09/08/2016

Note: The University of Illinois at Urbana-Champaign IRB will rely on the Carle Institutional Review Board as the IRB of oversight for this research. This determination is based on the Memoranda of Understanding in place between the UIUC IRB and the Carle IRB.

Consent: Per 45 CFR 46.117(c)(2), a waiver of documentation of informed consent has been granted for this study. A written information sheet will be given to the subjects.

HIPAA: Original signed copies of HIPAA Authorizations, **with approval date stamp**, should be kept with the study records, with copies to the subject and the medical chart. If HIPAA tracking is required please submit the electronic Accounting Disclosure Tracking form to Health Information Management (HIM) when appropriate. This form can be found on IRBNet.

Partial Waiver of HIPAA: A Partial Waiver of HIPAA Authorization has been granted for this study. Original signed copies of the Partial Waiver of HIPAA Authorizations should be kept with the study records. If HIPAA tracking is required please submit the accounting disclosure electronic tracking form to HIM at the appropriate time.

Study Amendments: Any changes to study materials and processes must be approved by the Carle IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to subjects. Please refer to Carle IRB Policy 403 (Modifications to Previously Approved Research) for information about how to submit such amendments to the Carle IRB for review.

Unanticipated problems: All unanticipated problems involving risks to subjects or others must be reported to the Carle Institutional Review Board in accordance with Carle IRB Policy 801. All FDA and sponsor reporting requirements should also be followed. Note that materials submitted to the Carle Institutional Review Board should not contain subject names, medical record numbers, or other individual identifiers.



**Carle Foundation Hospital
Institutional Review Board**

Prisoners: If a subject becomes incarcerated during the course of the study, contact the Carle IRB within 10 (ten) working days of becoming aware of the incarceration. We are required to conduct IRB review with a prisoner representative present before that subject may continue in the research.

Closure/ Re-approval: Until analysis of identifiable research data is complete, this study must be given annual continuing review by the Carle IRB. Please check the IRB submission deadlines online and file for continuing review in a timely fashion based on the expiration date stated in this letter.

If you have any questions about the IRB process, or if you need assistance at any time, please feel free to contact the Human Subject Protection Office. Include the study title and Carle study number with your correspondence.

Note: This letter has been electronically signed in accordance with applicable federal regulations and institutional policies. A copy is retained within the Carle IRB's records.

cc: Anita A. Balgopal, UIUC IRB Director

mlc



**Carle Foundation Hospital
Institutional Review Board**

DATE: February 22, 2017

TO: Anna Arthur, PhD, MPH, RD

FROM: Kyle L. Galbraith, PhD
Manager, Human Subject Protection
On behalf of the Carle IRB

PROJECT TITLE: Counseling and programming preferences for a combined nutrition and physical activity intervention for breast cancer survivors

IRB NO: 16082

SUBMISSION TYPE: Proposed Amendment

ACTION: Approved

APPROVAL DATE: February 22, 2017

EXPIRATION DATE: November 17, 2017

RISK DETERMINATION: No More than Minimal Risk

REVIEW TYPE: Expedited Review

Thank you for submitting the proposed research amendment for review by the Carle Institutional Review Board (IRB). The Carle IRB has approved the submission per the regulatory guidelines stated in 45 CFR 46.110(b)(2). The following study documents are now approved for use:

- Protocol, v. 02/14/2017
- Informed Consent, v. 02/14/2017
- Recruitment Messaging, v. 02/14/2017
- Appendix K: Co-Investigators and Key Research Personnel, dated 02/14/2017

Subject Notification: No subject notification is necessary with this modification.

Consent: Informed consent will be obtained in accordance with federal regulations and applicable institutional policies. Original signed copies of the consent form approved with this submission, **which has been stamped with an approval expiration date**, should be kept with your study records, and a copy given to the subject. If the study is treatment related, a copy should go in the medical chart. Per 45 CFR 46.117(c), a waiver of consent documentation has

been granted for the survey portion of the study. A written information sheet will be given to the subjects.

HIPAA: Original signed copies of HIPAA Authorizations, **with approval date stamp**, should be kept with the study records, with copies to the subject and the medical chart. If HIPAA tracking is required please submit the electronic Accounting Disclosure Tracking form to Health Information Management (HIM) when appropriate. This form can be found on IRBNet.

Partial Waiver of HIPAA: A Partial Waiver of HIPAA Authorization has been granted for this study. Original signed copies of the Partial Waiver of HIPAA Authorizations should be kept with the study records. If HIPAA tracking is required please submit the accounting disclosure electronic tracking form to HIM at the appropriate time.

Study Amendments: Any changes to study materials and processes must be approved by the Carle IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to subjects. Please refer to Carle IRB Policy 403 (Modifications to Previously Approved Research) for information about how to submit such amendments to the Carle IRB for review.

Unanticipated problems: All unanticipated problems involving risks to subjects or others must be reported to the Carle Institutional Review Board in accordance with Carle IRB Policy 801. All FDA and sponsor reporting requirements should also be followed. Note that materials submitted to the Carle Institutional Review Board should not contain subject names, medical record numbers, or other individual identifiers.

Prisoners: If a subject becomes incarcerated during the course of the study, contact the Carle IRB within 10 (ten) working days of becoming aware of the incarceration. We are required to conduct IRB review with a prisoner representative present before that subject may continue in the research.

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**Carle Foundation Hospital
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Closure/ Re-approval: Until analysis of identifiable research data is complete, this study must be given annual continuing review by the Carle IRB. Please check the IRB submission deadlines online and file for continuing review in a timely fashion based on the expiration date stated in this letter.

If you have any questions about the IRB process, or if you need assistance at any time, please feel free to contact the Human Subject Protection Office. Include the study title and Carle study number with your correspondence.

Note: This letter has been electronically signed in accordance with applicable federal regulations and institutional policies. A copy is retained within the Carle IRB's records.

mlp



**Carle Foundation Hospital
Institutional Review Board**

DATE: October 26, 2017

TO: Anna Arthur, PhD, MPH, RD

FROM: Molly Caldwell, MSW
Manager, Human Subject Protection
On behalf of the Carle IRB

PROJECT TITLE: Counseling and programming preferences for a combined nutrition and physical activity intervention for breast cancer survivors

IRB NO: 16082

SUBMISSION TYPE: Continuing Review

ACTION: Approved

APPROVAL DATE: October 26, 2017

EXPIRATION October 25, 2018

DATE:

RISK DETERMINATION: No More than Minimal Risk

REVIEW TYPE: Expedited Review

Thank you for submitting the above study for continuing review. The Carle Institutional Review Board has approved the submission in accordance with applicable federal regulations and guidance, as well as Carle institutional policies for a period of one year. The following study documents are now approved for use:

- Protocol, v. 02/14/2017
- Content Validity Informed Consent Form, v. 02/14/2017
- Pre-Survey Information Sheet, v. 09/08/2016
- Recruitment Messaging, v. 02/14/2017
- Breast Cancer Survey, v. 09/08/2016
- Medical Record Data Collection Form, v. 09/08/2016
- Appendix K: Co-Investigators and Key Research Personnel, dated 02/14/2017

Consent: Informed consent will be obtained in accordance with federal regulations and applicable institutional policies. Original signed copies of the consent form approved with this submission, **which has been stamped with an approval expiration date**, should be kept with your study records, and a copy given to the subject. If the study is treatment related, a copy

should go in the medical chart. Per 45 CFR 46.117(c), a waiver of consent documentation has been granted for the survey portion of the study. A written information sheet will be given to the subjects.

HIPAA: Original signed copies of HIPAA Authorizations, **with approval date stamp**, should be kept with the study records, with copies to the subject and the medical chart. If HIPAA tracking is required please submit the electronic Accounting Disclosure Tracking form to Health Information Management (HIM) when appropriate. This form can be found on IRBNet.

Partial Waiver of HIPAA: A Partial Waiver of HIPAA Authorization has been granted for this study. Original signed copies of the Partial Wavier of HIPAA Authorizations should be kept with the study records. If HIPAA tracking is required please submit the accounting disclosure electronic tracking form to HIM at the appropriate time.

Study Amendments: Any changes to study materials and processes must be approved by the Carle IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to subjects. Please refer to Carle IRB Policy 403 (Modifications to Previously Approved Research) for information about how to submit such amendments to the Carle IRB for review.

Unanticipated problems: All unanticipated problems involving risks to subjects or others must be reported to the Carle Institutional Review Board in accordance with Carle IRB Policy 801. All FDA and sponsor reporting requirements should also be followed. Note that materials submitted to the Carle Institutional Review Board should not contain subject names, medical record numbers, or other individual identifiers.

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**Carle Foundation Hospital
Institutional Review Board**

Prisoners: If a subject becomes incarcerated during the course of the study, contact the Carle IRB within 10 (ten) working days of becoming aware of the incarceration. We are required to conduct IRB review with a prisoner representative present before that subject may continue in the research.

Closure/ Re-approval: Until analysis of identifiable research data is complete, this study must be given annual continuing review by the Carle IRB. Please check the IRB submission deadlines online and file for continuing review in a timely fashion based on the expiration date stated in this letter.

If you have any questions about the IRB process, or if you need assistance at any time, please feel free to contact the Human Subject Protection Office. Include the study title and Carle study number with your correspondence.

Note: This letter has been electronically signed in accordance with applicable federal regulations and institutional policies. A copy is retained within the Carle IRB's records.

mlp



**Carle Foundation Hospital
Institutional Review Board**

DATE: December 20, 2017

TO: Anna Arthur, PhD, MPH, RD

FROM: Molly Caldwell, MSW
Manager, Human Subject Protection
On behalf of the Carle IRB

PROJECT TITLE: Counseling and programming preferences for a combined nutrition and physical activity intervention for breast cancer survivors

IRB NO: 16082

SUBMISSION TYPE: Proposed Amendment

ACTION: Approved

APPROVAL DATE: December 20, 2017

EXPIRATION DATE: October 25, 2018

RISK DETERMINATION: No More than Minimal Risk

REVIEW TYPE: Expedited Review

Thank you for submitting the proposed research amendment for review by the Carle Institutional Review Board (IRB). The Carle IRB has approved the submission per the regulatory guidelines stated in 45 CFR 46.110(b)(2). The following study documents are now approved for use:

- Breast Cancer Survey, v. 12/12/2017
- Appendix K: Co-Investigators and Key Research Personnel, dated 12/07/2017

Subject Notification: No subject notification is necessary with this modification.

Consent: Informed consent will be obtained in accordance with federal regulations and applicable institutional policies. Original signed copies of the consent form approved with this submission, **which has been stamped with an approval expiration date**, should be kept with your study records, and a copy given to the subject. If the study is treatment related, a copy should go in the medical chart. Per 45 CFR 46.117(c), a waiver of consent documentation has been granted for the survey portion of the study. A written information sheet will be given to the subjects.

HIPAA: Original signed copies of HIPAA Authorizations, **with approval date stamp**, should be kept with the study records, with copies to the subject and the medical chart. If HIPAA tracking is required please submit the electronic Accounting Disclosure Tracking form to Health Information Management (HIM) when appropriate. This form can be found on IRBNet.

Partial Waiver of HIPAA: A Partial Waiver of HIPAA Authorization has been granted for this study. Original signed copies of the Partial Waiver of HIPAA Authorizations should be kept with the study records. If HIPAA tracking is required please submit the accounting disclosure electronic tracking form to HIM at the appropriate time.

Study Amendments: Any changes to study materials and processes must be approved by the Carle IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to subjects. Please refer to Carle IRB Policy 403 (Modifications to Previously Approved Research) for information about how to submit such amendments to the Carle IRB for review.

Unanticipated problems: All unanticipated problems involving risks to subjects or others must be reported to the Carle Institutional Review Board in accordance with Carle IRB Policy 801. All FDA and sponsor reporting requirements should also be followed. Note that materials submitted to the Carle Institutional Review Board should not contain subject names, medical record numbers, or other individual identifiers.

Prisoners: If a subject becomes incarcerated during the course of the study, contact the Carle IRB within 10 (ten) working days of becoming aware of the incarceration. We are required to conduct IRB review with a prisoner representative present before that subject may continue in the research.

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**Carle Foundation Hospital
Institutional Review Board**

Closure/ Re-approval: Until analysis of identifiable research data is complete, this study must be given annual continuing review by the Carle IRB. Please check the IRB submission deadlines online and file for continuing review in a timely fashion based on the expiration date stated in this letter.

If you have any questions about the IRB process, or if you need assistance at any time, please feel free to contact the Human Subject Protection Office. Include the study title and Carle study number with your correspondence.

Note: This letter has been electronically signed in accordance with applicable federal regulations and institutional policies. A copy is retained within the Carle IRB's records

mlp



**Carle Foundation Hospital
Institutional Review Board**

DATE: July 16, 2018

TO: Anna Arthur, PhD, MPH, RD

FROM: Molly Caldwell, MSW
Manager, Human Subject Protection
On behalf of the Carle IRB

PROJECT TITLE: Counseling and programming preferences for a combined nutrition and physical activity intervention for breast cancer survivors

IRB NO: 16082

SUBMISSION TYPE: Proposed Amendment

ACTION: Approved

APPROVAL DATE: July 16, 2018

EXPIRATION October 25, 2018

DATE:

RISK DETERMINATION: No More than Minimal Risk

REVIEW TYPE: Expedited Review

Thank you for submitting the proposed research amendment for review by the Carle Institutional Review Board (IRB). The Carle IRB has approved the submission per the regulatory guidelines stated in 45 CFR 46.110(b)(2). The following study documents are now approved for use:

- Protocol, v. 2, 06/28/2018
- Online Consent Form, v. 06/28/2018
- Breast Cancer Survey, v. 3
- HIPAA Authorization, v. 06/05/2018
- Revised Partial Waiver of HIPAA Authorization, dated July 16, 2018
- Appendix K: Co-Investigators and Key Research Personnel, dated 07/10/2018

Subject Notification: No subject notification is necessary with this modification.

Consent: Informed consent will be obtained in accordance with federal regulations and applicable institutional policies. Original signed copies of the consent form approved with this submission, **which has been stamped with an approval expiration date**, should be kept with your study records, and a copy given to the subject. If the study is treatment related, a copy

should go in the medical chart. Per 45 CFR 46.117(c), a waiver of consent documentation has been granted for the survey portion of the study. A written information sheet will be given to the subjects.

HIPAA: Original signed copies of HIPAA Authorizations, **with approval date stamp**, should be kept with the study records, with copies to the subject and the medical chart. If HIPAA tracking is required please submit the electronic Accounting Disclosure Tracking form to Health Information Management (HIM) when appropriate. This form can be found on IRBNet.

Partial Waiver of HIPAA: A Partial Waiver of HIPAA Authorization has been granted for this study. Original signed copies of the Partial Wavier of HIPAA Authorizations should be kept with the study records. If HIPAA tracking is required please submit the accounting disclosure electronic tracking form to HIM at the appropriate time.

Study Amendments: Any changes to study materials and processes must be approved by the Carle IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to subjects. Please refer to Carle IRB Policy 403 (Modifications to Previously Approved Research) for information about how to submit such amendments to the Carle IRB for review.

Unanticipated problems: All unanticipated problems involving risks to subjects or others must be reported to the Carle Institutional Review Board in accordance with Carle IRB Policy 801. All FDA and sponsor reporting requirements should also be followed. Note that materials submitted to the Carle Institutional Review Board should not contain subject names, medical record numbers, or other individual identifiers.

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**Carle Foundation Hospital
Institutional Review Board**

Prisoners: If a subject becomes incarcerated during the course of the study, contact the Carle IRB within 10 (ten) working days of becoming aware of the incarceration. We are required to conduct IRB review with a prisoner representative present before that subject may continue in the research.

Closure/ Re-approval: Until analysis of identifiable research data is complete, this study must be given annual continuing review by the Carle IRB. Please check the IRB submission deadlines online and file for continuing review in a timely fashion based on the expiration date stated in this letter.

If you have any questions about the IRB process, or if you need assistance at any time, please feel free to contact the Human Subject Protection Office. Include the study title and Carle study number with your correspondence.

Note: This letter has been electronically signed in accordance with applicable federal regulations and institutional policies. A copy is retained within the Carle IRB's records.

mlp



**Carle Foundation Hospital
Institutional Review Board**

DATE: August 31, 2018

TO: Anna Arthur, PhD, MPH, RD

FROM: Molly Caldwell, MSW
Manager, Human Subject Protection
On behalf of the Carle IRB

PROJECT TITLE: Counseling and programming preferences for a combined nutrition and physical activity intervention for breast cancer survivors

IRB NO: 16082

SUBMISSION TYPE: Proposed Amendment

ACTION: Approved

APPROVAL DATE: August 31, 2018

EXPIRATION **October 25, 2018**

DATE:

RISK DETERMINATION: No More than Minimal Risk

REVIEW TYPE: Expedited Review

Thank you for submitting the proposed research amendment for review by the Carle Institutional Review Board (IRB). The Carle IRB has approved the submission per the regulatory guidelines stated in 45 CFR 46.110(b)(2). The following study documents are now approved for use:

- Protocol, v. 08/22/2018
- Online Consent Form, v. 08/13/2018
- eWeek Recruitment Message, v. 08/22/2018
- eWeek Recruitment Message for Groups, v. 08/22/2018
- Appendix K: Co-Investigators and Key Research Personnel, dated 08/13/2018

Subject Notification: No subject notification is necessary with this modification.

Consent: Informed consent will be obtained in accordance with federal regulations and applicable institutional policies. Original signed copies of the consent form approved with this submission, **which has been stamped with an approval expiration date**, should be kept with your study records, and a copy given to the subject. If the study is treatment related, a copy should go in the medical chart. Per 45 CFR 46.117(c), a waiver of consent documentation has

been granted for the survey portion of the study. A written information sheet will be given to the subjects.

HIPAA: Original signed copies of HIPAA Authorizations, **with approval date stamp**, should be kept with the study records, with copies to the subject and the medical chart. If HIPAA tracking is required please submit the electronic Accounting Disclosure Tracking form to Health Information Management (HIM) when appropriate. This form can be found on IRBNet.

Partial Waiver of HIPAA: A Partial Waiver of HIPAA Authorization has been granted for this study. Original signed copies of the Partial Waiver of HIPAA Authorizations should be kept with the study records. If HIPAA tracking is required please submit the accounting disclosure electronic tracking form to HIM at the appropriate time.

Study Amendments: Any changes to study materials and processes must be approved by the Carle IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to subjects. Please refer to Carle IRB Policy 403 (Modifications to Previously Approved Research) for information about how to submit such amendments to the Carle IRB for review.

Unanticipated problems: All unanticipated problems involving risks to subjects or others must be reported to the Carle Institutional Review Board in accordance with Carle IRB Policy 801. All FDA and sponsor reporting requirements should also be followed. Note that materials submitted to the Carle Institutional Review Board should not contain subject names, medical record numbers, or other individual identifiers.

Prisoners: If a subject becomes incarcerated during the course of the study, contact the Carle IRB within 10 (ten) working days of becoming aware of the incarceration. We are required to conduct IRB review with a prisoner representative present before that subject may continue in the research.

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**Carle Foundation Hospital
Institutional Review Board**

Closure/ Re-approval: Until analysis of identifiable research data is complete, this study must be given annual continuing review by the Carle IRB. Please check the IRB submission deadlines online and file for continuing review in a timely fashion based on the expiration date stated in this letter.

If you have any questions about the IRB process, or if you need assistance at any time, please feel free to contact the Human Subject Protection Office. Include the study title and Carle study number with your correspondence.

Note: This letter has been electronically signed in accordance with applicable federal regulations and institutional policies. A copy is retained within the Carle IRB's records.

mlp



**Carle Foundation Hospital
Institutional Review Board**

DATE: October 16, 2018

TO: Anna Arthur, PhD, MPH, RD

FROM: Mary Lyman-Parrish, BA, CIP
Senior IRB Coordinator, Human Subject Protection
On behalf of the Carle IRB

PROJECT TITLE: Counseling and programming preferences for a combined nutrition and physical activity intervention for breast cancer survivors

IRB NO: 16082

SUBMISSION TYPE: Proposed Amendment

ACTION: Approved

APPROVAL DATE: October 16, 2018

EXPIRATION DATE: October 15, 2019

RISK DETERMINATION: No More than Minimal Risk

REVIEW TYPE: Expedited Review

Thank you for submitting the proposed research amendment for review by the Carle Institutional Review Board (IRB). The Carle IRB has approved the submission per the regulatory guidelines stated in 45 CFR 46.110(b)(2). The following study documents are now approved for use:

- Appendix K: Co-Investigators and Key Research Personnel, dated 10/16/2018

Subject Notification: No subject notification is necessary with this modification.

Consent: Informed consent will be obtained in accordance with federal regulations and applicable institutional policies. Original signed copies of the consent form approved with this submission, **which has been stamped with an approval expiration date**, should be kept with your study records, and a copy given to the subject. If the study is treatment related, a copy should go in the medical chart. Per 45 CFR 46.117(c), a waiver of consent documentation has been granted for the survey portion of the study. A written information sheet will be given to the subjects.

HIPAA: Original signed copies of HIPAA Authorizations, **with approval date stamp**, should be kept with the study records, with copies to the subject and the medical chart. If HIPAA tracking is required please submit the electronic Accounting Disclosure Tracking form to Health Information Management (HIM) when appropriate. This form can be found on IRBNet.

Partial Waiver of HIPAA: A Partial Waiver of HIPAA Authorization has been granted for this study. Original signed copies of the Partial Waiver of HIPAA Authorizations should be kept with the study records. If HIPAA tracking is required please submit the accounting disclosure electronic tracking form to HIM at the appropriate time.

Study Amendments: Any changes to study materials and processes must be approved by the Carle IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to subjects. Please refer to Carle IRB Policy 403 (Modifications to Previously Approved Research) for information about how to submit such amendments to the Carle IRB for review.

Unanticipated problems: All unanticipated problems involving risks to subjects or others must be reported to the Carle Institutional Review Board in accordance with Carle IRB Policy 801. All FDA and sponsor reporting requirements should also be followed. Note that materials submitted to the Carle Institutional Review Board should not contain subject names, medical record numbers, or other individual identifiers.

Prisoners: If a subject becomes incarcerated during the course of the study, contact the Carle IRB within 10 (ten) working days of becoming aware of the incarceration. We are required to conduct IRB review with a prisoner representative present before that subject may continue in the research.

Closure/ Re-approval: Until analysis of identifiable research data is complete, this study must be given annual continuing review by the Carle IRB. Please check the IRB submission deadlines online and file for continuing review in a timely fashion based on the expiration date stated in this letter.

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**Carle Foundation Hospital
Institutional Review Board**

If you have any questions about the IRB process, or if you need assistance at any time, please feel free to contact the Human Subject Protection Office. Include the study title and Carle study number with your correspondence.

Note: This letter has been electronically signed in accordance with applicable federal regulations and institutional policies. A copy is retained within the Carle IRB's records.

mlp



**Carle Foundation Hospital
Institutional Review Board**

DATE: October 16, 2018

TO: Anna Arthur, PhD, MPH, RD

FROM: Mary Lyman-Parrish, BA, CIP
Senior IRB Coordinator, Human Subject Protection
On behalf of the Carle IRB

PROJECT TITLE: Counseling and programming preferences for a combined nutrition and physical activity intervention for breast cancer survivors

IRB NO: 16082

SUBMISSION TYPE: Continuing Review

ACTION: Approved

APPROVAL DATE: October 16, 2018

EXPIRATION DATE: October 15, 2019

RISK DETERMINATION: No More than Minimal Risk

REVIEW TYPE: Expedited Review

Thank you for submitting the above study for continuing review. The Carle Institutional Review Board has approved the submission in accordance with applicable federal regulations and guidance, as well as Carle institutional policies for a period of one year. The following study documents are now approved for use:

- EWeek Advertisement, v. 8/22/2018
- Social Media Recruitment Message, v. 8/22/2018
- Online Survey Consent Document, v. 8/13/2018
- Medical Record Data Collection Form, v. 9/8/2016
- Appendix K: Co-Investigators and Key Research Personnel, dated 10/16/2018
- Protocol, v. 8/22/2018
- Questionnaire/Survey, v. 6/5/2018

Consent: Informed consent will be obtained in accordance with federal regulations and applicable institutional policies. Original signed copies of the consent form approved with this submission should be kept with your study records, and a copy given to the subject. If the study is treatment related, a copy should go in the medical chart. Per 45 CFR 46.117(c), a waiver of

consent documentation has been granted for this study. A written information sheet will be available to subjects who complete the survey online; they may print the information sheet if they so choose.

HIPAA: Original signed copies of HIPAA Authorizations, **with approval date stamp**, should be kept with the study records, with copies to the subject and the medical chart. If HIPAA tracking is required please submit the electronic Accounting Disclosure Tracking form to Health Information Management (HIM) when appropriate. This form can be found on IRBNet.

Partial Waiver of HIPAA: A Partial Waiver of HIPAA Authorization has been granted for this study. Original signed copies of the Partial Waiver of HIPAA Authorizations should be kept with the study records. If HIPAA tracking is required please submit the accounting disclosure electronic tracking form to HIM at the appropriate time.

Study Amendments: Any changes to study materials and processes must be approved by the Carle IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to subjects. Please refer to Carle IRB Policy 403 (Modifications to Previously Approved Research) for information about how to submit such amendments to the Carle IRB for review.

Unanticipated problems: All unanticipated problems involving risks to subjects or others must be reported to the Carle Institutional Review Board in accordance with Carle IRB Policy 801. All FDA and sponsor reporting requirements should also be followed. Note that materials submitted to the Carle Institutional Review Board should not contain subject names, medical record numbers, or other individual identifiers.

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**Carle Foundation Hospital
Institutional Review Board**

Prisoners: If a subject becomes incarcerated during the course of the study, contact the Carle IRB within 10 (ten) working days of becoming aware of the incarceration. We are required to conduct IRB review with a prisoner representative present before that subject may continue in the research.

Closure/ Re-approval: Until analysis of identifiable research data is complete, this study must be given annual continuing review by the Carle IRB. Please check the IRB submission deadlines online and file for continuing review in a timely fashion based on the expiration date stated in this letter.

If you have any questions about the IRB process, or if you need assistance at any time, please feel free to contact the Human Subject Protection Office. Include the study title and Carle study number with your correspondence.

Note: This letter has been electronically signed in accordance with applicable federal regulations and institutional policies. A copy is retained within the Carle IRB's records.

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